Ref. No. 20034113

FINAL REPORT ON THE REVIEW OF PROGRESS TO IMPLEMENT THE RECOMMENDATIONS OF THE GISBORNE CERVICAL SCREENING INQUIRY - DR EUPHEMIA MCGOOGAN

REPORT

PURPOSE

1. Following the release of the Report of the Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region, Dr Euphemia McGoogan, Cytopathologist and adviser to the Minister of Health, was asked to review progress to implement the recommendations from the Gisborne Cervical Screening Inquiry. This is Dr McGoogan's second and final report on progress to implement the recommendations of the Gisborne Cervical Screening Inquiry.

2. This report summarises the findings of the second and final report from Dr McGoogan, cytopathologist and adviser to the Minister of Health, on progress to implement the recommendations of the Gisborne Cervical Screening Inquiry and documents the Ministry of Health's response.

BACKGROUND INFORMATION

3. In response to Recommendation 46 of the Inquiry Report, Dr Euphemia McGoogan, cytopathologist, was engaged by the Minister to provide independent advice on progress to implement the Inquiry Recommendations. For this purpose Dr McGoogan visited New Zealand in Oct-Nov 2001, April 2002 and January 2003.

4. Following her first visit, Dr McGoogan provided a report *"Progress in implementing the Cervical Screening Inquiry Recommendations"* to the Minister of Health in December 2001. At the same time the Office of the Controller and Auditor General also carried out a review of progress. The Ministry responded to Dr McGoogan's first report, and to the report of the Controller and Auditor General, in a report to the Minister in February 2002. [Health Report 20021940]

5. Dr McGoogan did not provide a second report following her visit in April 2002. Dr McGoogan's third and final visit to New Zealand was in January 2003, where she met with most of the Ministry of Health officials involved in the various projects to implement the Inquiry Recommendations. This is a response to her final report following that visit.

6. Throughout the period that Dr McGoogan was engaged by the Minister of Health, Dr McGoogan has been supplied with full documentation on all activity to deliver the Inquiry recommendations. The Ministry of Health has also regularly publicly reported on progress to deliver the recommendations initially through the provision of monthly progress reports and then quarterly progress reports. An annual report for the 2001/02 year and an annual plan for 2002/03 was also published. These reports can be found on the Cervical Screening Inquiry website www.csi.org.nz

COMMENT

Dr McGoogan's Report - Key Findings

5. This section outlines the key findings from Dr McGoogan's second report and provides a response to each finding.

6. In relation to the work to deliver the recommendations, Dr McGoogan states "I recognise that a vast amount of activity has occurred over the past three years and a structured National Cervical Screening Programme (NCSP) is emerging. The progress to date is the result of a great deal of effort on the part of a whole range of individuals in the National Screening Unit (NSU) and in related Government departments, as well as among Professional Bodies and individual health care professionals."

7. Without direct reference to the specific Inquiry Recommendations, Dr McGoogan also provides an assessment of the NCSP against the World Health Organisation guidance for successful cervical screening programmes.

8. Both in reviewing progress on implementation of the Inquiry Recommendations and assessing the NCSP against the World Health Organisation guidance, Dr McGoogan, identifies that there is still work to be done in some areas. In particular, she highlights the following areas.

The Audit of Invasive Cervical Cancer

9. Dr McGoogan expresses concern over the delay in completing the Audit of Invasive Cervical Cancer *(Recommendation 1, 2 and 3).* She notes that the final outcome from the Audit will not be known until the end of 2004 and that this is too late to reassure women that their National Cervical Screening Programme was safe and effective in the late 1990s.

10. The delays have occurred for a number of reasons. Significant development of the University of Otago's proposed audit methodology submitted to the CSI was required before it could be operationalised. In October 2001, the University of Otago advised the Ministry that they would not participate in the audit. Subsequently a team from the University of Auckland agreed to undertake the audit in conjunction with the Ministry. Before any operational work could commence, the audit methodology had to be finalised and the policies and procedures had to be established.

11. In May 2002 the Audit team obtained Ethics Committee approval to proceed. The audit methodology involves interviewing two samples of women identified by the National Cancer Registry (NCR) with a histologically confirmed diagnosis of ICC (between January 2000 and 30 September 2001, and October 2001 to September 2002 respectively) and undertaking an audit of their screening histories, including re-reading all their cervical slides. The addition of the second sample meant this data was not available until March 2003. Actual fieldwork began in June 2002, but further delays ensued in abstracting women's medical

records as the Ethics Committees had required the Audit team to contact each individual woman's doctor prior to the Audit team contacting the woman.

12. The women considered for inclusion in the second sample of the audit could not be confirmed until late March 2003. The high response rates from the two samples of women meant women wanted to be interviewed face to face. Although this was a positive reflection on the audit, it also meant that there were delays in undertaking these interviews.

13. Dr McGoogan has raised concerns about the audit's ability to determine whether there has been any systemic under-reporting in the programme in the late 1990s.

14. It was recognised from the outset that the methodology agreed upon for the Audit of Invasive Cervical Cancer (ICC) would not detect under-reporting if it existed. A number of overseas studies that have examined the screening histories of women who have developed ICC have revealed that a significant number of women with ICC had either not been screened or had been screened on an infrequent basis. This means that these women will have few or no cervical slides available which can be re-examined as part of an audit in ascertaining whether there has been any systemic under-reporting within a cervical screening programme.

