

Eleventh Monthly 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 will supply monthly reports to the Minister. This is the eleventh of these monthly reports.

COMMENT

Evaluation of the National Cervical Screening Programme

2. The Cancer Audit Project Team submitted its application to Ethics Committees, 18 February 2002. Approval is expected by early April.
3. Further staff have been appointed to the Cancer Audit Project Team and work is proceeding on the development of the audit database in readiness for the data collection phase to commence immediately following ethics approval.
4. The first Cancer Audit newsletter is due to be circulated to key stakeholders in March as part of the audit communications strategy of providing regular updates on audit developments and progress.

Changes to Legislation

5. Personal and Family Health Directorate and then Sector Policy Directorate (SPD) have led the consultation, policy development and Cabinet approval processes for proposed changes to section 74A of the Health Act 1956 (now referred to as the Health (Screening Programmes) Amendment Bill). The National Screening Unit has also had significant input to this work. In February 2002, SPD transferred responsibility for the Health (Screening Programmes) Amendment Bill to the Public Health Directorate's Public Health Legislative Review (PHLR) team. PHLR is acutely aware of the need to maintain continuity during the transitional period, especially including close consultation with the National Screening Unit.
6. Parliamentary Counsel Office has completed the fourth draft of the Health (Screening Programmes) Amendment Bill). The Minister agreed to the Ministry consulting with key stakeholders on this draft of the Bill. Stakeholder feedback was provided by 8 March 02 and is currently being analysed. Following analysis of this feedback a final draft should be completed by the end of March.
7. The Leader of the House has agreed that the Health (Screening Programmes) Amendment Bill will proceed through the House separately from other parts of the Comprehensive Bill. It is planned that the Bill will be introduced to the House end of April 2002. (Recommendations 14, 16, 17, 30)

8. Preparation of a discussion document on the review of the Kaitiaki Regulations has been completed and approved by Ministers. The document is being distributed to up to 3000 people and organisations in preparation for the 12 regional hui taking place between 12th March and 19th April. A communications strategy involving radio and print media advertising has been developed. It is envisaged that Cabinet policy approval for amendments to the Kaitiaki Regulations will occur in June, with drafting of new regulations to be completed around September 2002. (Recommendation 15)
9. An *indicative* summary of the timeline is as follows:

18 March	MoH internal meeting to review feedback from other depts and external stakeholders on the 4 th draft of the Bill – PCO to be instructed accordingly
5 April	PCO will need to have finalised the bill by about this time, and the draft LEG paper prepared
8 April	Minister's office begins political consultation (Alliance and Greens) <i>subject to confirmation by Minister's office</i>
9 – 16 April	Departments consulted on LEG paper and final version of bill
17 April	Final consultation <i>hui</i> on the proposed amendments to the Kaitiaki Regulation
18 April	Ministry submits LEG paper to Minister's office
22 April	CO Deadline for signed LEG paper
24 April	LEG
30 April	Bill introduced <i>Subject to confirmation by Minister's office and LEG</i>
May – June	Select Committee process for Screening Bill
June	EHC policy approval for amendments to the Kaitiaki Regulations
July/August	2 nd Reading/Committee of Whole House/ Enactment
September	Drafting of amendments to the Kaitiaki Regulations completed

10. A printed draft of the Health Practitioners Competence Assurance Bill will be forwarded to the Ministry of Health from the Parliamentary Counsel Office by Friday 8 March 2002. This will enable consultation to begin with other government departments. The legislation is scheduled to be introduced to the House by the end of April 2002. It has been prioritised on the legislative programme as priority level 3, which sets the expectation that the legislation is to be passed during 2002 if possible. (Recommendations 34, 35, 36, 44)

11. Recommendation 29 of the Inquiry Report 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 Ministry's initial view was not to pursue these amendments separately, given that the Health Professionals' Competency Assurance Bill (HPCA) which was on the 2001 Legislative Programme, would repeal the 11 occupational statutes and the regulations made under them (including the Medical Laboratory Regulations 1989). Discussions were, however, held with the Secretary of the Medical Laboratory Technologists Board on amendments that would give effect to Recommendation 29. These discussions have raised a number of issues related to training and workforce availability.
12. As part of the HPCA Bill it will be the role of each new occupational board to gazette scopes of practice for its registered practitioners, and to determine the qualifications required for registration. The Ministry believes that the most effective way of implementing the intention behind Recommendation 29 is to build on the earlier discussions with the Board, and provide advice to the new Board on competence, qualifications and scopes of practice under the coming HPCA regime. The HPCA will also allow requirements to be addressed for others involved in laboratory testing - laboratory assistants and trainees. While the Board has no jurisdiction over these people now, the registering body under the HPCA will be responsible for setting scopes of practice for this group in the future, and determining registration requirements.

