Ref. No.: 20011392

# The Six-Month Summary Report from the Ministry of Health to the Minister on the Implementation of the Recommendations of the Gisborne Cervical Screening Inquiry Report

# REPORT

## BACKGROUND INFORMATION

1 In response to recommendation 46 of the Inquiry Report, the Director General of Health will supply monthly reports to the Minister. Six of these reports have been supplied for each of the first 6 months. These reports provide details of progress against key project milestones on an ongoing basis.

2 In addition, this report provides a detailed summary of the progress to implement the Inquiry recommendations over the first 6 months, since the release of the Inquiry Report.

## COMMENT

### Overall Progress

3 In the first 6 months since the release of the Inquiry Report considerable progress has been made in the implementation of 45 of the recommendations, with 8 completed, and a further 16 on target to be completed in accordance with project plans. Some delays have been experienced in implementing 21 recommendations and revised schedules have been submitted.

4 Evaluation of the NCSP is proceeding. Part 2 of the Evaluation, *The Evaluation and Follow-up of Woman with Abnormal Smears* was completed in July 2001. Phase 1 of Part 3 of the Evaluation, *The Audit of Invasive Cancer,* which is being carried out under current legislation, was completed to plan, but delays in the delivery of Phase 2 are expected, affecting the overall Audit schedule. A revised date for the completion of the Audit is now expected.

5 The timeframe for the implementation of recommendations to deliver legislative change (Comprehensive Bill) before the end of the year was extremely tight. The Comprehensive Bill covers changes to the Health Act 1956, amendments to the Health and Disability Commissioner Act 1994, and the new Health Professional Competency Assurance Bill. Policy work was completed on time, but drafting of the legislation has taken longer then anticipated. Progress over the next few months will be dependent upon completion of the legislative drafting, departmental and Coalition consultation, further select committee consideration of the drafting and the legislative timetable within the House. A revised date for the introduction of this legislation is now expected following further briefings to the Minister.

6 Of the 6 recommendations of the Inquiry related to the ethics committees, four are to be dealt with by the National Advisory Committee on Health and Disability

Support Services Ethics (the National Ethics Committee). The National Ethics Committee, once established, is to carry out the review of the operation of ethics committees as recommended by the Inquiry. The National Ethics Committee is expected to be appointed by the end of November 2001.

7 Recommendations on guidance on privacy issues (20) and exemption of the audit of invasive cervical cancer from the requirement for the approval of ethics committees (18) will be dealt with in the revised operational standard for Health and Disability Ethics Committees. This is due to be published by 31 October, although some further work will be needed as part of the National Ethics Committee review.

8 Implementation of the National Cervical Screening Programme's Interim Operational Policy and Quality Standards (Interim Standards) was achieved for DHBs and Community Laboratories by July 2001 within the 12 months called for in Recommendation 4. The implementation of the Interim Standards has also meant that Laboratories must process a minimum of 15,000 cytology cases per year. As at 1 July 2001 a reduced number of laboratories are now reading cervical cytology slides.

9 The performance of programme providers, including laboratories is now being monitored against national indicators and the results published in quarterly Independent Monitoring Group reports, the first of which was released in July 2001 and the second report was due at the end of October. The production of annual statistical reporting has been delayed, however, due to lengthy peer review and finalisation.

10 The NSU's Workforce Development Project is making excellent progress towards the completion of its final report in December 2001. Information and survey data have been gathered on the workforce involved in the delivery of NCSP services, their training, and any issues related to capacity and implementation of standards. Consultation with the Clinical Training Agency (CTA), providers of undergraduate and graduate training, colleges and professional bodies, and laboratories have taken place.

11 Progress on the implementation of Information Systems improvements has been slower. These are complex projects requiring careful and detailed scoping and linkages with other Ministry of Health information system initiatives, including work on a population register.

12 A revised timetable for implementation of the Inquiry Recommendations is provided at Appendix 1.0. The revised timetable is compared with the timetable submitted to Cabinet 8 April 2001. The revised timetable will form the baseline for reporting over the next 6 to 12 months.

13 In summary:

| Status | Recommendation | Total Number |
|---|---|---|
| Complete | 4, 9, 10, 11, 12, 13, 25, 37 | 8[1] |
| Underway | 1, 3, 5, 6, 7, 8, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 38, 39, 40, 41, 42, 43, 44, 45, 46 | 37 |
| On Track | 5, 6, 15, 18, 19, 28, 29, 31, 32, 33, 40, 41, 42, 43, 45, 46 | 16 |
| Revised Delivery Date | 1, 3, 7, 8, 14, 16, 17, 20, 21, 22, 23, 24, 26, 27, 30, 34, 35, 36, 38, 39, 44 | 21 |

14 A more detailed summary of progress on the implementation of the recommendations is provided below.

[1] Previously included Recommendations 18 (refer Monthly Report 4) and 20, further analysis and planning work has meant that these recommendations have been transferred to the recommendations underway group.

**Evaluation of the National Cervical Screening Programme**

> *11.1 The remaining two phases of the national evaluation designed by the Otago University team must proceed. Until those phases are completed the Programme's safety for women cannot be known. It is imperative that this exercise is completed within the next six months. Particular attention should be given to the discrepancy between the average reporting rate of high-grade abnormalities of Douglas Hanly Moir Pathology (2.5%-3.7%) for the re-read of the Gisborne women's smear tests and the current New Zealand national average for reporting high-grade abnormalities (0.8%). Unless this exercise is carried out the possibility that the national average is flawed and that there is a systemic problem of under-reporting in New Zealand laboratories cannot be excluded.*

15 Recommendation 11.1 referred to Parts 2 and 3 of the National Evaluation:

- Part 2; The Evaluation of the Follow-up of Women with Abnormal Smears;
- Part 3; The Audit of Invasive Cervical Cancer.

16 The Advisory Group on Population-Based Screening Programmes, in its Review of the Inquiry recommendations, September 2001, has queried the ability of the completion of Parts 2 and 3 of the National Evaluation to address the question of the high grade abnormality rate, referred to in the second part of this recommendation. Further advice has been sought from Dr McGoogan regarding this question.

*Part 2 Evaluation of the Follow-up of Women with Abnormal Smears*

17 The University of Otago was commissioned to carried out this part of the National Evaluation. The work commenced in 2000 and a draft report was received by the NSU from the University in July 2001.

18 The NSU met with the authors on 30th August to provide feedback. The report has now been finalised. The findings of the Abnormal Smears report will be followed-up as part of the NSU's Quality Monitoring Audit & Analysis Team's workplan.

*Part 3 Audit of Invasive Cervical Cancer*

19 The Audit of Invasive Cervical Cancer represents perhaps the largest and most complex of the projects to implement the Inquiry Recommendations.

20 Recommendation 11.1 called for this work to be completed within 6 months. Officials advised the Minister of Health at the time of the Inquiry Report's release that this part of the National Evaluation would take at least 18 months to complete. An earlier protocol for this work supplied by Dr Brian Cox of the University of Otago set out a timeframe of 25 months for completion.

21 The Audit is now underway and entering its second phase. Phase 1 of the Audit was completed in accordance with the detailed project plan, meeting all major milestones. The following tasks have been completed:

a) Project Establishment; including

- A Phase 1 Project Team comprising 7 people, including Clinical Advisor, Project Manager, Quantitative Researchers and Auditors, Legal Advisor, Maori Health and Pacific women advisors.

