

**10 JUNE 2005 TO 10 MARCH 2006 REPORT FROM THE MINISTRY OF HEALTH
TO THE MINISTER ON THE IMPLEMENTATION OF THE RECOMMENDATIONS
OF THE CERVICAL SCREENING INQUIRY**

REPORT

BACKGROUND INFORMATION

1. The *Report of the Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region* was released in April 2001. That report contained 46 recommendations for future action that the Government or its agencies should consider taking. The then Minister of Health (Hon Annette King) subsequently accepted all 46 recommendations and directed the Ministry of Health to implement them. The Minister of Health identified \$3.96 million from within health baselines for 2001/2 and outyears for the implementation of the recommendations (Health Report reference number 20010396 refers). \$0.788 million of this funding has been transferred each year to the Information Services departmental expenses (Health Report reference number 20047183 refers).
2. A Ministry Steering Group comprising representatives of the National Screening Unit, and Personal Health (now Clinical Services), Sector Policy, and Corporate & Information Directorates, was formed to oversee implementation of the recommendations.
3. The Minister of Health also requested Dr Euphemia McGoogan, an independent cytopathology expert, to monitor the progress of the implementation of these recommendations. Dr McGoogan visited New Zealand in October and November 2001 to carry out a review of progress over the first six months. A written report summarising her findings was provided to the Minister of Health in December 2001.
4. In October 2001, The Office of the Controller and Auditor-General carried out a review to determine what action had been undertaken to implement the Inquiry Recommendations and released its first report in February 2002. In addition, the Office of the Controller and Auditor-General advised the Minister of Health that it intended to keep the progress in implementing the Committee of Inquiry's recommendations under review. The Office of the Controller and Auditor-General undertook this by maintaining contact with Dr McGoogan and reviewing the Ministry's monthly and quarterly reports to the Minister of Health.
5. In June 2003, Dr McGoogan produced her second and final report on the progress of the implementation of the recommendations. This report followed Dr McGoogan's last visit to New Zealand in January 2003. Following issues raised in Dr McGoogan's report, at the Minister of Health's request the Office of the Controller and Auditor-General undertook a follow-up review of the progress made in implementing the 46 recommendations in July 2003. The Office of the Controller and Auditor-General released their second report in December 2003. The Office of the Controller and Auditor-General looked at: what progress had been made by the Ministry of Health since Dr McGoogan's review (in January 2003); the issues and reasons why the Ministry of Health had not progressed as

quickly as recommended with the implementation of some recommendations; and how and when the Ministry of Health intended to address other issues raised in Dr McGoogan's reports.

6. Recommendation one of the Cervical Screening Inquiry 2001 required the review of the cervical screening history of women with cervical cancer. The Ministry of Health and the University of Auckland completed a review of 371 women who had developed cervical cancer between the period of 1 January 2000 – 30 September 2002. The *New Zealand Cervical Cancer Audit. Screening of Women with Cervical Cancer: 2000- 2002* (referred to as the Cervical Cancer Audit) published its findings in November 2004.
7. The aim of the Cervical Cancer Audit was to take a systems view of the National Cervical Screening Programme and determine where systemic issues might exist and what improvements are required to increase the effectiveness of the programme. The Audit found that from a national perspective the National Cervical Screening Programme operates to a generally high standard for women who are having regular cervical smears. The Audit did not find systemic issues in the laboratory reading and reporting of cervical smears. The Audit made 31 recommendations, which the Ministry of Health has been addressing.

COMMENT

Summary of Progress

8. Thirty-seven of the Cervical Screening Inquiry's 46 recommendations have now been implemented. Of the nine recommendations that remain outstanding: seven are expected to be implemented in 2006/07; and decisions have been made not to implement the other two.

Status of the Cervical Cancer Inquiry's Recommendations at May 2006

Status of the Recommendation	Recommendation Number	Total
Implemented – has become "business as usual".	1, 3, 4, 6, 7, 8 ¹ , 9, 10, 24, 26, 28, 29, 32, 37, 38, 42, 43, 45, 46	19
Implemented – no further work required.	5, 11, 12, 14, 15, 16, 17, 18, 19, 20, 22, 34, 35, 36, 39, 40, 41, 44	18
Work substantially complete – expected to be implemented in 2006/07.	21, 23, 25, 27, 30, 31, 33	7
Decision not to implement.	2, 13	2

¹ Further work is being done to look into correlating laboratory reporting rates with regional incidence of cancer.

