PROGRESS IN IMPLEMENTING THE CERVICAL SCREENING INQUIRY RECOMMENDATIONS

INDEPENDENT REPORT

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REMIT

My remit is to provide the Minister with independent expert advice on the progress, quality and thoroughness of implementation of the Cervical Screening Inquiry Recommendations.

REPORT

1. I read the *REPORT OF THE MINISTERIAL INQUIRY INTO THE UNDER-REPORTING OF CERVICAL SMEAR ABNORMALITIES IN THE GISBORNE REGION* with interest having been privileged to give evidence at the Inquiry itself. The Cervical Screening Inquiry (CSI) Team is to be commended. This is an excellent Report, written in plain everyday English and easy to read. It not only describes the deficiencies that were found in the Gisborne Region but also describes clearly what cervical screening is all about and what can and cannot be achieved. It is a good source of much useful information. I know that many computer generated copies were distributed when the CSI Report was made public in April 2001 and that the Report was posted on the Minister's website. However, I am very disappointed that the Report has never been published in hard copy form.

2. **I recommend that the CSI Report be published in hard copy form so that the public can purchase a copy in bookstores or borrow it from the library.**

3. The CSI Team required that implementation of their recommendations be completed within a year. This was a very tight timescale and to some extent a little idealistic. However, I understand that the Minister, in May 2001, accepted the Report together with its recommendations and gave a commitment to an open, transparent process of implementation.

4. Responsibility for implementation of the CSI Recommendations is split across four different directorates of the Ministry of Health: Sector Policy; Corporate and Information; Public Health and Personal and Family Health Services. Only thirty recommendations fall directly to the National Screening Unit (NSU) within the Public Health directorate. Cross directorate teams are responsible for implementing the remainder. These have brought together individuals with a wide range of expertise

based in different geographic locations many of whom have no previous experience in population screening programmes.

5. A CSI Steering Group has been established to coordinate activity across directorates of the Ministry of Health. The Ministry of Health issues monthly progress reports which are posted on the website.

6. **I note that there has been a slippage in milestones in several areas mainly due to the proposed legislative changes**. **I also have some concerns that, from time to time, there have been conflicts between the priorities of the CSI implementation and other Ministry business, which have resulted in delays.**

7. I visited New Zealand from 29 October – 10 November 2001 to undertake an on-site investigation into progress during the first six months. Prior to my visit, I was sent copies of the Ministry of Health Monthly Reports and other relevant documents and I was able to discuss these at regular teleconferences with Don Matheson, Deputy Director General and Karen Mitchell, Manager, NSU.

8. **Dr Julia Peters, Clinical Director, NSU has not participated in these monthly teleconferences but I believe her input would prove useful in the future.**

9. During my visit I had 35 separate meetings and met with over 100 individuals (Appendix 1). I am grateful to Karen Mitchell, Dr Julia Peters and all the staff of the National Screening Unit for facilitating these meetings with such a wide range of interested parties. I would particularly like to record my thanks to Esther Blomfield and Julie MacDonald for their excellent secretarial and personal assistance during my visit.

10. I am satisfied I have been able to have frank and open discussions with each of the groups with whom I met. I had not expected to be furnished with quite such an immense volume of information as I amassed during my first visit only six months after the CSI Report was published! I have tried to carefully consider all the information in order to provide as comprehensive a report as possible.

11. I would like to formally acknowledge the commitment, enthusiasm and dedication of the staff of the National Screening Unit (NSU). The Unit has put a tremendous effort into improving the quality of the National Cervical Screening Programme (NCSP) at all levels despite a serious shortfall of staff in post.

12. I was also struck by the overall willingness to accept change and a commitment to quality in the vast majority of the health professionals with whom I met during my visit.

13. I realise that many people in many areas have done a great deal of work. The NCSP is developing a strong identity and I sense the beginnings of real ownership of the Programme by health professionals and women. The culture is slowly changing from a "them and us" situation. This is definitely true of Laboratories and Regional Offices, and to a lesser extent, of Practice Nurses and Colposcopists. Unfortunately, I have the impression that General Practitioners still feel rather divorced from the Programme.

14. Quality standards for laboratories and colposcopy have been developed and are being implemented. Routine monitoring of performance indicators is being put in place with regular statistical reporting. Processes for NSU to contract for services are in place and most contracts signed. Much has been done in building sector relationships, workforce planning and health promotion as well as developing competent and appropriate media relationships.

15. While I take issue with the descriptors used in the Six Month Summary Report ("Complete" and "On Track"), I am satisfied that **progress** against the following recommendations is satisfactory:

Recommendation 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 1.

Recommendation 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.

Recommendation 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.

Recommendation 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.

Recommendation 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

Recommendation 11.10

There needs to be a balanced approach, which recognises the important 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.

Recommendation 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.

Recommendation 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

Recommendation 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 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

Recommendation 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.

Recommendation 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.

Recommendation 11.37

It is recommended that the Programme liaise 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.

Recommendation 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.

Recommendation 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 cytocreeners if they want to function as primary screeners.

Recommendation 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 then reactive in the delivery of the programme would be useful.

Recommendation 11.46

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

16. I note with disappointment that the Six Month Summary Report indicates that some delays have been experienced in implementing twenty-one of the recommendations (*11.1, 11.3, 11.7, 11.8, 11.14, 11.16, 11.17, 11.20, 11.21, 1.22, 11.23, 11.24, 11.26, 11.27, 11.30, 11.34, 11.35, 11.36, 11.38, 11.39* and *11.44*) and revised schedules have been submitted.