- Steering Group, a sub-group of the National Advisory Group for Population Based Screening Programmes, comprising Public Health Specialist, Pathologist, Gynaecologist, General Practitioners, Health Economist, Maori Health representative, and Cancer Society representative.

- Expert Advisors and key liaison people, including epidemiologists, consumer representatives, representatives of the Colleges of pathology, gynaecology, general practice and practice nurses, Maori health expert, legal advisor.

b) Preparation of an Options Paper entitled Method for Retrospective Audit of Screening Histories and Management of Women with Invasive Cervical Cancer in NZ, April 2001. This paper presented 3 options for the method to be employed for the audit. In June 2001, the Audit Steering Group endorsed the Project Team and Advisor's recommendation that a comprehensive audit design be adopted.

c) Audit Team visit to UK in June/July 2001 principally to learn more about how other programmes overseas were undertaking similar audits.

d) Data checking to ensure that data held on NCSP-register and Cancer register was accurate and up to date. The results of this exercise are detailed in the report entitled NCSP Cancer Audit Data Assurance, August 2001.

e) A review of selected, recently published literature relating to the audit of Invasive Cervical Cancers was completed and documented in a report entitled Audit Literature Review, September 2001.

f) A full legal review and analysis documented in a report entitled Legal Background of the Retrospective Audit of Invasive Cervical Cancers, September 2001.

g) A review of the application of the Medical Practitioner's Act Part VI in providing protection to the health workforce in the carrying out of the Audit. A briefing was provided to the Minister of Health outlining the Audit Team's recommendation that the Audit is carried out as an "open audit" and no special confidentiality arrangements for health professionals be sought.

h) Development of the Audit Document, Draft Framework for the Audit of Screening Histories of Women with Invasive Cervical Cancer, September 2001.

i) Provisional Data extract and high level analysis was undertaken on a sample of women for invasive cervical cancers diagnosed and reported to the NCSP-Register up to September 2001, covering a total of 429 women.

22 The second phase of the Audit will comprise:

j) Appointment of Auditors.

k) Finalisation of the Audit Protocol.

l) Completion of a Communications Plan.

m) Ongoing Stakeholder Liaison.

n) Consultation with the Kaitiaki and Pacific Women's Data Advisory Group.

o) Regional Ethics Committee Approval.

23 It is likely that due to the requirement to obtain the approval of each of the regional ethics committees, together with the appointment of auditors for the next phase of the project, delays in the project timetable will result. A revised project timetable will be submitted to the CSI Steering Group following further negotiation with the auditors planned for November.

*11.3 A comprehensive evaluation of all aspects of the National Cervical Screening Programme which reflects the 1997 Draft Evaluation Plan developed by Doctors Cox and Richardson should be commenced within 18 months. This exercise should build upon the three phase evaluation referred to in recommendation 11.1.*

24 The 1997 Draft Evaluation Plan was designed to evaluate the NCSP in terms of its effectiveness, acceptability and cost effectiveness. Six of the components have already been completed or are ongoing as part of the NSU's regular monitoring activities and statistical reporting. The six components are:

- Determining whether the NCSP provides appropriate data for evaluating the national cervical screening programme.
- Enrolment and coverage of the eligible population (included in Independent Monitoring Group (IMG) Reports and NCSP Statistical Reports) - ongoing
- Appropriateness of follow-up and treatment for women with abnormal smears, University of Otago, July 2001.
- Screening frequency and proportion of unsatisfactory smears (included in Independent Monitoring Group Reports and NCSP Statistical Reports) – ongoing.
- Incidence and mortality of invasive cervical cancer (included in Independent Monitoring Group Reports, NCSP Statistical Reports, NZHIS Cancer New Registrations and Deaths reporting) – ongoing.
- Summary of NCSP-Register Information.

25 Other components of the National Evaluation would be included in the Audit of Invasive Cervical Cancer, including:

- Estimating the Sensitivity of Cytology.
- Accurately Measuring the Stage Distribution of Invasive Cancer.
- Audit of Screening Histories and Management of Women with Invasive Cervical Cancer.

26 The remaining components - the Assessment of Organisational Features and Recruitment Strategies of the Programme, Economic Analysis, Evaluation of NCSP for Maori Women and the Evaluation of NCSP for Pacific women - will be part of separate projects for commencement before December 2002.

27 Given the passage of time since the November 1997 Evaluation Plan was produced, the later development of the HFA's Draft Evaluation and Monitoring Plan and the NSU's Monitoring Framework, the Advisory Group on Population-Based Screening Programmes has recommended that a review of these documents is carried out with the purpose of arriving at a single and more up to date framework for evaluation and monitoring. The NSU's has included this review in its workplan for 2001/02.

**Changes to Legislation**

*11.14 The Health Act 1956 should be amended to permit the National Cervical Screening Programme to be effectively audited, monitored and evaluated by any appropriately qualified persons irrespective of their legal relationship with the Ministry of Health. This requires an amendment to s.74A of the Health Act to permit such persons to have ready access to all information on the National Cervical Screening Register.*

*11.16 The present legal rights of access to information held on the Cancer Registry need to be clarified. The Ministry and any appropriately qualified persons it engages to carry out (external or internal) audits, monitoring or evaluation of cervical cancer incidence and mortality require ready access to all information stored on the Cancer Registry about persons registered as having cervical cancer.*

*11.17 The Health Act 1956 requires amendment to enable the Ministry of Health and any appropriately qualified persons it engages to carry out (external or internal) audits, monitoring or evaluation of cervical cancer incidence and mortality to have ready access to all medical files recording the treatment of the cervical cancer by all health providers who had a role in such treatment.*

28 Prior to the release of the Inquiry Report, Cabinet had already agreed to regulatory and legislative changes in order to facilitate access to personal information held on the NCSP-Register. Cabinet also noted that changes to Section 74A of the Health Act 1956 were likely to be required. [Ref. CAB Min (00) M 35/4]

29 In May 2001 Cabinet approved the release of a public discussion document recommending a number of changes to the Health Act. [Ref. CAB Min (01) 15/6]

These changes were aimed at allowing effective monitoring, audit and evaluation of the National Cervical Screening Programme. The discussion document was released publicly on 6 June 2001 and 101 public submissions were received.

30 After analysis of public submissions, a draft cabinet paper on the amendments to the Health Act 1956 was prepared and considered by the Cabinet Education and Health Committee 28 August 2001. As a result, further consultation took place between the Minister of Health, the Associate Minister of Health and the Minister of Women's Affairs on recommendations concerning access to women's clinical records.

31 On 3 September 2001 Cabinet agreed to amend Section 74A of the Health Act 1956 to enable the effective monitoring, audit and evaluation of the NCSP. [CAB Min (01) 27/17 refers]

- The proposed changes to the Health Act 1956 would allow the NCSP Register data and slides to be used and disclosed for monitoring, audit and evaluation.
- Cabinet agreed that clinical records would be made available for the audit of invasive cervical cancer where the woman has given consent.
- Cabinet agreed that consent should be sought from the woman at the time of treatment or registration on the Cancer Registry or from the next of kin where applicable.
- If a woman or, in the event of her death, her next of kin cannot be contacted for consent, the Director General of Health will be able to require the records be made available.

32 This proposal does not fully meet the requirements of the Recommendation 17, but acknowledges that almost three-quarters of the submissions received were opposed to auditors having access to medical files without consent.