Implementation of Remaining Recommendations

9. Two recommendations will not be implemented. Recommendation 2 refers to the re-enrolment and re-screening of all women in the event that the national evaluation throws doubt on the accuracy of high-grade abnormality reporting rates. The findings of the Cervical Cancer Audit did not support the implementation of recommendation 2.
10. Recommendation 13 refers to the management of the National Cervical Screening Programme being under the control of a second or third tier manager within the Ministry who has a specialist medical qualification in public health or epidemiology. In 2002 the National Screening Unit appointed a programme manager and clinical leader to jointly manage the National Cervical Screening Programme at the fourth tier. This decision reflected the clinical governance that is required to effectively manage a national cervical screening programme. The National Cervical Screening Programme clinical leader does have specialist medical qualifications in public health. (These two positions report to the National Screening Unit manager at the third tier.)
11. The remaining seven recommendations are substantially underway and are expected to be completed or implemented by 30 June 2007.
12. Recommendation 21 refers to guidelines to ethics committees for observational studies. The National Ethics Advisory Committee completed the work on the Observational Studies Guidelines at the end of 2005. The Minister approved these guidelines in December 2005 (refer to Health Report 20058881). The guidelines should be released in June 2006 following the completion of work by the Sector Policy Directorate on a process for expedited review of such studies.
13. Recommendation 23 refers to the appeal process for ethics committee decisions. The Minister accepted the recommendation of the National Ethics Advisory Committee that an appeals process be put in place. There have been some legal concerns raised around the appeals mechanism initially proposed (ie, a subcommittee of the National Ethics Advisory Committee). The Sector Policy Directorate is currently considering other options and expects to submit advice to the Minister in the near future.
14. Recommendation 25 refers to the electronic linkage between the Cancer Registry and the National Cervical Screening Programme Register. A process for linking and matching data manually has been implemented. The New Zealand Health Information Service in conjunction with the National Screening Unit are continuing to work on a project, which will assess the feasibility of electronically linking with the New Zealand Cancer Registry as part of the National Cervical Screening Programme Register redevelopment project.
15. Recommendation 27 refers to the two-yearly review of the National Cervical Screening Programme Operational Policy and Quality Standards. The review of Chapter 6 'Providing a Colposcopy Service' was completed and standards reissued in July 2003. A new Chapter 7 'Providing a National Cervical Screening Programme Regional Service' was completed. The revised 'Chapter 6' and the new 'Chapter 7' have been incorporated into District Health Board

Agreements from July 2003. All chapters have been updated to reflect the new roles and responsibilities as part of the implementation of the Health (National Cervical Screening Programme) Amendment Act 2004. A full review of the remaining 4 chapters has been scheduled for 2005/06 and 2006/07 as follows (Health Reports 20060944 and 20061243 refer):

- Chapter 2 'NCSP Policy' (June 2007)
 - Chapter 3 'Providing a Health Promotion Service' (June 2007)
 - Chapter 4 ' Providing a Smear Taking Service' (June 2007)
 - Chapter 5 'Providing a Laboratory Service' (September 2006).
16. Recommendation 30 refers to the legal obligations on storage of cervical screening slides. The Amendment to the Health Act 1956 updated the regulations in relation to the retention of health information to also include the retention of specimens (bodily sample or tissue sample taken from a person). The retention of laboratory samples for cervical cytology are currently covered by the National Cervical Screening Programme Operational Policy and Quality Standards and Agreements with laboratories, and those Agreements specify a minimum retention period for the samples. The Ministry considers that many of the proposed changes to the Health (Retention of Health Information) Regulations will be addressed through the proposed standard for the non-therapeutic use of tissue (refer Health Report 20046854). The Sector Policy Directorate is therefore considering what priority should be given to amending the Health (Retention of Health Information) Regulations and will report separately to you on this.
17. Recommendation 31 refers to the electronic linkages between the National Cervical Screening Programme Register (NCSP-Register) and laboratories. A pilot has been evaluated and electronic linkages have been implemented in three laboratories. Further rollout will occur in 2006/07 and all laboratories will be electronically linked to the NCSP-Register by 1 July 2007 as part of the NCSP-Register redevelopment project.
18. Recommendation 33 refers to the development of a population register for the National Cervical Screening Programme. 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. Work required includes improvements to data quality and establishing links with various registers. A health report will be sent to the Minister in September 2006 providing options for population register functionality for the National Cervical Screening Programme and other screening programmes. Population register functionality would be separate but linked to the NCSP-Register and incorporated into the functionality of the NCSP-Register redevelopment project.