17. **However, I am not satisfied that progress against Recommendations *11.11, 11.12, 11.13* and *11.25* is satisfactory far less "complete" as assessed in the Six Month Summary Report. Nor am I satisfied that enough progress has been made implementing Recommendations *11.15, 11.18, 11.19, 11.28, 11.29, 11.32, 11.33, 11.41, 11.42, 11.43, 11.45* which are listed as "On track".**

18. **Much work remains to be done and it is now extremely unlikely that all the recommendations will be implemented within the twelve months period. Despite very good progress in many areas, I have serious concerns about momentum in the following specific areas.**

THE RETROSPECTIVE CANCER AUDIT.

Recommendation 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 Douglass 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 systematic problem of under-reporting in New Zealand laboratories cannot be excluded.

Recommendation 11.2

If the national evaluation throws doubt on the accuracy of the current national average then the Committee recommends that all women who are or who have participated in the Programme should be invited to re-enroll on the register as new entrants and they should be offered two smear tests 12 months apart. Women who have never enrolled on the Register or who have had their names removed from the Register should be invited through notices in the print media to also go through the process of having two smear tests twelve months apart

19. **It is not acceptable that the audit of the clinical histories of women who have developed cervical cancer over the previous few years has not yet started. This should have been completed by now or at least be well advanced. It was the first and one of the most important recommendations of the CSI Team. We know that an effective cervical screening programme gives a huge benefit to women. In view of the deficiencies identified in the Gisborne Region, one cannot re-assure New Zealand women that their NCSP is safe and effective without confirmation from this retrospective cancer audit.**

20. The Cancer Epidemiology Unit at Otago University had been deeply involved in planning the audit and Professor David Skegg, Head of the Unit, gave vital evidence at the CSI. The Ministry of Health terminated the Cancer Audit contract with Otago University at the end of 2000 and the Otago team has indicated that they will not undertake the retrospective cancer audit.

21. In the meantime, the Cancer Audit Project Team within the NSU, headed by Dr Ruth Herbert has carried out a great deal of excellent work in preparation for the retrospective cancer audit. They have understood the need for a comprehensive audit model to include every woman who has had a cervical cancer diagnosed during the chosen time period, not just those women with smears on the NCSP-Register. They have undertaken a literature review and prepared a draft Framework document assimilating issues and decisions based upon the original the protocol proposed by the University of Otago. I am very impressed with the work that has been done to date.

22. However, the audit design has nine phases and only Phase One is completed. The resource and epidemiological expertise within the NSU is limited and this work now needs to be contracted out to a suitably skilled epidemiology unit**.** While there are other academic departments of epidemiology in New Zealand, I understand that the only cancer epidemiology unit is in Otago University.

23. **At the time of my visit, no contract was in place to undertake this audit although negotiations were underway with another academic epidemiology department.**

This group does not appear to have the same level of experience and expertise in population screening programmes as does the Otago Group and would probably require major support from the National Screening Unit (NSU) to deliver the retrospective cancer audit. As you will see in paragraphs 57 – 79 below, the resources within the NSU are already severely stretched and, in my opinion, the degree of support required cannot be delivered from within the NSU.

24. Furthermore it was considered that approaching 14 ethics committees, recruiting and training investigators, contacting the women for permission to review their screening history, carrying out the investigation and completing the analysis would take at least two years from the start date.

25. I cannot accept that New Zealand women must wait until 2004 for reassurance that their NCSP is safe and effective. More resource must be found to complete the retrospective cancer audit as quickly as possible while ensuring full collection of the necessary data.

26. The numbers of women who have developed cervical cancer over the last few years are relatively small in epidemiological terms and even a few women withholding their consent would compromise the validity of the results. Efforts must be made to explain carefully to the women involved the value of a comprehensive audit in identifying deficiencies that, if not addressed, might lead to other women developing cervical cancers that might have been prevented.

27. Access to GP records of women who develop cervical cancer is simply required to discover whether a smear test was ever offered to these women and to find smear test results not included in the NSCP-Register. It is not designed to provide a research opportunity for academics or to use women as experimental animals. In this respect, the checking of the GP records is no different from another healthcare professional checking hospital or laboratory records in the course of a patient's clinical care.

RELATIONSHIP BETWEEN OTAGO UNIVERSITY AND THE MINISTRY OF HEALTH

28. I am very concerned about the strained relationship between the Cancer Epidemiology Unit in Otago University and the Ministry of Health. The Otago team works closely with the NSU in the monitoring of both Breast Screen Aotearoa and the NCSP. The Otago team has an international reputation in the field of cancer epidemiology. It is extremely unfortunate that the situation between the Otago team and the Ministry of Health could not be resolved and that the Otago team feels unable to lead the retrospective cancer audit. The responsibility for auditing and monitoring the NCSP lies ultimately with the NSU. The NSU must collaborate closely with expert epidemiologists and statisticians so that each fully understands the others' point of view in setting up audits and to ensure that perceived deficiencies identified are appropriately investigated, clarified and / or resolved.

29. I hope that both sides will review the situation and attempt to resolve their differences so that the Otago team's expertise will continue to be available to support the NSU in the future.

LEGISLATIVE CHANGES:

Recommendations 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 section 74A of the Health Act to permit such persons to have ready access to all information on the National Cervical Screening Register.

Recommendations 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.

Recommendations 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.

Recommendations 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

Recommendations 11.34

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

Recommendation 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 here may be a public health risk involved. If that concern is present the tribunal should be required to inform the Minister of Health.

Recommendation 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.

Recommendation 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.

Recommendation 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.