33 Instructions have been issued to Parliamentary Counsel Office for the drafting of amendments to the Health Act as part of the Comprehensive Bill planned for introduction later this year. Drafting on other parts of the Comprehensive Bill has taken longer than anticipated. Progress over the next few months will be dependent upon completion of the legislative drafting, departmental and Coalition consultation, further select committee consideration of the drafting and the legislative timetable within the House. A revised date for the introduction of this legislation is now expected following further briefings to the Minister.

34 NZHIS commissioned a legal opinion to inform the development of a new information release policy, with specific reference to the legal right to access information from the Cancer Registry. A request made by a person external to

the Ministry for identifiable information from NZHIS is a request for official information and subject to the Official Information Act 1982 (OIA). Section 9(2)(a) of the Act is relevant when considering whether to release personal information. NZHIS's previous policy was too narrowly focused and required amendment to be consistent with the OIA. NZHIS's new information release policy will conform to the requirements of the OIA, with due regard given to the particular circumstances of each application.

35 NZHIS is also an agency within the definition of the Privacy Act 1993 and so is subject to that Act and the Health Information Privacy Code 1994. There are various situations that provide for disclosure of the information requested, not all of which require ethical approval. The National Screening Unit's use of Cancer Registry data will fall within the scope of Rule 10 of the Health Information Privacy Code 1994 and the Privacy Act 1993. However, in order to make sure that the NSU's access to Cancer Registry data does not depend upon interpretations of the Health Information Privacy Code, officials are investigating the possibility of an specific clause being added to the Health Act Amendment Bill that will explicitly enable the NSU to use Cancer Registry data.

*11.15 There needs to be a reconsideration of the Kaitiaki Regulations, and the manner in which those regulations currently affect the Ministry of Health gaining access to aggregate data of Maori women enrolled on the National Cervical Screening Register. The Ministry of Health and any appropriately qualified persons engaged by it (be they independent contractors, agents or employees) require ready access to the information currently protected by the Kaitiaki Regulations in order to carry out any audit, monitoring or evaluation of the Programme*

36 Cabinet has agreed that NCSP register data would continue to be subject to the Kaitiaki Regulations and that further consultation will be undertaken before any changes are made to these regulations.

37 On September 7th 2001 health officials met with the National Kaitiaki Group to discuss the review of the Kaitiaki Regulations. It was agreed that the officials would draft a discussion document that acknowledges the history of the group, the recommendations and the proposals that will be consulted upon. Work on this document has commenced.

38 This draft document will be passed on to the Kaitiaki Group for review before a focus group is convened. The focus group will comprise Kaitiaki Group members past and present, along with other Maori women and will be held in November 2001. Following on from this group, a revised discussion document will be

publicly released in January/ February 2002 followed by a series of 9-10 regional Hui.

*11.29 The Medical Laboratory Technologists 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.*

39 The Medical Laboratory Technologists Regulations 1989 can be amended to ensure Medical Laboratory Technologists who intend to be cytoscreeners are appropriately trained to read smears. A draft Cabinet paper has been prepared for consultation setting out the proposed amendments to these Regulations. The policy proposals in the draft Cabinet paper require further consultation and development with the NSU, particularly in relation to workforce implications. The paper is due for consideration by Cabinet early 2002.

40 Medical Practitioners registered under the Medical Practitioners Act 1995 (who would be expected to have vocational registration in pathology and who read smears) generally do not also register as medical laboratory technologists. Amending the Medical Laboratory Technologists Regulations 1989 would not enable the regulation of medical practitioners who are not registered as medical laboratory technologists.

*11.30 Legal obligations in addition to those mandated by IANZ must be imposed on all laboratories reading cervical cytology requiring them to retain records of patients' cytology and histology results (including slides, reports and any other material relating to the patient) in safe storage for a period of no less than five years from the date on which the results were reported. Secondly all laboratory owners must be made legally responsible for ensuring that a patient's records are readily accessible and properly archived during the five year storage period irrespective of changes in the laboratory's ownership through a sale of shares or a sale of the laboratory's business. The vendor of the shares or the laboratory's business should carry a primary legal responsibility to store the records, though the option to transfer this legal responsibility as a condition of the sale to the purchaser should be permitted. Similar provisions should apply to laboratory amalgamations. In this case the newly merged entity should be responsible for storing the records.*

41 The retention of records, cytology smears and histology specimens are closely linked with the Health (Retention of Health Information) Regulations 1996. Currently, the minimum retention period of 10 years does not apply to cytology or histology specimens. Cabinet has agreed that the Health Act be amended to enable the Health (Retention of Health Information) Regulations 1995 to be extended to include cervical slides and specimens. [CAB Min (01) 27/17 refers]

42 Laboratories will be required to retain slides and reports in safe storage for a minimum period. The ability to develop regulations for this area, however, is dependent upon legislative changes being made to the 'regulation-making' owers of the Health Act. Once these legislative changes are made (in association with the amendment of section 74A) work can commence on the development of regulations concerning the retention of slides and patient records.

*11.34 There should be a legal obligation on the Accident Compensation Corporation, the Medical Council and the Health and Disability Commissioner to advise the National Cervical Screening Programme's manager of complaints about the professional performance of providers to the Programme when complaints are made to those various organisations about the treatment of a patient in relation to the Programme.*

*11.35 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.*

*11.36 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.*

43 In October 2000 a discussion document was developed on a proposed Health Professionals Competency Assurance (HPCA) Bill to replace the current occupational statutes with updated legislation governing the regulation of all registered health professionals where there is a risk of harm to the public. This document sought comment on inter-agency information sharing on complaints about registered health professionals along with mechanisms for suspending practitioners considered to be a risk to public safety.

44 In May 2001 Cabinet approved a paper on a framework for the registration processes and competence provisions for all regulated health professionals.

45 A working group was established to consider proposed amendments to the Health and Disability Commissioner Act 1994 based on the Inquiry recommendations, the Cull report and the Stent report.

46 Over May and June 2001 the Comprehensive Bill Steering Group considered proposals for streamlining the complaints process for health and disability consumers and agreed to the development of a Cabinet paper proposing amendments to the Health and Disability Commissioner Act 1994 and the complaints and disciplinary procedures in the HPCA. Proposals included a legal obligation on the Health and Disability Commissioner to share information on complaints about health professionals who pose a risk to public safety, with ACC, registration bodies and the Director-General of Health

47 In August 2001, the Cabinet Education and Health Committee agreed to amendments to the Health and Disability Commissioner Act 1994 to streamline complaints processes, and to provisions for the inclusion in the Health Professionals Competency Assurance Bill for complaints and discipline. Cabinet confirmed the Education and Health Committee's amendments on the 13th August 2001. [CAB Min (01) 25/2 refers]

48 Instructions have been issued to Parliamentary Counsel Office for the drafting of the HPCA and amendments to the Health and Disability Act as part of the Comprehensive Bill planned for introduction later this year. Drafting has taken longer than anticipated. Progress over the next few months will be dependent upon completion of the legislative drafting, departmental and Coalition consultation, further select committee consideration of the drafting and the legislative timetable within the House. A revised date for the introduction of this legislation is now expected following further briefings to the Minister.

49 Royal assent was received for the Injury Prevention and Rehabilitation Bill in Mid September 2001. This legislation includes legal obligations on ACC to share information on medical misadventure claims with the Health and Disability Commissioner, registration bodies, employers and the Director-General of Health.