Routine Reporting

19. Now that the majority of the recommendations have either been completed or become part of business as usual, and the Ministry's Cervical Screening Inquiry Steering Group has been disbanded, the National Screening Unit requests that routine reporting end. The Minister would instead be kept informed of progress through the normal annual planning and reporting processes.

Cervical Screening Inquiry 2001 website

20. In 2000, a website was set up to keep women informed of the purpose and progress of the Cervical Screening Inquiry 2001. Once the Inquiry was over the website was maintained and updated with the Inquiry report and the monthly and quarterly reports on progress. The Cervical Screening Inquiry 2001 website can be found through a link from the Ministry of Health's website.
21. The National Screening Unit proposes that after the last report is published the contents of the Cervical Screening Inquiry 2001 website be migrated across to the new National Screening Unit's website.

New Zealand Health Information Service

22. The Minister of Health has approved annual expense transfers from the Management of National Screening Programmes Output Class to the New Zealand Health Information Service.

Status of other National Cervical Screening Programme Recommendations

Dr McGoogan's Recommendations

23. Of Dr McGoogan's 26 recommendations from her first report, and 10 recommendations from her second report, 26 have been implemented, 9 have work underway and a decision has been made not to implement one recommendation.

Office of the Controller and Auditor-General's Recommendations

24. Of the Office of the Controller and Auditor-General's 7 recommendations from its first report, and 3 recommendations from its second report, all 10 have been implemented.

Cervical Cancer Audit's Recommendations

25. Of the Cervical Cancer Audit's 31 recommendations 10 have been implemented, 20 are underway and 1 will not need to be actioned until 2010.

Review of the National Cervical Screening Programme

26. Recommendations 14, 15, 16, 17, and 30 of the Cervical Screening Inquiry 2001 required the amendment of the Health Act 1956 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. Section 112O of the Amendment to the Health Act 1956 requires the Minister of Health to establish a review committee at least once every three years. This provision came into force on 7 March 2005, so the latest the review committee should be established is 7 March 2008.

27. Under section 112O of the Act, the review committee can be comprised of up to three people. No person appointed to the review committee can be:
 - a Member of Parliament; or
 - an officer or employee of the Ministry of Health; or
 - a person who is, or has been, designated as a screening programme evaluator under the Act; or
 - a person who would have a material conflict of interest if appointed.
28. Under section 112O of the Act, the review committee are to review:
 - the operation of the National Cervical Screening Programme
 - evaluation activities that have been carried out or proposed to be carried out under the Act.
29. Under section 112O of the Act, appointments to the committee are required, collectively, to have an appropriate balance of skills and knowledge, including knowledge of cervical screening.
30. Under section 112P of the Act, the review committee must complete a review plan prior to the review and then submit their report to the Minister who must present the report to the House of Representatives and then make the report publicly available.
31. The National Screening Unit has received a request from an external research group to be appointed as screening programme evaluations under the Amendment to the Health Act 1956. The National Screening Unit is providing advice to the Acting Director-General of Health on this application and the appointment of evaluators.
32. The National Screening Unit can provide further advice to you on the review of the National Cervical Screening Programme.

APPENDIX 1: STATUS OF THE CERVICAL SCREENING INQUIRY 2001 RECOMMENDATIONS

Ref.	Recommendation	Implemented, Substantially Underway or Not to be Implemented.
1.	<p>Evaluation of National Cervical Screening Programme</p> <p>The remaining two phases of the national evaluation designed by the Otago University Team must proceed. Until those phases are completed the Programme's safety for women cannot be known. It is imperative that this exercise is completed within the next six months. Particular attention should be given to the discrepancy between the average reporting rate of high-grade abnormalities of Douglass Hanly Moir Pathology (2.5%-3.7%) for the re-read of the Gisborne women's smear tests and the current New Zealand national average for reporting high-grade abnormalities (0.8%). Unless this exercise is carried out the possibility that the national average is flawed and that there is a systematic problem of under-reporting in New Zealand laboratories cannot be excluded.</p>	<p>Implemented. The final report of the New Zealand Cervical Cancer Audit was publicly released on 19 November 2004.</p>
2.	<p>Re-enrolment and re-screening of women</p> <p>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 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.</p>	<p>Decision not to implement. There is no indication from the Cervical Cancer Audit that recommendation 2 needs to be responded to and therefore the decision has been made not to implement recommendation 2.</p>
3.	<p>Evaluation of National Cervical Screening Programme</p> <p>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 one.</p>	<p>Implemented. Parts 5, 6 and 8 have been included within the scope of Part 3 (Cancer Audit) – see recommendation 1 above.</p> <p>Parts 4, 7 and 10 are included within the scope of NCSP Statistical Reporting. Refer also to recommendation 7 below.</p>
4.	<p>Operational Policy and Quality Standards, and Evaluation and Monitoring Plan.</p> <p>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.</p>	<p>Implemented. The Interim Operational Policy and Quality Standards were implemented in October 2000.</p> <p>An Independent Monitoring Group is contracted to provide quarterly and annual monitoring reports.</p>

