

**Ministry of Health:
What Further Progress Has
Been Made To Implement
the Recommendations of
the Cervical Screening Inquiry?**

December 2003

This is the report of a performance audit we carried out under the authority of section 16 of the Public Audit Act 2001.

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Foreword

Organised cervical screening was established in New Zealand in 1990. The National Cervical Screening Programme (the Programme) consumes significant public resources, with a budget of more than \$30 million for 2003-04, and a further \$6.5 million for the personnel and operating costs of the National Screening Unit (NSU) – which delivers the Programme and BreastScreen Aotearoa.

Theoretically, organised cervical screening can be effective in reducing the incidence of cervical cancer by as much as 91%, with three-yearly screening. Since 1990, both the incidence of, and mortality from, invasive cervical cancer have declined in this country. Cervical cancer rates decreased by 39% from 1988 to 1997, and mortality rates decreased by 44% during the same period.

However, cervical screening is not without its limitations, and even high quality screening programmes will not be able to prevent all cases of invasive cervical cancer. These limitations can be minimised if screening is properly organised, and appropriately monitored and evaluated.

The Ministerial Inquiry into the under-reporting of cervical smear abnormalities in the Gisborne region raised some serious concerns about whether the Programme is as effective as it could be. The Committee of Inquiry's report, released in April 2001, made 46 recommendations for future action to improve the Programme.

Since then, the NSU and other parts of the Ministry of Health have been working to implement the recommendations. Progress has been monitored, and has also been reviewed by an independent expert, Dr Euphemia McGoogan, who has reported twice to the Minister of Health. My predecessor also reported (from a lay perspective) in February 2002. These reports raised additional issues and recommendations to improve the Programme.

In this follow-up review, I found that progress is continuing to be made in implementing the recommendations. However, the most significant issues for the future will involve ensuring that the appropriate assurance processes are in place around the quality aspects of the Programme – such as completing the Audit of Invasive Cervical Cancer, fully implementing the Operational Policy and Quality Standards and auditing service provider compliance with the standards, and continuing the reviews conducted by the Independent Monitoring Group. The NSU will need to be more open and collaborative with stakeholders, and ensure that all key staff positions are filled.

I also consider that the use of an independent expert to review implementation of the recommendations has added considerable value to the process, and would like to see this type of review continued and expanded to focus on the effectiveness of the whole Programme.

I will continue to keep the progress in implementing the Committee of Inquiry's recommendations under review.

K B Brady
Controller and Auditor-General
3 December 2003

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Part One

Background To Our Report

Introduction

- 1.1 This is our second report in relation to recommendations made to the Minister of Health (the Minister) in April 2001 by a Committee of Inquiry that was set up to look into the under-reporting of cervical smear abnormalities in the Gisborne region.
- 1.2 Our first report¹ – published in February 2002 – concluded that good progress was being made to implement the recommendations in a number of areas, but that effective monitoring, evaluation, and audit of the National Cervical Screening Programme (the Programme)² still required action.
- 1.3 At the same time, Dr Euphemia McGoogan³ – an independent expert engaged by the Minister to advise on progress in implementing the recommendations – also reported. Dr McGoogan visited New Zealand in November 2001 and provided a six-month progress report⁴ to the Minister, dated December 2001 and published in February 2002.
- 1.4 Dr McGoogan made a second visit to New Zealand in April 2002 (she did not report as a result of this visit) and again in January 2003, after which she made her second – and what she intends to be her final – report⁵ in June 2003.
- 1.5 We advised in February 2002 that we intended to keep implementation progress under review. We have done this by maintaining contact with Dr McGoogan and by reviewing the quarterly reports published on the National Screening Unit's (NSU)⁶ web site.

What Prompted a Further Review In 2003?

- 1.6 After Dr McGoogan's second report was made public in June 2003, the Minister contacted the Auditor-General, requesting us to do a follow-up report. The Minister was concerned about the issues raised by Dr McGoogan based on her visit in January 2003, and wanted to know whether any progress had been made since that date.
- 1.7 The Auditor-General's response to such requests is discretionary. However, we had intended to do a follow-up review six months after Dr McGoogan's second report had been issued. We decided to bring the timing of this review forward because of the high profile of the Programme and its importance from a public health perspective.

¹ *Ministry of Health: Progress in Implementing the Recommendations of the Cervical Screening Inquiry*, Report of the Controller and Auditor-General, February 2002, ISBN 0-477-02890-X (see www.oag.govt.nz).

² The Programme is also referred to by the abbreviation NCSP in some related titles, e.g. NCSP-Register.

³ Dr McGoogan is a cytopathologist and Associate Medical Director of Lothian University Hospitals National Health Service Trust in Edinburgh, Scotland. Dr McGoogan also provided evidence to the Committee of Inquiry.

⁴ E McGoogan, 2002, *Progress in Implementing the Cervical Screening Inquiry Recommendations*.

⁵ E McGoogan, 2003, *Report on the National Cervical Screening Programme and progress towards Implementation of the Gisborne Inquiry Recommendations*.

⁶ The NSU was established as a separate unit within the Ministry's Public Health Directorate in July 2001 and is responsible for the Programme and BreastScreen Aotearoa (the screening programme for breast cancer).

What Is the Scope of This Report?

1.8 In this report we have sought to establish:

- what progress the Ministry has made since Dr McGoogan’s review (in January 2003) to implement the 46 recommendations of the Committee of Inquiry;
- the issues and reasons why the Ministry is not progressing as quickly as recommended with the implementation of some recommendations; and
- how and when the Ministry intends to address other issues raised in Dr McGoogan’s reports.

How Did We Carry Out Our Review?

1.9 We interviewed and sought the views of a wide range of people and organisations. In particular, we met with:

- the Minister of Health;
- the Group Manager of the NSU, the Clinical Leaders of the Programme and BreastScreen Aotearoa, the Programme’s Operational Manager, and the NSU Public Health Leader;
- relevant staff within the Ministry of Health – including the Director-General of Health, the Deputy Director-General of Public Health, the Director of Public Health, and staff involved in legislative review, ethics committees, Kaitiaki Regulations⁷, IT services, and public health organisations;
- professionals with an ongoing interest in the Programme – for example, Professor David Skegg, Dr Charlotte Paul, and Dr Brian Cox from the University of Otago, Dr Julia Peters (a past Clinical Director of the NSU and currently involved in the Audit of Invasive Cervical Cancer⁸), and Sandra Coney (a consumer advocate);
- the chairperson of the National Ethics Advisory Committee;⁹
- staff of the Programme’s Wellington Regional Service;
- representatives from the Royal New Zealand College of General Practitioners;
- representatives from the New Zealand Medical Association;

⁷ Health (Cervical Screening (Kaitiaki)) Regulations 1999 (The Kaitiaki Regulations) - no person, including the Ministry and persons included in monitoring, audit, and evaluation of the Programme may use, disclose, or publish aggregate Maori women’s data from the NCSP-Register (the database of all women enrolled on the Programme) without the prior approval of the National Kaitiaki Group.

⁸ The Audit of Invasive Cervical Cancer (the Cancer Audit) is discussed in Part Seven of this report (see paragraphs 7.3-7.36 on pages 61-68).

⁹ The National Ethics Advisory Committee was set up under section 16 of the New Zealand Public Health and Disability Act 2000.

- community laboratory staff – including three pathologists (including the Vice-President for NZ of the Royal College of Pathologists of Australasia), and a cytotechnologist¹⁰;
- a general practitioner and practice nurse; and
- the programme manager for medical testing from International Accreditation New Zealand (IANZ)¹¹.

1.10 In addition, we had telephone interviews with:

- Dr McGoogan and Julietta Patnick (the Screening Programmes Co-ordinator for England) via video conference;
- the Chief Executive of IANZ;
- two cytotechnologists;
- staff from the Family Planning Association;
- staff from the Programme's Regional Services¹²;
- the chair of the College of Practice Nurses; and
- the chair of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and two gynaecologists.

1.11 We obtained and reviewed relevant documentation.

¹⁰ A cytotechnologist is a registered medical laboratory scientist who specialises in cytology (the study of cells). The majority of a cytotechnologist's work involves screening cervical smears.

¹¹ IANZ is the accreditation arm of the Testing Laboratory Registration Authority – a statutory body established in 1972 to provide laboratory accreditation.

¹² The Programme contracts Regional Services from 13 District Health Boards (DHBs). The services provided by each DHB vary depending on the terms of the contract. Some Regional Services have responsibility for processing the cytology and histology results from laboratories and entering them onto the NCSP-Register under the NCSP-Register Operating Protocols. Other Regional Services also undertake health promotion, smear-taking, and regional co-ordination of smear-taker and colposcopy providers.

Part Two

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

What is Cervical Screening?

- 2.1 Cervical screening is an internationally recognised means of reducing cervical cancer. It involves the taking of a sample of cells from the cervix (the neck of the uterus) and transferring them to a slide¹³ to be interpreted or “read” at a medical laboratory.
- 2.2 This cervical smear test can detect changes in cervical cells that, if not treated, may develop into cervical cancer. Where the test indicates pre-cancerous lesions and these are subsequently confirmed by diagnostic tests, the success rate for adequate treatment is very high.
- 2.3 Cervical cancer is usually a slow-developing disease, and a single incorrect laboratory reading 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.
- 2.4 For cervical screening to provide accurate results:
- the smear-taker¹⁴ must take and transfer to a slide a sufficient quantity and quality of cells from the cervix; and
 - the slide needs to be correctly read by the laboratory.
- 2.5 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.
- 2.6 Because of the subjective nature of cervical smear reading, the presence of some under-reporting is an acknowledged element of any cervical screening programme. It is important for such programmes to ensure that under-reporting is minimised, and that unacceptable levels of under-reporting are identified quickly – and well before regularly screened women present with cervical cancer.

Establishment of the National Cervical Screening Programme

- 2.7 The Programme was set up in 1990, in response to the recommendations of the Report of the Cervical Cancer Inquiry 1988 (also known as the Cartwright Inquiry), to reduce the incidence and effect of cervical cancer.
- 2.8 The Programme is based on a “well woman” philosophy – where a defined population of healthy women is given the opportunity to be screened for pre-cancerous lesions of the cervix, which may be amenable to early treatment.

¹³ A slide is a glass strip onto which the smear-taker transfers cells from the cervix so that they can be viewed under a microscope.

¹⁴ A smear-taker is usually a doctor, nurse, or midwife with training in smear-taking.

The Gisborne Committee of Inquiry

- 2.9 In 1995, a woman with cervical cancer, who had been screened by the Programme and whose smear test was misread, established a claim for medical misadventure with the Accident Compensation Corporation (ACC), and filed a complaint with the New Zealand Medical Council (Medical Council)¹⁵. As a result of the ensuing investigation, the Gisborne Laboratories' pathologist Dr Michael Bottrill was found guilty of "conduct unbecoming a medical practitioner".
- 2.10 The complainant then initiated a civil proceeding in the High Court. Although the claim failed, the case generated extensive publicity, which encouraged other women whose cervical smear tests had been read at Gisborne to come forward.
- 2.11 The (former) Health Funding Authority (HFA) consulted with various people and organisations – including the Royal College of Pathologists of Australasia and an expert advisory group – on the need to re-examine the cervical smear tests read at Gisborne Laboratories. Subsequently, in May 1999, the HFA decided that all the smear tests would be re-read. The re-examination exercise established that under-reporting appeared to be extensive.
- 2.12 The Gisborne Committee of Inquiry (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. The Committee was directed to conduct an Inquiry into the reading of abnormalities in cervical smears in the Gisborne region before March 1996, taking into account the results of the reviews of cervical cytology¹⁶ and histology¹⁷ samples carried out by the HFA.
- 2.13 The Committee of Inquiry's Report¹⁸ 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...*
- 2.14 The two groups of contributing factors related to:
- practices at Gisborne Laboratories; and
 - the wider delivery of cytology services throughout New Zealand between 1990 and 1996.

¹⁵ The Medical Council is a statutory body comprising doctors and lay people, involved with the registration of doctors and maintenance of standards.

¹⁶ Cytology is the study of cells, and involves examining them by microscope for signs of abnormality.

¹⁷ Histology is the microscopic study of the structure and composition of body tissues, and involves taking a tissue biopsy for analysis. In terms of cervical screening, tissue from the cervix is taken during a colposcopy examination.

¹⁸ AP Duffy QC, DK Barrett CNZM, MA Duggan FRCPC, April 2001, *Report on the Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region*, ISBN 0-478-2454-5 (book), ISBN 0-478-24355-3, (web) www.csi.org.nz.

2.15 The Committee of Inquiry’s report made 46 recommendations for future action by the Government or its agencies. The recommendations (and progress against them to November 2003) are set out in full in the Appendix on pages 97-109.

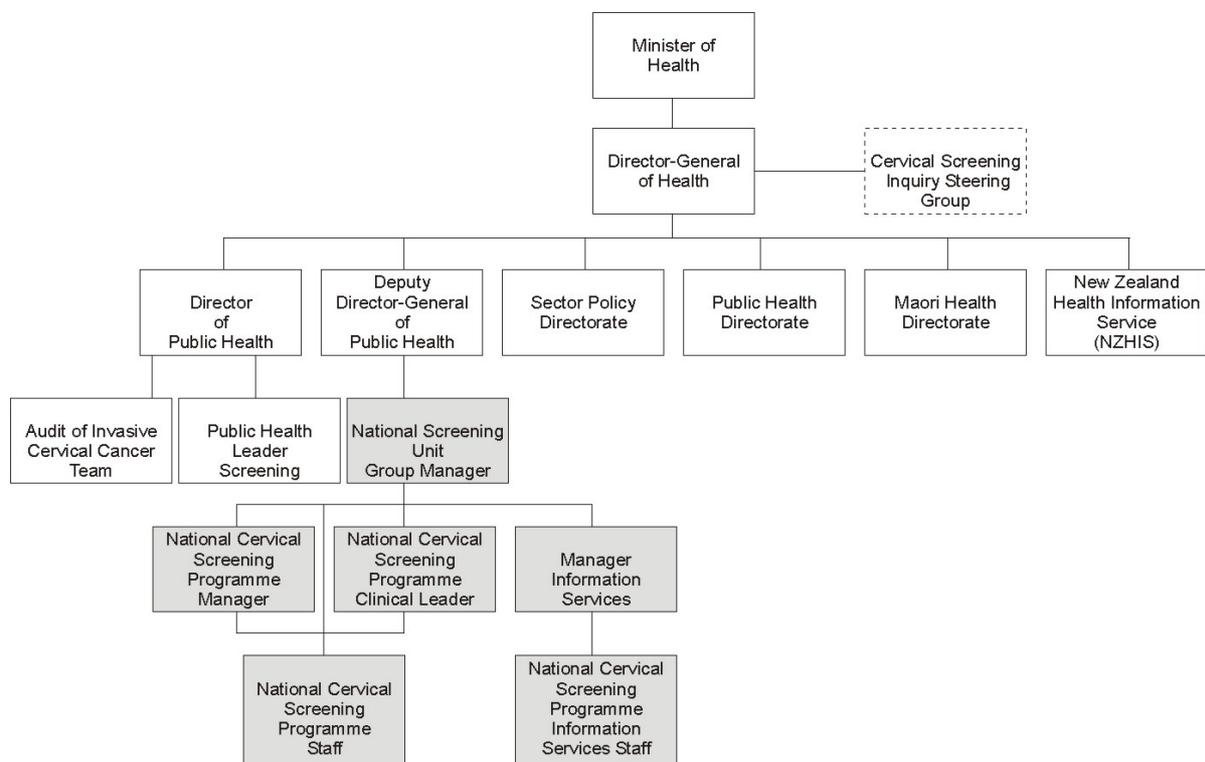
2.16 When the report was published in April 2001, the Minister accepted all the recommendations and directed the Ministry of Health (the Ministry) to implement them.

Responsibility For Implementing the Committee of Inquiry’s Recommendations

2.17 Responsibility for implementing the Committee of Inquiry’s 46 recommendations was assigned to various directorates and groups within the Ministry.

2.18 Figure 1 below shows the reporting structure for Ministry directorates and groups involved in implementing the Committee of Inquiry’s recommendations.

*Figure 1
Directorates and Groups Within the Ministry of Health Involved in Implementing the Committee of Inquiry’s Recommendations*



2.19 Figure 2 on the next page shows how responsibility has been assigned within the Ministry for implementing each of the Committee of Inquiry’s recommendations.