*11.44 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.*

50 The Cabinet Education and Health Committee has agreed the HPCA Bill will contain provisions that require:

- colleagues and employers to report health professionals who may not be fit to practise due to a mental or physical condition, or where they believe that a health professional is practising below an acceptable standard, to the appropriate registering authority;
- employers to notify the appropriate registering authority when a health professional has been dismissed or has resigned for reasons relating to competence, fitness to practise or posing a risk to the public.

51 The Cabinet Education and Health Committee also agreed that those who notify are protected from civil and criminal liability provided that they acted in good faith and with reasonable care.

**Ethics Committees**

> *11.19 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.*
>
> *11.21 Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies.*
>
> *11.23 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.*

52 Section 16 of the NZ Public Health and Disability Act 2000 requires the Minister of Health to establish a National Advisory Committee on Health and Disability Support Services Ethics (the National Ethics Committee) to advise on ethical issues of national significance related to health and disability support services. This committee is due to be established by 30 November 2001.

53 The National Ethics Committee's Terms of Reference identify, as its first task, the requirement to deal with Inquiry Report recommendations 19 and 21.

54 The National Ethics Committee will also be an independent body from which a second opinion may be obtained if there is dissatisfaction with an ethics committee decision regarding the approval or withholding of research on clinical practice.

55 The Ministry's intention was that these recommendations would be dealt with through revisions to the 1996 operational standard for ethics committees. The review of this standard had been underway prior to the completion of the Gisborne Inquiry. In June 2001 the revised *Draft for Health and Disability Ethics Committees,* incorporating the recommendations above, was released for consultation. The closing date for submissions was extended until the end of August at the request of chairs of regional ethics committees.

*11.18 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.*

*11.20 Ethics Committees require guidance regarding the application of the Privacy Act and the Health Information Privacy Code. Ethics Committees need to be informed that the interpretation 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.*

56 While not all submissions were unfavourable, significant concerns about the changes made to the 1996 standard in the June 2001 draft document were expressed by the Health Research Council (HRC) and the Chairpersons of Health and Disability Ethics Committees. The chairpersons advised the Minister that in their view the June 2001 draft Standard was unacceptable in terms of international practice, and would not be a workable replacement to the 1996 National Standard.

57 Officials met with the Ethics Committee chairpersons and representatives of the HRC on 24 August 2001, where it was agreed that the June 2001 draft would be replaced by a document that was more closely based on the 1996 National Standard. This document would be treated as an Interim Standard, as it would need to be reconsidered once the major review of the operation of ethics committees was completed by the National Ethics Committee. Where agreement could not be reached on controversial issues in the Interim Standard, it was agreed that these would be referred for consideration in National Ethics Committee review.

58 A further draft document was developed on this basis, and circulated in September. Meetings were held on 7 September and 8 October with representatives of the Health Research Council, the Ministry of Research, Science and Technology, regional ethics committees and University ethics committees to reach agreement on wording. It was intended that the Interim Standard would be published by 30 October 2001. This standard addresses both recommendations, although further work will be needed on defining audit, monitoring and evaluation as part of National Ethics Committee review.

*11.22 A national ethics committee should be established for the assessment of multi-centre or national studies.*

59 A briefing was provided to the Minister of Health on 27 August 2001 outlining the issues surrounding the Inquiry's recommendation to establish a National Ethics Committee to review proposals for multi-centre and national research. In the light of concerns that a national committee would not be able to adequately consider the impact that research may have on local communities, from which research participants are drawn, the Minister agreed on 8 October to direct the National Ethics Committees to consider this issue as part of the review of the operation of ethics.

## NCSP Operations

### Legal Assessment

> *11.5 There needs to be a full legal assessment of the Policy And Quality Standards For The National Cervical Screening Programme and the Evaluation and Monitoring Plan For The National Cervical Screening Programme to ensure that the requisite legal authority to carry out these plans is in place.*
>
> *11.6 The National Cervical Screening Programme should be thoroughly evaluated by lawyers to determine whether or not those persons charged with tasks under the Programme have the necessary legal authority to discharge them.*

60 Legal advisers have been appointed and documentation review is ongoing. On 11 June the NSU wrote to the Legal team outlining the identified issues requiring assessment. Attached were 41 NCSP (and related) documents for assessment and review.

61 The legal assessment is on track and the report is expected with the NSU by November 2001.

**Provision of statistical information**

*11.7 The National Cervical Screening Programme should issue annual statistical reports. These reports should provide statistical analysis to indicate the quality of laboratory performance. They should also provide statistical analysis of all other aspects of the Programme. They must be critically evaluated to identify areas of deficiency or weakness in the program. These must be remedied in a timely manner*

*11.8 Meaningful statistical information should be generated from both the National Cervical Screening Register and the Cancer Register on a regular basis. Attention must be paid not only to laboratory reporting rates but also to trends and the incidence of the disease, assessed by regions that are meaningful to allow some correlation between reporting profiles laboratories and the incidence of cancer. Because cervical smear tests may be read outside the region in which the smear test is taken, a recording system needs to be devised which identifies the region where smears are taken.*

62 The NSU intends to produce annual statistical reports. The first of these reports, covering the period 1996-98 is due for publication in December 2001. Peer review of this report is ongoing and there has been some delay in receiving feedback from reviewers.

63 A revised schedule has now been agreed for the publication of the 1999/2000 Statistical Report. The report will now be published in December 2002 allowing for delays in the publication of the 1996-98 report and for the external epidemiological input and expert peer review required.

64 Regular NCSP Independent Monitoring Group (IMG) reports are now being published. The first IMG report was publicly released on July 30th covering the three-month period October to December 2000. This is the first time that regular information is reported on how specific programme providers, including laboratories, are performing against a range of national indicators. The second IMG report is due for release in October 2001. There have been minor delays in the production of these reports and further consideration may be needed as to the frequency of publication of these reports. These are quarterly reports and hence, any minor delay impacts significantly on the publication date of subsequent reports.

65 The Cancer Registry currently produces annual statistics of the incidence of invasive cancer of the cervix and can provide regional breakdowns. NZHIS has

introduced internal measures to increase the timeliness, accuracy and completeness of reporting on the Cancer Registry. In addition, the redevelopment of the Cancer Registry currently underway, with completion due in November 2001, will enable the production of reports based on any subset of data, quickly and accurately.

66 Regional laboratory reporting rates are included in the quarterly monitoring reports. The University of Otago has been asked to assist with the correlation of reporting profiles of laboratories, the region in which smears were taken and the regional incidence of cervical cancer. Further discussion with the University on the timeframes for this work is required before a delivery date can be confirmed.

**Policy and Quality Standards**

*11.4 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.*

*11.9 The compulsory setting of a minimum number of smears that should be read 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 laboratory site will process a minimum of 15,000 gynaecological cytology cases; each pathologist will report at least 500 abnormal gynaecological cytology cases, cytotechnical staff must primary screen a minimum of 3,000 gynaecological cytology cases per annum. This should be implemented within 12 months.*

67 Community Laboratory Agreements incorporating the National Cervical Screening Programme's Interim Operational Policy and Quality Standards (Interim Standards) were signed in November 2000. Responsibility for the funding and contract monitoring of these agreements transferred to the NSU in July 2001.

68 The introduction of the Interim Standards resulted in 3 public hospital and 2 community laboratories ceasing to provide cervical cytology services. There are now 11 community laboratories and 2 public hospital laboratories providing cytology services to the NCSP.