15. Epidemiologists working on the current ICC audit have advised that the number of cervical slides that will be re-read as part of the audit are insufficient to detect an under-reporting of high grade abnormalities. In other epidemiological studies the problem could be overcome by increasing the number of slides. However, the number of slides that will be re-read in this audit are directly related to the number of women with invasive cancer, and only auditing those women who have developed ICC. The audit does not involve getting a representative sample of cervical slides from women who have not developed ICC.

16. ICC can take anywhere from 10 or more years to develop. For those women who had participated in the NCSP and had developed ICC it would be reasonable to assume that a significant number of these women developed ICC in the years preceding the current standards of practice in the NCSP Operational Policy & Quality Standards, October 2000. Therefore the information examined in this Audit will be historical in nature, and with limited comparisons being able to be made with the NCSP today.

17. The Ministry acknowledges the importance of the Audit of Invasive Cervical Cancer as one of a range of quality improvement activities for the NCSP. Recognising the limitations of the Audit and the time that may be required to implement recommendations arising from its findings, the NSU has implemented improvements based on recognised quality standards and ongoing review and monitoring against those standards.

18. NCSP Operational Policy and Quality Standards for laboratories have been in place since October 2000 and the overall monitoring suggests that an acceptable standard is being achieved. Since that time over 758,585 women have had one or more smears on the NCSP-Register, equating to around 70% of the eligible population. Over 1.6 million slides have been read and monitored in accordance

with new quality standards. Since the routine screening interval is three years, by 2005 most women on routine screening will have had a smear test that has been read by laboratories meeting the current quality standards

19. By the time the Audit report is released a further 400,000 women could have had a smear. *(In effect Recommendation 2 would have been largely implemented)*

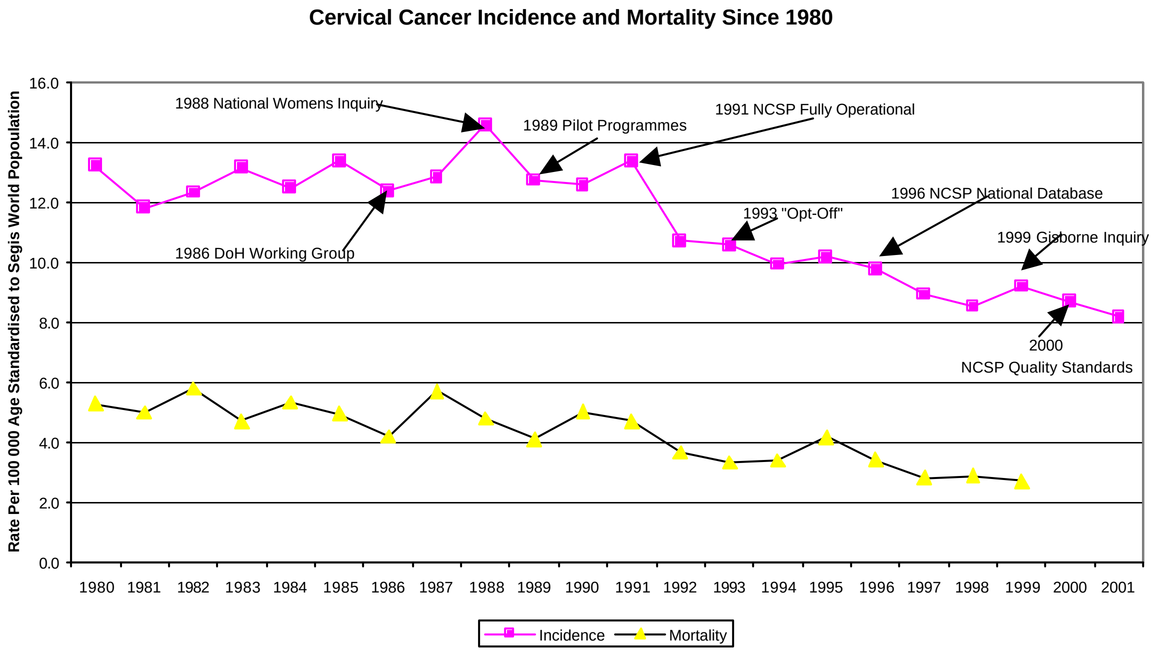
Programme Effectiveness

20. Further to comments on the delays associated with the Audit, Dr McGoogan states that, in the absence of the Audit findings, there is no explicit evidence to reassure women that the NCSP was safe and effective in the late 1990s.

21. The NSU has established a range of quality activities that help ensure the safety and effectiveness of the programme for women currently. These are described in more detail below.

22. The most important indicators of overall programme effectiveness are disease incidence and mortality. Figure 1 below illustrates the reduction in incidence of and mortality from cervical cancer in New Zealand, noting relevant key events.

Figure 1. Cervical cancer incidence and mortality since 1980



23. The NCSP has achieved a 39 percent reduction in incidence and a 44 percent reduction in mortality from cervical cancer under the current enrolment system.