Figure 2
How Responsibility for Implementing the Committee of Inquiry's Recommendations Is Assigned Within the Ministry of Health

Assigned to	Recommendation (number)
Director of Public Health	Evaluation of the Programme, including the Cancer Audit (1)
National Screening Unit	Re-enrolment and re-screening of women (2) Evaluation programme (3) Implementation of the Operational Policy and Quality Standards (4) Legal assessment of the Operational Policy and Quality Standards and the Evaluation and Monitoring Plan (5) Legal assessment of the Programme's authority (6) Annual statistical reports (7) Regular statistical information (8) <i>*jointly assigned to the NZHIS</i> Minimum volume standards for laboratories (9) Balanced approach to all aspects of the Programme (10) Preservation of developing culture (11) Separate unit (12) Controlled by 2 nd or 3 rd tier manager with specialist public health or epidemiology qualifications (13) Complaints' system (24) Electronic link between Cancer Registry and NCSP-Register (25) <i>*jointly assigned to the NZHIS</i> Performance standards for NCSP-Register (26) <i>*jointly assigned to the NZHIS</i> Standards for the Programme should be reviewed every two years (27) Government must ensure sufficient cytopathologists and training sites (28) Electronic link between NCSP-Register and Cytology Laboratories (31) Develop standard for accuracy of laboratory coding (32) Liaising with the Royal College of Pathologists of Australasia (37) Information to women (38) Letters to medical practitioners (39) Appropriately trained individuals should do cervical screening (40) All pathologists undertaking cytology should be appropriately trained (41) Cytopathologists must participate in continuing education (42) The Programme should have a system for identifying deficiencies (45)
New Zealand Health Information Service (NZHIS)	Development of a population-based register (33)
Public Health Directorate	Amendment to section 74 of the Health Act 1956 (14) Legal right to access information on the Cancer Registry (16) <i>*jointly assigned to the NZHIS</i> Amend Health Act 1956 to enable access to medical files (17) Impose legal obligations on retention of slides (phase 1) (30)
Maori Health Directorate	Kaitiaki Regulations (15)
Sector Policy Directorate	Change guidelines under which ethics committees operate (18) Review of operations of ethics committees (19) Provide guidelines to ethics committees regarding Privacy Act & Code (20) Guidelines to ethics committees for observations studies (21) National Ethics Advisory Committees – multi-centre studies (22) Appeal process for ethics committee decisions (23) Amend Laboratory Technologists Regulations 1989 (29) Legal mechanisms put in place to allow ACC, the Medical Council, and the Health and Disability Commissioner to share relevant information with the Programme (34) Medical tribunal to supply information to the Programme (35) Impose legal obligations on retention of slides (phase 2) (30) ACC and the Medical Council should exchange relevant information regarding claims for medical misadventure (36) The Medical Council should ensure that systems are in place to support reporting of errant medical practitioners by their colleagues (44) Pathologists ought to be more open-minded (43)
Cervical Screening Inquiry Steering Group	Process for monitoring the implementation of the Committee's recommendations (46)

Part Three

Our Overall Findings

Introduction

- 3.1 We have been advised that the recent reviews that recommend making changes to improve the Programme are making some women question whether or not it is worthwhile continuing to participate in the Programme.
- 3.2 Before reporting our findings, we wish to emphasise that 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 very high.
- 3.3 Our findings should in no way be interpreted as suggesting that the Programme is ineffective and that participating in the Programme is not worthwhile. Indeed, the New Zealand Medical Association (NZMA) recommends that women have regular cervical smear tests as part of maintaining a healthy lifestyle. Our findings are aimed at making the Programme more effective for women.

Progress to Implement the Committee of Inquiry's Recommendations

- 3.4 Figure 3 below sets out our views on the implementation status of the Committee of Inquiry's 46 recommendations as at November 2003. As it is sometimes difficult to determine exact status (for example, for recommendations that may be ongoing or have more than one part), we have provided a fuller explanation of the status of each recommendation in the Appendix on pages 97-109.

*Figure 3
Implementation Status of the Committee of Inquiry's
Recommendations as at November 2003*

Implementation Status of Recommendation	Recommendation Number/s	Total
Implemented – will become “business as usual”.	3, 7, 8, 9, 10, 26, 32 37, 38, 42, 43, 46	12
Implemented – no further work required.	5, 12, 18, 20, 34, 35, 36, 39, 40, 44	10
Work substantially complete – expected to be implemented in 2003 or early-2004.	4, 6, 11, 14, 16, 17, 29, 30	8
Being implemented – expected to be implemented by June 2004.	24	1
Work begun but still much to be done – not likely to be implemented before June 2004.	1, 25, 27, 28, 31, 33, 41, 45	8
Decision not to implement.	13, 15	2
Work to be done, but unclear whether will be implemented.	19, 21, 22, 23	4
Not started (as it is dependent on the outcome of Recommendation 1 - the Cancer Audit).	2	1

3.5 In summary, after two and a half years:

- **Thirty-one of the 46 recommendations have been implemented or are expected to be implemented by June 2004.** (These include legislative changes¹⁹, implementing the Programme's Operational Policy and Quality Standards²⁰ (Quality Standards), legal assessments of authority, statistical reports and independent monitoring reports, minimum-volume screening standards for laboratories, and getting more information to women).
- **Work has been planned or has begun on eight recommendations. However, the recommendations are unlikely to be implemented by June 2004.** (Recommendations 1, 25, 27, 28, 31, 33, 41, and 45. These include the Audit of Invasive Cervical Cancer (the Cancer Audit), the review of the Operational Policy and Quality Standards, training and continuing medical education, electronic access to the NCSP-Register²¹, and the need for a population register).
- **Two of the recommendations will not be implemented** (Recommendations 13 and 15 – that the NSU is under the control of a second- or third-tier manager with a specialist medical qualification, and the Kaitiaki Regulations).
- **Work has begun on a further four recommendations (relating to ethics committees) but it is unclear whether they will be implemented.** (Recommendations 19, 21, 22, and 23).
- **The Ministry of Health is still to decide whether one recommendation will be implemented** (Recommendation 2 – offering women two smear tests 12 months apart. This depends on the outcome of Recommendation 1).

3.6 The most significant progress has been made on recommendations that required legislative changes to be made, on which work was well advanced at the time of the Committee of Inquiry, or that were relatively straightforward to address.

3.7 The Cancer Audit (Recommendation 1) is currently two years behind schedule but it is difficult – given the magnitude of the audit – to see how more progress could have been made.

3.8 However, more work still needs to be done to ensure that appropriate assurance processes exist around the quality aspects of the Programme, and we consider that this is the most significant issue going forward.

3.9 Many of the recommendations relating to information technology have not yet been implemented.

¹⁹ The Ministry expects to implement Recommendations 14, 16, and 17 through the Health (Screening Programmes) Amendment Bill.

²⁰ With the exception of the smear-taking and colposcopy standards in relation to smear-takers and private colposcopists. The Quality Standards are discussed in Part Five on pages 37-48.

²¹ The NCSP-Register is a database containing the demographic details of all women enrolled in the Programme, and their cervical cytology and histology results, and details of smear-takers and laboratories. It is used for follow-up of abnormal smears and to recall women if they are overdue for a smear, as well as for monitoring aspects of the Programme.

3.10 We also consider that the NSU must be more willing to listen to the views of others who have an interest in the Programme.

Overseeing the Implementation of the Recommendations

A process has been established to monitor the implementation of the Committee of Inquiry's recommendations. (Recommendation 46)

3.11 Recommendation 46 of the Committee of Inquiry required that *...A process to ensure that the recommendations made by the Committee are implemented should be put in place.* To date this has been achieved by:

- the Ministry establishing a Cervical Screening Inquiry Steering Group (comprising managers of the various directorates and project teams responsible for implementing the recommendations) to oversee implementation; and
- the Director-General of Health providing the Minister with monthly reports (from May 2001 to May 2002) setting out progress against milestones for each recommendation, including a “current” status of each recommendation. From June 2002, these reports have been provided on a quarterly basis.

The independent expert engaged by the Minister to advise on progress in implementing the recommendations has completed her final report. We consider that monitoring by independent expert/s needs to continue and to be expanded to focus on the effectiveness of the Programme as a whole. (Recommendation 45)

3.12 In our view, these independent reviews should continue and it is timely for subsequent reviews to be expanded to focus on the effectiveness of the Programme as a whole. We suggest that independent reviews of the Programme be undertaken at the end of 2004, 2006, and 2011.

Progress in Relation to the Key Recommendations

Dr McGoogan likened the work that needed to be done to a jigsaw puzzle.

3.13 Dr McGoogan noted that:

...the value of a screening programme is greater than the sum of its individual component parts and it is the coherence of a well organized, structured, quality assured, population based programme that brings the full benefits to all women in a country. It can be likened to a jigsaw puzzle. We may know how many pieces we should have, we may have put some together but we do not achieve the completed picture until each is connected properly to the other pieces and only then do we recognise if there are some pieces missing or defective. I believe that most of the “pieces”, the component parts of a Cervical Screening Programme, are present in New Zealand but these are organised and monitored to varying degrees and some parts are further developed than others. They have still to come together to create a cohesive picture.

We were concerned to note that slow progress has been made in relation to recommendations that are key to completing “the puzzle”.

- 3.14 These recommendations relate to the following issues, which are discussed in more detail in the remainder of our report.

Further developing the culture of the NSU to be more open and collaborative with stakeholders. (Recommendation 11)

- 3.15 We consider that the NSU needs to be more open and collaborative with stakeholders. This includes not only drawing on the knowledge and resources of professional bodies (for example, the Professional Colleges²²), but also networking with agencies that also have a role in assessing service provider performance.

The Cancer Audit has taken longer than promised, and the results are not expected to be reported until the end of 2004 – two years later than promised. (Recommendation 1)

- 3.16 It is difficult to see how more progress could have been made with the Cancer Audit, given the magnitude of the audit. The Ministry acknowledges that it under-estimated the size of the task when it originally gave an undertaking to complete the Cancer Audit.

Providing electronic access to screening data for key stakeholders (for example, laboratories, colposcopists²³, and smear-takers). (Recommendation 31)

- 3.17 We consider that giving key users “ownership” of the screening data should help to improve the quality of the data, and the efficiency of data access. Currently, the information on the NCSP-Register is not easily available to key service providers of the Programme. To get access to the information, they must contact the Programme’s Regional Service Provider Staff and arrange for them to send copies.

The need for a population register. (Recommendation 33)

- 3.18 A population register provides a way of identifying and inviting women to participate in the Programme. The National Health Index (NHI)²⁴ could be used as the basis for a population register. However, improvements are needed to the NHI data quality before this can be done.

²² Professional (or Medical) Colleges – such as the Royal College of Pathologists of Australasia or the Royal New Zealand College of General Practitioners – are vocational branches of medicine that provide advocacy and support for their members, set quality standards, and deliver professional development opportunities in their own speciality areas.

²³ Colposcopy is an examination of the cervix, performed by a colposcopist i.e. a gynaecologist or sexual health specialist, to detect abnormal cells. If abnormal cells are present, the doctor may take a small sample of cells called a biopsy, which are sent to the laboratory to be examined by a pathologist.

²⁴ The NHI is an index of health care users, used by public hospitals and other health and disability support services to assign a unique number (the NHI number) to people who use their services.

Fully implementing the Quality Standards²⁵ (in that there are problems enforcing the Standards in relation to smear-takers and private colposcopists). (Recommendation 4)

- 3.19 The NSU does not include the Quality Standards as part of any contract²⁶ with general practitioners (GPs) and the Family Planning Association. Also, it does not contract with private colposcopists. Compliance by these groups with the Smear-taking Standards and the Colposcopy Standards is therefore voluntary.

Updating the Quality Standards. (Recommendation 27)

- 3.20 The 12 Colposcopy Standards were reviewed this year, and 13 new standards for providing an NCSP Regional Service were introduced in June this year. Three of the 22 Laboratory Standards have been reviewed, but the remainder will not be completed until 2004, and the Smear-taking Standards will not be reviewed until 2004-05.

Ensuring that service providers have the appropriate skills and that training courses are available. (Recommendations 28, 29, 40, 41, 42)

- 3.21 There are ongoing problems in providing suitable training courses for health professionals working in the Programme.

Measuring the proficiency of individual staff involved in cervical screening. (Recommendation 28)

- 3.22 The NSU is considering implementing individual proficiency testing for laboratory staff who process and interpret cervical smears. This is still to be decided and agreed.

Independent monitoring is a good overall indicator of problems with the Programme and service provider performance, and it needs to continue. (Recommendation 3)

- 3.23 The Independent Monitoring Group (IMG) carries out regular external monitoring of the Programme by measuring performance against a set of national indicators. These indicators cover the entire cervical screening pathway from enrolment and participation of eligible women²⁷ on the Programme, to laboratory reporting and follow-up of women with abnormal results. These reports need to continue. The NSU has advised us that it is committed to the ongoing production of independently generated monitoring reports.

²⁵ The Quality Standards include separate Standards for providing: a health promotion service, a smear-taking service, a laboratory service, a colposcopy service, and an NCSP regional Service.

²⁶ About one third of GP practices are subject to the arrangements under Section 88 of the Public Health and Disability Services Act 2000, and the other two thirds are covered by either Primary Health Organisation or Primary Care Organisation contracts with the Ministry of Health.

²⁷ "Eligible women" refers to all women aged between 20 and 69 who have ever been sexually active. This includes single women, lesbians, disabled women, women who have been through menopause, and women who are no longer having sex. Women who have had a hysterectomy need to check with their doctor or smear-taker if they still need to have cervical smear tests.

Ethics Committee issues are being worked on. (Recommendations 18 to 23)

- 3.24 Work on the Ethics Committees' issues is continuing, with the National Ethics Advisory Committee now scheduled to report to the Minister by 12 December. It is unclear whether some recommendations relating to ethics committees will be implemented.

Other Issues Raised By Dr McGoogan and By Us

NSU capacity has improved, but two key positions have not been filled.

- 3.25 The NSU has not been able to recruit an epidemiologist²⁸ or a manager for the Quality Monitoring Analysis and Audit Team (the QMAAT Manager). While epidemiology support is being provided from elsewhere in the Ministry, the QMAAT position has not been filled. We consider that the QMAAT position needs to be filled so that there is a dedicated person "driving" and co-ordinating audit, monitoring, and review. Our view is supported by the Royal New Zealand College of General Practitioners and by Dr McGoogan.

Auditing service provider compliance with the Quality Standards.

- 3.26 We are concerned that, apart from monitoring the number of smears that are being read by laboratories, there is presently no audit of service providers to ensure that they are complying with the Quality Standards.

Introducing a system to identify and assess new and emerging technologies.

- 3.27 We are concerned, as was Dr McGoogan, to learn that liquid-based cytology²⁹ is being introduced into New Zealand (10-15% of women are choosing to have their smears prepared this way) and yet this procedure is not covered by the Quality Standards.

²⁸ An epidemiologist specialises in the study of the distribution and determinants of health and disease in the community.

²⁹ Liquid-based cytology is an alternative to the conventional smear test (see paragraph 6.35 on page 56).

Part Four

The Ongoing Development of, and Current Issues for, the National Screening Unit

Introduction

- 4.1 The National Screening Unit (NSU) is responsible for delivering the Programme and BreastScreen Aotearoa, and for implementing the bulk of the Committee of Inquiry's recommendations (26 of 46), including three jointly with the New Zealand Health Information Service (NZHIS)³⁰.
- 4.2 Three of the recommendations relate specifically to the NSU's structure in regard to managing the Programme (Recommendations 11, 12, and 13).
- 4.3 In this Part, we discuss issues affecting implementation of the recommendations and the NSU's ongoing development and performance. This includes:
- the need to continue monitoring implementation of the Committee of Inquiry's recommendations;
 - the need for a more open and collaborative culture (Recommendation 11);
 - recruitment of skilled staff;
 - medical leadership and input (Recommendation 13); and
 - location of the NSU.

Ongoing Development of the National Screening Unit

The NSU was established as a separate unit within the Ministry in July 2001. (Recommendation 12)

- 4.4 Approval for the NSU to be established as a separate unit within the Ministry was given in November 2000 (before the Committee of Inquiry reported its findings in April 2001). However, the NSU was not established until July 2001.

In our previous report we noted that, for the first 12 months, the NSU was extensively involved in recruiting staff, addressing the Committee of Inquiry's recommendations, and responding to both Dr McGoogan's first review and our first review.

- 4.5 At the time the Committee of Inquiry reported, the NSU had 7.5 full-time-equivalent staff plus access to fixed-term contractors and external consultants. During the Inquiry, the approved level of permanent staff was increased to 33.
- 4.6 During the first 12 months, the recruitment and training of new staff for new roles placed the senior management of the NSU under severe pressure. They were effectively trying to create a new unit at a time when they also had to give high priority to the many tasks required to implement the Committee of Inquiry's recommendations, and to the operation of BreastScreen Aotearoa.

³⁰ The NZHIS is a group within the Ministry responsible for the collection and dissemination of health-related data.

The next 12 months was a period of consolidation, developing staff in their respective roles, and continuing the implementation of the recommendations.

- 4.7 The NSU's *Cervical Screening Inquiry Annual Review 2001/02 and Annual Plan 2002/03* highlights that, during its second year, the NSU was substantially driven by the Committee of Inquiry's recommendations and the recommendations from Dr McGoogan's first report.

The NSU is taking a more strategic and programme-oriented approach in 2003-04.

- 4.8 The NSU has drawn up a five-year Strategic Plan that has identified several key issues for the Programme and for BreastScreen Aotearoa. The Strategic Plan also includes performance indicators that the NSU will monitor to ensure the safety, effectiveness, and cost-effectiveness of both the screening programmes.
- 4.9 The NSU's 2003/04 draft Annual Plan and Work Plan reflect the strategic directions. Although the plans refer to work that will be done in response to the external reviews by Dr McGoogan and Professor Jocelyn Chamberlain³¹, the Work Plan is aimed at "business as usual" throughout the whole Programme rather than being focused solely on the Committee of Inquiry's recommendations.
- 4.10 The NSU is also introducing a planned approach to research and development, in order to be responsive to emerging issues. For example, it is currently looking at the potential effect of liquid-based cytology and Human Papilloma Virus³² testing on the Programme.

The NSU team continues to show a high level of dedication and commitment to making the Programme more effective.

- 4.11 We were impressed with the dedication and enthusiasm shown by NSU staff in relation to the Programme and to improving its effectiveness.

We were also impressed by the dedication shown by Regional Services' staff.

- 4.12 We found that staff employed by District Health Boards to provide Regional Services under contract to the NSU work hard to locate women who have had an abnormal smear and who have not attended for follow-up treatment. In addition, regional staff have used some innovative ideas – such as setting up mobile user-friendly clinics in the community – to reach women who would not usually attend for regular screening.