Ref.	Recommendation	Implemented, Substantially Underway or Not to be Implemented.
5.	<p>Full legal assessment of Operational Policy and Quality Standards.</p> <p>There needs to be a full legal assessment of the Policy & 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.</p>	Implemented. Report from Kim Murray (Barrister) provided to the National Screening Unit in December 2001.
6.	<p>Legal assessment of NCSP Authority.</p> <p>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.</p>	Implemented. Report from Kim Murray (Barrister) provided to the National Screening Unit in December 2001.
7.	<p>Statistical Reporting.</p> <p>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.</p>	<p>Implemented. 1996-98 Report Published.</p> <p><i>Cervical Screening in New Zealand: A Brief Statistical Review of the First decade</i> published in February 2005.</p> <p>Quarterly and Annual Monitoring Reports against national indicators and targets are also produced.</p>
8.	<p>Regular Statistical Information.</p> <p>Meaningful statistical information should be generated from both the National Cervical Screening 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. 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.</p>	Implemented. It is the considered opinion of the National Screening Unit and University of Otago that it is not currently possible to correlate laboratory reporting with regional incidence of cervical cancer in New Zealand.

Ref.	Recommendation	Implemented, Substantially Underway or Not to be Implemented.
9.	<p>Minimum Standards for Cytology Laboratories.</p> <p>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.</p>	<p>Implemented. DHB and National Cervical Screening Programme Laboratory Agreements began incorporating minimum volume standards from July 2001.</p> <p>All laboratories have been meeting the minimum volume standards since December 2005.</p>
10.	<p>Balanced Approach for National Cervical Screening Programme</p> <p>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.</p>	<p>Implemented. The Programme now has a more balanced approach.</p>
11.	<p>Culture of the National Screening Unit</p> <p>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 the Health Funding Authority has merged into the new Ministry of Health.</p>	<p>Implemented. National Screening Unit Strategic Plan and Communications Strategy in place.</p>
12	<p>Management of the National Cervical Screening Programme</p> <p>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 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.</p>	<p>Implemented. The National Screening Unit was established July 2001 and has the delegated power to contract directly with providers of the programme.</p>

Ref.	Recommendation	Implemented, Substantially Underway or Not to be Implemented.
13	<p>Management of the National Cervical Screening Programme</p> <p>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 hold as a minimum 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.</p>	<p>Decision not to implement. In 2002 the National Screening Unit appointed a programme manager and clinical leader to jointly manage the National Cervical Screening Programme at the fourth tier. This decision reflected the clinical governance that is required to effectively manage a national cervical screening programme. The National Cervical Screening Programme clinical leader does have specialist medical qualifications in public health. (These two positions report to the National Screening Unit manager at the third tier.)</p>
14.	<p>Amend section 74 of the Health Act 1956.</p> <p>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. This requires an amendment to section 74A of the Health Act to permit such persons to have ready access to all information on the National Cervical Screening Register.</p>	<p>Implemented. The Amendment to the Health Act 1956 contains provisions to permit the effective monitoring, audit and evaluation of the Programme.</p>
15.	<p>Kaitiaki Regulations</p> <p>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 Māori 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.</p>	<p>Implemented. The Cabinet decision on 25 June 2002 was to retain the status quo.</p>
16.	<p>Legal right to access information from the Cancer Register.</p> <p>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.</p>	<p>Implemented. The Amendment to the Health Act 1956 contains provisions to permit screening programme evaluators to access all information on the Cancer Registry that relates to a relevant woman.</p>

