Quarterly Report from the Ministry of Health to the Minister on the Implementation of the Recommendations of the Gisborne Cervical Screening Inquiry Report (10 June – 10 September 2002)

BACKGROUND INFORMATION

 In response to Recommendation 46 of the Inquiry Report, the Director General previously supplied monthly reports to the Minister. In the second year of reporting, these monthly reports have been replaced with quarterly reporting. This report covers the period 10 June to 10 September 2002 (i.e. the 15th, 16th, and 17th months)

COMMENT

Evaluation of the National Cervical Screening Programme

- 2. Phase 3 of the Audit of Invasive Cervical Cancer is now completed and Phases 4 and 5 have commenced. As at 30 August 70 women had been interviewed. Early indications show a high consent rate (90%) amongst women invited to participate in the Audit, exceeding all expectations. Higher than anticipated consent rates will mean that the projected timeframe required to interview all women and collect records will be extended.
- 3. The Audit Team has spent a considerable amount of time and effort on liaison with key medical professional groups. Although these groups have expressed their support in principle for the Audit, there continues to be discussions between the Audit Team and some groups on areas such as the dissemination of Audit findings. Additional work by the Audit Team to address the issues discussed will necessitate a revision of future activities and associated timeframes.

Changes to Legislation

- 4. The Health (Screening Programmes) Amendment Bill was introduced to the House on 16 May 2002. (Recommendations 14, 16, 17, 30)
- 5. The coming into force of the new Bill will have implications for the National Screening Unit (NSU). The NSU will need to implement new operational procedures at 8 NCSP-Regional Offices in preparation for the new Opt-Off provisions. In addition, a comprehensive communications and information strategy will be required to inform women, smear-takers, laboratories and DHBs of the new Bill and changes to the NCSP operations. The NSU estimates that a minimum of 6 to 9 months will be required to prepare for the Bill coming into force.
- 6. Following on from the Ministry's consultation process on proposed changes to the Health (Cervical Screening (Kaitiaki)) Regulations, Cabinet decided on 25 June 2002 that the status quo would remain. There is an option to consider

- amendments to these regulations in the future if appropriate. In addition, Cabinet decided that a Maori Advisory Group for the NSU should be set-up, distinct from the Kaitiaki Group. The NSU has included the requirement for this group in its 2002/03 workplan. (Recommendation 15)
- 7. The Health Practitioners Competence Assurance Bill (HPCA) was introduced to the House on 11 June 2002. (Recommendations 29, 34, 35, 36, 44)
- 8. Recommendation 29 called for the amendment of regulations to ensure that only medical practitioners with specialist qualifications in pathology and appropriate training in cytopathology or appropriately trained cytoscreeners should read smear-tests. The HPCA will repeal the Medical Laboratory Technologists Regulations. Implementing Recommendation 29 by way of amending the Regulations is not now practicable. More particularly, it is not the most effective way of implementing the intention behind the recommendation. That will be achieved by the Ministry building on the earlier discussions with the Board, and providing advice to the new Board as it develops scopes of practice and determines matters relating to competence and qualifications under the incoming HPCA regime.
- 9. The HPCA will allow requirements to be addressed for others involved in laboratory testing - laboratory assistants and trainees. While the MLT Board has no jurisdiction over these people now, the registering body under the HPCA (the renamed Medical Laboratory Scientists Board) will be responsible for setting scopes of practice for this group in the future, and determining registration requirements. This will include competencies for reading smear tests.
- 10. The bill will come into force a year after enactment. This will allow for the completion through 2003 of the complex preparatory work required before the Act comes into force. This includes the gazetting, by the registering authorities, of scopes of practice and the associated qualifications. Ministry of Health staff will work with the registering authorities though 2002/03 to ensure the smooth implementation of the new regime.
- 11. Part 8 of the HPCA amends the Health and Disability Commissioner Act.1994 to establish information sharing mechanisms. Changes to the ACC's legislation already allow for the sharing of information on systems issues. (Recommendation 34)
- 12. Recommendation 35 required the Medical Tribunal to inform the Minister of Health if there may be a risk to the public health in relation to a given case. Clause 34 of the HPCA requires an authority that has reason to believe that one of its health practitioners may pose a risk of harm to the public to notify the Accident Compensation Corporation, the Director-General of Health, the Health and Disability Commissioner, and any person who the authority believes is an employer of the health practitioner.
- 13. Recommendation 44 asks that the Medical Council to ensure that there are no deterrents on medical practitioners reporting their concerns about the practice of an individual medical practitioner. In fact, the HPCA actively encourages reporting - and requires the authorities to follow up. Clause 33 of the HPCA

supports reporting by allowing a health practitioner who has reason to believe that another health practitioner may pose a risk of harm to the public by failing to meet the required standard of competence to report the circumstances to the authority that the other health practitioner is registered with. Such reporting is further encouraged by a provision in the clause protecting any person who makes a report under the Act, in the absence of bad faith, from civil and disciplinary proceedings. Clause 35 requires an authority that receives a notice given under Clause 33 to investigate it (unless the notice is frivolous or vexatious).

