

# **QUARTERLY (10 DECEMBER 2002 to 10 March 2003) 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 December 2002 to 10 March 2003 (i.e. the 21st, 22nd and 23rd month reports).

## **COMMENT**

2. A substantial amount of work has been carried out to implement the recommendations from the Gisborne Cervical Screening Inquiry. This quarterly report provides an update on progress against key milestones and deliverables for those areas of work that remain outstanding and which relate predominantly to the following areas: the Audit of Invasive Cervical Cancer, legislative changes, recommendations relating to Ethics Committees, NCSP Operations, and the Population Health Register.

## **Evaluation of the National Cervical Screening Programme**

3. Phases 4 and 5 of the Cervical Cancer Audit are continuing.
4. The interviewing of women and extraction of data is nearing completion for the first sample of women. As at 3 March a total of 220 women have been interviewed. Consent rates remain high at 86% overall, and participation rates remain high for Māori women at 91%. The interviewing of women and collection of data for the second sample of women has commenced.
5. Ongoing concerns are being expressed by medical practitioners in relation to the Audit. Many of the concerns have been addressed and reflected in the progress of the Audit.
6. The decision to perform the re-read of the slides from the Audit offshore in Australia has been confirmed, and is nearing sign off. An operations manual for the slide review is currently being drafted.

## **Changes to Legislation**

7. The Health Screening Programmes Amendment Bill has completed its first reading and was referred to Health Select Committee on 18 February 2003. The deadline for submissions on the new Bill is 11 April, the Health Select Committee have asked the Ministry to submit a briefing to the Committee by 30

April. Hearings are due to commence on 7 May. The Committee is scheduled to report back to the House on 17 August 2003.

8. The Bill is currently a category two on the Legislation Programme for 2003. Enactment of the Bill is dependent on the Bill completing all of its parliamentary stages. Any further delays in the timing and content of the Bill will result in corresponding delays in the commencement and implementation date. It is estimated that it will take a minimum of 6 to 9 months to prepare for the Bill coming into force once the Bill is enacted.
9. The Health Practitioners Competence Assurance Bill (HPCA) is currently with Health Select Committee, oral submissions have closed and the Committee has commenced deliberations on the new Bill. The Health Select Committee is scheduled to report back to the House is due by the end of April 2003.

## **NCSP Operations**

### **Policy and Quality Standards**

10. The NSU is continuing in its work programme to negotiate direct contractual relationships with providers that contain, in addition to the policy and quality standards already in place, more explicit audit and monitoring requirements. Alongside of the two Public Hospital Laboratories that have now signed direct laboratory agreements with the NSU, agreements are now in place with three community laboratories. It is anticipated that Lab+, one of the two public hospital laboratories will be able to meet the minimum volume standard, Lab+ did not previously have a community laboratory agreement in place and numbers are now on the increase. Canterbury Health Laboratories, which did previously have a community laboratory agreement, is looking at additional ways to increase cytology volumes.
11. The NCSP Audit framework, which will establish a framework for carrying out provider compliance audits against the NCSP policy and quality standards is being consulted on with NCSP providers.
12. IMG Report 7 covering the period April to June 2002 has now been distributed to providers.
13. Work to re-programme the NCSP Register to support the NCSP Regional Services reconfiguration is continuing. A draft of the Policy and Quality standards for NCSP Regional Services, which includes performance standards for the NCSP Register, has now been distributed for consultation. A draft of Chapter Six of the NCSP Policy and Quality Standards, entitled "Providing a Colposcopy Service" has also been distributed widely for consultation.

### **Health Promotion**

14. The NCSP team have met with each NCSP Regional Service to discuss and support the health promotion initiatives planned. Emphasis is been given to

targeting the NCSP priority groups including Māori and Pacific women and women who have never had a cervical smear.

15. Planning for the Health Promotion Training Event for new health promoters is underway. The training event will occur in June 2003.

### **Information to Women**

16. The printing of the NCSP general pamphlet was delayed while some wording changes were consulted on around ThinPrep and New Zealand statistics were obtained for the risk table, and a peer review of the New Zealand statistics was undertaken. The pamphlet is now being printed and will be available for distribution by the end of March 2003.
17. The NSU has funded a range of health promotion initiatives this year with the aim of increasing coverage and participation of Māori and Pacific women in the NCSP. An evaluation of the one off health promotion initiatives will be undertaken at the end of this year.