³¹ British screening expert Professor Jocelyn Chamberlain reviewed BreastScreen Aotearoa, and her May 2002 report included an assessment of the relevance of the Committee of Inquiry's recommendations for BreastScreen Aotearoa – J Chamberlain, 2002, *BreastScreen Aotearoa – An Independent Review*.

³² Human Papilloma Virus (HPV or wart virus) – there are two types of the wart virus (types 16 and 18) known to cause abnormal cellular changes that can result in development of cervical cancer. HPV is recognised as one of the main causes of cervical cancer.

Need To Continue Monitoring Implementation of the Committee of Inquiry's Recommendations

We support the incorporation of the Committee of Inquiry's recommendations into the NSU's Strategic Plan and Annual Plan, but consider that monitoring of progress to implement the recommendations is still required.

- 4.13 We support the NSU in taking a programme-focused approach to its planning. However, we consider that monitoring is still required of progress against the recommendations, and of the wider Programme.
- 4.14 We prefer a two-tiered approach to monitoring. In our view, the Minister should continue to receive the quarterly monitoring reports of the Cervical Screening Inquiry Steering Group, and that these reports should continue to be made public. Also, that reviews by independent expert/s should continue.

The independent expert engaged by the Minister to advise on progress in implementing the recommendations has completed her final report. We consider that monitoring by independent expert/s needs to continue and to be expanded to focus on the effectiveness of the Programme as a whole.

- 4.15 We note that Dr McGoogan intends that her second report is her final report. We previously reported that:

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.

- 4.16 This continues to be our view. We do, however, consider that it is timely for subsequent reviews to be expanded from looking at implementation of the Committee of Inquiry recommendations to focus on the effectiveness of the Programme as a whole.
- 4.17 We suggest that independent reviews of the Programme be undertaken at the end of 2004, 2006, and 2011.

Need For a More Open and Collaborative Culture

The culture of the NSU still needs to be developed. (Recommendation 11)

- 4.18 The Committee of Inquiry recommended preserving and encouraging the culture that was developing in the former HFA regarding the management of the Programme, however, the recommendation did not explicitly set out the nature of this culture. We understand that the culture was open and collaborative, and that advice was proactively sought from health professionals, specialist groups, and the wider community. We therefore consider that the recommendation aimed to make sure that the NSU continued to collaborate with the wider health community and health experts, to ensure the future development and excellence of the Programme.

4.19 Our audit found mixed views about the NSU's culture. In particular:

- The Programme's Clinical Leader is making a concerted effort to engage health professionals in the Programme. This extends to presentations at smear-taker update courses, engaging with the Professional Colleges and experts, and liaising with laboratories. We were impressed with this approach.
- The Cervical Screening Programme Advisory Group was disbanded in November 2002. This group provided the NSU with professional guidance, advice, and support from a wide range of health professionals (a pathologist, gynaecologist, GP, public health professional, and a consumer representative). The Ministry proposes to replace this advisory group with a new set of advisory groups. The revised structure looks sound, and the first meeting of the Programme's new advisory group was held in early-November 2003. However, there has been a 12-month gap between the cessation and subsequent re-establishment of advisory groups.
- IANZ is in a unique position to assist the NSU with the monitoring and enforcement of the Programme's Laboratory Standards. Although there has been some engagement between the two in this regard, in our view, the NSU has not driven the opportunity to collaborate nor used IANZ expertise to the extent we would have expected. This is further discussed in paragraphs 5.36-5.44 on pages 45-46.

4.20 Accordingly, we still consider that the NSU can improve the way that it interacts with other agencies in regard to the Programme. The NSU must become more willing to interact with external agencies.

What Are Some of the Current Issues?

Recruitment of Skilled Staff

The NSU has an increased budget and more staff, but workforce issues remain.

4.21 The NSU has been allocated additional resources in the past three years. The number of permanent staff has grown from 33 in 2001-02 to 37 in 2002-03 and 42.6 in 2003-04. The NSU's cost of staff has increased from an actual cost of \$2.3 million to a budget cost of \$3.7 million over the same period.³³

4.22 We identified in our first report that recruitment of skilled staff had proved difficult because of the shortage of suitable candidates, and that the NSU had not filled the two key positions of a part-time epidemiologist and a manager of the Quality Monitoring Analysis and Audit Team (QMAAT).

³³ From the *National Screening Unit Annual Plan 2003-04*, Draft 3b.

Two key positions have still not been filled.

- 4.23 The NSU has still not been able to recruit a part-time epidemiologist and, instead, contracts epidemiological support from other parts of the Ministry.
- 4.24 Nor has a manager been appointed for QMAAT. Rather, this function has been absorbed into the NSU's operational teams on the basis that all staff must be conscious of quality issues. While we agree that quality needs to be a focus for all staff, we consider that the QMAAT position needs to be filled so that there is a dedicated person "driving" and co-ordinating audit, monitoring, and review. Our view is supported by the Royal New Zealand College of General Practitioners and by Dr McGoogan on page 20 of her first report.

The NSU is under considerable pressure to perform.

- 4.25 We consider that the NSU continues to be under considerable pressure to perform, arising from:
- the significant workload involved in implementing the Committee of Inquiry's recommendations;
 - the high profile of the NSU screening programmes; and
 - adverse media comment after the release of Dr McGoogan's reports.
- 4.26 We consider that these pressures pose significant risks to the future of the Programme – in particular, the risk that the NSU will lose key staff.
- 4.27 The Ministry considers that the success of both the Programme and BreastScreen Aotearoa relies on the availability of adequate numbers of well-qualified staff. It is intended that the *Draft Workforce Development Strategy and Action Plan 2002-07* will address the workforce issues that face the screening programmes, such as recruitment, retention, availability of appropriate education and training, support systems, and morale. The draft Workforce Development Strategy sets out some initiatives for training and professional development for NSU staff.

Medical Leadership and Input

Medical input into the Programme has increased since our first report.

- 4.28 Since our first report:
- A Public Health Leader for Screening has been appointed to provide public health input into both screening programmes, and advice on other screening activities across the public health sector.
 - The Clinical Director (a fulltime position responsible for both screening programmes) resigned and was replaced by two part-time (60% each) Clinical

Leaders – one for the Programme³⁴ and one for BreastScreen Aotearoa - who report directly to the Group Manager of the NSU.

- The Programme’s Clinical Leader and the Operational Manager are jointly responsible for the national management of the Programme, and they share line management responsibility for Programme staff.

However, the Programme is not medically led as recommended by the Committee of Inquiry. (Recommendation 13)

4.29 The Committee of Inquiry recommended that the Programme should be under the control of a second- or third-tier manager within the Ministry who holds – as a minimum – specialist medical qualifications in public health or epidemiology³⁵.

4.30 The Committee of Inquiry was concerned that the previous head of the Programme *...did not have the necessary power to ensure the Programme’s effective management and co-ordination. She had no authority to require action to be taken or to impose sanctions when nothing happened. All she could do was request others to carry out whatever action she thought advisable ... the Programme had no control over funding, if a person or entity was failing to perform, the sanction of denying payment was unavailable.*

4.31 The Committee of Inquiry also noted *...that as a third tier manager her ability to advance issues depended upon her ability to identify them, make a case for action and influence colleagues.*

4.32 Some of these issues have been addressed in that:

- the NSU is a separate business unit within the Ministry with its own staff and budget;
- the NSU Group Manager reports to the Deputy Director-General of Public Health (who has specialist public health medical qualifications);
- although the NSU is required to prepare annual plans and other accountability documents, it does have considerable autonomy in the work that it undertakes and priorities that it sets; and
- at no time during the course of our review did we identify any tasks not being undertaken because the NSU did not have the authority to do so.

4.33 However, as the Programme is under the control of a third-tier manager who does not have a specialist medical qualification in public health or epidemiology, the Programme is not medically led as recommended by the Committee of Inquiry. Dr McGoogan reached the same conclusion.

³⁴ The current Clinical Leader for the Programme works three days a week with the NSU and practices as a clinician in sexual and reproductive health – which includes the taking of cervical smears – for two days a week.

³⁵ Epidemiology is the study of the distribution and determinants of health and disease in the community.

4.34 We note that Professor Chamberlain – in her 2002 report on BreastScreen Aotearoa – considers that the role of NSU Group Manager is not exclusively the province of a public health specialist. Professor Chamberlain said that the current manager has all the desired qualities, and noted that public health advice is certainly needed:

Gisborne Recommendations 11.11 to 11.13. The National Screening Unit now meets these requirements, with the exception that the manager does not hold specialist medical qualifications in public health or epidemiology. Given the complexity of the Manager's role, in managing the funding of providers of screening, developing information systems, ensuring quality standards are met, managing improvements and changes to both programmes, responding to political and media questions, and more, I do not consider that this role is exclusively the province of a public health specialist. Public health advice is certainly needed, but the person in charge must first and foremost be a competent manager with ability to communicate effectively and strongly, not only with the National Screening Unit staff, but also with the providers of screening, the Groups who audit and monitor, and others with an interest in both programmes. I consider that the present manager has all the desired qualities.

During our review, significant concerns were expressed at the lack of medical leadership and medical input into the Programme.

4.35 Some academics, and consumer group advocates have expressed significant reservations about the lack of medical leadership and input into the Programme.

4.36 In particular, they have identified the following matters as areas of concern:

- The two medically qualified people involved in the Programme are not sufficiently involved in an operational sense to provide the medical input that a medical leader would provide.
- From November 2002 to November 2003 – considered to be a critical 12-month period – the Programme has been without the benefit of the independent expertise and advice offered by advisory groups.

4.37 We also have some reservations about the revised leadership structure, in that:

- joint responsibility potentially weakens accountabilities;
- the Clinical Leader has a significant workload. We are unsure whether a person working three days a week can perform all the tasks required; and
- the Cervical Screening Programme Advisory Group, which provided the NSU with professional guidance, advice, and support, was disbanded in November 2002, and nothing was established in its place until November 2003.

4.38 We consider that an appropriate level of medical input into the Programme is critical and needs to be carefully managed. At this stage, it is too early to determine whether the recent initiatives and revised structure will ensure an appropriate level of medical input into the Programme.

- 4.39 Monitoring the level of medical input into the Programme should be included in the terms of reference of independent expert/s (if appointed to review the Programme in future).

Location of the NSU

Suggestions have been made that the NSU should be located outside the Ministry.

- 4.40 The NSU was established to provide the co-ordination, funding, policy development, and monitoring of the Programme and BreastScreen Aotearoa. The NSU has had a rather tumultuous existence, with intense media and political interest in the Programme since the Committee of Inquiry reported.
- 4.41 Some people have suggested to us that if the NSU was located outside the Ministry and established as a stand-alone Crown entity, it may be less vulnerable to media and political pressures.
- 4.42 Our view is that a period of stability is currently needed to allow the NSU the opportunity to consolidate and continue to improve the Programme.
- 4.43 This view is supported by Professor Chamberlain who stated in paragraph 13.3 of her report that:

...It was suggested to me by the Advisory Committee and others that the NSU might be less vulnerable to these pressures if it were not part of the Ministry of Health, but a stand-alone organisation, or attached to a Cancer Control Agency (which is proposed but does not yet exist). But, given that the NSU would still remain the only publicly-funded body managing both the national cancer screening programmes, I cannot see that a different location would necessarily lessen the demands, and another major organisational change might well have a destabilising effect. What the NSU needs most at present is a period of stability in which to settle down and have time to develop the skills it needs to maintain high quality breast and cervical cancer screening services.

Part Five

Quality Standards, and Monitoring and Auditing of the National Cervical Screening Programme

Introduction

- 5.1 The Committee of Inquiry made 12 recommendations (3, 4, 5, 7, 8, 9, 27, 28, 32, 40, 41, and 42) about setting performance standards, and monitoring and auditing service provider compliance with the standards. They included:
- fully implementing Operational Policy and Quality Standards (Quality Standards) for the Programme (Recommendation 4), and reviewing the Quality Standards every two years or more frequently if monitoring indicates that some of the standards are inappropriate (Recommendation 27);
 - monitoring the Programme – including statistical analyses of the quality of laboratory performance and of other aspects of the Programme (Recommendation 7); and
 - providing appropriately skilled and qualified people to undertake the work to run an effective screening programme (Recommendation 28).
- 5.2 In this Part, we discuss progress in regard to the Quality Standards. We also discuss other issues such as auditing service provider compliance, use of independent accreditation, quality improvement and assurance, and independent monitoring of the Programme.
- 5.3 We discuss the Committee of Inquiry’s recommendations relating to the capability of people carrying out cervical screening in Part Six on pages 49-58.

Operational Policy and Quality Standards

- 5.4 Setting performance standards, and monitoring and auditing service provider compliance with those standards is critical to ensuring the quality of the Programme.
- 5.5 This is widely recognised. In the 1980s, the World Health Organisation issued guidance on the requirements of a successful cervical screening programme. The essential elements included standards and an organised programme of quality control. The *European Guidelines for Quality Assurance In Cervical Cancer Screening*, published in 1993, state:
- A pre-condition of quality assurance is the establishment of standards. The aim of the quality assurance programme is to ensure that these standards are met.*
- 5.6 Dr McGoogan raised concerns about a number of quality-related issues – particularly around quality control of smear-taking, testing the competency of individuals, notification to the Programme of laboratories with poor performance in the external quality assurance programme, and the absence of standards for monitoring liquid-based cytology.

- 5.7 We also expressed concern in our first report about the slow progress in setting up an effective monitoring, evaluation, and auditing³⁶ regime, concluding that *...changes relating to effective monitoring, evaluation and audit of the Programme are continuing to prove the most intractable.*

Have The Quality Standards Been Fully Implemented?

The NSU produced the Quality Standards for cervical screening in October 2000.

- 5.8 The Quality Standards collectively cover the services provided to the Programme within the following categories:
- *Providing a Health Promotion Service* (Health Promotion Standards);
 - *Providing a Smear-taking Service* (Smear-taking Standards);
 - *Providing a Laboratory Service* (Laboratory Standards);
 - *Providing a Colposcopy Service* (Colposcopy Standards); and
 - *Providing an NCSP Regional Service* (Regional Service Standards).
- 5.9 The Quality Standards detail the required standard of service provision, as well as offering guidance on good practice. They include training requirements, quality control activities, and minimum workloads.

The Quality Standards have not been fully implemented, in that they cannot be enforced for smear-takers and private colposcopists. (Recommendation 4)

- 5.10 Although the Quality Standards state – *Providers performing health services associated with the Programme... shall comply with all the provisions of this publication that relate to the provision of those health services* – they cannot be enforced for smear-takers and private colposcopists.
- 5.11 General practitioners (GPs) and practice nurses are the predominant smear-takers. However, the Programme does not have a contract with GPs for smear-taking services. About one third of GP practices are subject to the arrangements under section 88 of the Public Health and Disability Services Act 2000, and the other two-thirds are covered by Primary Health Organisation or Primary Care Organisation contracts with the Ministry of Health. None of these arrangements require smear-takers to comply with the Smear-taking Standards.

³⁶ 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 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.
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- 5.12 The Royal New Zealand College of General Practitioners has designed a practice review tool that incorporates the Quality Standards. However, the College wrote to the NSU in May 2002 noting that it did not endorse the Quality Standards, and that it had included the Quality Standards in its practice review *to raise awareness of government set standards*. Further, that it considers that the *standards cannot be attained in the current environment*.
- 5.13 The Smear-taking Standards have been used in complaint cases by the Health and Disability Commissioner as a benchmark for measuring the quality of service provision. We were also told by smear-takers that, while compliance is voluntary, they considered that many of the requirements in the Smear-taking Standards would be met as they reflect good practice.
- 5.14 Colposcopists employed by a DHB must comply with the Colposcopy Standards because the NSU has a contract with the DHB to provide these services.
- 5.15 However, as the NSU does not have a contract with private colposcopists, there is currently no way of enforcing their compliance with the Colposcopy Standards. Dr McGoogan was particularly concerned about this in her final report. She stated that women should be aware of this, and that they should insist that the same service-provision standards be met when attending a private colposcopist. The NSU intends to distribute to smear-takers a list of preferred providers, so that the smear-takers can advise their patients which colposcopists comply with the Colposcopy Standards.

These problems may be resolved once the Health (Screening Programmes) Amendment Bill is enacted.

- 5.16 The Health (Screening Programmes) Amendment Bill contains a clause that would allow the NSU to make regulations to prescribe standards that must be met by providers of screening, diagnostic, and treatment services relevant to a screening programme, and the means of implementing those standards. This could cover smear-takers and private colposcopists. The NSU is considering whether or not it would use this regulation-making power to make compliance with the Quality Standards compulsory should the Bill be enacted.

Have The Quality Standards Been Reviewed As Recommended?

The Committee of Inquiry recommended that Quality Standards be reviewed every two years, or more frequently if monitoring indicates that some of the Standards are inappropriate (Recommendation 27). We noted during our review that it is not always clear what is required to comply with the Quality Standards, and we consider that, in order to meet the Committee of Inquiry’s recommendation, this aspect should have been rectified immediately.

- 5.17 The Quality Standards contain specific “rules” that must be complied with, as well as guidance and good practice. It is not always clear what are rules and what is guidance – and therefore what is necessary to comply with the Quality Standards. For example, the guidance for internal quality control in the

Laboratory Standards states ...*Laboratories must have policies and practices that ensure the quality of gynaecological cytology and histology assessment. Policies must define staff responsibilities and laboratory procedures...* The use of “must” suggests that it is mandatory rather than guidance.

- 5.18 The NSU acknowledges that inadequate differentiation between specific policies and good practice guidance is a problem, and that it was addressed successfully in the revision of the Colposcopy Standards. The NSU will apply this approach as the remaining Quality Standards are reviewed.

The Colposcopy Standards were reviewed in 2003.

