QUARTERLY (10 SEPTEMBER 2002 TO 10 DECEMBER 2002) REPORT FROM THE MINISTRY OF HEALTH TO THE MINISTER ON THE IMPLEMENTATION OF THE RECOMMENDATIONS OF THE GISBORNE CERVICAL SCREENING INQUIRY REPORT

BACKGROUND INFORMATION

1. 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 were replaced with quarterly reporting. This report covers the period 10 September 2002 to 10 December 2002 (i.e. the 18th, 19th, and 20th month reports).

Comment

2. The Ministry of Health has recently reported on the key milestones and deliverables achieved to implement the recommendations from the Gisborne Cervical Screening Inquiry, as well as key milestones for 2002/03 to continue to progress the implementation process. This was provided in a Health Report [20022130], which included the CSI Annual Review 2001/02 and Annual Plan 2002/03.

3. A substantial amount of work has been carried out to implement the Inquiry recommendations, some recommendations have been completed, other recommendations have reached a stage of completion and have an ongoing component that has now been incorporated as part of the work programme for the NCSP. Much of the work outstanding relates to the following areas: The Audit of Invasive Cervical Cancers, the legislative changes, recommendations relating to Ethics Committees and the Population Health Register.

4. The Ministry has been awaiting Dr McGoogan's second report to provide an outline of a revised approach to measuring the way recommendations are measured and completed.

Evaluation of the National Cervical Screening Programme – The Cervical Cancer Audit

5. Phase 4 and 5 of the Cervical Cancer Audit are continuing. As at 2 December 205 women have consented to interview. Consent rates remain outstandingly high at 88% (93% for Maori women). These particularly high consent rates mean that the projected timeframe required to interview all women, collect records and perform the slide review will be extended.

6. The audit team continues to spend a considerable amount of time and effort on liaison with key stakeholders. This process is seen as a key factor in order to ensure the success of the Audit. A formal meeting was held with the

multidisciplinary liaison and advisory group on the 8 November. Discussions also continue with some groups on areas such as the dissemination of findings and the slide review. This liaison process has also lead to a revision of future activities and associated timeframes.

Changes to Legislation

7. The Health (Screening Programmes) Amendment Bill was introduced to the House on 16 May 2002. Debate began on the first reading of the Bill on 15 October 2002 but was interrupted, as at 16 December 2002 the first reading debate is yet to be completed. Enactment is dependent upon the new bill completing all of its parliamentary stages. Once the new bill is enacted the Ministry estimates that a minimum of 6 to 9 months will be required to prepare for the Bill coming into force. A bid has been prepared for inclusion of the Screening Bill as a category 2 (must be passed) on the 2003 legislation programme (Recommendations 14, 16, 17, 30).

8. The Health Practitioners Competence Assurance Bill (HPCA) is currently with Health Select Committee. Submissions on the Bill closed on 27 November 2002 with oral submissions to be heard in late January and February 2003. A report back to the House is due by the end of April 2003 (Recommendations 29, 34, 35, 36, 44).

NCSP Operations

Policy and Quality Standards and Ongoing Monitoring

9. The programming of the NCSP Register to support the reconfiguration of Regional services is continuing and is due to be completed by June 2003. This is later than January 2003 as previously reported. The transfer of NCSP-R responsibilities from one region to another NCSP Regional Service has commenced and will continue to be implemented during this period. Good progress is being made with the development of Policy and Quality Standards for NCSP Regional Services including development of performance standards for the NCSP Register.

10. During 2002/03 the NCSP is continuing to strengthen the relationship between smear takers and the NCSP, review individual policies and review the NCSP Register management reports sent to smear takers. Work has recently been completed to modify the electronic Laboratory Referral Forms generated by the Patient Management Systems.

11. During 2002/03 there will be a continued focus on training of new health promoters and the development of a national health promotion strategy for the NCSP and BreastScreen Aoteaora.

12. Good progress is also being made with the review of Chapter Six of the NCSP Policy and Quality Standards, entitled “Providing a Colposcopy Service”. The draft will include performance measures for providing a Colposcopy Service and is due out for consultation in February/ March 2003.