Ref.	Recommendation	Implemented, Substantially Underway or Not to be Implemented.
17.	<p>Amend Health Act 1956 to enable access to medical files.</p> <p>The Health Act 1956 requires amendment to enable 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.</p>	<p>Implemented. The Amendment to the Health Act 1956 contains provisions to permit the effective monitoring, audit and evaluation of the Programme.</p>
18.	<p>Change guidelines under which ethics committees operate.</p> <p>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.</p>	<p>Implemented. The Operational Standards for Ethics Committees have been amended.</p>
19.	<p>Review of operations of ethics committees.</p> <p>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.</p>	<p>Implemented. Ethics committees have been reviewed and a new ethics committee structure put in place. The National Ethics Advisory Committee undertook this work over 2002/03, and culminated in the presentation of advice to the Minister of Health in December 2003 (refer to Health Report 20045250). The Ministry has implemented almost all of the National Ethics Advisory Committee's recommendations.</p>
20.	<p>Provide guidelines to ethics committees regarding Privacy Act & Code.</p> <p>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 are 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.</p>	<p>Implemented. The Operational Standards for Ethics Committees have been updated, see also recommendation 18 above.</p>
21.	<p>Guidelines to ethics committees for observational studies.</p> <p>Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies.</p>	<p>Work substantially underway. The National Ethics Advisory Committee completed the work on the Observational Studies Guidelines at the end of 2005. The Minister approved these guidelines in December 2005 (refer to Health Report 20058881). The guidelines should be released in June 2006 following the completion of work by the Ministry on a process for expedited review of such studies.</p>

Ref.	Recommendation	Implemented, Substantially Underway or Not to be Implemented.
22.	<p>National ethics committee – multi-centre studies.</p> <p>A national ethics committee should be established for the assessment of multi-centre or national studies.</p>	<p>Implemented. A national multi-region ethics committee was established in December 2004.</p>
23.	<p>Appeal process for ethics committee decisions.</p> <p>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.</p>	<p>Work substantially underway. The Minister accepted the recommendation of the National Ethics Advisory Committee that an appeals process be put in place. There have been some legal concerns raised around the appeals mechanism initially proposed (ie, a subcommittee of the National Ethics Advisory Committee). The Ministry is currently considering other options and expects to submit advice to the Minister in the near future.</p>
24.	<p>National Cervical Screening Programme Complaints System.</p> <p>The National Cervical Screening Programme requires its own system to deal with complaints regarding the Programme's delivery. It also needs to have in place a user-friendly system which can respond to complaints of Programme failures, such as under-reporting. The difficulty that witness A experienced in having her medical misadventure recognised as a failure of the Programme and a failure of Gisborne Laboratories must be avoided in the future.</p>	<p>Implemented. The National Screening Unit complaints process has been implemented.</p> <p>See also recommendation 45.</p>
25.	<p>Electronic Link Cancer Registry & National Cervical Screening Programme Register.</p> <p>The National Cervical Screening Register needs to be electronically linked with the Cancer Registry.</p>	<p>Work substantially underway. A process for linking and matching data manually has been implemented.</p> <p>The New Zealand Health Information Service in conjunction with the National Screening Unit are continuing to work on a project, which will assess the feasibility of electronically linking with the New Zealand Cancer Registry as part of the National Cervical Screening Programme Register redevelopment project.</p>

Ref.	Recommendation	Implemented, Substantially Underway or Not to be Implemented.
26.	<p>Performance Standards for National Cervical Screening Programme Register and Cancer Registry.</p> <p>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.</p>	<p>Implemented. A new chapter of the National Cervical Screening Programme Operational Policy and Quality Standards 'Providing a Regional Service' was completed in July 2003. The chapter includes performance standards for the National Cervical Screening Programme Register. The new chapter was included in the District Health Board Agreements from 2003/04.</p>
27.	<p>Standards for the National Cervical Screening Programme should be reviewed every two years.</p> <p>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.</p>	<p>Work substantially underway. The review of Chapter 6 'Providing a Colposcopy Service' was completed and standards reissued in July 2003.</p> <p>A new Chapter 7 'Providing a National Cervical Screening Programme Regional Service' was completed. The revised 'Chapter 6' and the new 'Chapter 7' have been incorporated into District Health Board Agreements from July 2003.</p> <p>All chapters have been updated to reflect the new roles and responsibilities as part of the implementation of the Amendment to the Health Act 1956.</p> <p>A full review of the remaining 4 chapters has been scheduled for 2005/06 and 2006/07 as follows:</p> <ul style="list-style-type: none"> • Chapter 2 'NCSP Policy' (June 2007) • Chapter 3 'Providing a Health Promotion Service' (June 2007) • Chapter 4 'Providing a Smear Taking Service' (June 2007) • Chapter 5 'Providing a Laboratory Service' (September 2006) <p>See also recommendation 26 above.</p>