24. Coverage is another indicator of programme effectiveness. A high level of coverage gives confidence that the decline in incidence and mortality noted above is due, in a large part, to the NCSP. As at May 2003, 1,084,592 women or 99.14 percent of the eligible population are currently enrolled on the NCSP-Register. Table 1 compares the NCSP coverage with that of two other overseas

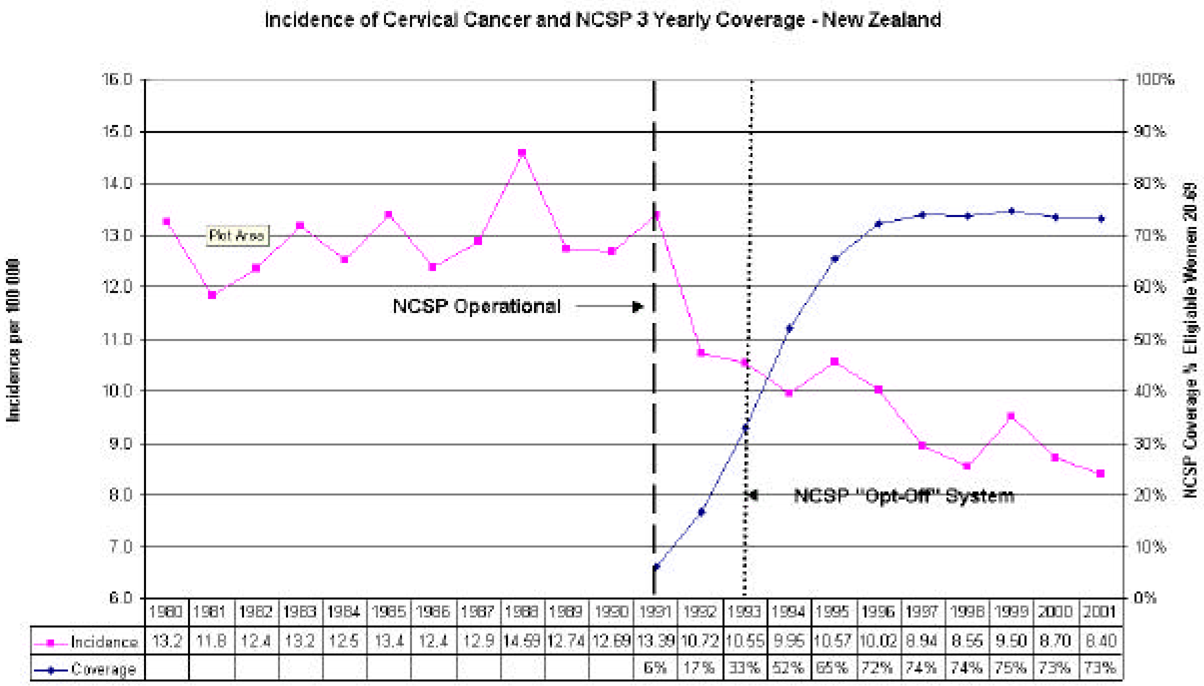
programmes. Figure 2 shows the relationship between programme coverage and cervical cancer incidence.

Table 1 Comparison of cervical screening programme coverage rates in the UK, New South Wales and New Zealand.

Programme	3 Yearly Coverage	5 Yearly Coverage	Enrolment
UK - 2001	66%	83%	-
New South Wales 2001	73%	-	-
New Zealand 2001	72%	88%	95%
New Zealand 2002	72%	89%	99%

25. High levels of participation also indicate that the programme is acceptable to most women. It is important to note, and this is not referred to in the report, that Mäori women have lower participation rates than non-Mäori women in the NCSP. This is a priority area that the NCSP is addressing through a range of initiatives.

Figure 2. Incidence of cervical cancer and NCSP 3 yearly coverage



	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001
Incidence	13.2	11.8	12.4	13.2	12.5	13.4	12.4	12.9	14.59	12.74	12.69	13.39	10.72	10.55	9.96	10.57	10.02	8.94	8.55	9.50	8.70	8.40
Coverage												6%	17%	33%	52%	65%	72%	74%	74%	75%	73%	73%

26. Independent Monitoring of the programme against agreed indicators and targets has been carried out since October 2000. The Independent Monitoring Group, based at the University of Otago, has published nine quarterly monitoring reports reporting on NCSP-Register data to the end of December 2002. These reports are distributed to providers and are publicly available providing statistical data on the performance of the NCSP and NCSP providers. These reports show that the national indicators of performance are largely being met; where there are recommendations to follow up with providers, the NSU addresses these directly with the service provider concerned. Dr McGoogan herself states in her report that current monitoring of the programme suggests that an acceptable standard is being achieved.

27. Overall in terms of safety and effectiveness the NCSP is able to demonstrate reducing incidence and mortality from cervical cancer, moderately high levels of programme coverage, and good results from ongoing monitoring following the introduction of quality standards.

28. Improvements continue to be implemented, and in 2003/04 the programme will see the introduction of new and revised standards for colposcopy and NCSP Regional Services, the implementation of Provider Compliance Audits, a new Complaints System, and a range of workforce development and training initiatives. In addition, a number of evaluation activities aimed at investigating where further improvements may be made are planned or underway e.g. the review of the developments in Liquid Based Cytology and Human Papilloma Virus testing.