Ethics Committees

13. Progress to implement the Inquiry Recommendations regarding ethics committees has not been straightforward. Dr Euphemia McGoogan concluded in her 6-Month Report that progress is unlikely to be made at present. She commented that ethics committees were in danger of taking an entrenched position. In this 11th Month Report we provide some further background to these issues, in advance of Dr McGoogan's return visit in April.
14. The Inquiry Report made five recommendations related to the operation of ethics committees (Recommendations 18, 19, 20, 21, 22, 23). These recommendations as written were not specific to the NCSP, but applied to the whole area of health and ethical review in NZ. Given that ethics committees in NZ are not established in legislation, it was necessary to find an appropriate vehicle for implementing the recommendations of the Inquiry. At the time the Inquiry Report was released, two methods were identified:
- Through amendments to the National Standard, to which ethics committees are obliged to conform; and/or
 - As part of the work of the National Ethics Committee which was already planned to be set up under the new NZ Public Health and Disability Act.
15. At the time of the Inquiry Report, the National Standard for ethics committees had been under review. The opportunity was taken to incorporate the recommendations of the Inquiry within this review. The Health Research Council

and Regional Ethics Committees, users of the National Standard, were strongly opposed to the Inquiry Recommendations. There was therefore strong opposition to the redrafted standards incorporating the requirements of the Inquiry Recommendations. This resulted in the redrafted standards that were circulated in June 2001 being withdrawn by the Ministry, as it was clear that no agreement would be achieved. It was agreed instead that non-controversial changes would be made to the original 1996 Standard, and controversial issues would be referred to the new National Ethics Committee.

16. The publication of the revised 1996 Standard was further delayed as a result of the difficult process of arriving at a final draft acceptable to the Health Research Council and Regional Ethics Committee. Delays also occurred as a result of a request from Hon Tariana Turia for a revision of the content of the standard in relation to Maori. We now expect that the revised Standard will be published by April, completing the process for implementing recommendations 18 and 20.
17. The Minister of Health agreed to the incorporation of recommendations 19, 21, 22 and 23 into the terms of reference for the new National Ethics Committee. Following a process of public advertising and Cabinet approvals, membership of this committee was announced in December 2001 and they are due to convene their first meeting in April 2002. The Committee will be expected to report back to the Minister of Health on the proposed timeframe for responding to the relevant Inquiry recommendations. Given the complexity of the issues, and the requirement for consultation specified in the legislation, it is likely to be some time before the Committee is able to report back. In particular, the proposal for establishment of a national ethics committee for the assessment of multi-centre or national studies (Recommendation 22) is controversial due to concerns about how local and Maori perspectives would be integrated into national decisions. If a separate committee were to be established, it is likely that the number of ethics committees would need to be reviewed, as several of the smaller committees have few other types of research proposals referred to them.

NCSP Operations

Provision of Statistical Information

18. The 1996-98 NCSP Statistical Report is undergoing final editing changes prior to printing. Around 5000 copies will be available for distribution in April 2002 to stakeholders, DHBs, Colleges and Professional Groups, Libraries etc, and smear-takers and other service providers (on request).
19. NCSP-Register Data has been extracted for the 1999-2000 NCSP Statistical Report and is currently being analysed by an external epidemiologist who will also prepare the report. (Recommendation 7)
20. A draft template has been prepared for an Annual Monitoring Report for the year 2001.

Policy and Quality Standards and Ongoing Monitoring

21. The fourth Independent Monitoring Group's NCSP quarterly monitoring report (covering the period July 2001 to September 2001) is currently being finalised. (Recommendation 4)

Workforce Development

22. The NSU Workforce Development Strategy document has been completed. Plans to implement the strategy are now being developed. Priority will be given to CSI workforce recommendations in this implementation phase. In the first instance a review of cytology education and training is planned for the period up to 30 June 02. Correspondence between the Royal College of Pathologists and Clinical Training Agency continues regarding cytopathology registrar training sites. (Recommendations 28, 40, 41, 42)

Information to Women

23. The detailed NCSP Booklet has now been produced in its design format and is out for its second round of pre-testing with consumers and health professionals. (Recommendation 38)

Dr McGoogan's Review

24. Dr McGoogan is due to visit NZ again in April for her 12 month review. She will carry out her review between the 2nd April and 17th April. Dr McGoogan and requested meetings with around 30 people and organisations.

APPENDIX 1.0

TABLE 1.0: SUMMARY OF RECOMMENDATIONS UNDERWAY OR IMPLEMENTED AND/OR WHICH FORM PART OF ONGOING NCSP OPERATIONS

	Status	Recommendations	Total Number
1.	Implemented and/or ongoing component of NCSP	4, 5, 6, 9, 10, 11, 12, 13, 25, 36, 37, 39	12
2.	Underway	1, 3, 7, 8, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 38, 40, 41, 42, 43, 44, 45, 46	33