Ref.	Recommendation	Implemented, Substantially Underway or Not to be Implemented.
28.	<p>The Government must ensure sufficient cytotechnologists and cytopathologists and training sites.</p> <p>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 training requirements and maintenance of competence of smear test readers and cytopathologists.</p>	<p>Implemented. The Vocational Registration Programme in Cervical Cytology has been implemented.</p> <p>Canterbury Health Laboratory (Canterbury District Health Board) has been appointed as the Cytology Training Agency.</p> <p>Implementation of National Screening Unit Workforce Development Strategy and Initiatives commenced and ongoing.</p>
29.	<p>Amend Medical Laboratory Technologists Regulations 1989.</p> <p>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.</p>	<p>Implemented. The Health Practitioners Competence Assurance Act 2003 was passed. The Act contains provisions that will give effect to the intent of the recommendations from the Inquiry including the establishment of new registration authorities and the development of gazetted scopes of practice.</p>
30.	<p>Impose legal obligations on storage of slides.</p> <p>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 be 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.</p>	<p>Work substantially underway. The Amendment to the Health Act 1956 updated the regulations in relation to the retention of health information to also include the retention of specimens (bodily sample or tissue sample taken from a person).</p> <p>The retention of laboratory samples for cervical cytology are currently covered by the National Cervical Screening Programme Operational Policy and Quality Standards and Agreements with laboratories, and those Agreements specify a minimum retention period for the samples.</p> <p>The Ministry considers that many of the proposed changes to the Health (Retention of Health Information) Regulations will be addressed through the proposed standard for the non-therapeutic use of tissue (refer Health Report 20046854). The Sector Policy Directorate is therefore considering what priority should be given to amending the Health (Retention of Health Information) Regulations and will report separately to you on this.</p>

Ref.	Recommendation	Implemented, Substantially Underway or Not to be Implemented.
31.	<p>Ensure electronic linkage between National Cervical Screening Register and Cytology Labs.</p> <p>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.</p>	<p>Work substantially underway. A pilot has been evaluated and electronic linkages have been implemented in three laboratories. Further rollout will occur in 2006/07. All laboratories will be electronically linked to the NCSP-Register by 1 July 2007 as part of the NCSP-Register redevelopment project.</p>
32.	<p>Develop Standards for accuracy of laboratory coding.</p> <p>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.</p>	<p>Implemented. Bethesda 2001 implemented in July 2005. Laboratory coding is standardised throughout the country and will be updated as part of some Ministry of Health projects.</p> <p>See also recommendations 27.</p>
33.	<p>The National Cervical Screening Programme should develop a population- based register.</p> <p>The National Cervical Screening Programme should work towards developing a population based register and move away from being the utility based register that it is now.</p>	<p>Work substantially underway. 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. Work required includes improvements to data quality and establishing links with various registers.</p> <p>A health report will be sent to the Minister in September 2006 providing options for population register functionality for the National Cervical Screening Programme and other screening programmes. Population register functionality would be separate but linked to the NCSP-Register. The NCSP-Register redevelopment project will also enhance the functionality of the NCSP-Register.</p>

Ref.	Recommendation	Implemented, Substantially Underway or Not to be Implemented.
34.	<p>Legal mechanisms should be in place to allow the ACC, Medical Council and the Health & Disability Commissioner to share relevant information with the National Cervical Screening Programme.</p> <p>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.</p>	<p>Implemented. The Accident Compensation Corporation is required to report complaints to the Medical Council under the Injury Prevention, Rehabilitation, and Compensation Act 2001.</p> <p>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.</p> <p>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 a potential risk of harm to the public from a health practitioners' practice. In addition under the Health Practitioners Competence Assurance Act 2003, the Medical Council must inform the Director-General of Health of possible harm posed by the health practitioner.</p>
35.	<p>Medical Tribunal to supply information to National Cervical Screening Programme.</p> <p>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.</p>	<p>Implemented. Refer to recommendation 34 above.</p>
36.	<p>The Accident Compensation Corporation and the Medical Council should exchange relevant information regarding claims for medical misadventure.</p> <p>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.</p>	<p>Implemented. Implemented through the Injury Prevention and Rehabilitation Act 2001.</p>