29. The NSU reviewed its advisory group structure in 2002 and subsequently disestablished the Population Based Screening Advisory Group, originally established by the HFA in 1998. Prior to its disestablishment, this Group approved the NSU's revised advisory group structure reflecting separate Advisory Groups for the breast and cervical screening programmes and a generic screening advisory body to reflect the NSU's wider screening focus.

30. Input from women on the development of the programmes is important and calls for nominations for the Consumer Advisory Group are currently being sought. This advisory group (alongside a Mäori advisory group) will provide the NSU with advice on all screening programmes. A specific advisory group for the NSU will include a representative from the College of Gynaecologists, Pathologists, General Practitioners and Practice Nurses. The Advisory Group will also have input from an epidemiologist/Public Health Physician, a Pacific woman, a representative from the Consumer Advisory Group and Maori Advisory Group. Calls for nominations for the NCSP Advisory Group will be sought at the end of July.

Population Register

31. Dr McGoogan believes that a fundamental deficiency in the NCSP is the lack of a population register in New Zealand. In her view such a register would be used for directly inviting individual women to be screened and for improving the monitoring of the programme, identifying more accurately those attending for cervical screening and those who do not.

32. While acknowledging the value of a population register, it should be recognised that it is only one of a number of tools to assist the programme in improving coverage and to monitor outcomes for individuals and the programme overall. Of the three programmes shown in Table 1 – New South Wales, New Zealand and the United Kingdom – only the latter has a population register.

33. The development of a population register is relevant to other areas of health care including immunisation and chronic disease management. There is ongoing work at the Ministry of Health to upgrade the National Health Index register, and the NSU is contributing to that work at several levels.

34. The development of Primary Healthcare Organisations in New Zealand, with age/sex registers of their enrolled populations, will improve the ability of primary care practitioners to identify and invite eligible women for a cervical smear. Evidence shows that a personal invitation from a general practitioner is more effective than a letter from a national register at increasing screening.

Full Audit of New Cases of Cervical Cancer

35. Dr McGoogan recommends “new cases of cervical cancer should not just be ‘reviewed’ but be fully audited as soon as they arise.”

36. The Ministry acknowledges that this is good clinical practice and multidisciplinary case reviews are included as a policy in the Laboratory and Colposcopy chapters in the NCSP Operational Policy and Quality Standards. In addition most primary care groups undertake their own clinical audits as part of ongoing professional development and continuous quality improvement.

37. The review of each new case of cervical cancer using the data on the NCSP-Register to identify any programme issues that require changing is underway. This reflects in part Dr McGoogan’s recommendation of fully audited as soon as they arise. Further consideration of individual case reviews will be considered with the passage of the Health (Screening Programmes) Amendment Bill.

Primary Care Involvement

38. Dr McGoogan refers to primary care team involvement in the NCSP in a number of places in her report. Although there are no Inquiry Recommendations solely related to primary care involvement, there are several that call for primary care support for the NCSP, including those related to the implementation and monitoring of quality standards, and the introduction of legislation supporting improved operation and evaluation of the NCSP.

39. Dr McGoogan notes that primary care teams are not contracted and funded to undertake cervical screening at present, nor are they subject to the same quality assurance in the same way that other component parts of the programme are. The NCSP Operational Policy and Quality Standards, October 2000, includes a chapter on “Providing a Smear-taking Service.” These standards are referred to in the Royal New Zealand College of General Practitioners practice review resource on cervical screening. The policy and quality standards for smear-taking are also recognised by the Health and Disability Commissioner as relevant standards when assessing practitioners’ performance in relation to smear-taking.

40. Dr McGoogan also believes that the new legislation [Health (Screening Programmes) Amendment Bill] falls short in relation to primary care, given that primary care records are not as readily available for evaluation purposes as other records may be.

41. The new Health Screening Programmes Amendment Bill strengthens existing provisions regarding primary care involvement in the NCSP, although in line with the Cabinet decision on September 3rd 2001, consent will still be required prior to

access to primary care records for evaluation purposes [CAB (01)27/17]. The new Bill also includes regulation-making powers that will give the programme the ability to mandate and enforce standards across the programme.

Understanding of Screening

42. Dr McGoogan expresses concern regarding the poor understanding of public health screening programmes in NZ. She comments that she believes that most of 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.

43. The issue of poor public and professional understanding of screening is not unique to New Zealand or the NCSP, and is acknowledged in the work of the UK National Screening Committee. The NCSP works with health sector organisations, women's groups and national focus groups to develop information resources to assist women to understand the nature of cervical screening and the NCSP. These initiatives inform women and health professionals about screening, its benefits and harms.

44. Over the last three years the NCSP has developed new resources including a new general pamphlet, a detailed booklet, a colposcopy pamphlet and an understanding cervical smear tests results pamphlet. The booklet *"Cervical Screening: a guide for women in New Zealand"* provides detailed information on cervical screening and the NCSP. The new general pamphlet 'Cervical smear tests: what women need to know" provides general cervical screening information including New Zealand figures on the absolute risk reduction from three-yearly screening for developing or dying from cervical cancer. The general pamphlet, detailed booklet and the tear off cervical screening information sheet have been widely distributed by the NCSP as recommended in Dr McGoogan's first report.