- 5.19 The review of the Colposcopy Standards in 2003 resulted in much-improved standards, which clearly set out what is required of colposcopists. The standards also set out what additional data the NSU will collect to help encourage good practice in colposcopy and to define future targets and standards.
- 5.20 The NSU convened a Colposcopy Working Group to provide advice on the implementation of the new Colposcopy Standards, including performance monitoring of colposcopists. The revised standards were also circulated in draft to all District Health Board colposcopy clinics for feedback.

The review of the Quality Standards for providing laboratory, smear-taking, and health promotion services is overdue.

- 5.21 Three of the 22 Laboratory Standards have been reviewed, but the remainder will not be completed until 2004. The Smear-taking Standards will not be reviewed until 2004-05.
- 5.22 The NSU has begun to review the Laboratory Standards, and anticipates this will be completed in 2003-04 – four years after they were introduced. The Laboratory Standards currently do not cover liquid-based cytology, and an external reviewer – IANZ – has problems assessing whether the laboratories that it accredits are complying with the Laboratory Standards. In our view, this indicates that the Laboratory Standards are inappropriate and should have been reviewed sooner, in order to comply with the Committee of Inquiry’s recommendation.
- 5.23 The review of the Smear-taking Standards is not planned to start until the Health (Screening Programmes) Amendment Bill has been passed. The regulation power in the Bill would require the Smear-taking Standards to be set out in the regulations, which would require consultation. As the review of the Smear-taking Standards will also require consultation, the NSU intends that consultation should be done only once.
- 5.24 Review of the Health Promotion Standards is planned for 2004-05, once the NSU has established a Health Promotion Framework. As an interim measure, the NSU has drawn up a new service specification that has been incorporated in the DHB and Independent Service Provider Agreements.
- 5.25 The Regional Service Standards were introduced in June 2003.

Is Service Provider Compliance With the Quality Standards Being Audited?

- 5.26 We are concerned that there is presently no audit of service providers by the NSU to ensure that they are complying with the Quality Standards.

The NSU is aware of some areas of non-compliance with the Quality Standards – particularly by laboratories that are not meeting minimum-volume requirements. (Recommendation 9)

- 5.27 The Laboratory Standards require that a laboratory must process 15,000 gynaecological cytology cases³⁷ a year. (The Committee of Inquiry recommended that it should be compulsory for laboratories to process a minimum of 15,000 cases a year.) As we reported in February 2002, this requirement resulted in three public hospitals and two community laboratories ceasing to provide cytology services.
- 5.28 The two remaining hospital laboratories that provide cytology services are not meeting the minimum-volume requirement. One laboratory is processing about 5000 cases a year, and the other about 10,000.
- 5.29 The NSU considers that public hospital laboratories are needed to train registrar pathologists. At present, about half of all pathology students are trained in cytology in the public hospital environment. The remainder of students are placed in community laboratories for training.
- 5.30 The NSU has decided to extend the deadline for hospital laboratories to meet the 15,000 cases minimum-volume requirement. The NSU considers that it would be a loss to the health infrastructure if capability in cytology in the public sector was lost and, in addition, that options for providing refresher training for cytotechnical staff would be reduced if more public hospital cytology laboratories closed.
- 5.31 The minimum-volume requirement was introduced as a means of ensuring that cytoscreeners were reading a sufficient number of slides to maintain their skills. In situations where the minimum volume is not being met, the NSU needs to recognise and mitigate the increased risk through its quality assurance and audit process. This may mean that laboratories that do not meet the minimum-volume requirement are audited on a more frequent basis than those that are meeting the requirement.

The NSU is not auditing³⁸ service providers to ensure that they are complying with the Quality Standards.

- 5.32 The preparation and issuing of the Quality Standards is an important first step. Equally critical, however, is checking that service providers are actually complying with the Quality Standards. We consider that the value of the Quality Standards is substantially reduced by not auditing compliance.

³⁷ A “case” may comprise more than one smear – if two smears are provided from the same woman, they count as one case.

³⁸ This audit of compliance with Quality Standards differs from the Audit of Invasive Cervical Cancer, which is discussed in Part Seven on pages 59-74.

- 5.33 In addition, auditing of service provider compliance with the Quality Standards will provide information to:
- service providers – as to whether they are meeting the Quality Standards and, if not, what they need to do to comply; and
 - the NSU – as to which of the Quality Standards needs to be reviewed.
- 5.34 The NSU has advised us that it has not undertaken any service provider audits to date because:
- the previous contract with laboratories was between the DHBs and the laboratories, and the NSU was not party to the contract. A new contract has been drawn up for laboratories that provide cytology services, and this gives the NSU a direct contractual relationship with the laboratories. Nine of the 12 laboratories³⁹ have signed the Programme’s Laboratory Agreement which includes more stringent monitoring, evaluation, and audit requirements;
 - there were no standards in place (then) for Regional Services;
 - there were known quality issues with the Colposcopy Standards that needed to be addressed before the Standards could be used to audit against; and
 - the NSU does not consider that it is in a position to audit all 5300 smear-takers. In addition, smear-takers are not contractually bound to adhere to the Smear-taking Standards.

Use of Independent Accreditation

As the NSU did not have the contractual basis to audit laboratory service providers, we consider that it should have investigated other interim arrangements to mitigate this risk. One such arrangement could have been to rely on the work undertaken by accreditation agencies⁴⁰.

- 5.35 The Committee of Inquiry noted the benefits of independent accreditation with an independent laboratory control authority:

Accreditation does not guarantee that laboratories will not under-report an unacceptable number of smear tests. It focuses on the systems and procedures a laboratory uses to achieve its results and not on the substance of the results. What it does is set in place systems and procedures to ensure that a laboratory has appropriately trained staff, well maintained equipment and recognised methods and procedures in place. However, if these systems and procedures are properly followed they should enhance a laboratory’s performance substantively as well as procedurally... they are likely to lead to good quality results and to reduce opportunities for error.

³⁹ Negotiations are under way with the remaining laboratories.

⁴⁰ Relying on the work of another auditor is an accepted audit practice, provided that the credentials of the other auditor are checked, and that the audit methodology is appropriate and some testing is performed.

- 5.36 One such accreditation agency, IANZ, wrote to the NSU twice, each time expressing an interest in establishing a formal relationship between the two organisations and in co-ordinating efforts to enable the NSU to fully meet its quality objectives. Although IANZ had not received a reply from the NSU, it was nevertheless recognising and reviewing cytology and histology laboratory compliance against the Laboratory Standards.
- 5.37 In fact, many of the requirements of the Laboratory Standards are also included in *NZS/ISO 15189:2003 Medical Laboratories – Particular requirements for quality and competence* (the ISO Standard).
- 5.38 IANZ assesses medical laboratories against the ISO Standard. In particular, it looks at:
- staff knowledge, competence, and experience;
 - integrity and traceability of equipment and materials;
 - technical validity of methods and their correct application;
 - validity and suitability of results; and
 - quality management system effectiveness and conformance to international requirements.
- 5.39 Technical professional experts assist IANZ in the peer assessment process. As part of the new ISO Standard for medical laboratories, IANZ will also assess procedures for sample collection – for cytology, this would include assessing procedures for smear-taking.
- 5.40 IANZ assesses each medical laboratory every year, with a full assessment with peer review a maximum of every fourth year. If non-compliance is found, IANZ issues a corrective action request which specifies what activity should be corrected and by when. The amount of time given is relative to the risk. IANZ may require some activities to cease immediately.
- 5.41 Although IANZ can check compliance with the Laboratory Standards – for example, the requirement for cytology laboratories to process 15,000 slides a year – it cannot issue a corrective action request. Instead, it has advised non-complying laboratories to contact the NSU for clarification where non-compliance is identified.
- 5.42 Poor compliance with the ISO Standard can result in IANZ suspending a laboratory's accreditation. Laboratories cannot claim payment for services without accreditation.
- 5.43 The Programme's Laboratory Standards require laboratories to inform the NSU of the results of their IANZ assessment, but this has not been happening on a regular basis. We would have expected the IANZ assessments to be sent to the NSU as a matter of course. Moreover, we would have expected that the NSU would have followed up the non-receipt of these reports.

The NSU and IANZ have now agreed to work collaboratively to ensure that auditing and accreditation assessments are closely aligned.

- 5.44 Since we began our review, IANZ and the NSU have met and agreed that there is a difference between the audit work that the NSU intends to undertake and the assessments currently done by IANZ. The NSU has announced that it intends to undertake the service provider audits internally, and IANZ supports this decision. In addition, the NSU and IANZ have agreed to work collaboratively to ensure that auditing and accreditation assessments are closely aligned. A Memorandum of Understanding is being prepared to ensure that the IANZ laboratory accreditation report will be shared with the NSU.

Quality Improvement and Assurance

The NSU is drafting a Quality Framework to guide existing and future quality improvement.

- 5.45 The NSU is in the process of drafting the *Screening Programmes Quality Framework*, which draws on the (draft) *New Zealand Health and Disability Sector Quality Improvement Strategy*. It is intended that the Quality Framework will guide existing and future quality improvement initiatives for cancer screening in New Zealand. Operational documents will be required to ensure that the requirements of the Quality Framework are met.
- 5.46 The Quality Framework and the inclusion of audit clauses into the Programme's service provider agreements now form a basis to begin service provider audits for health promotion services, laboratories, DHB colposcopy services, and Regional Services.
- 5.47 Private colposcopists and smear-takers still need to be bound to adhere to the Quality Standards. There may be scope to include an audit requirement under the intended Health (Screening Programmes) Amendment Bill regulations.

Laboratories are not reporting their External Quality Assurance results to the NSU.

- 5.48 The Royal College of Pathologists of Australasia runs an external quality assurance (EQA) programme in which, four times per year, each participating laboratory is sent smears to review and report a diagnosis. Participation to a satisfactory standard in an EQA programme is a requirement of the Laboratory Standards.
- 5.49 Dr McGoogan's first report criticises the lack of obligation for laboratories to declare any "poor performance" in the EQA programme to the NSU. We agree with Dr McGoogan that regular reporting of these results to the NSU would enable the NSU to monitor laboratory performance and investigate any poor performance.
- 5.50 IANZ monitors laboratory performance in the EQA programme as part of its assessment. Laboratories must show what action was taken to review slides where an incorrect response was given. Consistent poor performance in the EQA

programme could ultimately result in the laboratory losing accreditation and being unable to claim payment for services. Provision of the IANZ accreditation report to the NSU will enable the NSU to access this information.

What Monitoring is Being Undertaken?

Independent monitoring is a good overall indicator of problems with the Programme and service provider performance, and it needs to continue.

- 5.51 The Independent Monitoring Group (IMG)⁴¹ carries out regular external monitoring of the Programme by measuring performance against a set of national indicators. These national indicators were established to improve the overall quality assurance processes of the Programme, and they cover the entire screening pathway from enrolment and participation of eligible women on the Programme, to laboratory reporting and follow-up of women with abnormal results.
- 5.52 Monitoring is intended to identify problems with the screening pathway so that any issues can be addressed at an early stage. The results of the review are publicly reported and are available online at www.healthywomen.org.nz. The reports include the monitoring data, its analysis, and recommended action to address any issues that have been identified

Monitoring the effectiveness of colposcopy is affected by the lack of data.

- 5.53 One of the national indicators for colposcopy is the time that women must wait before having a colposcopic assessment. This waiting-time data is collected by the DHB colposcopy units and reported to the Ministry. Four DHB colposcopy clinics did not provide this data to the Ministry in the last quarter of 2002, and another five DHBs did not provide complete data.
- 5.54 An analysis of the data that was provided showed that, in some areas, women waited longer than four weeks for a colposcopy assessment after a high-grade smear result. The NSU cannot determine how widespread such a problem is if it does not have data for all DHBs. In our view, the NSU needs to find some way of ensuring that DHBs forward the required information.
- 5.55 We were told that the collection of waiting-time data from private colposcopy clinics is also difficult. We consider that the NSU should look at whether this can be covered by its regulatory powers as intended under the Health (Screening Programmes) Amendment Bill.

⁴¹ The IMG is based in the University of Otago's School of Medicine. Its members include public health physicians, a gynaecologist, pathologists, an epidemiologist, a GP, a cytotechnologist, and Maori and consumer representatives.

The IMG reports have been used by the NSU to effect quality improvements.

- 5.56 The NSU produces regular update reports that outline the action taken by the NSU to address the IMG recommendations. The follow-up of IMG recommendations has resulted in laboratories internally reviewing their reporting patterns when they have fallen outside the national averages.
- 5.57 In addition, when the IMG identified issues relating to a lack of follow-up biopsy results on the NCSP-Register for women with abnormal smears, the NSU was able to check that the women had been seen at colposcopy. In another example, the NSU was able to resolve a technical problem to ensure that biopsy results were recorded on the NCSP-Register.

Independent monitoring of the Programme should continue.

- 5.58 In her first report, Dr McGoogan noted that communication between the IMG and the NSU must be improved, and that each should have a better understanding of the other's needs. During our review, the relationship had deteriorated to the point that ongoing production of the monitoring reports by the IMG was threatened.
- 5.59 The NSU has extended the current contract with the IMG until December 2003.
- 5.60 It is beyond the scope of this review to determine the reasons for the relationship problems. However, we consider that external monitoring of this type should continue after December 2003.
- 5.61 The NSU has advised us that it is committed to the ongoing production of independently generated monitoring reports.

Part Six

Capability of People Carrying Out Cervical Screening, and Use of New Technologies

Introduction

- 6.1 The Committee of Inquiry's Recommendations 28, 40, 41, and 42 relate to training, continuing medical education, and proficiency testing of people involved in cervical screening.
- 6.2 In addition, Dr McGoogan has raised the issue of a lack of systems to introduce new technologies for screening, such as liquid-based cytology.
- 6.3 In this Part, we discuss ongoing issues relating to having appropriately skilled and qualified people to provide laboratory, smear-taking, and colposcopy services, and the need for a system to introduce new technologies.

Capability of People Carrying Out Cervical Screening (Laboratory Staff, Smear-takers, and Colposcopists)

Are Appropriately Skilled and Qualified People Undertaking the Work In Laboratories?

- 6.4 We note that Dr McGoogan was particularly concerned about the lack of training for laboratory staff, particularly in liquid-based cytology. We discuss liquid-based cytology and introduction of new technologies in paragraphs 6.34-6.51 on pages 56-58.

While some continuing education is available within New Zealand, there is no practical course designed to maintain competency in cervical cytology.

- 6.5 The Laboratory Standards state that all cytotechnical staff and pathologists should take part in a formal update course in cervical cytology every three years. Exactly what a "formal update course" encompasses is open to interpretation; however, it is reasonable to consider that this course should be designed to maintain competency in cytology. There is currently no course offered in New Zealand that is designed to maintain competency in cervical cytology.
- 6.6 The New Zealand Society of Cytology holds an annual conference (partially funded by the Programme) that usually includes workshop sessions on topical issues in cytology. The conference is valuable in providing a forum for ongoing learning, but does not fill the need for a New Zealand-based practical course in cervical cytology.
- 6.7 Post-graduate training in cytopathology is not yet available in New Zealand.

There is some informal continuing education.

- 6.8 Some ongoing education is available in New Zealand, but mostly on an informal basis. This includes:
- internal teaching sessions or journal article review groups;

- participation in the external quality assurance programme;
- bringing an expert from overseas to run a training course for staff; and
- participation in a voluntary Competency and Professional Development Programme run by the New Zealand Institute of Medical Laboratory Scientists.

6.9 In addition, pathologists must complete continuing medical education each year to maintain their annual practising certificate from the Medical Council. The Royal College of Pathologists of Australasia audits 5% of the continuing medical education returns by its members to ensure validity of the claims. The Medical Laboratory Technologists Board is preparing a similar programme.

The NSU is currently consulting on a proposal for a National Cervical Cytology Training Organisation.

6.10 The NSU has investigated options for providing nationally co-ordinated training in cytology for laboratory staff, pathology registrars, and cytopathologists⁴² and released a proposal in October 2003 for providing this training. The proposal, which discusses the advantages and disadvantages of four options (including the establishment of a training centre at a fixed location, a mobile training centre, or using training available in Australia), was distributed to the NCSP Laboratory Workforce Working Group⁴³, and will be used for external consultation.

The NSU is considering implementing individual proficiency testing for laboratory staff that process and interpret cervical smears. (Recommendation 28)

6.11 The need for a programme that measures the competency of all the individuals involved in cervical cytology was raised by the Committee of Inquiry and in both of Dr McGoogan's reports. Although the day-to-day quality assurance systems in laboratories should detect staff that need additional training, we agree with Dr McGoogan that an independent assessment of proficiency for individual staff involved in cervical cytology is also a critical part of an overall quality system, and needs to be introduced.

6.12 The NSU has produced a draft discussion document for proficiency testing and competency assurance, which has been discussed with the NCSP Laboratory Workforce Working Group and at the Society of Cytology Conference in 2003.

6.13 There are differing views within the laboratory workforce on the introduction of individual proficiency testing:

- Some pathologists we spoke to were reluctant to implement individual competency assessments.
- One cytotechnologist considered that the profession has been expecting individual proficiency testing, and that a requirement to participate in a

⁴² A cytopathologist is a medical specialist with expertise in cytology.

⁴³ A group of laboratory representatives convened to provide advice to the Programme on laboratory workforce initiatives.

proficiency test is likely to be included in the scope of practice under the Health Practitioners Competence Assurance Act 2003. If this was implemented, passing a proficiency test could be required to maintain professional registration.

- Other laboratory staff questioned the value of implementing such testing, especially considering that laboratories already participate in an external quality assurance programme. In their opinion, individual proficiency testing is an artificial situation as it is difficult to re-create a realistic screening situation, and most laboratory staff would always spend more time screening a slide that they know is part of a test.