30. The Personal and Family Health Services directorate within the Ministry undertook the initial work drafting the amendments to section 74A of the Health Act and the subsequent consultation process. I understand that the NSU had little input into the process at this stage. The proposal seems to have floundered on legal, ethical and methodological issues that could be resolved. There appears to have been a lack of accurate information disseminated and perhaps even some misinformation. Clearly this raised fears from the public's perspective. I have had several comments from

different groups expressing disappointment that the basis of the consent issues, the intentions behind the audit proposal and the type of approach planned were not made clear to people whose opinions were being canvassed. I have been informed that the legal perspective has become irrelevant since consent is now necessary in order to maintain public confidence in the NCSP. I am extremely concerned that promulgation of this opinion will lead to a belief that consent is necessary for review of case records for the purposes of audit.

31. The changes to Section 74A of the Health Act are now being taken forward by a NSU Project Team who recognise the importance of having well drafted, well thought through, robust, legislation that also makes sense operationally.

32. In addition to amendments to section 74A of the Health Act, the Comprehensive Bill originally proposed changes to the Health and Disability Commissioner Act 1994, the new Health Professional Competency Assurance Bill and an amendment to the Medicines Act. I understand that constraint on Parliamentary time is a major concern and therefore consideration is now being given to splitting the Comprehensive Bill into two or more parts on order to get it through Parliament within the available timeframes. The changes to the Health Act will go ahead first, followed at a later date by the other three.

33. **I am concerned that even the amendments to the Health Act may not get through Parliamentary within the next six months. The remainder of the Comprehensive bill does not have a time frame in place for implementation.**

34. The proposed Health Professionals Competency Assurance Bill is required for implementation of recommendations *11.34, 11.35, 11.36* and *11.44*.

35. Thus the systems currently in place are inadequate to ensure that the NSU is advised, where appropriate, about complaints relating to professional performance or disciplinary matters. The current systems are also inadequate to ensure that health professionals are not inhibited from expressing concerns about the competency of other health professionals. Since the results of the retrospective

cancer audit will not be available for some time, it is imperative that the best systems are in place to facilitate the identification of areas where improvements in quality may be urgently needed.

36. There is a great deal of confusion about the legal position regarding the retrospective cancer audit. I have had the benefit of expert legal advice that suggests that the situation has been allowed to become more complicated than it need have been. A great deal of time has been wasted since the retrospective cancer audit must now go ahead under existing legislation.

37. As I understand it, the proposed retrospective cancer audit involves access to:
    - The National Cancer Register
    - National Cervical Screening Register
    - GP level medical records and laboratory records
    - Women themselves (via interview)

    I have been advised that different legal provisions apply to each stage.

The National Cancer Register

38. The register is established pursuant to the Cancer Registry Act 1993. The purpose of the Cancer Registry under that Act is to provide information on the incidence of, and mortality from, cancer and to provide a basis for cancer survival studies and research programmes.

39. The proposed retrospective cancer audit is consistent with these objectives. Access can be given to audit personnel and researchers, but they must comply with the Health Information Privacy Code 1994 (HIPC). There should be no problems with this as the HIPC permits uses and disclosures of information "for the purposes for which the information was obtained".

National Cervical Screening Register

40. Access to the NCSP Register is governed by section 74A(5) of the Health Act. It says that no person may disclose information on the Register that identifies a woman, unless the information is disclosed with the consent of the woman, or for the purpose of giving access to the Register to persons studying cancer in accordance with regulations made under subsection 7(a).

41. The legislation considers regulations permitting access for investigations of the nature contemplated in the retrospective cancer audit. Regulations have not been promulgated. An interpretation is clearly available that in the absence of regulations, access can only be given in accordance with the other exceptions to the prohibition, such as consent.

42. It is clearly arguable that the monitoring of the clinical effectiveness of the programme is an integral part of any screening programme, and as such the Ministry is entitled to conduct an audit, where necessary with the assistance of expert agents such as epidemiologists. Arguably such an audit is not prohibited because no "disclosure" is required. The audit is a quality control measure, and as such is part of the maintenance of the Register. However, this interpretation has been questioned because, the epidemiologists commissioned to conduct the audit may have their own additional purposes for accessing the information such as for associated research projects and / or the publication of academic papers. In this respect they would be acting as more than mere agents, and information must in those situations thereby be "disclosed".

43. These, together with clinical and cultural reasons lead the project to favour consent of each woman as the basis for conducting the audit. In addition, Kaitiaki Regulation require the consent of a Kaitiaki committee before information relating to Maori women can be the subject of research.

GP level medical records, hospital records, laboratory records and other relevant health records.

44. The audit personnel will require to investigate the medical records of women who have developed cervical cancer to ascertain if and when smear tests had been offered and

what results were obtained. Scrutiny of all medical records is necessary to find the results of any smears not recorded on the NCSP Register for whatever reason.

45. The GP and laboratory records are not covered by the strict secrecy of section 74A. They are covered by the Health Information Privacy Code 1994 (HIPC). This code is a regulation under the Privacy Act that I understand is the New Zealand equivalent of the UK Data Protection Act.

46. The Code is intended to reflect the normal expectations of confidentiality between doctors and patients, as well as other actors in the health sector. Access to records is not absolutely predicated on patient consent. Medical records can be disclosed without consent in a number of circumstances, including where the information is required for a professionally recognised external quality assurance programme or for the purposes of research where information is not going to be published in a form that identifies an individual person and ethics committee approval (where necessary) has been obtained. These exceptions to confidentiality are available only where obtaining consent is either not desirable or not reasonably practicable.

Women themselves (via interview)

47. In addition to ethical requirements as to the involvement of live subjects in research, medical research is subject to consumer protection rights in the Code of Health and Disability Consumers' Rights. I understand that this document has its origins in the Royal Commission of Inquiry chaired by Dame Sylvia Cartwright in the 1980s which recommended consumer protection legislation. The Code provides detailed rules about informed consent.