45. Dr McGoogan is pleased to note the National Health Committee (NHC) has also recently published *"Screening to Improve Health in New Zealand: Criteria to assess Screening Programmes,"* which you launched in April 2003. The NHC acknowledges the issue of limited public and professional understanding of screening, and the report is intended *inter alia* to assist in increasing the knowledge of health professionals and the public about public health screening programmes. The report has been very well received and widely distributed, and is being reprinted this month.

Privacy Concerns

46. Dr McGoogan notes that the ability to monitor the programme is limited by excessive concern with privacy over access to screening records and that these concerns would also have implications for the introduction of a population register.

47. New Zealand is unique internationally in its approach to individual privacy and informed consent, particularly in relation to all aspects of an individual's health care. In the case of cervical screening privacy concerns are critical given the history of the NCSP and its relationship to the events at National Women's

Hospital that lead to the Cartwright Inquiry. The high priority that consumer groups place on privacy is evidence to their responses to the new Screening Programmes Amendment Bill.

48. Dr McGoogan noted her concern that the decision was made not to implement changes to the National Kaitiaki Group (NKG). The NKG was established under the Health (Cervical Screening (Kaitiaki)) Regulations 1995. Under Regulations 3 and 4, the NKG considers applications for the disclosure, use or publications of Maori women's aggregate data from the NCSP-Register. Aggregate data is information that is totalled together to provide statistics about a group of individuals and which does not allow the identification of the individual woman concerned. Without NKG approval, this data cannot be disclosed, used or published.

49. However, the NCSP can access identifiable Maori women's data for operational and evaluation purposes, but the NCSP cannot go onto disclose or publish Maori statistical or aggregate data without the approval of the NKG.

50. The NKG is required to consider applications to use aggregate Maori women data from the NCSP-Register (usually for research and evaluation purposes) using the following criteria;
    - the need to ensure that protected information is used for the benefit of Maori women
    - the principle of sanctity of te whare tangata
    - the need to ensure that the information is protected in a culturally appropriate manner.

51. The Gisborne Inquiry recommended that the Regulations be reviewed to allow independent teams to have ready access to Maori women's data on the Register (without the need for Kaitiaki approval), for the purposes of monitoring and evaluation of the NCSP. Consultation with Maori women on these regulations began in early 2002, and in September 2002 Cabinet announced its decision to retain the system under the regulations with improved processes for the NCSP to access data.

NCSP Clinical Leadership

52. In her report Dr McGoogan notes that since her previous visit three new clinical leader positions have been created within the National Screening Unit, one of which is the Clinical Leader position for the NCSP. Dr McGoogan expresses concern at the part-time nature of the latter position and suggests that the Clinical Leaders in the NSU hierarchy limits their authority and influence.

53. The Clinical Leader of the NCSP, Dr Hazel Lewis is jointly accountable for the national management of the NCSP alongside Ms Jane McEntee, the Operational Manager. Both Dr Lewis and Ms McEntee work at a tier two level within the NSU. The full-time Public Health Leader is available to provide clinical input as required, including cover when Dr Lewis is unavailable.

54. Dr Lewis works three days a week with the NSU and practices as a clinical smear taker for two days a week, however she is contactable by the NCSP at all times.

Her continuing clinical work is extremely valuable, providing practical knowledge of cervical screening, and also contributes to policy development and programme oversight. Thus, the new clinical leadership position strengthens the NCSP by providing a linkage between policy and service provision bringing together all programme components.

55. The new joint accountability structures have resulted in the formation of stronger linkages with professional colleges and organisations, clinical providers, the IMG and women's groups.

56. All three clinicians in the new "leader" roles are on the NSU Senior Management Team where they are able to strongly influence the development and implementation of screening policy.

57. Prof Jocelyn Chamberlain on page 37 of her report 'BreastScreen Aotearoa An Independent Review,' May 2002, in response to Inquiry recommendation 11.12 and 11.13 states "…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."

58. In relation to the location of the National Screening Unit within the Ministry of Health Prof Jocelyn Chamberlain stated "13.3…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."

Workforce Development

59. Dr McGoogan has noted that recommendations 28 and 41 as "work begun but still much to be done". These are being implemented as part of the NSU's Workforce Development Strategy.

60. The NSU has appointed a Laboratory Workforce Advisory Group to work with the NCSP on the implementation of the Inquiry Recommendations. The Advisory Group has been very active in examining workforce issues and identifying solutions. Discussions have also been held with the Royal Australasian College of Pathologists regarding Dr McGoogan's suggestion that a Diploma in

Cytopathology should be mandatory for pathologists providing cervical cytology services.

61. In addition, Dr McGoogan expresses concern regarding the availability of appropriate training and development courses to all groups of health professionals. Whilst not a recommendation of the Inquiry, initiatives to support training and development across the screening pathway are included within the NSU's Workforce Development Strategy and work is ongoing.

62. Also following comments in Dr McGoogan's first report regarding the need to raise the profile of practice nurses in the NCSP and provide specific funding for smear taker training, the NSU has implemented a Nurse Smear Taker Training fund. Practice Nurses can apply for funding for training at one of several accredited training agencies.