69 DHB Agreements for NCSP Services, incorporating the Interim Standards, came into effect on July 1st 2001.

70 Further work is needed with regard to implementation of standards for smear takers. It was hoped to incorporate these standards into 2001/02 agreements with New Zealand Medical Association and Independent Practitioners Association Council. Given the limited time for negotiation the parties agreed that further work was needed. It is unlikely, given the reliance on contractual mechanisms to implement standards amongst providers, that standards could be implemented for smear-takers before June 2003. Additional work is required to explore other possibilities for the implementation of standards amongst smear-takers, including reference to the Health Professional Competency Assurance Bill, the Safety Bill and the reference to NCSP Interim Standards by the Health & Disability Commissioner in rulings on smear-taker cases. There are currently more than 6,000 smear-takers providing services to the NCSP.

71 There are two evaluation plans referred to in the Inquiry Report 1) the National Evaluation 1997, and 2) the HFA Evaluation and Monitoring Plan. Both plans will be reviewed, together with the NSU's Monitoring Framework in an effort to arrive at a single and more up to date framework for monitoring and evaluation.

*11.27 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.*

*11.32 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*

72 The current standards used by the NCSP are Interim Standards. A scoping document and project plan has been developed for their review. It is intended that the Standards will be reviewed for publication by December 2002. This revised schedule will ensure the Standards are well researched and consulted upon.

73 The NSU has commenced a review of laboratory coding issues. Standards will be developed in line with the review of the Policy and Quality Standards.

**NCSP Structure**

*11.10 There needs to be a balanced approach, which recognises the importance of all aspects of the National Cervical Screening Programme. The emphasis on smear taking and increasing the numbers of women enrolled on the Programme needs to be adjusted.*

*11.11 The culture which was developing in the Health Funding Authority regarding the management of the National Cervical Screening Programme under the management of Dr Julia Peters needs to be preserved and encouraged now that the Health Funding Authority has merged into the new Ministry of Health.*

*11.12 The National Cervical Screening Programme must be managed within the Ministry of Health as a separate unit by a manager who has the power to contract directly with the providers of the Programme on behalf of the Ministry. The Programme's delivery should not be reliant on the generic funding agreements the Ministry makes with providers of health services. For this purpose the unit will require its own budget.*

74 The above recommendations form part of current practice within the National Screening Unit.

75 The NSU recognises the importance of all aspects of the NCSP. Considerable emphasis has been placed on the implementation of Interim Standards and in establishing ongoing monitoring, audit and evaluation.

76 Continued emphasis is also placed on ensuring women obtain regular smear tests. The proportion of women aged 20-69 years who had a smear recorded on the NCSP-Register within the last 3 years was 73.1% (hysterectomy adjusted). The Independent Monitoring Group's first quarterly monitoring report recommended increased efforts to recruit women to the programme.

77 The NSU currently contracts directly with programme service providers through separate agreements, with the exception of smear-takers. Funding for colposcopy, laboratory and regional office and health promotion services was transferred to the NSU on 1 July 2001.

*11.13 The National Cervical Screening Programme should be under the control of a second or third tier manager within the Ministry. The Manager of the unit should as a minimum hold specialist medical qualifications in public health or epidemiology. As a consequence of the Programme's link with the Cartwright Report it has always had a female national co-ordinator. While there are understandable reasons for having the Programme managed by a woman it is not necessary for cervical screening programmes to have female managers. The cervical screening programme in New South Wales is managed by a male medical practitioner. The time has arrived for the National Screening Programme to be treated as a medical programme which is part of a national cancer control strategy. In the past its link with the Cartwright Report has at times resulted in its purpose as a cancer control strategy being compromised for non-medical reasons.*

78 Dr Julia Peters, a specialist in public health medicine is the clinical leader for the National Screening Unit's two screening programmes. The National Screening Unit retains its emphasis on maintaining strong clinical leadership for the programmes. The Unit also employs a further two public health medicine specialists within its Quality, Monitoring, Audit and Analysis Team. In addition, a Group Manager was appointed earlier this year and is a third tier management position within the Ministry of Health. On a day-to-day basis the Unit has a management approach which combines effective health service management with a strong clinical perspective. The complexity and make up of the two screening programmes within a Unit comprising 33 FTEs necessitates this type of approach.

*11.24 The National Cervical Screening Programme requires its own system to deal with complaints regarding the Programme's delivery. It also needs to have in place a user-friendly system, which can respond to complaints of Programme failures, such as under-reporting. The difficulty that witness A experienced in having her medical misadventure recognised as a failure of the Programme and a failure of Gisborne Laboratories must be avoided in the future.*

79 A mechanism to address individual complaints will need to tie in with legislative changes proposed within the Comprehensive Bill, including the sharing of information between agencies, and with procedures adopted by DHBs and

NCSP providers in meeting the requirements of the service specifications attached as schedules to agreements with the NSU.

**Workforce Development**

*11.28 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.*

*11.40 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.*

*11.41 If cytology is a significant component of a pathologist's practice then he or she must participate in continuing medical education in that subject.*

*11.42 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.*

80 In February 2001 the NSU commenced a Workforce Development Project to review education and training issues for all groups within both screening programmes and produce a Workforce Development Strategy. Three experienced contractors were engaged to review previously undertaken research, national and international literature and meet and consult with key stakeholders within the screening workforces, including professional groups, consumer groups, providers and educational institutions. A Research Report has been produced to inform the strategy development work. The Workforce Development Strategy is due for completion by 31 December 2001.

81 The recommendations of the Inquiry are a priority for this project and extensive work has been carried out to determine the issues related to cytoscreeners, cytotechnologists and pathologists undertaking cytopathology.

82 There is no current data regarding pathology workforce numbers, roles, and qualifications, hours worked, training and education requirements. The NSU therefore carried out a workforce survey in August 2001. Data collation is currently in progress.

83 Discussions with representatives of the Royal College of Pathologists Australasia (RCPA) have been held. Specific issues discussed have related to the impact the implementation of the NCSP Interim Standards and the setting of minimum smear volumes for laboratory sites and individuals, will have on training sites for the gynaecological cytology component of anatomical pathology registrar training. The Clinical Training Agency is also closely involved in discussions on this issue and continues to help address issues.

84 The project team has also met with representatives of all 3 education providers of the Bachelor of Medical Laboratory Science programme regarding the practical training component for those wishing to choose cytology as a sub-speciality option.

85 Discussions have followed with key personnel within the majority of NCSP laboratory sites providing undergraduate cytology training. Appropriate initiatives regarding recruitment, competence and ongoing training and education are being developed with input from the providers for inclusion in the Workforce Development Strategy.

86 The Interim Standards require minimum continuing educational requirements be met. The Workforce Development Strategy will identify initiatives for consideration of funding that will ensure availability of appropriate continuing education.

87 General discussions have been held regarding the requirement for cytoscreening training for pathologists wishing to function as primary screeners. It has become apparent that pathologists do not generally undertake, nor do they wish to undertake primary screening. Concerns have been expressed that Recommendation 11.40 came about as a result of the particular circumstances of Dr Bottrill's laboratory. The Workforce Development Project team and the NSU are currently not aware of any pathologist undertaking primary screening. The Workforce Development project survey should identify any pathologists who may be undertaking primary screening and thus enable the specific circumstances of any individual to be reviewed.

88 In addition to appropriate training for individuals undertaking cervical smear reading (screening), all cytoscreeners must meet the NCSP Interim Standards requirements for quality and minimum volumes effective from 1 July 2001.