48. Clearly these complex legal issues are outside my area of expertise and I hesitate to comment other than to express extreme concern at the delays to implementing processes for ensuring the quality of the NCSP that are resulting from the legislative process. Whatever the issues are, they must be addressed by urgent

legislation if this is proved necessary to overcome the obstacles that appear to be frustrating the performance of the retrospective cancer audit.

ETHICS COMMITTEES

Recommendation 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.

Recommendation 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.

Recommendation 11.20

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

Recommendation 11.21

Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies.

Recommendation 11.22

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

Recommendation 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.

49. It is clear that the CSI Recommendations relating to Regional Ethics Committees caused great disquiet among members of these committees. This concern was further intensified by the first draft of the revised Operational Standard for Health and Disability Ethics Committees that went out for consultation in June 2001. A second draft "interim standard" is being prepared that will attempt to take account of concerns expressed that the first draft would not have been a workable replacement to the 1996 Standards.

50. **A mechanism must be in place without delay to standardise the approach taken by each of the 14 regional ethics committees with respect to research and audit projects for the NCSP.**

51. I think that the only way to make progress is to provide specific guidance to regional ethics committees. The terms of reference of the National Ethics Committee identify as its first task the requirement to deal with recommendations *11.19* and *11.21*. I understand that the Chair of the National Ethics Committee will have been appointed by the end of December 2001. However, it will take some time for this committee to become established and to develop policy and guidance in these complex matters.

52. **I am unclear about the role and remit of the proposed National Ethics Committee particularly with respect to its relationship with regional ethics committees, multi centre ethics applications and to the proposed Bioethics Council. This needs to be clarified as soon as possible.**

53. CSI Recommendation requiring the National Ethics Committee to deal with multi centre applications was controversial and vehemently opposed. The regional ethics committees see no need to change the current procedure whereby a proposal for a multi centre study goes to all 14 regional committees, and is coordinated by the primary regional ethics committee.

54. In discussion with some of the chairs of regional ethics committees, there was general agreement that clinical audit per se does not require ethics committee consent.

55. However, where an audit project attempts to gather new information not part of the healthcare record, lies in the gray area between audit and research or where clinical information is disclosed to a third party who is not part of clinical team then they believe that an application should be made for ethics committee approval.

56. **I understand that it is proving difficult to incorporate the policy changes required by the CSI recommendations into the second revision of the Operational Standard**

for Ethics Committees. I do not see any progress being made at present and I am concerned that regional ethics committees are at risk of taking an entrenched position.

NATIONAL SCREENING UNIT

Recommendation 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.

Recommendation 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.

Recommendation 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.

57. I have three main areas of concern regarding the NSU: its governance, its management and its manpower resource.

Governance of the National Screening Unit

58. The NSU has undergone several moves and re-structures over the years. With the merge of the Health Funding Authority and the Ministry of Health, the NSU has now moved to the Public Health directorate of the Ministry of Health, under Dr Don Matheson, Deputy Director General. Many individuals expressed their concerns to me about this new "home" for the NSU but no one could suggest a more suitable location

for it at present. There does not appear to be a natural home for screening units currently within the New Zealand healthcare system.

59. While the Unit does have its own budget and contracts directly with providers, it is not seen as being "independent" as stipulated in *CSI recommendation 11.12*. It is my impression that the NSU is somewhat constrained by generic Ministry rules, policies and processes that limit Karen Mitchell's ability to run the Unit in the optimal way. For example, the culture of the Ministry of Health does not sanction succession planning and thus it is difficult to cultivate and retain expertise within the NSU. Furthermore there are issues about where the responsibility of the NSU starts and ends - and who decides. This is illustrated by the work on the amendments to section 74A initially being undertaken by a different directorate of the Ministry of Health with little or no reference to the NSU despite the implications for the retrospective cancer audit.

60. It is my opinion that the NSU has been in its current location too short a time for any conclusions to be drawn. However, we need to closely monitor developments within the NSU, the Ministry of Health and the healthcare system in general in New Zealand. It may, for example, be possible at a later date to bring all screening programmes together as a larger body or to contract the NSU out to a lead District Health Board.

61. I am concerned that the Manager of the NSU does not have sufficient authority and independence to run the NSU as stipulated by CSI recommendation 11.13. While the NSU remains an integral part of the Ministry of Health, it is important that the Unit is allowed to function as intended without pressure or undue influence from other sections of the Ministry or politicians. I will review the situation on my next visit.

Management structure of NSU

62. As the Manager of the NSU, Karen Mitchell is responsible for both Breast Screen Aotearoa and the National Cervical Screening Programme. This is an enormous task. At present there is a need for a huge amount of managed re-organisation of the NCSP,

a change in the structure of the NSU, negotiations for provider contracts and liaison with other directorates of the Ministry.

63. **I am extremely impressed by Karen Mitchell's managerial skills. I believe the NSU's success to date owes a great deal to her leadership and expertise.**

64. **However, I note with concern that Dr Julia Peters, as Clinical Director, has a direct line management to the NSU Manager, Karen Mitchell who is not medically qualified. Thus, the manager of the unit does not hold specialist medical qualifications in public health or epidemiology as stipulated as a minimum in *CSI Recommendation 11.13*.**

65. Furthermore, as the NSU is structured at present, the Clinical Director is not the direct line manager to any permanent staff. I understand that this managerial structure was discussed and agreed with Dr Peters before implementation. However, there is a serious risk that the Clinical Director could be excluded from decision-making and the clinical input to the NSU sidelined.