63. Dr McGoogan expressed concern regarding training in liquid-based cytology, however the taking of cervical smear tests using liquid based cytology is not NCSP policy. The manufacturer provides training and updates. Approximately 15% of cervical smears are currently processed in this manner.

64. Dr McGoogan raised concerns about laboratory participants in External Quality Assurance (EQA) programmes. In particular, she is concerned that there is no obligation on the part of laboratories to declare any "poor" performance to the NSU. The Royal College of Pathologists Australasia provides a Quality Assurance Programme (QAP) for laboratories 6 times per year where Laboratories receive their results and an annual summary. It is a contractual requirement that NCSP laboratories take part in this or a similar programme (refer pg 5.11 of NCSP Policy and Quality Standards). This is also linked with IANZ accreditation. Dr McGoogan suggests that the NSU needs to consider developing a NZ EQA scheme for individual laboratory staff with a facility to break anonymity if there is a persistent poor performer. The NSU is currently working with its Laboratory Advisory Group on proposals for the introduction of a New Zealand education based competency assurance programme, inclusive of individual proficiency assessment for those who process and interpret cervical smears.

Overall Status of Inquiry Recommendations

65. At the time of her 6-month report, Dr McGoogan was concerned with the terminology used to describe the status of the recommendations (complete, underway, on track and revised delivery date). Further clarification was sought from Dr McGoogan as to her views on the most appropriate way of reporting the status of the Inquiry recommendations. In her second report she has identified the status of the recommendations as follows:

Measure of Progress	Number of Recs
Work begun but much still to be done	7
Not yet implemented	6

Being implemented	7
Completed	2
Implemented	8
Decision not to implement	1
In progress – Bill before Parliament	8
Reviewed but cabinet decision not to implement	1
Part of the remit of the National Ethic Committee	6
TOTAL	46

66. The Ministry's analysis of their 6 and 20 month progress against the Inquiry's recommendations is as follows:

Measure of Progress	**6 months (Oct – Nov 01)**	**20 months (January 03)**
Recommendations Underway	37	23
Recommendations Complete	8	22
Recommendation not yet implemented	1	1
TOTAL	46	46

Overall Status of Dr McGoogan's Recommendations from her First Report

67. As part of her first report, Dr McGoogan made a further 25 recommendations for operational improvements to the NCSP, bringing the total number of recommendations from the Inquiry and Dr McGoogan to 71.

68. The Ministry's analysis of their progress against the Dr McGoogan's 25 recommendations is as follows:

Measure of Progress	**20 months (January 03)**
Recommendations Underway	13

Recommendations Complete	11
Recommendation not yet implemented	1
TOTAL	25

69. Some of the comments made in Dr McGoogan's second report relate to these and progress has been made in a number of areas, including:

- Changes to the operation of the NCSP-Register at the regional level introduced and in the process of being implemented.
- Implementation of a Smear Taker Training Fund in 2002/03 for practice nurses.
- Review of smear takers forms completed.
- Review of short-interval re-screening.
- Commencement of work on introduction of new Bethesda 2001 laboratory coding.
- Commencement of work on the introduction of proficiency testing in Laboratories.
- NCSP funding granted to the 2002 and 2003 Society of Cytology conference.
- Commencement of work on the SNOMED codes accepted by the NCSP.

APPENDIX 1.0

SUMMARY OF PROGRESS AGAINST EACH OF THE INQUIRY RECOMMENDATIONS

Ref	Recommendation	Summary of progress.
1.	Evaluation of NCSP *The remaining two phases of the national evaluation designed by the Otago University team must proceed.*	Phases 1 to 7 (of 9 Phases) of the Audit of Invasive Cervical Cancer are completed or underway *(Recommendations 1, 2 and 3).* Near completion of interviewing of first sample of women. Interviewing commenced for sample two women. Collecting relevant GP and hospital records for women from both samples and abstracting relevant information. Contract agreed with Laverty Pathology in Sydney for slide reread. Slide reread commenced.
2.	Re-enrolment and re-screening of women. *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 and offered two smears two years apart.*	The Minister has requested that the Ministry seeks a recommendation from Dr McGoogan in relation to this recommendation.
3.	Evaluation of NCSP *A comprehensive evaluation of all aspects of the NCSP which reflects the 1997 Draft Evaluation Plan developed by Cox should be commenced within 18 months.*	Parts 5, 6 and 8 included within the scope of Part 3 (Cancer Audit) – see recommendation 1 above. Parts 4, 7 and 10 included within scope of NCSP Statistical Reporting. Refer to recommendation 7 below.

Ref	Recommendation	Summary of progress.
4.	Operational Policy and Quality Standards & Evaluation & Monitoring Plan. *The Policy & Quality Standards for the NCSP and the Evaluation and Monitoring Plan for the NCSP must be implemented within the next 12 months.*	NCSP Policy and Quality Standards across the programme were introduced from November 2000. These mandate standards for laboratory and publicly funded colposcopy services. Independent monitoring of indicators of programme and provider performance (against standards) has been in place since October 2000. Nine Quarterly Independent Monitoring Group Reports have been published covering the period October 2000 to December 2002. The NCSP Audit Framework has been consulted on and provider compliance audits will commence this year.
5.	Full legal assessment of Operational Policy and Quality Standards. *There needs to be a full legal assessment of the Policy & Quality Standards for the NCSP and the Evaluation and Monitoring Plan to ensure that the requisite legal authority to carry out these plans is in place.*	Report provided to NSU.
6.	Legal assessment of NCSP Authority. *The NCSP should be thoroughly evaluated by lawyers to determine whether or not those persons charged with tasks under the NCSP have the necessary legal authority to discharge them.*	Report provided to NSU.