Information to Women

13. The National Screening Unit has received very positive feedback on the detailed booklet 'Cervical Screening – A Guide for Women in New Zealand'. Printing of the new NCSP General Pamphlet, will be undertaken in February.

NSU Complaints System

14. NSU complaints process has been circulated to the NSU management team for review and comment. The next key milestone for this project is finalisation of the complaints process and the development of a complaints database.

Ethical Recommendations

15. As you are aware the National Ethics Advisory Committee work programme, which includes the recommendations relating to ethics from the Gisborne Cervical Screening Inquiry, has now been signed off. The work is scheduled to be completed by the end of November 2003. The National Ethics Advisory Committee will be reporting separately on the work achieved to implement these recommendations. The Ministry will be monitoring progress.

Dr Euphemia McGoogan - Third Visit to New Zealand

16. Dr Euphemia McGoogan will be making her third visit to New Zealand between 20 January and 31 January 2003. The purpose of the visit will be to provide a report on progress, to implement the recommendations from the Gisborne Cervical Screening Inquiry.

APPENDIX 1.0

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

Ref.	Recommendation	Reporting Milestones[1] for September to December 2002
1.	Evaluation of NCSP *The remaining two phases of the national evaluation designed by the Otago University team must proceed.*	Part 3 (Cancer Audit). Phase 4 and 5 commenced Interviewing first sample of women Collecting and abstracting GP records for first sample Operationalising slide review Commencing sample 2 Decision confirmed on the slide review being performed off shore.
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.*	No Reporting Milestone this period.
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 September to December 2002
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.*	Development of Operational and Policy and Quality Standards Project Scope Review
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. *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 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 September to December 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*	The first reading of the Bill commenced on 15 October 2002 but is yet to be completed.
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.*	The first reading of the Bill commenced on 15 October 2002 but is yet to be completed.

Ref.	Recommendation	Reporting Milestones[1] for September to December 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.*	The first reading of the Bill commenced on 15 October 2002 but is yet to be completed.
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.*	The National Ethics Advisory Committee work programme to be completed 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 work programme to be completed by November 2003.

Ref.	Recommendation	Reporting Milestones[1] for September to December 2002
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 work programme to be completed by November 2003.
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 work programme to be completed 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.*	The NSU complaints process has been circulated to appropriate NSU managers for review and comment
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. Project work on the development of policy and standards for the NCSP Regional Services has commenced.

Ref.	Recommendation	Reporting Milestones[1] for September to December 2002
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.
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 HPCA.
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 first reading of the Bill commenced on 15 October 2002 but is yet to be completed.
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.*	Work on this recommendation is being included in the NCSPP Regional Service reconfiguration project and the project developing policy and standards for the NCSP Regional Service.

Ref.	Recommendation	Reporting Milestones[1] for September to December 2002
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.
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.*	Included in HPCA – Bill presently with Health Select Committee. Submissions closed 27 November 2002, Health Committee will hear oral submissions in late January and February 2003. The Bill must be reported back to the House by the end of April 2003.
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.*	Included in HPCA – Bill presently with Health Select Committee. Submissions closed 27 November 2002, Health Committee will hear oral submissions in late January and February 2003. The Bill must be reported back to the House by the end of April 2003.
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

Ref.	Recommendation	Reporting Milestones[1] for September to December 2002
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.*	Very positive feedback received on the NCSP detailed booklet to women. Printing of the NCSP general pamphlet has been delayed until February 2003 while some wording changes were consulted on around ThinPrep and NZ Statistics were obtained for the risk table. Due to consultation feedback the NCSP Results pamphlet has been put on hold until Bethesda 2001 is introduced in New Zealand in 2003.
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.

Ref.	Recommendation	Reporting Milestones[1] for September to December 2002
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.
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.*	Included in HPCA – Bill presently with Health Select Committee. Submissions closed 27 November 2002, Health Committee will hear oral submissions in late January and February 2003. The Bill must be reported back to the House by the end of April 2003..
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.*	NSU complaints process has been circulated to appropriate NSU managers for review and comment.
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.