66. I recognise that Karen Mitchell and Dr Julia Peters have very different but complementary skills. I acknowledge that they work well together at the moment but a system that is dependent on personalities for smooth running is likely to fail long term.

The NSU Manpower Resource

67. The NSU is severely under-resourced particularly at this early stage when so much work is required over a short timeframe to implement the CSI recommendations.

68. The NSU currently has a total establishment of 33 posts. At the time of my visit, 6 posts were still unfilled including two Manager posts. Several of the staff appointed are relatively inexperienced in the field of screening and require a high level of support, training and development.

69. The NSU is divided into six teams: Breast Screen Aotearoa (BSA), National Cervical Screening Programme (NCSP), Maori Health Screening Development, Quality, Monitoring Analysis and Audit (QMAA), Information Services and Contracts and Finance. The Clinical Director and a Senior Communications Advisor support the NSU Manager.

70. One of the key vacant posts is that of Manager for the NCSP team. Jane McEntee, appointed as the Coordinator, Provider Development and Relationships is "acting up" as Manager at present but there is no one to backfill her post. Another key post that remains unfilled is that of Manager for the QMAA team. Dr Peters is at present acting as Manager in addition to all her other roles.

71. As it stands the full clinical responsibility is, in effect, invested in one person. The two Public Health Consultants employed by NSU have little clinical experience in screening and therefore opportunities for delegation are limited. In my opinion, Dr Julia Peters is severely overloaded and over-stretched. She is trying to provide clinical leadership to both Breast Screen Aotearoa and the NCSP, training and development of new staff in post, managing the QMAA team, interfacing with professional bodies and dealing with the huge volume of clinical inquiries that arrive in the NSU.

72. This situation presents a major risk and cannot be allowed to continue. There is a clear need for much greater and more experienced clinical input into the NSU. There is sufficient work for Clinical Leads for both Breast Screen Aotearoa and the NCSP in addition to a Clinical Director of the NSU.

73. There appears to be no real understanding or sympathy within other directorates of the Ministry of Health for the wide-ranging nature, volume, or intensity of work of the NSU. I was surprised to discover that the NSU is regarded as "very well off" compared with units in other directorates of the Ministry.

74. Responding to ministerial inquiries alone consumes an enormous amount of time and effort for the NSU. Political and media attention regularly changes the priorities of the day. The NSU is required to respond in a timeframe set by political imperatives to the detriment of other meetings that should be attended or work that has been scheduled for that day. This leaves the NSU in a state of constant crisis.

75. The current establishment is clearly inadequate for the enormous amount of work that requires to be done at this early stage in implementing the CSI recommendations. The necessary experience and expertise is also lacking. This must be addressed quickly.

76. I urge the NSU to identify as soon as possible what can - and cannot - be done with the manpower resource available. If the current pressure continues, there is a major risk of "burn out" of the staff in post.

77. While outside of my remit, I am also concerned that members of staff are frequently pulled from breast screening duties to cover crises arising in the NCSP and that there is inadequate time to further the development of staff in this area of the NSU. In time, this could compromise the safety of the Breast Screen Aotearoa.

78. Since there are few applicants, if any, for advertised posts, recruitment is clearly an issue. Opportunities for additional earnings for public health consultants are greater at District Health Board level and taking up a post in the Ministry of Health is apparently not perceived to be a good career move. There is a need to advertise posts at the right level and remuneration to attract appropriately qualifies individuals.

79. In view of the difficulties in recruiting appropriately trained staff, an external review of recruitment should be considered.

WORKFORCE AND ORGANISATIONAL DEVELOPMENT

Recommendation 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 sties for them. There should also

be a review of the training requirements and maintenance of competence of smear test readers and cytopathologists.

Recommendation 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.

Recommendation 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.

Recommendation 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. Historically the NSU has taken only a limited role in workforce development but, over the past few months, a colossal amount of work has gone into this area. A Workforce Development Strategy for the next five years has been prepared and is out for consultation with the professions.

81. The NCSP incorporates a wide range of Health Professionals who are involved in public health, health promotion, smear taking (general practitioners, nurses, midwives, and lay smear takers), smear reading (cytotechnologists, cytotechnicians, pathologists), diagnostic services (colposcopists, histopathologists), treatment services (oncologists) as well as management of the NCSP and the Register.

82. Recently the NSU has undertaken several workforce development initiatives including training of health promoters/educators, setting up unidisciplinary group meetings and the specification of professional quality standards. The NSU has contributed funding for educational sessions during the forthcoming NZ Society of Cytology Conference in 2002.

83. This is a very good start but much work still needs to be done in this area. In particular, there are two areas I believe need urgent attention.

84. It is important to raise the profile of practice nurses and lay smear takers in the NCSP since they provide an increasingly substantial input to smear taking and high quality smear taking is necessary for an effective screening programme.

85. I am concerned about the cost incurred by practice nurses in accessing approved smear taking training programmes. The fees can amount to over NZ$500 for a three day course. While some employers fund this training for their practice nurses, not all do and some nurses may also suffer loss of earnings to attend courses. I have no information about formal courses for lay smear takers but I do not believe that situation will be substantially different.

86. Unless nurses have completed an approved smear taker training course they cannot appear as named smear takers on the NCSP-Register. The smears they take are included with those of the responsible doctor

87. Thus it is not possible audit the quality of the smears taken by nurses who have not undertaken formal professional training in smear taking. I could not access any information about how many smears are taken by Practice Nurses or lay smear takers who have not undergone the formal training programme.

88. Similarly cervical screening update courses are available for nurses in the larger centres but it is often difficult for nurses working in geographically remote areas to access these. Most nurses participate in continuing professional development but not specifically in cervical screening unless this is the major part of their work.