Ref	Recommendation	Summary of progress.
7.	Statistical Reporting. *The NCSP 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 NCSP, these must be remedied in a timely manner.*	1996-98 Report Published. 1999-00 Report in progress Work on 2001 annual monitoring report underway and will be published in September.
8.	Regular Statistical Information. *Meaningful statistical information should be generated from both the NCSP-Register and the Cancer Registry on a regular basis. Attention must be paid not only to laboratory reporting rates but also trends and the incidence of disease, assessed by regions that are meaningful to allow some correlation between reporting profiles of laboratories and the incidence of cancer.*	The NSU and University of Otago consider that it is not possible currently to correlate laboratory reporting with regional incidence of cervical cancer in NZ however work is still underway to consider the implementation of this recommendation.

Ref	Recommendation	Summary of progress.
9.	Minimum Standards for Cytology Laboratories. *The compulsory setting of a minimum number of smears that should be ready 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 site will process a min of 15,000 gynaecology cytology cases, each pathologists will report at least 500 abnormal gynaecological cytology cases, cytotechnical staff must primary screen a min of 3,000 gynaecological cytology cases per annum. This should be implemented within 12 months.*	DHB and Community Laboratory Agreements incorporate minimum volume standards. Public Hospital laboratories did not meet minimum volume standards in 2002/03.
10.	Balanced approach recognising the importance of all aspects of the NCSP. *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.*	This is implemented through the NCSP Workplan with all aspects of the screening pathway being recognised.

Ref	Recommendation	Summary of progress.
11.	Culture within the NSU *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.*	The NSU is developing as an organisation and its culture is maturing.
12.	NSU Structure *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.*	Implemented in July 2001

Ref	Recommendation	Summary of progress.
13.	NSU Structure *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*	The Clinical Leader of the NCSP, Dr Hazel Lewis is jointly accountable for the national management of the NCSP alongside Ms Jane McEntee the Operational Manager. Both Dr Lewis and Ms McEntee work at a tier tow level within the NCSP.

Ref	Recommendation	Summary of progress.
14.	Amend S74 of the Health Act 1956. *The Health Act 1956 should be amended to permit the NCSP to be effectively audited, monitored and evaluated by any appropriately qualified persons irrespective of their legal relationship with the Ministry. This requires an amendment to section 74A of the Health Act to permit such persons to have ready access to all information on the NCSP-Register*	The Health (Screening Programmes) Amendment Bill is currently before Health Select Committee. Oral submissions on the new Bill were heard on 4 June and the Health Select Committee is scheduled to report back to the House by 17 August 2003.
15.	Kaitiaki Regulations. *There needs to be reconsideration of the Kaitiaki Regulations, and the manner in which those regulations currently effect the Ministry of Health gaining access to aggregate data of Mäori Women enrolled on the NCSP-Register. The Ministry of Health and any appropriately qualified persons engaged by it 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.*	Cabinet decision 25 June to retain status quo.

Ref	Recommendation	Summary of progress.
16.	Legal right to access information from the Cancer Register. *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 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 Health (Screening Programmes) Amendment Bill is currently before Health Select Committee. Oral submissions on the new Bill were heard on 4 June and the Health Select Committee is scheduled to report back to the House by 17 August 2003.
17.	Amend Health Act 1956 to enable access to medical files. *The Health Act 1956 requires amendment to enable Ministry of Health and any appropriately qualified persons it engages to carry out 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 Health (Screening Programmes) Amendment Bill is currently before Health Select Committee. Oral submissions on the new Bill were heard on 4 June and the Health Select Committee is scheduled to report back to the House by 17 August 2003.
18.	Change guidelines under-which ethics committees operate. *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.*	Guidelines updated.

Ref	Recommendation	Summary of progress.
19.	Review of operations of ethics committees. *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 will report back to the Minister by November 2003.
20.	Provide guidelines to ethics committees regarding Privacy Act & Code. *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 interpretations 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.*	Guidelines updated.
21.	Guidelines to ethics committees for observational studies. *Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies.*	The National Ethics Advisory Committee will report back to the Minister by November 2003.
22.	National ethics committee – multi-centre studies. *A national ethics committee should be established for the assessment of multi-centre or national studies.*	The National Ethics Advisory Committee will report back to the Minister by November 2003.