Are Appropriately Skilled and Qualified People Taking Smears?

No practical refresher course is available for improving the quality of smear-taking.

- 6.14 There is no training course designed for smear-takers who require refresher training in the practical side of smear-taking. Some doctors we spoke to saw this as a deficiency in the Programme, and a particular problem for doctors who have higher inadequate smear rates than expected and who would like additional training. Informally, individual practitioners may ask a peer, or a trainer from the Family Planning Association or the local Polytechnic, to review their technique.

Smear-taker training courses vary throughout the country.

- 6.15 In her first report, Dr McGoogan stated that *...high quality smear taking is necessary for an effective screening programme.*
- 6.16 The Smear-taking Standards, produced by the Programme in May 2002, require that *...all smear-takers will complete a recognised educational course in smear-taking practice prior to providing a smear-taking service for women.*
- 6.17 The Smear-taking Standards are supported by the New Zealand Qualifications Authority (NZQA) Unit Standard 1098 “*Cervical Screening: Perform cervical screening and cervical smear taking*” which outlines the content of the smear-taker training course, and was designed to ensure nationally consistent teaching and assessment standards. Training providers are required to be registered and accredited by the NZQA.
- 6.18 Smear-taker training is provided by Polytechnics in Waikato, Hawkes Bay, and Manawatu, and by the Family Planning Association. However, there is still much variation in the courses provided. Each of the training providers has designed their own material and course structure, as there is no training manual or course material provided by the Programme.
- 6.19 We understand that one course did not allow the trainees to actually take a smear during the course. The NZQA is currently drawing up a moderation process to ensure consistency of the content of courses throughout the country.
- 6.20 In addition, smear-takers that we spoke to were concerned that there is much variation in the quality of support and guidance offered to the trainees during the

practical part of their training. Many trainees would like more guidance. In response to this concern, the NSU is establishing workforce initiatives to strengthen supervision of smear-taker trainees.

A smear-taker training fund has increased access to training for practice nurses.

- 6.21 In response to Dr McGoogan’s comments that *...the lack of free training and easily accessible update courses is a barrier to safe practice. Smear taker training and update courses should be provided free for practice nurses and lay smear takers and be more geographically available*, the Programme is now reimbursing smear-taker training course fees to practice nurses who complete the course.
- 6.22 Practice nurses we spoke to were very positive about the introduction of this funding, and considered that it has increased access to training for smear-takers.
- 6.23 Geographically, access may still be limited, although the Family Planning Association could provide training in other areas if there is a demand and funding is available. Travel and accommodation costs may be additional barriers for some. However, nurses see this course as part of their professional development, and are particularly motivated to do the course in clinics where a female smear-taker is otherwise not available.

Regional Services’ staff are providing feedback to individual smear-takers.

- 6.24 Regional Services’ staff provide smear-takers in their region with a six-monthly or annual report – known as a *Quality of Smears* report – showing the percentage of “satisfactory but limited”⁴⁴ or “unsatisfactory”⁴⁵ smears that have been taken by that person. Rates of greater than 20% “satisfactory but limited” smears or more than 2% of “unsatisfactory smears” indicate that additional training or a smear-taker refresher course is required.

The value of this feedback would be increased if the reports were used to identify smear-takers who need to improve the quality of their smear-taking.

- 6.25 The *Quality of Smears* reports are a useful measure of an individual’s quality of smear-taking, and provide good feedback to smear-takers on their performance. However, the action taken to follow up on the poor performers varies between regions⁴⁶. In some regions, the Regional Service, Independent Practitioners Association, or the Primary Health Organisation use the *Quality of Smears* reports to identify smear-takers who need additional training⁴⁷. In other regions, the reports are not reviewed.

⁴⁴ “Satisfactory but limited” means the smear is adequate for evaluation, but the quality of the smear is limited. The women may have to return for a repeat smear within one year if she has a normal smear history, or six months if she has an abnormal history.

⁴⁵ “Unsatisfactory” means the smear cannot be evaluated. The women should return for a repeat smear within one to three months.

⁴⁶ Some Regional Services’ staff will approach a nurse smear-taker and arrange for a supervisor to watch the smear-taker take a smear to identify the problem. The nurse may have to re-do the smear-taker training course. In other regions, the Independent Practitioners Association (IPA) or the Primary Health Organisation (PHO) monitors the adequate smear rates.

⁴⁷ For example, in one region, the IPA was able to identify that a number of smear-takers were having problems related to preserving the cells on the slides used for screening, and was able to remedy the problem.

- 6.26 Dr McGoogan also raised the issue of uncertified nurses taking smears and using the doctor's NCSP-Register number. This means the *Quality of Smear* reports will give results for the doctor when the smear was actually taken by the nurse. The NSU has implemented a new policy where smears must be recorded under the names of the actual smear-taker, and not the doctor's number. The Family Planning Association has advised us that it has no record of being notified of this change.
- 6.27 Nurses who are taking smears, but have not undergone a formal training course, are now able to apply for their own NCSP-Register identification number and receive *Quality of Smear* reports in their own name. This will enable the NSU to monitor who has been trained, who has not, and the quality of their smear-taking.
- 6.28 Nurses who receive an NCSP-Register identification number without undergoing training are still eligible to undergo formal training and to receive funding from the smear-taker training fund.

Smear-taker update courses are a valuable forum for information exchange.

- 6.29 The Family Planning Association, Regional Services, and Regional Public Health all run regular smear-taker update courses. These courses are generally well attended and provide a useful forum for information dissemination and discussion. For example, a recent course held in the Hutt Valley attracted more than 100 smear-takers, including a number of doctors. Speakers included the Programme's Clinical Leader for cervical screening, a cytotechnologist, and a colposcopist. Issues such as liquid-based cytology and screening of women less than 20 years old were discussed.
- 6.30 One practice nurse that we spoke to was not routinely giving brochures about cervical screening to women as she thought they looked too expensive. She learned at a smear-taker update course that the Programme encouraged smear-takers to give out as many brochures as required. As a result, the women in her practice are now provided with comprehensive information on cervical screening.

Are Appropriately Skilled and Qualified People Undertaking the Work In Colposcopy?

Initial training and continuing education are undertaken for colposcopy. The introduction of a higher certificate in colposcopy is being considered.

- 6.31 All doctors who specialise in obstetrics and gynaecology undertake training in colposcopy. Once qualified, a practising obstetrician or gynaecologist must re-certify their Fellowship every three years. This requires proof of continuing medical education, which may or may not be in colposcopy.
- 6.32 The Royal Australian and New Zealand College of Obstetricians and Gynaecologists is discussing the introduction of a Higher Certificate in Colposcopy.

- 6.33 The recently reviewed Colposcopy Standards include requirements to ensure that colposcopists are qualified and registered to practice in New Zealand, and for maintaining skill levels through attendance at national or international meetings, and by continuing medical education. We understand that compliance with the Colposcopy Standards will be checked during service provider audits.

No System for Introducing New Technologies

Introducing a system to identify and assess new and emerging technologies.

- 6.34 We are concerned, as was Dr McGoogan, to learn that liquid-based cytology is being introduced into New Zealand (10-15% of women are choosing to have their smears prepared this way) and yet this procedure is not covered by the Quality Standards. In our view, this is a significant omission.

Introduction of Liquid-based Cytology

Liquid-based cytology is an alternative method for processing cervical smears.

- 6.35 With a conventional smear test, cells from the cervix are smeared directly onto a glass slide and preserved. Then, in the laboratory, the cells are stained and viewed under a microscope. Liquid-based cytology is an alternative to this technique – cells are preserved in a liquid and, in the laboratory, special equipment is used to distribute the cells onto a glass slide in an even layer, then the cells are stained and viewed under a microscope.
- 6.36 Liquid-based cytology now makes up about 10-15% of the 410,000 smears processed each year. Most people in the profession consider that liquid-based cytology is here to stay and is likely to gain popularity if the technology can also be used for Human Papilloma Virus (HPV) testing.

Liquid-based cytology has been introduced into New Zealand in a haphazard fashion.

- 6.37 Dr McGoogan commented in both her reports on the way liquid-based cytology is being introduced to New Zealand. She was concerned that there is no training required by the Programme, or available in New Zealand, for laboratory staff performing liquid-based cytology, and no quality standards for reading and reporting liquid-based cytology.
- 6.38 She recommended that the change to liquid-based cytology should be monitored, and that laboratory results for conventional smears and liquid-based cytology samples should be recorded separately.
- 6.39 Dr McGoogan was also concerned that there is no process in place for evaluating other new technologies as they become available.
- 6.40 In 2000, the (former) HFA commissioned a report into liquid-based cytology, which concluded that the conventional smear test should remain the standard of care within the Programme, and that liquid-based cytology was not the recommended standard for smear-taking. Despite this, many primary care

providers have opted to provide this option to their patients, and laboratories have provided a diagnostic service for the new technology.

The NSU is undertaking an additional review of liquid-based cytology.

6.41 The NSU is beginning another review of liquid-based cytology to update the HFA's previous work. This review will take into account new evidence, and recent reviews and studies. It will examine clinical and funding issues, and whether consideration should be given to introducing a pilot programme.

Staff receive specific training before performing liquid-based cytology.

6.42 Evaluation of cells with the liquid-based technology is very different compared with conventional smear methods, and training is required before laboratory staff are able to evaluate smears prepared with the new technology. This training currently takes place in Australia over two days and refresher courses are held in New Zealand. Some cytology staff may have received "in house" training in liquid-based cytology rather than attending an overseas course.

6.43 However, the training available for New Zealand cytology staff is not as robust as the measures introduced in Scotland, which require the screener to attend a five-day course and then screen 600 slides under supervision.

6.44 IANZ checks to see that laboratory staff have received training for liquid-based cytology as part of its assessments.

There are no quality standards for reading and reporting liquid-based cytology.

6.45 In spite of the fact that the NSU does not support liquid-based cytology and the Laboratory Standards do not cover liquid-based cytology, 10-15% of the smears processed in New Zealand use this technology. We consider this to be a significant omission as it means that about 40,000-60,000 smears are processed without any minimum-volume standards. As most of the smears using liquid-based cytology are processed in Auckland, it is likely that screeners in other parts of the country are processing only low numbers of liquid-based cytology smears.

6.46 We note that the NSU intends to review the Laboratory Standards in 2003-04, and that this review will include drawing up of standards for liquid-based cytology.

A process has begun to allow liquid-based cytology results to be differentiated from conventional smear results on the NCSP-Register.

6.47 The NSU has written to around half the laboratories, requesting that they update their software so that they can record when a smear result is produced using liquid-based cytology. This information will be recorded on the NCSP-Register. A similar request will go out to the remaining laboratories on completion of a project to update the codes that laboratories use to report cytology results. This will allow the laboratories to make all the required changes to their software at one time.

If the NSU is to ensure that quality services are provided to women, it needs the support and co-operation of the wider medical community.

- 6.48 Dr McGoogan noted that many more new technologies will become available soon, and there will be no control on how these are implemented in New Zealand under the current regime.
- 6.49 The NSU considers that the review of new technologies is a part of the Programme's ongoing quality initiatives, and that careful and ongoing consideration is given to the risks and benefits of introducing these technologies as part of organised screening programmes in New Zealand. This may be so, but the introduction of liquid-based cytology into New Zealand has occurred regardless of the Ministry's opinion of the technology. As a result, the use of this technology is currently unregulated, and women are paying an additional cost for a test that is not supported by the Ministry.
- 6.50 The NSU now directly controls the funding for cervical screening tests and has the power to specify which tests it will fund. However, while women are willing to cover the additional cost of the test, this provision is not effective in preventing public demand for the technology.
- 6.51 The NSU also has concerns about the introduction of a test for HPV, and has recently requested the withdrawal of this test from the market. The NSU has advised DHB and community laboratories that it will not fund the HPV test. However, this has not prevented some gynaecologists from requesting the test and one laboratory from performing the test.

Part Seven

Evaluation of the National Cervical Screening Programme

Introduction

- 7.1 The Committee of Inquiry made a number of recommendations in regard to evaluation of the Programme.
- 7.2 In this Part, we discuss progress to implement five of these recommendations and issues arising in regard to Recommendation 1 – the Audit of Invasive Cervical Cancer (the Cancer Audit), and Recommendations 14, 15, 16, and 17 – access to medical records and screening data.

Progress on the Cancer Audit

The Cancer Audit has taken longer than promised but, in our view, it is difficult to see how more progress could have been made. (Recommendation 1)

- 7.3 In May 1999, the Ministry contracted a team from the University of Otago to evaluate the Programme in three phases:
- Phase One – to establish the data required for monitoring and audit had been completed when the Committee of Inquiry reported its findings in April 2001.
 - Phase Two – a review of the adequacy of diagnosis, treatment, and follow-up of women with abnormal smears – was completed before our February 2002 report.
 - Phase Three – the Cancer Audit – was initially co-ordinated by the NSU, but was transferred to the Director of Public Health in April 2002, and is still in progress.
- 7.4 In its April 2001 report, the Committee of Inquiry said that it was imperative that the Cancer Audit be completed within six months. The Committee of Inquiry said: *...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 ... 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.*
- 7.5 It is generally acknowledged that the Cancer Audit is bigger than the Committee anticipated, and that six months was an inadequate time for completion.
- 7.6 The Ministry assessed the task and undertook to complete the Cancer Audit within 18 months. If this had been achieved, the results would have been reported in October 2002. However, the Cancer Audit has taken longer than promised, and the results are not expected to be reported until the end of 2004 – two years later than promised.
- 7.7 In our view, it is difficult to see how more progress could have been made with the Cancer Audit, given the magnitude of the audit. The Ministry acknowledges that it under-estimated the size of the task when it gave its original undertaking.

What Is the Cancer Audit?

The Cancer Audit looks at the screening histories of women who have developed invasive cervical cancer to see if any lessons can be learned to improve the Programme.

- 7.8 The Cancer Audit aims to establish the screening histories of women diagnosed with invasive cervical cancer from 1 January 2000 to 30 September 2002, and to collate, analyse, and interpret the data to find ways to improve the Programme. Currently 440 women have been identified who meet the specified criteria within the defined period.⁴⁸
- 7.9 Where the woman, or her personal representative or next of kin, has given consent, the woman or her family are interviewed and relevant data are extracted from GP records and specialist (usually hospital) records. If the woman has had any cervical smears in the four years before her diagnosis with invasive cervical cancer and consents to the re-reading of her slides for the Cancer Audit, then steps are taken to retrieve her slides from the laboratory or laboratories.
- 7.10 One of the main reasons for interviewing the woman and obtaining access to her records is to gain a complete picture of her screening history and follow-up treatment. The previous “opt-on” and current “opt-off” provisions mean that the NCSP-Register may not record all of the woman’s smear results and therefore will not provide her complete screening history.
- 7.11 Once the complete screening history is established for the women in the Cancer Audit, epidemiologists can then determine what factors may have contributed to them developing invasive cervical cancer; for example:
- intermittent or non-involvement in the Programme and therefore insufficient smears;
 - failure to receive the necessary follow-up treatment despite abnormal smear results; or
 - whether – despite participating fully in the Programme – they still developed invasive cervical cancer.
- 7.12 The very nature of screening programmes means that not all cases of the disease will be detected and/or prevented.

⁴⁸ Although about 550 women were diagnosed with invasive cervical cancer from 1 January 2002 to 30 September 2002, about 110 of these are not included in the Cancer Audit because they are more than 80 years old, were not diagnosed in New Zealand, were not present in New Zealand for at least four years before their diagnosis, or do not have histological confirmation of a diagnosis of primary cervical cancer.

Why Has the Cancer Audit Taken So Long?

There has been public criticism of the length of time that the Cancer Audit has taken.

- 7.13 Ministry staff advised us that, in terms of scope, the Cancer Audit was a “first of its kind” in the world. They do not know of any other audit of invasive cervical cancer of such breadth (involving so many women) and to such depth (interviews, treatment histories, and slide re-reads).
- 7.14 Equally, they had not anticipated such a positive response from the women involved, with more than 357 or 77.4%⁴⁹ of the women agreeing to be interviewed by the Cancer Audit team, and a similar percentage agreeing to the relevant information being collected from their medical records, and to their slides being re-read.
- 7.15 The extraction of the data from GP records has also proved to be more time-consuming than originally anticipated, because many of the records are handwritten and some women attended multiple GPs during the relevant period.
- 7.16 A three-month delay was also experienced in the early fieldwork phase (August to October 2002) when the Professional Colleges asked to revisit the question of whether the Cancer Audit should be conducted under Part VI of the Medical Practitioners Act 1995.⁵⁰

Could More Progress Have Been Made?