89 Options for cytopathology-specific educational qualifications for pathologists practising cytopathology are being assessed according to international availability. These options have been presented to NCSP pathologists, although at this stage there would appear to be a lack of support for the project initiatives from pathologists practising cytopathology. Further advice will be sought from Dr McGoogan on this issue.

90 No New Zealand pathologists have ever undertaken the RCPA Part II Anatomical Pathology examination slanted toward cytopathology. Few Australians have undertaken this examination and thus the RCPA will cease to offer this as an option for anatomical pathology trainees (registrars) from 2001. From 2001 all anatomical pathology trainees will be required to successfully complete a cytology component for the standard Part II examination. No New Zealanders have ever completed the RCPA post-Fellowship Diploma in Cytopathology.

91 In addition to the standard Part II examination in Anatomical Pathology, all trainee anatomical pathologists will be required to undertake a practical examination in cytology from 2002. This will ensure a degree of practical competence for all new anatomical pathologists. The Workforce Development Project is awaiting further information regarding the specifics of this examination.

*11.39 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.*

92 The NSU recognised that in order for this message to be communicated in the most effective way a multi-focussed approach was necessary. Discussion with the Royal New Zealand College of General Practitioners has commenced and various options have been discussed on how best to convey this message. It is also acknowledged that the NZ Nurses Organisation would also be an appropriate contact. A letter for distribution is being finalised and was due to be sent to all individual smear takers before the end of October. Articles in medical and nursing journals will also be written for publication later in the year.

*11.37 It is recommended that the Programme liase with the Royal College of Pathologists of Australia. In its submissions the Royal College advised that it believed that the collaborative relationship the college had with the Federal Government in Australia might be a model worth consideration by the Inquiry. It was suggested that it was appropriate to use medical colleges as an over-arching body to provide advice on issues. The benefit of this is, if the College is asked to provide an opinion on issues such as professional practice, quality or standards, it has access to the views from multiple professionals and also a critical evaluation of current literature in contemporary standard practices. It is suggested that the National Cervical Screening Programme, which has achieved a great deal, would benefit from greater professional input at a College level. In particular, it is suggested that a National Cervical Cancer Register and a Cervical Cancer Mortality Review process be a means of continually evaluating the Programme's effectiveness. The Committee supports the College's submission and recommends that it be acted upon.*

*11.43 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.*

93 The NSU has developed a collaborative relationship with the Royal College of Pathologists of Australasia (NZ). The ongoing relationship with the College is part of NSU current practice. Representation is sought on all matters where expert pathology advice is required. College nominees sit on the NSU Advisory Group and the Independent Monitoring Group.

94 A meeting with the Royal College of Pathologists of Australasia (NZ) was held to discuss the issue of "open mindedness" and the issue of encouraging pathologists to be more critical of laboratory performance.

*11.45 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.*

95 The NSU employs a number of mechanisms in order to identify deficiencies in the NCSP, over and above ongoing monitoring reports. These include:

- Monthly DHB and community laboratory contract monitoring.
- Quarterly qualitative reporting from NCSP Regional Offices identifying emergent issues.
- Annual reporting from DHBs on Colposcopy Services.
- A Provider Self-Assessment Questionnaire regarding compliance with Interim Standards – all NCSP community laboratories completed this exercise in March 2001. The two public hospital laboratories are currently completing this exercise.
- Handling of complaints which may highlight a particular deficiency in the programme or at a programme provider level.
- Handling of requests for information from the Health & Disability Commissioner, which may highlight a particular deficiency to the NSU.

96 User Surveys and Provider Compliance Audits, similar to those carried out within the BreastScreen Aotearoa, are planned for the future and work is ongoing to scope these activities.

**Information to Women**

*11.38 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.*

97 Prior to the release of the Inquiry report the NSU contracted Women's Health Action (WHA) to develop a new, more detailed brochure for women regarding the NCSP including the benefits and risks of screening. The NSU has a user-friendly website as well as an 0800 number to give easy access to women. It is recognised however, that information to women will come in different ways.

98 It was hoped that the brochure would be available by December 2001. A revised schedule was agreed between NSU and WHA for delivery of the Brochure by June 2002. The new brochure will also need to incorporate the requirements associated with changes to Section 74A of the Health Act. The first draft of the detailed brochure has been delivered to the NSU. Feedback has been given by NSU in preparation for the first focus group.

**Information technology**

*11.25 The National Cervical Screening Register needs to be electronically linked with the Cancer Registry.*

99 Information from the Cancer Registry for 1996-2000 has been released to the NSU in electronic form, and this process will continue in the future. However, the current non-disclosure provisions of Section 74A of the Health Act prevent the NSU from providing the Cancer Registry with information that would allow it to improve the quality of its information where the only source for such corrections is the NCSP-Register.

100 The NSU and NZHIS have finalised a scoping paper detailing the process for data assurance between the NCSP-Register and the Cancer Registry.

101 A data assurance exercise has been performed between the NCSP-Register and the Cancer Registry, linking data between the Register and the Registry electronically. This exercise, referred to in previous monthly reports as Phase 1, is now complete.

102 Further investigation has taken place into the requirements for automated electronic links between the NCSP-Register and the Cancer Registry (referred to in previous monthly reports as Phase 2). No compelling requirements for automated electronic links, beyond those already successfully implemented, have been identified. Phase 2 has therefore been discontinued.

*11.26 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.*

103 The currency of information on the Cancer Registry has been a priority in recent times with information now being available up to the year 2000. This level of timeliness ranks New Zealand as a leader internationally. Laboratory reporting to NZHIS has shown a marked improvement in terms of timeliness and completeness in recent months. Internal measures introduced by NZHIS have led to reporting on the Cancer Registry with regard to cancer of the cervix being up-to-date within two weeks of receipt of laboratory reports.

104 Performance standards for the NCSP-Register have been incorporated into DHB Agreements. The NCSP-Register Operating Protocol Version 2.0 has been released in draft and awaits final release in the next month.

105 Further research is being carried out on current performance standards, and a scope for the remaining work will commence shortly.

*11.31 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.*

106 This requirement will form part of the NSU's development of an Information Systems Strategy. The Strategy in turn will be informed by other developments currently under way within the Ministry of Health, notably the WAVE project. The aim is to develop a common approach, encompassing common standards for messaging and coding, the use of open technology standards rather than proprietary standards, and a common and secure transport mechanism for data.

*11.33 The National Cervical Screening Programme should work towards developing a population based register and move away from being the utility based register that it now is.*

107 The current NCSP-Register is a 'utilisation' register. This means it is based only on the women choosing to participate in the NCSP, rather than being based on population criteria (for example, all eligible women living in a defined area). While there are a number of population databases in existence in New Zealand, further work needs to be carried out to assess the feasibility of using such databases as an integral and ongoing part of the NCSP.

108 A draft scoping paper has been prepared. The NSU is developing a policy for the utilisation of a population-based register for screening programmes. This policy will be a significant input into a cross-directorate workgroup within the Ministry for the establishment of a common population register. The directorates involved are Public Health, Personal and Family Health and Corporate Information and Finance. A convergence of requirements has been identified, encompassing the needs of an Immunisation Register, the screening programmes, primary care and the findings presented in the WAVE report. The primary candidate identified to date for use as a population register is the National Health Index (NHI), and detailed analysis of its suitability and necessary improvements for this purpose is underway.