NCSP Operations

Provision of Statistical Information

- 14. Work on the 1999-2000 NCSP Statistical Report is progressing and is currently being peer reviewed prior to finalisation and publication.
- 15. The Independent Monitoring Group has prepared a draft Annual Monitoring Report for the year 2001, for publication later this year. (Recommendations 7 & 8)

NCSP Regional Office Changes

- 16. The National Screening Unit has recently advised the 14 DHB NCSP Regional Offices that changes to the NCSP Register operations will be implemented this year. This will mean that 6 of the 14 NCSP Regional Offices will no longer process cytology and histology results on the NCSP Register from January 2003. These six offices will instead focus on coordination and health promotion activities relating to the programme.
- 17. Alongside the NCSP Regional Office changes, the NSU's 2002/03 workplan for Regional Offices includes the following:
 - Monitoring of NCSP Regional Office Performance.
 - Legal review of the responsibilities of the NCSP.
 - Review of international programme configurations.
 - Review and implementation of NCSP colposcopy standards.
 - Online laboratory access to the NCSP-Register for cervical screening histories.
 - Review and implementation of NCSP Regional Office standards including a review of the NCSP Register Operating Protocol.
 - Implementation of laboratory reporting errors reports.
 - Modifications to the electronic smear taker laboratory forms.
 - Introduction of new laboratory coding.
 - Review NCSP Management Reports sent to General Practitioner's
 - Introduction of NCSP Provider Compliance Audits.
- 18. Many of these activities are related to a number of the Ministerial Inquiry recommendations including:

Recommendation 4:

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

Recommendation 26:

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

Recommendation 27:

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

Recommendation 32

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

19. In her 6-Month Review Report, publicly released in February 2002, Dr McGoogan raised several issues related to the operation of the NCSP Regional Offices. The above work is also intended to address these issues and ongoing monitoring of the changes to NCSP Regional Offices operations may result in further reconfiguration options been considered in the future.

Policy and Quality Standards and Ongoing Monitoring

- 20. In 2001/02 the Independent Monitoring Group produced a NCSP Monitoring Plan and Quarterly Monitoring Reports 1, 2, 3 and 4. These quarterly reports contained a number of recommendations for the NSU and provider follow-up, including: (Recommendation 4)
 - Recommendations related to NCSP Register data quality and completeness.
 - Recommendations to increase enrolment, improve participation and coverage of women in the programme.
 - Recommendations related to the levels of short-interval re-screening.
 - Recommendations related to the follow-up and recall of women with high grade abnormalities.
 - Recommendations related to laboratory reporting.
 - Recommendations related to colposcopy waiting times.

- Recommendations related to smear-taking.
- 21. The NSU has commenced a project to examine issues related to the participation and coverage of Maori and Pacific women in the programme. A project to review the short-interval re-screening rate has also started and the NSU is following up specific recommendations related to three laboratories in the Waikato and Bay of Plenty Regions. Consideration of colposcopy waiting times was included in the 2002/03 volume negotiations with DHBs recently completed.
- 22. The fifth Independent Monitoring Group's NCSP quarterly monitoring report (covering the period October 2001 to December 2001) was published at the end of July 2002.

NCSP Laboratory Agreements

- 23. The NSU is still attempting to implement new NCSP laboratory agreements with the 11 community and two public hospital laboratories providing cervical cytology services. The process is becoming protracted as the Association of Community Laboratories representing community laboratories attempts to link NSU requirements to the resolution of other laboratory issues not related to cervical screening. Laboratories are also seeking an increase in the cytology test price and are concerned over the extent of the NCSP monitoring and audit provisions within the new agreement.
- 24. The two public hospital laboratories did not meet the minimum volume requirements for cytology test processing in 2001/02. The NSU continues to support the need to retain public hospital cytology services and improve cytology education/training and academic pathology opportunities. In the current training year the two public hospital laboratories are contracted by the Ministry to train 21.5 FTE registrars in pathology, representing 48.3% of the total training in pathology, including cytology, in New Zealand. Generally community laboratories do not have a direct contractual provision for the training of pathology registrars, although some do provide this training on a sub-contract basis with DHBs. The National Screening Unit is reviewing this situation further to determine whether there are other opportunities in 2002/03 for increasing cytology test volumes at these laboratories, given their significant role in providing pathology training and education in New Zealand. (Recommendations 9, 28, 41)

Workforce Development

25. Further to recommendations from Dr McGoogan, and as a result of feedback from NZ nursing organisations and independent service providers, the NSU is in the process of implementing a non-medical smear-taker training fund for 2002/03. This initiative is aimed at encouraging practice nurses and others to access smear-taker training courses and become trained smear-takers, which meet NCSP standards. (Recommendations 28, 40, 41, 42)

Information to Women

26. The new detailed NCSP Booklet was published in June 2002 and distributed to smear-takers and other providers to give to women. The 56 page booklet covers in detail all aspects of cervical screening from having a cervical smear test to cervical cancer to details on the NCSP. The booklet explains the benefits and limitations of cervical screening. Introduction of the new Health (Screening Programmes) Amendment Bill will mean the booklet will need to be updated in the future. The booklet will be a valuable addition to the material that currently exists on the programme and it is anticipated that it will be distributed widely.