### **NSU Complaints System**

18. The proposal for the development of a NSU complaints system has previously been circulated within the NSU for comment. An analysis of the feedback is now been undertaken.

### **Ethics Committee Recommendations**

19. The recommendations relating to ethics committees are now part of the work programme for The National Ethics Advisory Committee. The National Ethics Advisory Committee will be reporting to you separately in November 2003.

### **Dr Euphemia McGoogan – Third NZ Visit (18 January to 26 January 2003)**

20. Dr Euphemia McGoogan completed her third visit between 18 January and 26 January 2003. Meetings were held with the NSU and Ministry project teams involved with the implementation of the inquiry recommendations and the Cervical Cancer Audit. A report following up on the findings of her visit is now anticipated.
21. The Ministry is still awaiting further advice from Dr McGoogan on how recommendations are measured and determined as complete.

## APPENDIX 1.0

### IMPLEMENTATION OF RECOMMENDATIONS AND PROGRESS AGAINST REPORTING MILESTONES FOR 10 DECEMBER 2002 TO 10 MARCH 2003

Ref.	Recommendation	Reporting Milestones <sup>1</sup> for December to March 2003.
1.	<p>Evaluation of NCSP</p> <p><i>The remaining two phases of the national evaluation designed by the Otago University team must proceed.</i></p>	<p>Part 3 (Cancer Audit).</p> <p>Phase 4 and 5 commenced</p> <p>Completing sample one women interviews, record collection and abstraction.</p> <p>Operationalising slide review</p> <p>Commenced sample 2 interviewing and collection of records. Decision confirmed on the slide review being performed off shore.</p>
2.	<p>Re-enrolment and re-screening of women.</p> <p><i>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.</i></p>	No Reporting Milestone this period.
3.	<p>Evaluation of NCSP</p> <p><i>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.</i></p>	<p>Parts 5, 6 and 8 included within the scope of Part 3 (Cancer Audit) – see recommendation 1 above. No Reporting Milestone this period.</p> <p>Parts 4, 7 and 10 included within scope of NCSP Statistical Reporting. Refer to recommendation 7 below.</p> <p>Project to develop new and updated Evaluation Plan commenced.</p>

<sup>1</sup> 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 <sup>1</sup> for December to March 2003.
4.	<p>Operational Policy and Quality Standards &amp; Evaluation &amp; Monitoring Plan.</p> <p><i>The Policy &amp; Quality Standards for the NCSP and the Evaluation and Monitoring Plan for the NCSP must be implemented within the next 12 months.</i></p>	<p>Direct contractual agreements are now in place with three community laboratories, alongside the agreements with the two public hospitals that are already in place.</p> <p>The NCSP IMG Quarterly Report 7, April to June 2002 has been distributed to providers.</p> <p>The NCSP Audit Framework is currently being consulted on.</p>
5.	<p>Full legal assessment of Operational Policy and Quality Standards.</p> <p><i>There needs to be a full legal assessment of the Policy &amp; 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.</i></p>	<p>Report provided to NSU.</p>
6.	<p>Legal assessment of NCSP Authority.</p> <p><i>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.</i></p>	<p>Report provided to NSU.</p>
7.	<p>Statistical Reporting.</p> <p><i>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.</i></p>	<p>1996-98 Report Published</p> <p>1999-00 Report in progress</p> <p>Work on 2001 report is underway.</p>
8.	<p>Regular Statistical Information.</p> <p><i>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.</i></p>	<p>NSU and University of Otago consider that it is not possible currently to correlate laboratory reporting with regional incidence of cervical cancer in NZ.</p>