109 In addition, research on international models of population registers is being undertaken.

**Progress Reporting and Dr McGoogan's Visit**

*11.46 A process to ensure that the recommendations made by the Committee are implemented should be put in place.*

110 Monthly Reports have been produced in the first 6 months since the Inquiry Report was released. These reports chart progress on the implementation of

the Inquiry recommendations against an agreed milestone plan. These reports are available on the website www.csi.org.nz

111 Over 50 staff and contractors are engaged in the implementation of the Inquiry recommendations. A number of sub-project teams are responsible for delivery of one or more of the recommendations:

- NCSP Evaluation; 2 sub-project teams.
- Legislative changes; 3 sub-project teams.
- Ethics committees; 2 sub-project teams.
- NCSP operations; 5 sub-project teams.

112 Each sub-project team reports in detail on a monthly basis to the CSI Steering Group.

113 Monthly teleconferences have been held between the DDG Public Health, Don Matheson, the Chair of the CSI Steering Group, Karen Mitchell, and Dr McGoogan. Dr McGoogan has received over 45 documents and reports covering information and progress on the various recommendations.

114 Following on from Dr McGoogan's 6-month visit to NZ, she will provide a report to the Minister of Health on progress over the first 6 months. During Dr McGoogan's 10-day visit she is scheduled to meet with Ministry staff, sub-project teams and external stakeholders. She will also accompany the Minister and Director General to Gisborne on 8th November 2001.

## APPENDIX 1

## TABLE 1.0 IMPLEMENTATION OF RECOMMENDATIONS REVISED SCHEDULE

| Ref. | Recommendation | Underway/ Complete | Original Timetable (Commence/ Complete | Revised Timetable (Commence/ Complete | Comment |
|---|---|---|---|---|---|
| 1. | Part 2; and<br><br>Part 3<br><br>of the National Evaluation Plan of the NCSP to be completed within six months | Complete<br><br>Underway | June 2001<br><br>August 2002 | July 2001<br><br>**October 2002** | Delays due to need to seek ethics approval and appointment of auditors. |
| **2.** | Once Part 3 is completed and if there is doubt about the acceptable rate of abnormal smears in New Zealand, then all women should be asked to re-enrol in the NCSP and have two annual smears | | | | |
| **3.** | Cox's 1997 recommended evaluation of the NCSP should be commenced within eighteen months | Underway | To commence by August 2002 | December 2002 | Some aspects already completed or included within other work including Cancer Audit and Statistical Reporting.<br><br>Overall delay partly due to late publication of NCSP Statistics Report 1999/00. Consultation on finalisation of NCSP Statistics Report 1996/98 has pushed out preparation of next report. |

| Ref. | Recommendation | Underway/ Complete | Original Timetable (Commence/ Complete | Revised Timetable (Commence/ Complete | Comment |
|---|---|---|---|---|---|
| **4.** | The Policy and Quality Standards for the NCSP and the Evaluation and Monitoring Plan for the NCSP should be implemented within the next 12 months.<br><br>DHBs & Laboratories<br><br>Smear Takers | <br><br><br><br>Complete<br><br>Underway | <br><br><br><br>July 2001 | <br><br><br><br>July 2001<br><br>**July 2003** | Delay in implementing smeartaking standards. NSU does not contract directly with smeartakers. Negotiations with NZMA and IPAC required more time and consultation to implement the standards. |
| **5.** | There should be a full legal assessment of the Policy and Quality Standards for the NCSP and the Evaluation and Monitoring Plan. | Underway | November 2001 | November 2001 | On track to complete draft report by November 2001. Legal assessment may highlight the need for further work in some areas |
| **6.** | The NCSP should be thoroughly evaluated by lawyers to determine whether or not those persons charged with tasks under the Programme have the necessary legal authority to discharge them. | Underway | November 2001 | November 2001 | On track to complete draft report by November 2001. Legal assessment may highlight the need for further work in some areas |
| **7.** | The NCSP should issue annual statistical reports.<br><br>1996-98<br><br>1999-00 | <br><br>Underway | <br><br>June 2001<br><br>Dec 2001 | <br><br>**Dec 2001**<br><br>**Dec 2002** | Overall delay partly due to planned late publication of NCSP Statistics Report 1990/00. Consultation on finalisation of NCSP Statistics Report 1996/98 has pushed out preparation of next report. |

| Ref. | Recommendation | Underway/ Complete | Original Timetable (Commence/ Complete | Revised Timetable (Commence/ Complete | Comment |
|---|---|---|---|---|---|
| **8.** | Meaningful statistical information should be generated from both NCSP-Register and Cancer Registry. | Underway | December 2001 | Dec 2002 | Overall delay partly due to planned late publication of NCSP Statistics Report 1990/00. Consultation on finalisation of NCSP Statistics Report 1996/98 has pushed out preparation of next report. |
| **9.** | The compulsory setting of a minimum number of smears that should be read by laboratories each year must be put in place. | Completed | July 2001 | July 2001 | |
| **10.** | There needs to be a balanced approach, which recognises the importance of all aspects of the NCSP. | Completed | | | |
| **11.** | The culture that was developing in the HFA regarding the management of the NCSP under the management of Dr Julia Peters needs to be preserved. | Completed | | | |
| **12.** | The NCSP must be managed within the MoH as a separate unit by a manager who has the power to contract directly with the providers of the programme. | Completed | | | |
| **13.** | The NCSP should be under the control of a second or third tier manager within the Ministry. The Manager of the unit should as a minimum hold specialist medical qualifications | Completed | | | |

| Ref. | Recommendation | Underway/ Complete | Original Timetable (Commence/ Complete | Revised Timetable (Commence/ Complete | Comment |
|---|---|---|---|---|---|
| **14.** | The Health Act 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. | Underway | June 2002 | June 2002 | Legislative drafting taking longer than anticipated, further progress dependent upon departmental and Coalition consultation, further select committee consideration and legislative timetable in the House. |
| **15.** | There needs to be reconsideration of the Kaitiaki Regulations, and the manner in which those regulations currently affect the Ministry of Health gaining access to aggregate data of Maori women enrolled on the NCSP. | Underway | June 2002 | June 2002 | |
| **16.** | The present legal rights of access to information on the Cancer Registry need to be clarified. | Underway | June 2002 | June 2002 | Legislative drafting taking longer than anticipated, further progress dependent upon departmental and Coalition consultation, further select committee consideration and legislative timetable in the House. |

| Ref. | Recommendation | Underway/ Complete | Original Timetable (Commence/ Complete | Revised Timetable (Commence/ Complete | Comment |
|---|---|---|---|---|---|
| **17.** | The Health Act 1956 requires amendment to enable the MoH and any appropriately qualified persons it engages to carry out audits, monitoring or evaluation of cervical cancer incidence to have ready access to medical files recording the treatment of cervical cancer by all health providers who had a role in such treatment. | Underway | June 2002 | June2002 | Will not be implemented as recommended. |
| **18.** | There needs to be a change to guidelines under which ethics committees operate. | Underway[2] | To commence September 2001 | Commenced. | Interim Standard to be published 30 October 2001. |
| **19.** | 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 NZ | Underway | To commence September 2001 | Commenced. | To be referred to the National Ethics Committee for further consideration, once established. |
| **20.** | Ethics Committees require guidance regarding the application of the Privacy Act and the Privacy Health Information Code. | Underway[3] | June 2001 | **September 2001** | Interim Standard to be published 30 October 2001. |

[2] Was previously identified as Complete in Monthly Report 3 and corrected in Monthly Report 4. Further analysis indicated a need to re-designate this recommendation as underway.
[3] Was previously identified as Complete in Monthly Reports 3, 4, 5 and 6. Further analysis has indicated a need to re-designate this recommendation as underway.