TABLE 2.0 IMPLEMENTATION OF RECOMMENDATIONS AND PROGRESS AGAINST REPORTING MILESTONES FOR 10 FEBRUARY TO 10 MARCH 2002

Ref.	Recommendation	Underway/ Implemented	Reporting Milestones ¹ for 10 February to 10 March 2002	Milestone Achieved
1.	Evaluation of NCSP – Part 3 (Cancer Audit).	Underway	Ethics application submitted.	✓
2.	Re-enrolment and re-screening of women.		No Reporting Milestone this period.	
3.	Cox's 1997 comprehensive evaluation of the NCSP should be commenced within 18 months.	Underway	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.	
4.	Implementation of Operational Policy and Quality Standards & Evaluation & Monitoring Plan.	Underway	Further project work to take place with regard to implementation of standards for Smear-Takers. Finalisation of fourth Independent Monitoring Group NCSP quarterly monitoring in process.	
5.	Full legal assessment of Operational Policy and Quality Standards.	Implemented	Report provided to NSU.	✓
6.	Legal assessment of NCSP Authority.	Implemented	Report provided to NSU.	✓
7.	Statistical Reporting.	Underway	Milestone Delayed 1996-98 Report in process of final editing prior to printing. Work on the 1999/00 report is underway.	x
8.	Regular Statistical Information.	Underway	NSU and University of Otago consider delivery of aspects of this recommendation not possible.	

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 Current Practice/ 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	Underway/ Implemented	Reporting Milestones ¹ for 10 February to 10 March 2002	Milestone Achieved
9.	Minimum Standards for Cytology Laboratories.	Implemented	DHB and Community Laboratory Agreements incorporate minimum volume standards. Public Hospital laboratories struggle to meet minimum volume standards.	✓
14.	Amend S74 of the Health Act 1956.	Underway	Fourth draft of legislation completed.	✓
15.	Kaitiaki Regulations.	Underway	Discussion document completed.	✓
16.	Legal right to access information from the Cancer Register.	Underway	Fourth draft of legislation completed.	✓
17.	Amend Health Act 1956 to enable access to medical files.	Underway	Fourth draft of legislation completed.	✓
18.	Change guidelines under-which ethics committees operate.	Underway	Milestone delayed.	x
19.	Review of operations of ethics committees.	Underway	Work to be undertaken by the National Advisory Committee on Health and Disability Support Services Ethics (The National Ethics Committee).	x
20.	Provide guidelines to ethics committees regarding Privacy Act & Code.	Underway	Milestone delayed.	x
21.	Guidelines to ethics committees for observational studies.	Underway	Work to be undertaken by the National Advisory Committee on Health and Disability Support Services Ethics (The National Ethics Committee).	x
22.	National ethics committee – multi-centre studies.	Underway	Work to be undertaken by the National Advisory Committee on Health and Disability Support Services Ethics (The National Ethics Committee).	x
23.	Appeal process for ethics committee decisions.	Underway	Work to be undertaken by the National Advisory Committee on Health and Disability Support Services Ethics (The National Ethics Committee).	x

Ref.	Recommendation	Underway/ Implemented	Reporting Milestones¹ for 10 February to 10 March 2002	Milestone Achieved
24.	NCSP Complaints System.	Underway	Contractor appointed to commence project.	✓
25.	Electronic Link Cancer Register & NCSP Register.	Implemented	Processes for linking and matching data implemented.	✓
26.	Performance Standards for NCSP Register and Cancer Register.	Underway	Delays to commencement of project work	✗
27.	Standards for the NCSP should be reviewed every two years.	Underway	Delays to commencement of project work.	✗
28.	The Government must ensure sufficient cytotechnologists and cytopathologists and training sites.	Underway	Final Draft Workforce Development Strategy Completed.	✓
29.	Amend Medical Laboratory Technologists Regulations 1989.	Underway		
30.	Impose Legal obligations on storage of slides.	Underway	Fourth draft of legislation completed.	✓
31.	Ensure electronic linkage between NCSP Register and Cytology Labs.	Underway	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.	Underway	Delays to commencement of project work.	✗
33.	The NCSP should develop a population-based register.	Underway	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	Underway	Initial draft of legislation completed.	✓

Ref.	Recommendation	Underway/ Implemented	Reporting Milestones ¹ for 10 February to 10 March 2002	Milestone Achieved
	Ministry's NCSP.			
35.	Medical Tribunal to supply information to NCSP.	Underway	Initial draft of legislation completed.	✓
36.	ACC & Medical Council should exchange relevant information regarding claims for medical misadventure.	Implemented	Royal assent received for Injury Prevention and Rehabilitation Bill – to come into effect April 02	✓
38	Information to Women.	Underway	Draft detailed brochure completed and out for consumer testing	✓
39	Letters to Medical Practitioners.	Implemented	Letter sent.	✓
40	Appropriately trained personnel should do cervical screening.	Underway	Final Draft Workforce Development Strategy Completed.	✓
41	All pathologists undertaking cytology should be appropriately trained.	Underway	Final Draft Workforce Development Strategy Completed.	✓
42	Cytopathologists must participate in continuing education in cytopathology.	Underway	Final Draft Workforce Development Strategy Completed.	✓
43	Pathologists ought to be more open-minded.	Underway	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.	Underway	Included in HPCA bill. Initial draft of legislation completed.	✓
45	NCSP should have a system for identifying deficiencies.	Underway	No Reporting Milestone this period.	
46	There should be a process for monitoring the implementation of the Committees Recommendations.	Underway	Dr McGoogan's 6-Month Report released.	