89. **Smears should only be taken by health professionals who have undergone specific formal training in smear taking and who participate in continuing professional development in the area of cervical screening.**

90. **The lack of free training and easily accessible update courses is a barrier to safe practice. Smear taking training and update courses should be provided free for practice nurses and lay smear takers and be more geographically available**.

91. While there appears to be a satisfactory training for laboratory staff in the reading and reporting of cervical smears, I am concerned at the unplanned introduction of the ThinPrep methodology. The only training appears to be that provided by the commercial company. No NCSP performance standards have been set for reporting ThinPrep slides.

92. The NCSP needs to design an appropriate training programme and quality standards for staff reading and reporting liquid based cervical preparations.

93. Laboratories must participate in external quality assurance (EQA) for IANZ accreditation and I understand that most choose to participate in the Australian cytology EQA scheme. The EQA scheme looks at overall laboratory performance, and there is no external check on the continuing competence of all individuals working in the laboratory. There is a reluctance to move to an EQA scheme in which all staff must participate. Some laboratory managers have suggested that losing a few hours work if all staff must participate in a formal EQA scheme would not be tenable. Furthermore, there is no obligation on the part of laboratories to declare any "poor" performance (as defined in their EQA scheme) if and when it occurs to the NSU. The NSU has no input to the performance standards applied in the EQA.

94. At present there could be a laboratory with a persistent poor performance in their EQA scheme about which the NSU is unaware. This is unacceptable.

95. NCSP needs to consider developing a New Zealand EQA scheme in collaboration with the professional bodies for individual technical and medical laboratory staff with a facility to break anonymity if there is a persistent poor performance. The format, protocols and criteria of the EQA scheme should meet NCSP standards.

96. Some concern has been expressed that the new laboratory operational standards have resulted in fewer cytology laboratories and this will impinge on the opportunity for training junior pathologists with respect to cervical cytology. In theory trainee pathologists could sit the Part One professional examination without interpreting

cytology. It has been suggested that training agreements should be incorporated into laboratory contracts in order to address this.

97. Another concern is the lack of availability of cervical cytology update courses for pathologists within New Zealand. Most must travel to Australia or further afield to access such courses. It is important that pathologists reporting cervical smears participate in continuing professional development in the area of cervical cytology. However, it is not reasonable to expect pathologists to travel abroad for cytology update courses especially when their main interest may lie in other areas of histopathology that will dictate the nature of any international meetings they choose to attend. The same is true but to a lesser extent for cytology technical staff.

98. Consideration should be given to providing regular cytology update courses within New Zealand for all grades of laboratory staff.

99. An area that has not been addressed as yet is the Organisational Development of the NSU and NCSP. I understand that everyone is so very busy trying to cope with the day-to-day work in hand, that there has been no time to consider and develop an understanding of the NSU and NCSP as organisations. While staff are aware of their own area and what needs to be done immediately, there is little comprehension of what is happening in other sections of the NSU and how the NSU should be developing as an organisation. A balance needs to be achieved between undertaking chunks of work, all members of the Unit pulling together and building up internal expertise and the NSU developing as an organisation.

100. In addition to addressing the manpower resource issue in the NSU, consideration should be given to organisational development.

INFORMATION FOR WOMEN

Recommendation 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.

101. The policy of the NSU has been to develop a single up-to-date repository containing all the information about every component of the NCSP in very great detail. A draft has already been sent for preliminary consultation but the final document must await the outcome of the legislative changes before more wide consultation and consumer testing.

102. However praiseworthy this plan, it remains an urgent necessity to provide accurate basic information about the NCSP in brochure or pamphlet for General Practitioners, Practice Nurses, lay smear takers and women. Similarly information about the significance of abnormal smear results and what colposcopic examination entails must be readily available for women who are referred for colposcopy. This includes information for immigrant non- English speaking minority groups.

103. It is clear that there is little understanding about what cervical screening can and cannot achieve. There is a high level of ignorance about the risks, benefits and limitations of cervical screening programmes among the public and among healthcare professionals. Women are being encouraged to enroll on the NCSP-Register with no clear understanding of the benefits. Gynaecologists use smear tests for reasons other than screening. Both smear takers and gynaecologists fail to understand the health economics of the screening interval and advocate early recall at great expense but little benefit to many women. There is a view that everyone is so hyped up about medico-legal issues that women are being referred for early repeat smear or colposcopy at the drop of a hat.

104. It is important that the NCSP is acceptable to women. Greater understanding of the fact that the cervical smear is a screening test and not a diagnostic test and of the benefits of participating in a screening programme with comprehensive audit built in must be promoted among women. The safety checks built into the NCSP are there to protect women who should be demanding, not merely consenting to these processes. It is important for women to feel safe so the risks of "opting-off" must be explained fully

to them. Some women are badly informed and opt-off the NCSP-Register without fully understanding the risks incurred by doing so.

105. More work must be done to develop and promote an understanding of clinical audit as an integral part of good quality healthcare delivery. Regular critical review of how well clinical care is being delivered is vital to improving the quality of healthcare. I suspect that the "external" audit suggested for the retrospective cancer audit has mistakenly been portrayed as similar to financial auditors checking up on one's income tax returns and snooping into other private matters. The retrospective cancer audit is not "external" in that sense. It simply means that experts will be commissioned to investigate and evaluate the information collected on behalf of the NSU. Women will be approached by nurses or trained healthcare professionals who will be sensitive to local customs and cultural needs so that the full information about screening histories can be gathered. They are in effect functioning as part of the NCSP. As with all healthcare records, all information gathered will be handled with great sensitivity and kept confidential.