| Ref. | Recommendation | Underway/ Complete | Original Timetable (Commence/ Complete | Revised Timetable (Commence/ Complete | Comment |
|---|---|---|---|---|---|
| **21.** | Ethics Committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies. | Underway | June 2001 | **Dependent upon National Ethics Committee timetable.** | To be referred to the National Ethics Committee for further consideration, once established. |
| **22.** | A national ethics committee should be established for the assessment of multi-centre or national study | Underway | September 2001 | **Dependent upon National Ethics Committee timetable.** | To be referred to the National Ethics Committee for further consideration, once established. |
| **23.** | The procedures underwhich 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. | Underway | To commence September 2001 | **Dependent upon National Ethics Committee timetable.** | To be referred to the National Ethics Committee for further consideration, once established. |
| **24.** | The NCSP requires its own complaints system to deal with complaints regarding programme delivery. | Underway | November 2001 | **June 2002** | Delivery of this recommendation will be tied in with Comprehensive Bill |
| **25.** | The NCSP-R needs to be electronically linked with the Cancer Registry. | Complete | From June 2002 | | |
| **26.** | Performance Standards should be put in place for the NCSP-Register and the Cancer Registry. | Underway | December 2001 | **June 2002** | This work will be tied in with the review of the NCSP quality standards and the development of routine monitoring and audit. |
| **27.** | Standards for the NCSP should be reviewed every two years and more frequently if monitoring indicates that some of the standards are inappropriate. | Underway | June 2002 | **December 2002** | The scope of this project includes extensive consultation and resources hence the projected delay. |

| Ref. | Recommendation | Underway/ Complete | Original Timetable (Commence/ Complete | Revised Timetable (Commence/ Complete | Comment |
|---|---|---|---|---|---|
| **28.** | 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. | Underway | Project work complete by December 2001 | December 2001 | On track. |
| **29.** | The Medical Laboratory Technologists 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 cytology | Underway | June 2002 | June 2002 | |

| Ref. | Recommendation | Underway/ Complete | Original Timetable (Commence/ Complete | Revised Timetable (Commence/ Complete | Comment |
|---|---|---|---|---|---|
| **30.** | Legal obligations in addition to those mandated by IANZ must be imposed on all laboratories reading cervical cytology requiring them to retain records of patients' cytology and histology results (including slides, reports and any other material relating to the patient) in safe storage for a period of no less than five years from the date on which the results were reported. Secondly all laboratory owners must be made legally responsible for ensuring that a patient's records are readily accessible and properly archived during the five year storage period irrespective of changes in the laboratory's ownership through a sale of shares or a sale of the laboratory's business. The vendor of the shares or the laboratory's business should carry a primary legal responsibility to store the records, though the option to transfer this legal responsibility as a condition of the sale to the purchaser should be permitted. Similar provisions should apply to laboratory amalgamations. In this case the newly merged entity should be responsible for storing the records. | Underway | June 2002 | June 2002 | Legislative drafting taking longer than anticipated, further progress dependent upon departmental and Coalition consultation, further select committee consideration and legislative timetable in the House. |
| **31.** | The cervical smear test and histology histories of women enrolled on the NCSP-R should be made electronically available online to all laboratories. | Underway | June 2002 | June 2002 | |

| Ref. | Recommendation | Underway/ Complete | Original Timetable (Commence/ Complete | Revised Timetable (Commence/ Complete | Comment |
|---|---|---|---|---|---|
| **32.** | Standards must be developed for ensuring the accuracy of laboratory coding and this aspect of the NCSP-R must be subject to an appropriate quality assurance process. | Underway | June 2002 | June 2002 | |
| **33.** | The NCSP should work towards developing a population register and more away from being the utility based register that it is now. | Underway | | June 2003 | |
| **34.** | There should be a legal obligation on the Accident Compensation Corporation, the Medical Council and the Health and Disability Commissioner to advise the National Cervical Screening Programme's manager of complaints about the professional performance of providers to the Programme when complaints are made to those various organisations about the treatment of a patient in relation to the Programme. | Underway | June 2002 | June 2002 | Legislative drafting taking longer than anticipated, further progress dependent upon departmental and Coalition consultation, further select committee consideration and legislative timetable in the House. |

| Ref. | Recommendation | Underway/ Complete | Original Timetable (Commence/ Complete | Revised Timetable (Commence/ Complete | Comment |
|---|---|---|---|---|---|
| **35.** | 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. | Underway | June 2002 | June 2002 | Legislative drafting taking longer than anticipated, further progress dependent upon departmental and Coalition consultation, further select committee consideration and legislative timetable in the House. |
| **36.** | 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. | Underway | June 2002 | June 2002 | Legislative drafting taking longer than anticipated, further progress dependent upon departmental and Coalition consultation, further select committee consideration and legislative timetable in the House. |

| Ref. | Recommendation | Underway/ Complete | Original Timetable (Commence/ Complete | Revised Timetable (Commence/ Complete | Comment |
|---|---|---|---|---|---|
| **37.** | It is recommended that the Programme liase with the Royal College of Pathologists of Australia. In its submissions the Royal College advised that it believed that the collaborative relationship the college had with the Federal Government in Australia might be a model worth consideration by the Inquiry. It was suggested that it was appropriate to use medical colleges as an over-arching body to provide advice on issues. The benefit of this is, if the College is asked to provide an opinion on issues such as professional practice, quality or standards, it has access to the views from multiple professionals and also a critical evaluation of current literature in contemporary standard practices. It is suggested that the National Cervical Screening Programme, which has achieved a great deal, would benefit from greater professional input at a College level. In particular, it is suggested that a National Cervical Cancer Register and a Cervical Cancer Mortality Review process be a means of continually evaluating the Programme's effectiveness. The Committee supports the College's submission and recommends that it be acted upon. | Complete | | | |

| Ref. | Recommendation | Underway/ Complete | Original Timetable (Commence/ Complete | Revised Timetable (Commence/ Complete | Comment |
|---|---|---|---|---|---|
| **38.** | 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. | Underway | Ongoing | **June 2002** | Revised schedule agreed with Women's Health Action. |
| **39.** | Medical practitioners need to be reminded that cervical smear tests are not a means of diagnosing cervical cancer. | Underway | May 2001 | **October 2001** | |
| **40.** | Primary screening of cervical smears should only be performed by individuals who are appropriately trained for the task. | Underway | December 2001 | December 2001 | On track. |
| **41.** | If cytology is a significant component of a pathologists practice then he or she must participate in continuing medical education. | Underway | December 2001 | December 2001 | On track. |

| Ref. | Recommendation | Underway/ Complete | Original Timetable (Commence/ Complete | Revised Timetable (Commence/ Complete | Comment |
|---|---|---|---|---|---|
| **42.** | If cytology is a major component of a pathologists practice, it is desirable that he or she should have added qualifications in cytopathology. | Underway | December 2001 | December 2001 | On track. |
| **43.** | 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. | Underway | December 2001 | December 2001 | On track. |
| **44.** | 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. | Underway | June 2002 | June 2002 | Legislative drafting taking longer than anticipated, further progress dependent upon departmental and Coalition consultation, further select committee consideration and legislative timetable in the House. |
| **45.** | The NCSP should have 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. | Underway | Ongoing | Ongoing | |
| **46.** | A process to ensure that the recommendations made by the committee are implemented should be put in place. | Underway | | | |