Ref.	Recommendation	Reporting Milestones <sup>1</sup> for December to March 2003.
9.	<p>Minimum Standards for Cytology Laboratories.</p> <p><i>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.</i></p>	<p>DHB and Community Laboratory Agreements incorporate minimum volume standards.</p> <p>Public Hospital laboratories did not meet minimum volume standards in 2001/02.</p>
14.	<p>Amend S74 of the Health Act 1956.</p> <p><i>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</i></p>	<p>The first reading of the Bill commenced on 15 October 2002. The Bill completed its first reading and was referred to Health Select Committee on 18 February 2003. Submissions on the Bill are due 11 April, the committee has sought a briefing from the Ministry of Health due 30 April, hearings begin on 7 May. The Committee is scheduled to report back to parliament on 17 August 2003.</p>
15.	<p>Kaitiaki Regulations.</p> <p><i>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 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.</i></p>	<p>Cabinet decision 25 June to retain status quo.</p>
16.	<p>Legal right to access information from the Cancer Register.</p> <p><i>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.</i></p>	<p>The first reading of the Bill commenced on 15 October 2002. The Bill completed its first reading and was referred to Health Select Committee on 18 February 2003. Submissions on the Bill are due 11 April, the committee has sought a briefing from the Ministry of Health due 30 April, hearings begin on 7 May. The Committee is scheduled to report back to parliament on 17 August 2003.</p>

Ref.	Recommendation	Reporting Milestones <sup>1</sup> for December to March 2003.
17.	<p>Amend Health Act 1956 to enable access to medical files.</p> <p><i>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.</i></p>	<p>The first reading of the Bill commenced on 15 October 2002. The Bill completed its first reading and was referred to Health Select Committee on 18 February 2003. Submissions on the Bill are due 11 April, the committee has sought a briefing from the Ministry of Health due 30 April, hearings begin on 7 May. The Committee is scheduled to report back to parliament on 17 August 2003.</p>
18.	<p>Change guidelines under-which ethics committees operate.</p> <p><i>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.</i></p>	<p>Guidelines updated.</p>
19.	<p>Review of operations of ethics committees.</p> <p><i>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.</i></p>	<p>The National Ethics Advisory Committee will report back to the Minister by November 2003.</p>
20.	<p>Provide guidelines to ethics committees regarding Privacy Act &amp; Code.</p> <p><i>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.</i></p>	<p>Guidelines updated.</p>
21.	<p>Guidelines to ethics committees for observational studies.</p> <p><i>Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies.</i></p>	<p>The National Ethics Advisory Committee will report back to the Minister by November 2003.</p>

Ref.	Recommendation	Reporting Milestones <sup>1</sup> for December to March 2003.
22.	<p>National ethics committee – multi-centre studies.</p> <p><i>A national ethics committee should be established for the assessment of multi-centre or national studies.</i></p>	The National Ethics Advisory Committee will report back to the Minister by November 2003.
23.	<p>Appeal process for ethics committee decisions.</p> <p><i>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.</i></p>	The National Ethics Advisory Committee will report back to the Minister by November 2003.
24.	<p>NCSP Complaints System.</p> <p><i>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.</i></p>	The NSU complaints process has been circulated to appropriate NSU managers for review and comment. An analysis of the comments is now being undertaken.
25.	<p>Electronic Link Cancer Register &amp; NCSP Register.</p> <p><i>The National Cervical Screening Register needs to be electronically linked with the Cancer Register.</i></p>	Processes for linking and matching data implemented.
26.	<p>Performance Standards for NCSP Register and Cancer Register.</p> <p><i>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.</i></p>	Work on NCSP-Register performance standards has commenced.



Ref.	Recommendation	Reporting Milestones <sup>1</sup> for December to March 2003.
27.	<p>Standards for the NCSP should be reviewed every two years.</p> <p><i>Standards for the NCSP should be reviewed every two years and more frequently if monitoring indicates that some of the standards are inappropriate.</i></p>	<p>A draft of chapter six of the NCSP Policy and Quality Standards, October 2000 "Providing a colposcopy Service" is now out for consultation.</p> <p>A draft of the Policy and Quality standards for NCSP Regional Services which includes performance standards for the NCSP Register has now been distributed for consultation.</p>
28.	<p>The Government must ensure sufficient cytotechnologists and cytopathologists and training sites.</p> <p><i>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.</i></p>	<p>Implementation of Workforce Development Strategy commenced.</p>
29.	<p>Amend Medical Laboratory Technologists Regulations 1989.</p> <p><i>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.</i></p>	<p>Addressed through scopes of practice provisions of HPCA.</p>
30.	<p>Impose Legal obligations on storage of slides.</p> <p><i>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.</i></p>	<p>The first reading of the Bill commenced on 15 October 2002. The Bill completed its first reading and was referred to Health Select Committee on 18 February 2003. Submissions on the Bill are due 11 April, the committee has sought a briefing from the Ministry of Health due 30 April, hearings begin on 7 May. The Committee is scheduled to report back to parliament on 17 August 2003.</p>