106. I understand the dilemma between getting a simple easily read pamphlet out immediately and getting it "right". However, I believe that information about cervical screening is needed now – even if it has to be revised in a year's time when the legislation has changed. I commend the NSU to proceed quickly with their plan to send interim cervical screening information leaflet pads to every general practitioner, practice nurse, District Health Authority, colposcopy clinic, regional office and cytology laboratory, and for similar information to be posted on all relevant websites.

STATISTICAL REPORTS AND PROVIDER DATA

Recommendation 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 weaknesses in the program. These must be remedied in a timely manner.

Recommendation 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.

107. Although laboratories are required to use the same terminology to report cervical smears (The Bethesda System), the criteria applied by different laboratories to assess adequacy of smears has not been defined and is not standardised. This has led to wide variations in unsatisfactory rates between laboratories that are probably due more to commercial pressures than the quality of the smears being taken.

108. **There needs to be more standardised criteria for reporting unsatisfactory smears.**

109. A revised Bethesda classification "Bethesda 2001" was published earlier this year. This deletes some of the previous categories and changes the criteria for others. The NSU has provided funding to the NZ Cytology Conference next year to provide some discussion on whether to implement Bethesda 2001.

110. In order to prevent distortion of the data gathered in the monthly statistics, it is necessary to ensure that laboratories do not implement "Bethesda 2001" but continue to use the previous version of The Bethesda System until such time as the NCSP agrees that implementation of "Bethesda 2001" is desirable and a specific date is set for such a change.

111. The NSU should issue guidance to laboratories about the implementation of Bethesda 2001.

112. I have some concerns about the quality of the laboratory results data being collected.

113. No attempt is being made to identify duplicate additional smears taken at colposcopy from women referred with HSIL. If colposcopy clinics repeat the

smear tests on these women prior to treatment, this will artificially increase the high grade-reporting rate for the laboratory compared to another laboratory that does not receive such colposcopy smears.

114. Similarly the denominator for the calculation of reporting rates (total numbers of smears) will be artificially increased if a substantial proportion of normal women return for routine smears earlier than the recommended interval. This will result in an artificial reduction in the percentage of HSIL reported compared to other laboratories. It is important to define who is being screened by each laboratory and how often.

115. There is no audit of the laboratory returns. These will include smears "opted off" the NCSP Register and thus NCSP Register data cannot be used for verification or sanity checks on the laboratory data.

116. Since the Broadstock Report concluded that liquid based cytology was not cost effective for use in New Zealand at present, I had assumed that only conventional smears were being taken. However, I note that a variable proportion of smear tests, up to 25% in some laboratories, are done as liquid based cytology samples (ThinPrep). This information is not being gathered in the monthly laboratory statistics. This method has been FDA approved as offering improved sensitivity so it could skew the reporting profiles of laboratories.

117. The change to liquid based cytology needs to be monitored. Laboratory monthly returns should record results for conventional smears and ThinPrep samples separately.

118. The SNOMED system used for coding cervical biopsy histological diagnoses is also due for review. The NSU must take similar action when the revised system is published.

119. The coding of biopsy specimens required by the NCSP Register is also causing problems for some laboratories. The codes are used for the electronic download of

biopsy information to the Register. Here the needs of the NCSP conflict with the coding needs of the laboratory.

120. **The range of diagnostic codes for cervical biopsy samples acceptable to the NCSP Register needs to be reviewed.**

121. Registry staff have a problem resulting from women who have been referred for colposcopy and have attended but who have not had a biopsy taken. If the regional site does not receive a histology result they do not know if this is because no sample was taken or if the result has not arrived from the laboratory. If the Register received and held information from colposcopy clinics this could be avoided.

122. The time lag for publishing Annual Statistical Reports is still too long. The 1996/1998 Report is due in December 2001 and the 1999/2000 Report is not expected before Summer 2002. These need to be provided in a more timely fashion for public scrutiny.

123. In the meantime, the Independent Monitoring Group (IMG) has published its first two quarterly monitoring reports. These have generated a huge amount of activity for both laboratories and the Otago team since they are prepared initially in draft form for checking by the Providers before being published in final form.

124. I am concerned that there is not yet a smooth and straightforward communication between the IMG, the Providers and the NSU. Providers are very anxious. This situation must be improved as soon as possible. A better understanding of the reasons behind the data gathering must be promoted between all three groups to help bring about a better understanding of each others needs.

125. Only a very few laboratories now provide a regional service. Many laboratories receive smears from a wide range of geographic areas throughout New Zealand. Smear takers choose the laboratory to which they send their smears according to a variety of commercial and organisation factors which change with time.

126. **Therefore no useful information about the surrounding population can be derived from a laboratory's data and it is not possible to correlate information about regional variations in incidence of cervical cancer with local laboratory reporting rates**. **Another means of evaluating this must be identified.**

127. While quarterly reporting is reasonable at present, it should be possible to reduce the frequency of publication of the IMG Reports to six monthly and eventually annually once the system is well established.

NCSP REGISTER OFFICES

Recommendation 11.25

The National Cervical Screening Register needs to be electronically linked with the Cancer Register

Recommendation 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.

Recommendation 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.

128. **NCSP Register staff now have access to the Cancer Registry to confirm or clarify information held on the NCSP Register. However, NCSP Registry staff may not disclose information on the NCSP Register to Cancer Registry staff even when they know the data held on the Cancer Registry is erroneous. This needs to be rectified. In addition the decision to abandon efforts to provide Phase 2 of the electronic link between the Cancer Registry and the National Cervical Screening Register needs to be reconsidered.**

129. I must question the need for the numbers of NCSP Register offices. Data entry occurs at 14 register sites throughout New Zealand although almost 33% of the data is processed in one of these offices (the Auckland office). Some sites have experienced

rapid turnover of staff and the quality of training of new staff is variable. The number of sufficiently qualified individuals in New Zealand is limited.