Ref.	Recommendation	Implemented, Substantially Underway or Not to be Implemented.
37	<p>Liaison with the College of Pathologists</p> <p>It is recommended that the Programme liaise with the Royal College of Pathologists of Australia. In its submissions the Royal College advised that it believed that the collaborative relationship the college had with the Federal Government in Australia might be a model worth consideration by the Inquiry. It was suggested that it was appropriate to use medical colleges as an over-arching body to provide advice on issues. The benefit of this is, if the College is asked to provide an opinion on issues such as professional practice, quality or standards, it has access to the views from multiple professionals and also a critical evaluation of current literature in contemporary standard practices. It is suggested that the National Cervical Screening Programme, which has achieved a great deal, would benefit from greater professional input at a College level. In particular, it is suggested that a National Cervical Cancer Register and a Cervical Cancer Mortality Review process be a means of continually evaluating the Programme's effectiveness. The Committee supports the College's submission and recommends that it be acted upon.</p>	Implemented. Regular meetings held.
38.	<p>Information to Women.</p> <p>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.</p>	Implemented. Resources have been updated for the Amendment to the Health Act 1956. The results pamphlet is to be updated for Bethesda 2001 by 1 August 2006.
39.	<p>Letters to Medical Practitioners.</p> <p>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.</p>	Implemented. Letter sent December 2001. An article will be published in the June 2006 edition of Screening Matters.
40.	<p>Appropriately trained personnel should do cervical screening.</p> <p>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.</p>	<p>Implemented. Primary screening policies and standards are covered in the National Cervical Screening Programme Operational Policy and Quality Standards. Pathologists are specifically excluded from primary screening.</p> <p>Refer also to 28 above.</p>

Ref.	Recommendation	Implemented, Substantially Underway or Not to be Implemented.
41.	<p>All pathologists undertaking cytology should be appropriately trained.</p> <p>If cytology is a significant component of a pathologist's practice then he or she must participate in continuing medical education in that subject.</p>	<p>Implemented. Pathologist continuing education requirements are covered in the National Cervical Screening Programme Operational Policy and Quality Standards. Achievements include the establishment of the Cytology Training School, workshops held in 2005, and the publishing of 'Lessons from the Past' resource in April 2006.</p>
42	<p>Cytopathologists must participate in continuing education in cytopathology.</p> <p>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.</p>	<p>Implemented. Pathologist qualification requirements are covered in the National Cervical Screening Programme Operational Policy and Quality Standards. These policies and standards are made mandatory through the Agreements with the laboratories.</p> <p>The Health Practitioners Competency Assurance Act 2003 also enforces qualification requirements.</p>
43	<p>Pathologists ought to be more open-minded.</p> <p>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.</p>	<p>Implemented. Pathologists have demonstrated their open-mindedness through participation in advisory and working groups, and participation in external quality assurance programmes.</p>
44	<p>The Medical Council should ensure that systems are in place to support the early reporting of errant medical practitioners by their colleagues.</p> <p>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.</p>	<p>Implemented. The recommendation has been given effect 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.</p>

Ref.	Recommendation	Implemented, Substantially Underway or Not to be Implemented.
45.	<p>National Cervical Screening Programme should have a system for identifying deficiencies.</p> <p>The screening programme should have in place a system over and above the audit of monitoring reports, to identify deficiencies in the 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.</p>	<p>Implemented. The National Screening Unit complaints process has been implemented.</p> <p>Service users were surveyed in 2004 to inform a communications campaign for the National Cervical Screening Programme (Phoenix report).</p> <p>User feedback is received through advisory (eg, Consumer Reference Group) and working groups.</p> <p>See also recommendation 24.</p>
46.	<p>There should be a process for monitoring the implementation of the Committees Recommendations.</p> <p>A process to ensure that the recommendations made by the Committee are implemented should be put in place.</p>	<p>Implemented. Dr McGoogan's 6-Month Report – dated December 2001.</p> <p>Dr McGoogan's second and final report – dated June 2003.</p> <p>Office of the Controller and Auditor-General first report – dated 14 February 2002.</p> <p>Office of the Controller and Auditor-General second report – dated 8 December 2003.</p> <p>Section 112O of the Amendment to the Health Act 1956 requires that the programme is independently reviewed at least once every three years.</p>