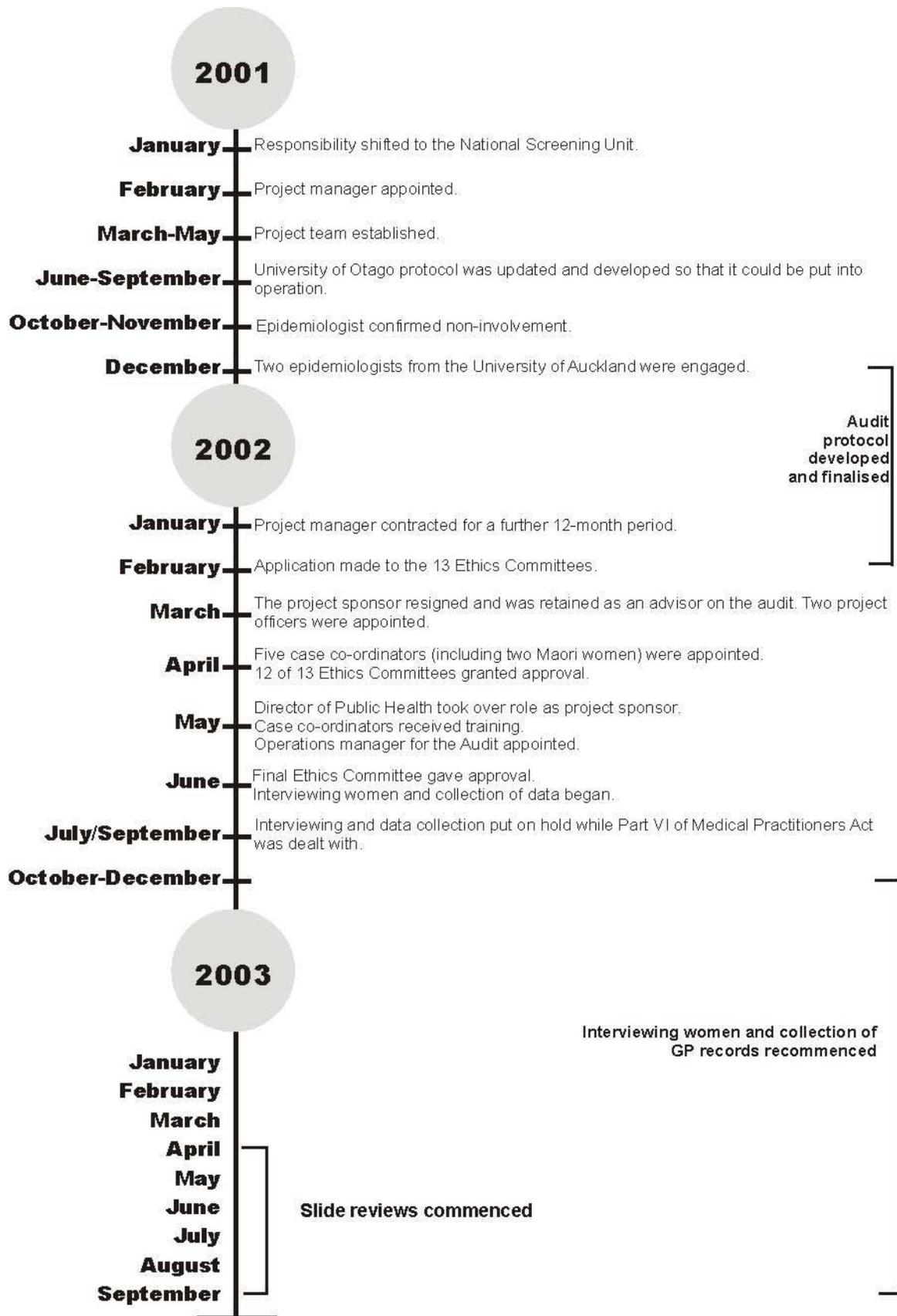
In our view, it is unlikely that significantly more progress could have been made to date. More epidemiological resources could, however, speed up the final phase of the Cancer Audit.

- 7.17 Figure 4 on the opposite page shows a timeline summary of the actual progress of the Cancer Audit.
- 7.18 We looked at what work has been undertaken on the Cancer Audit since the Committee of Inquiry reported. In particular, we were interested in identifying blocks of time where nothing had been done, or where applying larger numbers of staff might have expedited the Cancer Audit.
- 7.19 We looked in detail at five specific blocks of time – May to September 2001 when the protocol was updated; February to September 2001 when discussions were held with an epidemiologist; August to October 2002; the interview and data collection phase; and the final phase of the Cancer Audit.

⁴⁹ This is the consent rate for all women (including the next of kin for deceased women). The consent rate for living women is 81%.

⁵⁰ The purpose of Part VI of the Act is to encourage quality assurance activities in relation to health services provided by medical practitioners by protecting the confidentiality of the information or documents that become known or brought into existence solely as a result of such activities and gives immunity from civil liability to persons engaging in such activities in good faith. Under section 68, the activity has to be declared a quality assurance activity by the Minister.

*Figure 4
Timeline Showing the Actual Progress of the Cancer Audit*



- 7.20 From May 2001 to September 2001, experts and the project team worked on updating the protocol created by the University of Otago. The final protocol was not too dissimilar from the original protocol. We have talked to the Ministry and established that the following work was undertaken during this period:
- Updating the literature review of audits of invasive cervical cancers.
 - An analysis of each phase of the Cancer Audit, including the legal requirements.
 - Data checking and correction between the Cancer Registry⁵¹ and the NCSP-Register.
 - Consideration of whether the Cancer Audit should be conducted under Part VI of the Medical Practitioners Act 1995.
 - Provisional data was extracted from the Cancer Registry and the NCSP-Register and high-level analysis was undertaken for planning purposes.
- 7.21 From February to September 2001, the NSU regularly communicated with an epidemiologist about participating in the update of the protocol, and to sign a Heads of Agreement as a basis for a future role in the Cancer Audit. By September 2001, the difficulties in reaching agreement were beginning to delay the Cancer Audit. It had been hoped that, by then, the protocol would have been finalised for the project, to be given to the ethics committees for approval. It transpired that agreement could not be reached between the parties and, in November 2001, the epidemiologist confirmed that they did not wish to be involved in the Cancer Audit project.
- 7.22 There was a three-month delay from August to October 2002 while issues around Part VI of the Medical Practitioners Act 1995 were addressed with the Professional Colleges. However, during this time, progress was made to establish a database to record data on the women included in the Cancer Audit, and also to act as a tool to manage the co-ordination of obtaining the women's consent, data collection, and case co-ordinator workloads.
- 7.23 We questioned whether time could have been saved in the interviewing/data collection phase by involving more interviewers. However, we were advised that the following factors determined the speed with which the data collection could occur:
- Next of kin are not contacted until six months after a woman's death. For example, the next of kin of a woman who died on 1 February 2003 would not be contacted until 1 August 2003. Seventeen per cent of the women in the Cancer Audit sample are deceased.
 - The samples of women have been systematically advised from the Cancer Registry. The Cancer Audit team does not receive notification of cases until

⁵¹ The Cancer Registry is a national database that records all primary diseases diagnosed in New Zealand, including all instances of cervical cancer (and other cancers, excluding squamous cell and basal cell skin cancers). It was used to identify the women relevant to the Cancer Audit.

six months after each diagnosis period. For example, cases diagnosed up to 30 March 2002 were not notified to the Cancer Audit team until 30 September 2002, and cases diagnosed up until 30 September 2002 (the end of the sample) were not notified until 30 March 2003.

- The speed at which cases can be completed depends upon the time taken to confirm each woman's histological diagnosis, for the GP and/or specialist to respond, and to contact the woman and get her consent.
- Mayne Health Laverty Pathology (a Sydney-based laboratory which is undertaking the re-read of slides) only has capacity to re-read the slides at a certain rate. The completion of other data collection was timed to coincide with the completion of the slide re-read – November 2003.

7.24 The final phase of the Cancer Audit – the analysis by the epidemiologists – appears to be constrained by the time that the epidemiologists are available (i.e. two epidemiologists working 15 hours each a week). This phase could be shortened if more resources were available. The Ministry also noted that Maori researchers, who are an integral part of the analysis and interpretation of the Cancer Audit data, are also a difficult resource to secure.

7.25 We are satisfied that, although there were delays, they were largely a result of issues arising from the nature of the Cancer Audit, and were not caused by inactivity or understaffing on the Ministry's part.

What the Cancer Audit Won't Tell Us

The Cancer Audit will not establish whether or not there has been a systemic problem of under-reporting of high-grade cytology abnormalities in New Zealand laboratories.

7.26 In its *Review of the Inquiry Recommendations* in September 2001, the Cervical Screening Programme Advisory Group queried the ability of the Cancer Audit to address whether there is a systemic problem of under-reporting. The Minister was advised of this concern in October 2001.

7.27 Epidemiologists working on the Cancer Audit have advised that the number of cervical slides that will be re-read as part of the Cancer Audit are insufficient to detect previous under-reporting of high-grade abnormalities (if this existed).⁵²

7.28 In other epidemiological studies, this problem could be overcome by increasing the number of slides. However, in this audit, the number of slides that will be re-read is directly related to the number of women with invasive cancer. The Cancer Audit does not involve getting a statistically representative sample of cervical slides from women who have not developed invasive cervical cancer.

7.29 Also, the Cancer Audit is retrospective, so, should it identify any systemic problems with under-reporting, these problems will relate only to the period from 1997 to 2002.

⁵² The Cancer Audit may indicate possible areas of systemic failure or other related inadequacies in the Programme, for example, under-reporting of high grades, but it is likely that this would require additional investigation to provide conclusive evidence.

What The Cancer Audit Will Tell Us

The Cancer Audit will still provide much useful information, in that it will establish the extent to which women who have developed invasive cervical cancer have participated in the Programme, and also test the completeness and reliability of the information currently stored on the NCSP-Register.

7.30 The Cancer Audit will identify screening-related contributory factors to the development of invasive cervical cancer, including:

- establishing the number of women who developed invasive cervical cancer who either had not been screened or had been screened on an infrequent basis;
- identifying women whose screens showed abnormal (or pre-cancerous cells) but who have not had follow-up investigations, and possible reasons why the follow-up did not occur;
- re-reading of the slide may detect false negative⁵³ results (also described as under-reporting) where abnormal cells are present but are not detected by the slide reader. Because of the subjective nature of smear interpretation and the limitations of the test, not all abnormalities can be detected and this is an acknowledged element of any screening programme. As noted in paragraph 7.27, the Cancer Audit is unlikely to be able to identify whether there has been a systemic level of under-reporting of high-grade smear abnormalities; and
- the Cancer Audit will also attempt to determine whether the factors that contribute to Maori women developing invasive cervical cancer differ from those of non-Maori women.

What Effect Will the Cancer Audit's Limitations Have on Recommendation 2?

The fact that the Cancer Audit will not establish whether or not there has been systemic under-reporting of high-grade abnormalities has serious implications for the Committee of Inquiry's second recommendation.

7.31 Recommendation 2 says: *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.*

⁵³

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

- 7.32 Dr McGoogan noted in her final report that *...in view of the delay incurred in the Cancer Audit ... and the concerns that the Cancer Audit, as currently designed, will not address the question of systematic [sic] under-reporting in New Zealand in the late 1990s, I regret that there is still no explicit evidence that the NCSP was safe and effective at that time* [her emphasis]...
- 7.33 She also said *...Laboratory quality standards have now been fully implemented for over 12 months and the monitoring in place suggests that an acceptable standard is being achieved. Since the routine screening interval is 3 years, most women on routine screening attending for a further smear test till the end of 2004 will have had their smears read by laboratories meeting the current quality standards. Furthermore, I suspect that smear takers and the laboratory capacity might not be able to deliver a mass repeat testing programme within a shorter timescale... in the meantime, it may be that particular consideration should be given to women who had been screened prior to 2002 before the laboratory quality assurance programme was fully implemented and who will not return for repeat testing (e.g. have reached the upper age limit for recall).*
- 7.34 The Ministry has written to Dr McGoogan to clarify her view on what needs to be done. Until advice is received from Dr McGoogan, the NSU intends to continue with the current three-yearly screening interval process on the basis that, by 2005, most women will have had a smear test that has been read by laboratories operating under the Quality Standards.
- 7.35 If the results of the Cancer Audit highlight potential systemic problems, Recommendation 2 may need to be implemented in whole or in part.
- 7.36 In the meantime, the NSU is considering re-screening women who have left the Programme and will not be returning for repeat testing. The NSU has provided us with an analysis of the number of women aged 70 and over who would be involved – in total 49,094 women have stopped participating in the Programme from 1 November 2000 to 1 June 2003. Allowing for those women who have since died, have had a hysterectomy, have requested not to participate in the Programme, are too sick to be screened, or have gone overseas – 19,822⁵⁴ women aged 70 and over with a normal screening history could be invited for re-screening⁵⁵.

Access to Medical Records and Screening Data

- 7.37 Four of the Committee of Inquiry's recommendations (14, 15, 16, and 17) relate to improving access to medical records and screening data, to allow effective monitoring, evaluation, and audit.

⁵⁴ This includes 1701 women who have requested no further recall.

⁵⁵ Women over 70 with an abnormal screening history continue to be recalled by the Programme.

What Are the Current Rules Around Access To Cervical Screening Records?

7.38 Data relating to the Programme may be held in a number of different ways or locations, which are:

- **The Cancer Registry** – data can be disclosed under the *Health Information Privacy Code*⁵⁶ for the purposes of auditing cervical cancer.
- **The NCSP-Register** – under section 74(A) of the Health Act 1956 (the Health Act), relevant women must give consent before information from this source can be used for audit or monitoring purposes.
- **Medical records** – Generally consent is required for medical records to be disclosed.
- **Access to and use of laboratory specimens** – access for the purposes of evaluation is governed by Right 7(10) of the *Code of Health and Disability Services Consumer Rights*. It is the view of the Health and Disability Commissioner that consent to re-reading for quality assurance purposes may be implied, so long as there was express consent to the original reading of the slide. However, there is no legal obligation on laboratories to release the slides.
- **Health (Cervical Screening (Kaitiaki)) Regulations 1999 (The Kaitiaki Regulations)** – no person, including the Ministry and persons included in monitoring, audit, and evaluation of the Programme may use, disclose, or publish aggregate Maori women’s data from the NCSP-Register without the prior approval of the National Kaitiaki Group.

What Are the Problems With These Current Rules?

The Committee of Inquiry found that these rules inhibit effective monitoring, evaluation, and audit.

7.39 The Committee of Inquiry said that:

The need to obtain informed consent before gaining access to protected information poses practical and technical problems. Women are not always easily traceable. Secondly for the conclusion of an evaluation to be statistically meaningful and therefore informative to medical experts the evaluation exercise must cover a sufficiently large group of women. If only a small number give their consent the exercise will be pointless. The Committee considers that faced with these problems the best choice is to permit medical experts who have been engaged for the purpose of evaluating the NCSP to have access to the information without the need to obtain women’s consent. It is difficult to see why women might object to an independent evaluation team seeing information to

⁵⁶

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.

which those medical persons who are involved in their treatment have unrestricted access. If evaluation is seen as an integral part of a woman's treatment under the NCSP there is no difference. (para 6.98)

7.40 The Committee of Inquiry found that the difficulty in tracing women and gaining consent or authorisation to use identifiable data placed at risk the ability to monitor, audit, and evaluate the Programme.

7.41 Accordingly, the Committee of Inquiry considered that this risk should be eliminated by enacting legislation so that all relevant required information was made available. Specific recommendations were:

- Recommendation 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.*
- Recommendation 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.*
- Recommendation 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.*
- Recommendation 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.*

What Is Proposed to Solve These Problems?

The Kaitiaki Regulations have now been reviewed (Recommendation 15) and no substantive changes have been made.

7.42 The Committee of Inquiry was concerned that the Kaitiaki Regulations, as they currently stood, allowed for the National Kaitiaki Group to potentially withhold the release of data that would enable effective monitoring, evaluation, and audit of the Programme.

- 7.43 The Ministry of Health carried out a nationwide consultation process with Maori women, and a public discussion document was released (*Review of the Health (Cervical Screening) (Kaitiaki) Regulations 1995*) that sought comment on four options for the future of the Regulations and the role of the National Kaitiaki Group.
- 7.44 Most of the submissions favoured Option One – *The status quo (existing system) with improved process for the NCSP to access Maori women’s aggregate data*. On 25 June 2002, Cabinet agreed to confirm this option.
- 7.45 The improved processes referred to in Option One relate to processes put in place between the Programme and the National Kaitiaki Group to facilitate consideration of an application. For example, the Programme requires ad hoc monitoring reports for service planning. For these reports, the Programme requests similar data on an irregular basis. Arrangements have now been put in place so that the Programme can apply for all of this data with one annual application.
- 7.46 We consider that the outcome of the review of the Kaitiaki Regulations was not that envisaged by the Committee of Inquiry. The Inquiry considered that the Kaitiaki Regulations could potentially adversely affect effective monitoring of the Programme. The outcome of the review does not change the Inquiry’s finding, as the only changes made to the regulations relate to a revised process by which the Programme can make applications.

The Health (Screening Programmes) Amendment Bill is intended to implement some of the Committee of Inquiry Recommendations.

- 7.47 The Health (Screening Programmes) Amendment Bill (the Bill) proposes to implement Recommendations 14, 16, and 17 by:
- providing new rules and procedures for enrolling and cancelling enrolment on the Programme;
 - allowing for a range of evaluation activities, including the Cancer Audit, as well as the review and evaluation of the Programme to be undertaken by appropriately qualified experts, irrespective of their relationship to the Ministry; and
 - providing revised rules for access to data on the Cancer Registry and the NCSP-Register, as well as to medical and laboratory records.

If the Bill is enacted, more complete information will be contained on the NCSP-Register.

- 7.48 Currently, section 74A of the Health Act requires that, every time a woman has a cervical smear or biopsy taken, she is advised that her results will be entered onto the NCSP-Register unless she objects. Before a smear or biopsy is taken, it is currently expected that the smear-taker will explain the clinical procedure, the importance of having regular smear tests, and the purpose of the Programme and

the NCSP-Register. The smear-taker should also ask the woman if she wishes to have her results forwarded to the NCSP-Register.