Ref	Recommendation	Summary of progress.
23.	Appeal process for ethics committee decisions. *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 will report back to the Minister by November 2003.
24.	NCSP Complaints System. *The NCSP requires its own system to deal with complaints regarding the Programme's delivery. It also needs to have in place a user-friendly system which can respond to complaints of Programme failures, such as under-reporting.*	An NSU Complaints System has been developed for implementation in 2003/04.
25.	Electronic Link Cancer Register & NCSP Register. *The National Cervical Screening Register needs to be electronically linked with the Cancer Register.*	Processes for linking and matching data implemented.
26.	Performance Standards for NCSP Register and Cancer Register. *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 "Providing a NCSP Regional Service" chapter in the NCSP Operational Policy and Quality Standards includes performance measures for the NCSP-Register. The reconfiguration of the NCSP Regional Services is underway. See also recs 27 and 32 below.

Ref	Recommendation	Summary of progress.
27.	Standards for the NCSP should be reviewed every two years. *Standards for the NCSP should be reviewed every two years and more frequently if monitoring indicates that some of the standards are inappropriate.*	Revision of NCSP Operational Policy and Quality Standards Colposcopy Chapter completed. Completed development of new NCSP Operational Policy and Quality Standards chapter for the NCSP Regional Services. Ongoing review of policies and standards is included in the NCSP workplan.
28.	The Government must ensure sufficient cytotechnologists and cytopathologists and training sites. *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.*	Implementation of Workforce Development Strategy ongoing.
29.	Amend Medical Laboratory Technologists Regulations 1989. *The Medical Laboratory 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.*	Addressed through scopes of practice provisions of Health Practitioners Competence Assurance Bill (HPCA). The HPCA Bill has completed the Select Committee Stage and has been reported back to Parliament for further debate.

Ref	Recommendation	Summary of progress.
30.	Impose Legal obligations on storage of slides. *Legal obligations in addition to those mandated by IANZ must be imposed on all laboratories reading cervical cytology requiring them to 1) retain records of patients' cytology and histology results in safe storage for a period of no less than five years from the date on which the results were reported and 2) ensure that a patient's records are readily accessible and properly archived during the five year storage period.*	The Health (Screening Programmes) Amendment Bill is currently before Health Select Committee. Oral submissions on the new Bill were heard on 4 June and the Health Select Committee is scheduled to report back to the House by 17 August 2003.
31.	Ensure electronic linkage between NCSP Register and Cytology Labs. *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.*	Work has commenced on this recommendation.
32.	Develop Standards for accuracy of laboratory coding. *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 standards will be developed in line with ongoing review of the Policy and Quality Standards for NCSP Regional Services.

Ref	Recommendation	Summary of progress.
33.	The NCSP should develop a population-based register. *The NCSP should work towards developing a population based register and move away from being the utility based register that it now is.*	The National Screening Unit is represented on the Ministry's Population Register Project led by NZHIS.
34.	Legal mechanisms should be in place to allow the ACC, Medical Council and the Health & Disability Commissioner to share relevant information with the Ministry's NCSP. *There should be a legal obligation on the ACC, the Medical Council and the Health and Disability Commissioner to advise the NCSP'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.*	The HPCA Bill has completed the Select Committee Stage and has been reported back to Parliament for further debate.
35.	Medical Tribunal to supply information to NCSP. *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 Minster of Health.*	The HPCA Bill has completed the Select Committee Stage and has been reported back to Parliament for further debate.

Ref	Recommendation	Summary of progress.
36.	ACC & Medical Council should exchange relevant information regarding claims for medical misadventure. *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.*	Royal assent received for Injury Prevention and Rehabilitation Bill – came into effect April 02

Ref	Recommendation	Summary of progress.
37.	NCSP liase with the Royal College of Pathologists of Australasia. *It is recommended that the Programme liase with the Royal College of Pathologists of Australia. In its submissions the Royal College advised that it believed that the collaborative relationship with 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 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.*	The NCSP has regular communication with the Royal College of Pathologists.

Ref	Recommendation	Summary of progress.
38.	Information to Women. *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.*	New resources for informing women and health professionals have been produced and distributed. These include the NCSP General Pamphlet, NCSP Detailed Information Booklet, NCSP Colposcopy pamphlet and tear off information sheets for women.
39.	Letters to Medical Practitioners. *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.*	Letter sent.
40.	Appropriately trained personnel should do cervical screening. *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.*	Implementation of Workforce Development Strategy commenced and ongoing.

Ref	Recommendation	Summary of progress.
41.	All pathologists undertaking cytology should be appropriately trained. *If cytology is a significant component of a pathologist's practice then he or she must participate in continuing medical education in that subject.*	Implementation of Workforce Development Strategy commenced and ongoing.
42.	Cytopathologists must participate in continuing education in cytopathology. *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.*	Implementation of Workforce Development Strategy commenced and ongoing.
43.	Pathologists ought to be more open-minded. *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.*	No Reporting Milestone this period.

Ref	Recommendation	Summary of progress.
44.	The Medical Council should ensure that systems are in place to support the early reporting of errant medical practitioners by their colleagues. *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.*	The HPCA Bill has completed the Select Committee Stage and has been reported back to Parliament for further debate.
45.	NCSP should have a system for identifying deficiencies. *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.*	An NSU Complaints System has been developed for implementation in 2003/04.
46.	There should be a process for monitoring the implementation of the Committees Recommendations. *A process to ensure that the recommendations made by the Committee are implemented should be put in place.*	Dr McGoogan's 6-Month Report released. Dr McGoogan's 12-Month Report to be released.