Ref.	Recommendation	Reporting Milestones <sup>1</sup> for December to March 2003.
31.	<p>Ensure electronic linkage between NCSP Register and Cytology Labs.</p> <p><i>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.</i></p>	<p>No Reporting Milestone this period.</p> <p>This requirement will form part of the National Screening Units development of an Information Systems Strategy. Work has commenced on this strategy.</p>
32.	<p>Develop Standards for accuracy of laboratory coding.</p> <p><i>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.</i></p>	<p>Work on this recommendation is being included in the NCSP Regional Service reconfiguration project.</p>
33.	<p>The NCSP should develop a population-based register.</p> <p><i>The NCSP should work towards developing a population based register and move away from being the utility based register that it now is.</i></p>	<p>No Reporting Milestone this period.</p> <p>The National Screening Unit is represented on the Ministry's Population Register Project led by NZHIS.</p>
34.	<p>Legal mechanisms should be in place to allow the ACC, Medical Council and the Health &amp; Disability Commissioner to share relevant information with the Ministry's NCSP.</p> <p><i>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.</i></p>	<p>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.</p> <p>The Bill must be reported back to the House by the end of April 2003.</p>
35.	<p>Medical Tribunal to supply information to NCSP.</p> <p><i>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.</i></p>	<p>Included in HPCA – Bill presently with Health Select Committee. Submissions closed 27 November 2002, Oral submissions are closed. The Health Select Committee has commenced its deliberations on the Bill.</p> <p>The Committee is due to report back to parliament by the end of April 2003.</p>

Ref.	Recommendation	Reporting Milestones <sup>1</sup> for December to March 2003.
36.	<p>ACC &amp; Medical Council should exchange relevant information regarding claims for medical misadventure.</p> <p><i>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.</i></p>	Royal assent received for Injury Prevention and Rehabilitation Bill – to come into effect April 02
38	<p>Information to Women.</p> <p><i>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.</i></p>	<p>Printing of the NCSP general pamphlet was delayed while some changes were consulted on around ThinPrep and NZ Statistics were obtained for the risk table. The NZ Statistics have now been peer reviewed and the pamphlet is being printed. The pamphlet will be available for distribution by the end of March.</p> <p>Due to consultation feedback the NCSP Results pamphlet has been put on hold until Bethesda 2001 is introduced in New Zealand in 2003.</p>
39	<p>Letters to Medical Practitioners.</p> <p><i>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.</i></p>	Letter sent.
40	<p>Appropriately trained personnel should do cervical screening.</p> <p><i>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.</i></p>	Implementation of Workforce Development Strategy commenced.
41	<p>All pathologists undertaking cytology should be appropriately trained.</p> <p><i>If cytology is a significant component of a pathologist's practice then he or she must participate in continuing medical education in that subject.</i></p>	Implementation of Workforce Development Strategy commenced.

Ref.	Recommendation	Reporting Milestones <sup>1</sup> for December to March 2003.
42	<p>Cytopathologists must participate in continuing education in cytopathology.</p> <p><i>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.</i></p>	Implementation of Workforce Development Strategy commenced.
43	<p>Pathologists ought to be more open-minded.</p> <p><i>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.</i></p>	No Reporting Milestone this period.
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><i>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.</i></p>	<p>Included in HPCA – Bill presently with Health Select Committee. Submissions closed 27 November 2002, Oral submissions are closed. The Health Select Committee has commenced its deliberations on the Bill.</p> <p>The Committee is due to report back to parliament by the end of April 2003.</p>
45	<p>NCSP should have a system for identifying deficiencies.</p> <p><i>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.</i></p>	NSU complaints process has been circulated to appropriate NSU managers for review and comment. Feedback is being analysed and will be included in the next stage of the database development.
46	<p>There should be a process for monitoring the implementation of the Committees Recommendations.</p> <p><i>A process to ensure that the recommendations made by the Committee are implemented should be put in place.</i></p>	<p>Dr McGoogan's 6-Month Report released.</p> <p>Dr McGoogan's 12-Month Report awaited.</p> <p>Dr McGoogan completed a third NZ Visit between 18 January and 26 January 2003. The Ministry is now awaiting a report of her findings.</p>