- 7.49 Under current rules, a woman can request that a particular test result not be sent to the NCSP-Register at the time the smear or histology specimen is taken. If a woman wishes to “opt-off” a particular result from the Programme, the Programme does not receive any notification of the decision to “opt-off”.
- 7.50 Because “opting-off” a single result does not constitute an exit from the Programme, this can lead to the appearance of a complete history for the woman on the NCSP-Register, when in fact one or more results may be missing.
- 7.51 Incomplete screening histories not only reduce the ability of the Programme to be effectively evaluated, but may pose a risk to the woman whose treatment and management may depend on her previous screening history.
- 7.52 The Bill proposes to change this situation. It aims to improve the information contained on the NCSP-Register by amending the Health Act so that women cannot choose to have particular smear results opted off the Register. Rather, the Programme becomes an opt-off programme. Women will still be able to decide whether to opt-off the Programme or to remain enrolled on the Programme. If they remain on the Programme, then all of their cervical screening laboratory results will be recorded on the NCSP-Register. This will mean that the Programme, its service providers, and women can be more confident that a woman’s screening history on the NCSP-Register is complete.
- 7.53 We consider this would be a significant improvement to the current system for recording smear and laboratory results on the NCSP-Register.

The Bill sets out a comprehensive regime for the monitoring, evaluation, and auditing of a screening programme.

- 7.54 The Programme needs to be routinely evaluated to ensure that it is operating as effectively as possible. Indeed, the effective monitoring and auditing of screening programmes is critical to their success. This point is reflected in the 1986 World Health Organisation’s *Control of Cancer of the Cervix Uteri* which stated that:
- Screening programmes can be evaluated by their failures. Cases of symptomatic invasive cancer of the cervix, and especially of advanced disease, can be regarded as failures of a screening programme. Knowledge of the age distribution of such cases and of their screening history provides information on the effectiveness of the programme in reaching the intended age groups and the quality of the screening being carried out.*
- 7.55 The Bill sets out a comprehensive regime for the monitoring, evaluation, and auditing of the Programme. It is a significant advancement over the current regime.
- 7.56 Under the Bill, “evaluators” would be able to conduct “evaluation” activities. Broadly, an evaluation is an assessment of the service delivery and outcomes of a

screening programme, and whether any systemic issues exist for the programme. The term “evaluation” is used in the Bill in its broadest sense, covering monitoring, evaluation, and auditing. Depending on the nature of the evaluation, this may include reviewing or investigating the cases of women who:

- are enrolled in the Programme (whether or not they have developed cervical cancer);
- have developed cervical cancer (whether or not they are enrolled in the Programme); and
- at the time of their death, were enrolled in the Programme or had developed cervical cancer.

7.57 The evaluations relating to the Programme would include audits of invasive cervical cancer, routine monitoring using non-identifiable NCSP-Register data, statistical reports, and periodic service provider audits against the Quality Standards and contracts.

7.58 Evaluators would only be allowed to access the particular information necessary for the purposes of performing their functions as evaluators. Evaluators are required to keep all personal information disclosed to them confidential and secure.

The Bill sets out revised rules for access to data on the Cancer Registry and the NCSP-Register, as well as medical and laboratory records.

7.59 Much of the information that needs to be accessed for monitoring and evaluation purposes is currently subject to consent or authorisation from the woman to whom it relates. Requirements to gain informed consent and/or authorisation were identified by the Committee of Inquiry as a potentially significant barrier to effective and efficient monitoring, evaluation, and audit of the Programme and gave rise to Recommendations 16, 17 and 18.

7.60 The Bill provides for a set of revised rules around the access to Cancer Registry data, NCSP-Register data, cervical slides, and clinical information. Generally these rules are:

- **Cancer Registry** – Evaluators will have full access to and use of all Cancer Registry data to the extent necessary to perform their functions.
- **NCSP-Register** – Evaluators will have access to all identifiable NCSP-Register data.
- **Medical records** – Initially, the Bill gave evaluators access to hospital records and required them to obtain the woman’s consent before being able to access primary care records. However, in reporting the Bill back to Parliament, the Health Committee has recommended that evaluators be allowed access to both hospital and primary care records. If this proceeds, the woman’s explicit consent will not be required.

- **Access to and use of laboratory specimens** – All records and all cervical cytology and histology slides of women who are enrolled on the NCSP-Register, or who have cervical cancer, are to be made available for the purpose of routine monitoring and evaluation of the Programme. Informed consent that is given at the time a smear is taken is to include the potential use of slides for evaluation.

7.61 Accordingly, Recommendations 14, 16, and 17 will be implemented if the Bill is enacted in its current form.

7.62 The Bill was referred back to Parliament for its second reading on 22 September 2003.

Part Eight

Role of Data Registers

Introduction

- 8.1 The Committee of Inquiry recommended improved use of the NCSP-Register (Recommendations 25, 26, and 31) and the introduction of a population register (Recommendation 33).
- 8.2 In this Part, we discuss progress to implement the recommendations, and the respective roles of the Registers.

The NCSP-Register

- 8.3 The NCSP-Register is a database that was established in 1997 by linking 14 separate registers that had been in use since 1992. The database contains the demographic details of all women enrolled in the Programme, and their cervical cytology and histology results (subject to opt-on/opt-off provisions, as noted in paragraph 7.49 on page 72), and details of smear-takers and laboratories. It is used for follow-up of abnormal smears and to recall women if they are overdue for a smear, as well as for monitoring aspects of the Programme.
- 8.4 The Committee of Inquiry made three recommendations in relation to the NCSP-Register:
- Recommendation 25 – *The National Cervical Screening Register needs to be electronically linked with the Cancer Register.*
 - Recommendation 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.*
 - Recommendation 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.*

To What Extent Have the Recommendations Been Implemented?

Good progress has been made to match the data on the NCSP-Register to the Cancer Registry, and to ensure the currency of the data on both systems. (Recommendation 25)

- 8.5 The recommendation has not been strictly implemented in that a manual process is used to check the data on the NCSP-Register and the Cancer Registry. The process does, however, achieve the overall aim of the recommendation in that the data on both registers are checked for accuracy and agreement. A detailed protocol – *The National Cervical Screening Programme and Cancer Registry Data Assurance Protocol* – is in place to govern the exchange. This protocol was originally drawn up to support the Cancer Audit.

- 8.6 The Cancer Registry is administered by the NZHIS. NSU staff have advised us that it takes six months to confirm the accuracy of the data on the Cancer Registry and this is evidently good compared to other countries which can be up to two years behind with their data.

The cervical smear test and histology histories of the women enrolled on the NCSP-Register have not been made available on-line to laboratories that read cervical cytology or histology. (Recommendation 31)

- 8.7 The current NCSP Information System became fully operational in early 1992 with the installation of 14 stand-alone database registers in the 14 (former) Area Health Boards. Each region was supplied with the same software and hardware, but the systems were not linked electronically, which meant that the transfer of information between sites was done manually. The registers were configured into a central register – the NCSP-Register – in 1997.
- 8.8 Regional Services are now contracted through 13 DHBs. Eight of the Regional Services' sites have responsibility for entering laboratory results onto the NCSP-Register.
- 8.9 Laboratories must comply with the Laboratory Standards as a condition of their contract with the Programme. The Standards require laboratories to forward to the NCSP-Register (except those accompanied by written notice of a woman's objection):
- all cytology results within 16 working days of receipt of the specimen;
 - 90% of histology results within 10 working days of receipt of the specimen; and
 - 100% of histology results within a reasonable time period of receipt of the specimen.
- 8.10 Laboratory data is sent to the relevant Regional Service in electronic format on a computer floppy disk, for entry onto the NCSP-Register.
- 8.11 Regional Services are also covered by the Quality Standards which require:
- 95% of cytology results to be fully processed including posting within five days of being received; and
 - 95% of histology results to be fully processed within 10 working days of receipt.
- 8.12 Currently, laboratories do not have electronic access to the information on the NCSP-Register nor is the information easily available. To get access to the information, they must contact Regional Services' staff and ask to be sent hard copies.

- 8.13 We consider that giving key service providers “ownership” of the screening data on the NCSP-Register should help to improve the quality of the data, and the efficiency of data access and entry.

The NSU’s *Information Services Strategic Plan* for 2003-04 has identified a number of issues around the NCSP-Register, including electronic access to the register by laboratories and smear-takers. There is a proposal to replace the current NCSP-Register, however, the timetable is still to be determined.

- 8.14 The NSU’s *Information Services Strategic Plan* for 2003-04 proposes to replace the existing NCSP-Register, and to address the issues noted below. However, although each milestone has an elapsed time, there is no actual timetable for project completion. A business case is currently being prepared.

- 8.15 The NSU has identified the following problems with the NCSP-Register:

- an inability to reject data at its source, requiring extensive checks within maintenance protocols;
- manual duplicated and triplicated data entry;
- inadequate automatic validation, leaving operators able to miscode data;
- a fragmented register across multiple locations;
- a design that ignores the screening pathway of a woman;
- poor matching with the NHI and the Cancer Registry;
- no link with the NSU complaints database and issues register;
- lack of a comprehensive audit trail of all changes made in the NCSP-Register, their authors, and identification of the source;
- inability to record colposcopy data;
- inability to record service providers’ accreditation status and date of next audit;
- a data structure that separates women into regions, rendering a national view difficult;
- inability to extract data on health professionals to facilitate monitoring against the Laboratory Standards – e.g. case-volumes for primary screeners⁵⁷, secondary screeners, and pathologists;

⁵⁷ 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.

- inability to view and change automatically generated letters, to batch letters by type, or to translate letters into various languages; and
 - inability to set and record parameter values.
- 8.16 There are issues around the inability to change the NCSP-Register’s information system quickly to reflect urgent business requirements, for example:
- an obsolete business platform;
 - lack of regular backup; and
 - old security mechanisms.
- 8.17 In addition, the NSU also recognises that laboratories need to have improved data quality and that there needs to be a direct electronic linkage between smear-takers and the NSU, in order to reduce the NSU’s operational and manual handling. Likewise, smear-takers need electronic access (subject to appropriate security requirements) to NCSP-Register data and a reduction of overheads created by manual reporting requirements.

Need for a Population Register

8.18 The Committee of Inquiry’s Recommendation 33 said:

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

8.19 Dr McGoogan also raised the point that the Programme does not meet World Health Organisation guidance on the requirements for a successful cervical screening programme as it does not use a population register to identify eligible women.

8.20 The NZHIS – which was allocated responsibility for implementing Recommendation 33 – has a role to provide appropriate databases, systems, and information products. Two of the information systems that it currently supports are the Cancer Registry and the NHI.

Why Have a Population Register?

Population registers help the health system to assist individuals to manage their own health.

8.21 A population register provides a way of identifying and inviting a member of the whole population, who is eligible, to participate in a screening programme.

8.22 To assess the proportion of the population that is being screened, it is necessary to know the number of women between the ages of 20 and 69 who are participating in the screening programme (the numerator), and the number of women between

the ages of 20 and 69 that actually exist (the denominator). Without this accurate measure it is difficult to be sure what percentage of the population is being screened or to provide a measure of population health.

- 8.23 More importantly, it provides a mechanism by which people can be contacted by a health provider. For example, women between the ages of 20 and 69 on the population register who are not enrolled in the Programme could be invited to join the Programme. By not having a register, the Programme must rely on reaching these women through advertising and other communications. For example, GPs and health providers are currently recruiting “opportunistically” by inviting an unenrolled woman to participate in the Programme when she presents to the health system for another reason.

New Zealand Attitude to Population Registers

New Zealand does not have a population register, and New Zealanders have been criticised in this regard because their attitude to individual privacy on health matters is seen as compromising the ability of the public health system to better manage health outcomes.

- 8.24 Dr McGoogan and Professor Chamberlain have both expressed views on the need to have a population health register. One of the main barriers to setting up a population register is the attitude of New Zealanders to individual privacy on health matters which, in both Dr McGoogan and Professor Chamberlain’s view, must be addressed if the health system is to be effective in assisting individuals to manage their own health.

- 8.25 Professor Chamberlain remarked:

...the offer of preventative service is regarded with extreme suspicion, fearing that a paternalistic medical profession is taking away people’s freedom of choice... I found the level of concern about protecting privacy extraordinary... If the popular feeling remains “Privacy at all costs”, then it must be recognised that one of those costs is ineffective and inefficient public health systems.⁵⁸

Once the NZHIS has sorted out the data quality issues, the NHI could be linked to individual screening registers to provide details of the total population.

- 8.26 Since 1992, New Zealand has maintained an index of health care users, known as the National Health Index (NHI). The NHI is a system used by public hospitals and other health and disability support services to assign a unique number (the NHI number) to people who use their services. The number is usually assigned at birth. The NHI holds a person’s name, ethnicity, date of birth, sex, and date of death and the NHI number is used to link health data to the person that it relates to. It is also used to facilitate the accurate exchange of data (such as laboratory test results) between health services, and to locate previous health records.

- 8.27 Population information for specific population programmes, such as the Programme, could be drawn from the NHI. This has the advantage that details of

⁵⁸

J Chamberlain, 2002, *BreastScreen Aotearoa – An Independent Review*. May 2002.

each programme can be kept separate from each other and the NHI with individual privacy requirements, rather than having one single large population register with all details of individual participation in all programmes.

- 8.28 However, considerable work is required before the NHI can be used as the basis for the population register – including improvements to data quality, establishing processes to maintain data quality, and establishing linkages and reporting processes for individual registers.

What Effect Does the Lack of a Population Register Have On the Programme?

Without knowing the total population, the number of women covered by the Programme can only be determined by using 1996 census data. Women in the “priority group” category⁵⁹ may be overlooked.

- 8.29 The NSU currently reports that:

- A total of 99%⁶⁰ of women are enrolled in the Programme – this is the number of women aged 20 to 69 years who have EVER had a result (cytology or histology) registered with the Programme.⁶¹ The NSU therefore considers that almost all women in the eligible age range have had some contact with the Programme at some time; and
- to December 2001 – 73% of women registered (referred to as “coverage”) have had a smear in the last three years, and 87% (referred to as “participation”) have had a smear in the last six years (both of these figures have been adjusted by excluding those women who have had a hysterectomy).

- 8.30 However, without having a population register, these figures cannot be known with any accuracy. The coverage figures are a percentage of the number of women enrolled, however, the number of women enrolled is calculated using the total population of women. This figure is extracted from the 1996 census data projected out to 2001, so the actual data is more than seven years old. Furthermore this figure is not adjusted for the number of women turning 20 or immigrating in the intervening period, and is updated for women who emigrate or die only if the Programme is notified⁶² by the woman’s GP or by the woman who is emigrating.

- 8.31 During our review, we had cause to doubt the accuracy of the NSU’s reported figures, in that:

- some NCSP-Register sites have enrolments of more than 100% (caused by duplicate entries), while others report enrolment around 80%;

⁵⁹ The “priority group” category refers to women who are not participating in the Programme but have not formally opted off the Programme.

⁶⁰ Extracted from the NCSP-Register’s monthly statistics for May 2003.

⁶¹ For example, if a women had a smear 10 years ago and then opted off the NCSP-Register or failed to return for further smears, she is still classified as being enrolled.

⁶² The NSU acknowledges that some of the enrolled women will have gone overseas and some may have died, and the NCSP-Register has not been notified.

- the review of the 23 cases of invasive cervical cancer that have been undertaken since October 2002 indicate that 50% of the women (at least 11 women) had not been enrolled on the Programme before their diagnosis of invasive cervical cancer; and
- the figure used to adjust for hysterectomies, is based on 1987 to 1992 data (this data is now more than 11 years old)⁶³ and assumes that the incidence and type of hysterectomy has not altered since that time.

8.32 We consider that greater urgency needs to be given to developing the NHI to provide population data so that women who are not enrolled on the Programme can be identified, as well as the reason why they are not enrolled, so that any barriers to enrolment can be removed. The NHI would also provide the most recent contact details for locating women who are overdue for a smear or who need to attend for follow-up treatment.

⁶³

The population was split into five-year age groups (e.g. 20-24, 25-29) and, using data of actual incidence of hysterectomy from 1987 to 1992, a six-year average was calculated. The future incidence rates for each group were then estimated (for 1996 to 2001) and the cumulative incidence rate of hysterectomy at the midpoint of each age group was calculated.

Part Nine

Role of Ethics Committees

Introduction

The Committee of Inquiry thought that ethics committees might inhibit monitoring and audit of the Programme. The issues that were raised by the Inquiry are being worked on, but may not implement all the relevant recommendations.

9.1 The Committee of Inquiry was concerned that an ethics committee decision had prevented an audit of the Programme, and that statements in the *National Standards for Ethics Committees* (1996) in New Zealand were contradictory.

9.2 As a result of these concerns, the Inquiry made six recommendations in relation to ethics committees:

- Recommendation 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;*
- Recommendation 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;*
- Recommendation 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;*
- Recommendation 21 – *Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies;*
- Recommendation 22 – *A National Ethics Advisory Committee should be established for the assessment of multi-centre or national studies; and*
- Recommendation 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.*

Progress to Implement the Recommendations

There is a National Ethics Advisory Committee (Recommendation 22) and 15 Regional Ethics Committees.

9.3 The National Advisory Committee on Health and Disability Support Services Ethics (the National Ethics Advisory Committee) was established under section

16 of the New Zealand Health and Public Disability Act 2000. Members were appointed from December 2001.

- 9.4 The National Ethics Advisory Committee's statutory functions are to:
- provide advice to the Minister on ethical issues of national significance regarding health and disability research and services;
 - determine nationally consistent ethical standards; and
 - provide scrutiny for such research and services.
- 9.5 Accordingly, the National Ethics Advisory Committee can be regarded as being a policy committee.
- 9.6 The National Ethics Advisory Committee can be distinguished from regional ethics committees. There are currently 15 regional ethics committees, approved by the Health Research Council Ethics Committee (under section 25(1) of the Health Research Council Act 1990) for the independent ethical review of health research. The regions covered by these ethics committees are broadly in line with those of the former Area Health Boards. The regional ethics committees assess particular studies against ethical considerations.