Dr McGoogan's 12 Month Review Visit

27. Dr McGoogan completed her 12-month review visit between 2 April and 20 April 2002. Upon completion of her visit Dr McGoogan is to prepare a 12th Month Review Report. We are currently awaiting her report.

APPENDIX 1.0

IMPLEMENTATION OF RECOMMENDATIONS AND PROGRESS AGAINST REPORTING MILESTONES FOR 10 JUNE TO 10 SEPTEMBER 2002

Ref.	Recommendation	Reporting Milestones ¹ for June to September 2002
1.	Evaluation of NCSP	Part 3 (Cancer Audit).
	The remaining two phases of the national evaluation designed by the Otago University team must proceed.	Phase 4 and 5 commenced
	tourn made proceed.	Interviewing first sample of women
		Collecting and abstracting GP records
		for first sample
		Draft protocol for slide review circulated for comment
2.	Re-enrolment and re-screening of women.	No Reporting Milestone this period.
	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.	
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. No Reporting Milestone this period. Parts 4, 7 and 10 included within scope of NCSP Statistical Reporting. Refer to recommendation 7 below. Project to develop new and updated
		Evaluation Plan commenced.

¹ Reporting Milestones refer to those tasks and activities that need to be completed in the period covered by the report, against which progress on the implementation of the recommendations is measured.

Those recommendations and their Reporting Milestones marked Ongoing/or Completed will not be reported in subsequent reports, as they have already been implemented. Recommendations where there is no Reporting Milestone against which to report for this month are marked No Reporting Milestone this period; work may however be already underway.

Ref.	Recommendation	Reporting Milestones ¹ for June to September 2002
4.	Operational Policy and Quality Standards & Evaluation & Monitoring Plan.	Further project work to take place with regard to implementation of standards for Smear-Takers.
	The Policy & Quality Standards for the NCSP and the Evaluation and Monitoring Plan for the NCSP must be implemented within the next 12 months.	Independent Monitoring Group fifth NCSP quarterly monitoring report published at end of July.
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.
7.	Statistical Reporting.	1996-98 Report Published
	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.	1999-00 Report being peer reviewed. Work on 2001 report is underway.
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.	NSU and University of Otago consider that it is not possible currently to correlate laboratory reporting with regional incidence of cervical cancer in NZ.

Ref.	Recommendation	Reporting Milestones ¹ for June to September 2002
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 2001/02.
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	Awaiting first reading
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 Maori 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.
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.	Awaiting first reading

Ref.	Recommendation	Reporting Milestones ¹ for June to September 2002
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.	Awaiting first reading
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.
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.	Work to be undertaken by the National Advisory Committee on Health and Disability Support Services Ethics (The National Ethics Advisory Committee).
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.	Work to be undertaken by the National Advisory Committee on Health and Disability Support Services Ethics (The National Ethics Advisory Committee).
22.	National ethics committee – multicentre studies. A national ethics committee should be established for the assessment of multi-centre or national studies.	Work to be undertaken by the National Advisory Committee on Health and Disability Support Services Ethics (The National Ethics Advisory Committee).

Ref.	Recommendation	Reporting Milestones ¹ for June to September 2002
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.	Work to be undertaken by the National Advisory Committee on Health and Disability Support Services Ethics (The National Ethics Advisory Committee).
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.	Work in progress.
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.	Work on NCSP-Register performance standards has commenced.
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.	Project work on the review of Colposcopy standards has commenced.
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 commenced.

Ref.	Recommendation	Reporting Milestones ¹ for June to September 2002
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.	Included in HPCA – awaiting first reading.
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.	Awaiting first reading
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.	No Reporting Milestone this period. This requirement will form part of the National Screening Units development of an Information Systems Strategy.
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.	Delays to commencement of project work.
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.	No Reporting Milestone this period. The National Screening Unit is represented on the Ministry's Population Register Project led by NZHIS.

Ref.	Recommendation	Reporting Milestones ¹ for June to September 2002
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	Included in HPCA – Awaiting first reading.
35.	relation to the Programme. Medical Tribunal to supply information	Included in HPCA – Awaiting first reading.
	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.	
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 – to come into effect April 02
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.	Detailed booklet published.

Ref.	Recommendation	Reporting Milestones ¹ for June to September 2002
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.
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.
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.
43	Pathologists ought to be more openminded. 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 suboptimal.	No Reporting Milestone this period.

Ref.	Recommendation	Reporting Milestones ¹ for June to September 2002
44	The Medical Council should ensure that systems are in place to support the early reporting of errant medical practitioners by their colleagues.	Included in HPCA – Awaiting first reading.
	The Medical Council should ensure that systems are in place whereby medical practitioners are not deterred from reporting to it their concerns about the practice of an individual medical practitioner. Complainants should be assured that their reports will not result in them being penalised in any way.	
45	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.	No Reporting Milestone this period.
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 awaited.