The National Ethics Advisory Committee has agreed a work programme with the Minister to consider the recommendations.

- 9.7 The National Ethics Advisory Committee has agreed with the Minister, a work programme that gives priority to consideration of the issues raised by the relevant Committee of Inquiry recommendations (with the exception of Recommendation 20).
- 9.8 The Ministry was allocated responsibility for implementing Recommendation 20, requiring each ethics committee to have a legally qualified person on the committee. The Ministry told us that it has implemented Recommendation 20 through changes incorporated into the *2001 Operational Standard for Regional Ethics Committees* (the Operational Standard).
- 9.9 The Ministry also told us that Recommendation 18 has been implemented through amendments to the Operational Standard. While the National Ethics Advisory Committee accepts that the Ministry has implemented Recommendation 18, it considers that some audit-related activities have not been fully addressed by the Ministry, so it is continuing to examine policy in this area.

Much work still needs to be done before advice can be given to the Minister.

- 9.10 The Terms of Reference for the National Ethics Advisory Committee were formally signed off in December 2001. However, the Committee did not agree its work programme to consider the priority matters in its Terms of Reference until November 2002.
- 9.11 Three of the Committee of Inquiry's recommendations (19, 21, and 23) were included in the Terms of Reference. The recommendations related to the review of operations of ethics committees and the effect of their decisions, advice on observational studies, and the application of second opinion and appeal processes.
- 9.12 In April 2002, the Minister also asked the National Ethics Advisory Committee to consider a fourth priority matter (Recommendation 22) – to review the current processes for the ethical review of national and multi centre research.
- 9.13 The National Ethics Advisory Committee has made progress on its work programme. In particular, it has sought advice from Crown Law on the application of second opinions and the appeal processes, and has released two discussion documents⁶⁴.
- 9.14 Submissions on these documents closed on 7 November 2003, and the National Ethics Advisory Committee was originally scheduled to report to the Minister by 30 November 2003. However, we have now been told that the Advisory Committee is to report to the Minister by 12 December 2003.

There is uncertainty about whether recommendations will be implemented.

- 9.15 It is still too early to say whether the Committee of Inquiry recommendations relating to ethics will be implemented. This will ultimately depend on the outcome of National Ethics Advisory Committee's work and Ministerial decisions.

⁶⁴ *System of Ethical Review of Health and Disability Research in New Zealand* which addresses Recommendations 19, 22 and 23, and *Ethical Review of Observational Research, Audit and Related Activities*, which addresses Recommendations 19 and 21, and matters dealt with by the implementation of Recommendation 18.

Part Ten

Complaints' Monitoring and Communications

Introduction

10.1 The Committee of Inquiry made eight recommendations in regard to complaints' monitoring and reporting, and to communications about the Programme. They were:

- Recommendation 24 – to establish a user-friendly system which can respond to complaints of Programme failures, such as under-reporting;
- Recommendation 34 – that the ACC and the Health and Disability Commissioner should inform the Programme of any complaints made about the treatment of a patient in relation to the Programme;
- Recommendation 35 – that, if medical disciplinary proceedings uncover a public health risk, it should be reported to the Minister;
- Recommendation 36 – that there should be an exchange of information between the ACC and the Medical Council regarding claims for medical misadventure and disciplinary actions against medical practitioners;
- Recommendation 44 – relating to medical practitioners reporting concerns about another medical practitioner to the Medical Council;
- Recommendation 38 – to provide women with information to enable them to make informed decisions about screening and provide them with information regarding potential risks and benefits – especially in relation to areas of the Programme where the quality has not been tested, and the fact that screening will not necessarily detect cervical cancer;
- Recommendation 39 – requiring that medical practitioners be reminded that a cervical smear test is not a diagnostic test; and
- Recommendation 45 – to establish a system over and above the audit and monitoring reports, to identify deficiencies in its process. The Committee of Inquiry suggested a survey of users.

10.2 In addition, in her final report, Dr McGoogan raised issues in relation to the general understanding of screening programmes, communication between agencies, and communication between the NSU and the relevant professional groups.

Progress to Implement the Recommendations

Preparation of a system to monitor and respond to complaints is under way.

10.3 Five recommendations referred to complaints' monitoring and reporting. Recommendations 34, 35, and 44 are covered under the Health Practitioners Competence Assurance Act 2003, and Recommendation 36 has been

implemented under section 284 of the Injury Prevention, Rehabilitation, and Compensation Act 2001.

- 10.4 In regard to Recommendation 24, the NSU is preparing a complaints' monitoring system that covers both the Programme and BreastScreen Aotearoa. The aim of the system is to collect information about complaints relating to any aspect of the screening programmes. Sources for complaints include consumers, the Health and Disability Commission (HDC), ACC, and professional bodies such as the Medical Council and the New Zealand Nursing Council (NZNC).
- 10.5 Memoranda of Understanding between the HDC, ACC, the Medical Council, and the NZNC are being prepared, as well as a complaints database for electronically recording information and trends analysis.

The NSU has provided an information booklet about cervical screening, and has written to medical practitioners.

- 10.6 In response to Recommendation 38, the NSU has published a comprehensive guide – *Cervical Screening – A guide for women in New Zealand*. The booklet has been given to GPs and other health providers to pass on to women. The booklet contains a section on the effectiveness of cervical smear testing – explaining that it is not a diagnostic test – and that occasionally abnormal cells may be missed.
- 10.7 In response to Recommendation 39, medical practitioners were written to and reminded of the limitations of cervical smear tests as a means of diagnosing invasive cervical cancer.

Dr McGoogan noted in her final report that there is not a good understanding of public screening programmes generally within the Ministry, among health professionals, or by the public in New Zealand.

- 10.8 The NSU is currently drafting a *Communications Strategy*. One of the intended strategies is to *manage perceptions of the NSU, its role and programmes to create realistic expectations of programme benefits and limitations*. To achieve this, the Programme will work to ensure that the differences between screening and other health services are well understood by both the public and health professionals.
- 10.9 The NSU also intends to include known risks relating to screening programmes (e.g. false negatives and false positives) in background information that it produces to increase knowledge of the risks and potential harms of screening programmes. The NSU considers that open and honest communication about known risks will assist women to make informed decisions and contribute towards realistic expectations about the Programme's benefits and limitations.

When the NSU implements another of its strategic goals in its draft Communications Strategy – *to build understanding and partnership among key stakeholders* – this will address Dr McGoogan's concern that professional guidance and support are essential.

- 10.10 Dr McGoogan noted in her final report that she was concerned that the Cervical Screening Programme Advisory Group that she met with on her first and second

visits has been disbanded and she went on to note that *professional guidance, advice and support from such a forum are essential.*

10.11 We share Dr McGoogan's concerns and discussed the role of the advisory group earlier in this report in paragraph 4.19 on page 32.

10.12 We note that the NSU has identified obtaining professional guidance and support as an issue in its draft Communications Strategy, and has introduced appropriate actions to address the issue, such as:

- establishing a planned co-ordinated programme to communicate with key stakeholder groups;
- building more collaborative relationships with service providers, Maori, consumer groups, independent service providers, and the professional bodies and Colleges to build understanding of the principles of screening and the Programme as a whole;
- taking a collaborative approach to establishing new quality and monitoring initiatives; and
- maximising the use of the intended new advisory and reference groups.

10.13 However, having prepared a strategy and identified appropriate actions to address the issues, the NSU must now follow through and actually implement the action points.

In our view, Dr McGoogan's reviews have to a large extent addressed Recommendation 45 – to establish a system over and above the audit and monitoring reports to identify deficiencies in the Programme's process.

10.14 We consider that independent reviews should continue (see paragraph 3.12 on page 23).

Appendix

Appendix

Progress Made Towards Implementing the Committee of Inquiry's Recommendations

The 46 recommendations of the Committee of Inquiry are set out below. Under each recommendation, we have recorded the current status of implementation as at November 2003.

- 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 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.*

The third phase of the national evaluation – the Cancer Audit – is proceeding. However, the Cancer Audit will not be completed until the end of 2004. Moreover, the Cancer Audit will not determine whether there was a systemic problem of under-reporting in New Zealand in the late 1990s. Doubts as to whether this would be achieved were first raised in October 2001.

- 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 12 months apart.*

The Ministry has not yet determined how it will respond to this recommendation, but we understand that it has asked Dr McGoogan for her views on the recommendation. The results of the Cancer Audit may also provide information to guide the Ministry on how it should respond to this recommendation. Since this recommendation was made, 750,000 women have already been re-screened but some women, for example, those who have turned 70 since the Committee of Inquiry reported, have not had another smear since the Operational Policy and Quality Standards were in place. It may be appropriate to re-screen this group of women.

- 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.*

The Draft Evaluation Plan was made up of 13 parts. Some parts of this plan are part of the work undertaken by the Independent Monitoring Group (IMG) and annual statistical reporting. Others, such as economic evaluation of the Programme, have not

been specifically undertaken, but have been incorporated into other work, such as the review of liquid-based cytology and Human Papilloma Virus testing.

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.***

This recommendation is currently being implemented. In particular, the Programme's Operational Policy and Quality Standards were introduced from October 2000. However, there is only voluntary compliance for smear-takers and private colposcopists.

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.***

This has been implemented.

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.***

A legal review was commissioned which identified areas for improvement, such as strengthening the legislation – for example, for the Programme to have the power to regulate its standards. This is included in the Health (Screening Programmes) Amendment Bill. A further legal review is currently under way to look at the obligations and responsibilities of all Programme service providers.

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.***

Delays in reporting are such that it raises questions about the usefulness of these reports. The 1996-98 report has been published. The 1999-2000 report is still in progress. Work on the 2000-01 report is under way.

8. ***Meaningful statistical information should be generated from both the National Cervical Screening Programme 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.***

Progress has been made over the last six months, in that the National Screening Unit is now analysing the incidence of invasive cervical cancer on a regional basis.

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.***

The standards have been set. However, we note that the two public-hospital-based laboratories did not meet minimum-volume standards in 2002.

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.***

The Programme now has a more balanced approach, in that it has become more medically focused, rather than participation focused. Smear-taking, and increasing the number of women participating in the Programme – particularly Maori and Pacific Island women – are still key aspects for the Programme.

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.***

There has been some confusion about what this recommendation means and how implementation can be measured. We were told that the approach was open and collaborative and that advice was proactively sought from health professionals, specialist groups, and the wider community. We note that the Population Screening Programmes Advisory Group has been disbanded, but that the Ministry is in the process of establishing, or has established, new advisory groups. However, we note that some outside the Ministry believe that the culture still needs to be more open and collaborative.

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.***

This has been implemented.

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.

This recommendation has not been implemented.

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.*

The Ministry of Health intends this recommendation to be implemented through the Health (Screening Programme) Amendment Bill.

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.*

The Kaitiaki Regulations have been reviewed. However, the outcome of the review was not that anticipated by the Committee of Inquiry.

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.*

The Ministry of Health intends this recommendation to be implemented through the Health (Screening Programme) Amendment Bill.

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.*

The Ministry of Health intends this recommendation to be implemented through the Health (Screening Programme) Amendment Bill.

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.***

The Ministry of Health considers that this recommendation has been implemented through changes to the Operational Standards for Ethics Committees in March 2002.

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.***

The National Ethics Advisory Committee is currently reviewing the operation of ethics committees and the effect that their decisions are having on independently funded evaluation exercises and medical research generally in New Zealand. However, the National Ethics Advisory Committee is still drawing up guidelines for Ethical Review of Observational Research, Audit, and Related Activities, and plans to report back to the Minister of Health by 12 December 2003.

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.***

This recommendation has been implemented.

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

This issue has been allocated to the National Ethics Advisory Committee. The Committee now intends to report to the Minister of Health by 12 December 2003.

22. ***A National Ethics Advisory Committee should be established for the assessment of multi-centre or national studies.***

The National Ethics Advisory Committee members were appointed in December 2001. The Committee has issued a discussion paper on the "System of Ethical Review of Health and Disability Research in New Zealand", and is now due to report to the Minister of Health by 12 December 2003.

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.***

The National Ethics Advisory Committee is considering this recommendation. The Committee has asked for a legal opinion on whether or not the ethics committee decisions can be appealed, and to what sort of body. The Committee is now due to report to the Minister of Health by 12 December 2003.

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 that 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 Committee of Laboratories must be avoided in the future.***

While a system is currently in place to deal with complaints, work to establish a comprehensive complaints' system is under way. Memoranda of Understanding between the National Screening Unit, the Health and Disability Commission, the Accident Compensation Corporation, the New Zealand Medical Council, and the Nursing Council of New Zealand are being drawn up. A complaints' database is also being established.

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

The recommendation has not been strictly implemented, in that a manual process is used to check the data on the NCSP-Register and the Cancer Register. The National Screening Unit considers that it is not possible to electronically link the two registers at present without risk of incorrectly merging patient records. A data assurance protocol is in place to govern the exchange of data.

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.***

The NCSP-Register has an operations protocol, and the Programme has recently issued Standards for Providing a Regional Service. Laboratories are contractually obliged to provide data to Regional Services in a timely manner. There is a six-month delay for entry of data onto the Cancer Registry; some of this time is necessary to confirm the cancer diagnosis.

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.***

The Operational Policy and Quality Standards were issued in October 2000 and these Standards should have been reviewed by October 2002. The 12 Colposcopy Standards were reviewed this year and re-issued in July 2003. The review of the Laboratory Standards is planned for 2004. No date has been set for the review of the Smear-taking Standards.

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.***

The Ministry of Health prepared a *Draft Workforce Development Strategy and Action Plan 2002-07*, which is still to be finalised. More work is required to provide appropriate training and development of health professionals involved in cervical screening. In addition, consultation is currently being undertaken on a proposal for a National Cervical Cytology Training Organisation.

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.***

This recommendation will be addressed through the “scopes of practice” in the Health Practitioners Competence Assurance Act 2003. The Medical Laboratory Technologists Board will set the scope of practice for laboratory staff. While the Act has been passed, the scopes of practice still need to be developed.

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.***

The Ministry of Health intends this recommendation to be implemented through the Health (Screening Programme) Amendment Bill.

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.***

A business case is currently being prepared to replace the existing information system. Electronic access to the NCSP-Register cannot be addressed until the new information system has been implemented.

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.***

Laboratory coding is standardised throughout the country, and will be updated as part of some Ministry of Health projects. Some inaccurate coding may be noted at the Regional Service sites and remedied through contact with the laboratory. Regional Service sites are subject to quality assurance processes.

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.***

This is still to be implemented. The New Zealand Health Information Service is responsible for developing an index of health users – the National Health Index – from which population-specific data for specific population programmes will be able to be drawn. However, considerable work is required – including improvements to data quality, and establishing linkages with the various registers – before this will happen.

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.***

ACC is required to report complaints to the Medical Council under the Injury Prevention, Rehabilitation, and Compensation Act 2001.

Under the Health Practitioners Competence Assurance Act 2003, the Medical Council must inform the Director-General of Health of possible harm posed by a health practitioner.

Under the Health and Disability Commissioner Amendment Act 2003, the Health and Disability Commissioner may refer a complaint to the Director-General of Health if it appears that the complaint is a result of inadequacies of the healthcare provider that may harm the health and safety of the public.

Under the Health Practitioners Competence Assurance Act 2003, the Health and Disability Commissioner is required to raise with the Medical Council matters where there is potential risk of harm to the public from a health practitioner’s practice.

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.***

The Ministry of Health intends this recommendation to be implemented through the Health (Screening Programme) Amendment Bill.

The Medical Council is advised of the Tribunal’s concern and must report the concern to the Minister/Ministry 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.***

This has been implemented through the Injury Prevention, Rehabilitation, and Compensation Act 2001.

37. ***It is recommended that the Programme liaise with the Royal College of Pathologists of Australia [sic]. 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.***

Initial liaison has been established. The National Screening Unit needs to work at establishing and maintaining closer links with the colleges, especially in the areas of standards' development, competency testing, and service provider auditing.

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.***

The Ministry of Health has produced and distributed the NCSP General Pamphlet, NCSP Detailed Information Booklet, and tear-off information sheets for women. Information leaflets will need to be updated when the relevant Acts are passed. A Communications Strategy has been prepared.

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.***

This recommendation has been implemented by the National Screening Unit, which sent a letter to medical practitioners setting out the limitations of cervical smears as a means of diagnosing invasive cervical cancer.

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.***

This recommendation has been implemented.

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.***

Currently there are no practical or post-graduate cytology courses in New Zealand. This recommendation may take some time to address but it has been included in the *Draft Workforce Development Strategy and Action Plan 2002-07*, and training for pathologists is included in the proposal for a National Cervical Cytology Training Organisation.

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.***

The Operational Policy and Quality Standards set out training requirements for pathologists.

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.***

While difficult to measure, we consider that this recommendation has been implemented.

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.***

This recommendation has been given effect to by the Health Practitioners Competence Assurance Act 2003. Section 34 of the Act protects health practitioners who report concerns about other health practitioners from civil or disciplinary proceeding, unless the reporting was done in bad faith.

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.***

We consider that the independent reviews completed by Dr McGoogan would come under this recommendation. As Dr McGoogan has completed what is intended to be her final report, we consider that the Programme would continue to benefit from the review of an independent expert. However, we also consider that it is timely for the independent review to be expanded from looking at implementation of the 46 Committee of Inquiry recommendations to focus on the Programme as a whole. The

reviews should be staggered to reflect the ongoing maturity of the Programme. We suggest reviews be undertaken at the end of 2004, 2006, and 2011. The NSU has also planned a survey of women's awareness of the Programme.

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

This recommendation has been implemented. The responsibility for completion of each recommendation has been assigned, and quarterly monitoring reports – reporting achievement against each recommendation – are submitted to the Minister of Health.