130. Provision of smear histories to laboratories is now a routine part of Register office work. Many laboratories find they have to relate to several sites and thus have multiple "contacts" for smear histories.

131. I have concerns about some of the roles undertaken particularly in relation to advice about the need for repeat smears for individual women. There is not sufficient clinical oversight at many sites to ensure that inappropriate decisions are not made.

132. I do not believe that maintaining 14 Register office sites is an efficient use of resource. Consideration must be given to a more appropriate number and location of Register data entry sites and to the roles and responsibilities of register office staff.

133. Greater attention is needed in the area of the quality of patient identification data given by smear takers to laboratories. An immense volume of phone calls result from errors or inconsistencies in patient identification. There are a variety of different cervical smear request forms in use some of which do not collect all the relevant patient demographic or clinical information. This may lead to inappropriate recall times on laboratory reports, unnecessary reminder letters and failure of failsafe follow up systems for women with abnormal smears.

134. Consideration should be given to a standard national request form that is also available in electronic form.

135. Currently most exchange of information about smear histories is by telephone or fax. Electronic access to the NCSP Register should be extended to all laboratories and smear takers.

ROLE OF GENERAL PRACTITIONERS AND PRIMARY CARE

136. There is no national funding for taking cervical smears in General Practice. In the past, there has been a general view that the NCSP was putting a whole lot of resources into other areas but the GP was just getting the added workload and administrative hassle with no recompense for the additional activity. Thus GPs had absolutely no ownership of cervical screening with a potential for GPs to say that it was not important for women to belong to the NCSP or stay on the Register. Tracking smear results performed in other sectors such as Family Planning and not copied to GPs created more difficulties in their attempts to ensure appropriate call and recall. .

137. The biggest issue for smear takers is discussing informed consent since it is not easy in a 15-minute consultation to do this competently especially if the smear is tacked on the end of several other problems the patient wishes to discuss. There are particular difficulties associated with providing smears for the growing number of refugees and non-English speaking immigrants. There are no additional fees available to GPs for interpreters and few cervical screening pamphlets have been translated into these languages.

138. **While more recently there has been a change in culture and primary care sees a clear role working with the NCSP, many of the previous obstacles still remain. Since there is no contractual relationship with the NSU, it is difficult to implement standards for smear taking and failsafe follow up among GPs. There is a significant cost that is being carried by GPs which needs to be taken into account**.

139. The support of women from all ethnic groups is necessary for the NCSP to be a success. As data is cleaned up the population coverage looks like it is less than previously thought at under 70% across NZ. Coverage is higher in the Tairawhati region following the programme of repeat smears instituted after the CSI Report and this may artificially inflate the figures.

140. I understand that some smear takers only offer women the new ThinPrep smear tests that are more expensive for women.

141. While there must be a balanced approach that recognises the importance of all aspects of the NCSP, it is clear that New Zealand cannot be complacent about its population compliance in cervical screening. Participation in the NCSP must be further improved. The cost of the smear test consultation is undoubtedly a barrier in some areas.

FINAL COMMENTS

142. I am aware how difficult it is to strive to develop a screening programme under the constant pillory of a media that focuses only on negative events or that only sees the negative aspects in reports such as this. I hope that the New Zealand media will take a balanced position and turn its to attention to reporting positive news about the NCSP as it occurs. While I have identified areas needing more attention, I wish to record the immense amount of work done to date by very dedicated health professionals working in the NCSP and the enthusiasm of all whom I met during my visit.

143. The serious concerns I have expressed about the failure to carry out the retrospective cancer audit must not be misinterpreted. I do not have any evidence to suggest that the NCSP is below an acceptable quality standard. There has been a major reduction in the incidence of cervical cancer in New Zealand so what little evidence there is would suggest that the NCSP is doing well. I look forward to returning to New Zealand at the end of the first year following the CSI Report publication when I am certain that further great progress will have been made.

Euphemia McGoogan
16 December 2001]

Dr Euphemia McGoogan's NZ Visit

October/November 2001

MEETING ATTENDEES

	MEETING	ATTENDEES	DATE / TIME OF MEETING	WHERE
1	**Chairman Gisborne Cervical Screening Inquiry**	Alisa Duffy	29.10.01 11am-2pm	Auckland
2	**The Minister**	The Minister	30.10.01 8am-pam	Wellington
3	**Director General Deputy Director General**	Karen Poutasi (Dr) Don Matheson (Dr)	30.10.01 9.30am- 10.30am	Wellington
4	**Cervical Screening Inquiry Steering Group**	Karen Mitchell, Group Manager NSU Julia Peters (Dr) Clinical Director NSU Helen Wyn, Sector Policy Judy Glackin, Personal & Family Health (PFH) Grant Adam, Chief Legal Advisor	30.10.01 11am-2.30pm	Wellington
5	**Legal Advisors**	Grant Adam, Chief Legal Advisor Kim Murray, Legal Advisor	30.10.01 3pm-4pm	Wellington
6	**Royal College of GPs**	Helen Rodenberg (Dr) Claire Austin	31.10.01 8.30am- 9.30am	Wellington
7	**NCSP Register Staff**	Catherine Scollay, IS Manager, NSU Sandie Matcham, Systems Analyst, NSU Philip Saysell, Systems Analyst, NSU Emma Dudding, Systems Analyst, NSU	31.10.01 9.45am- 10.30am	Wellington
8	**Health Act Project Team**	Julia Peters (Dr), Clinical Director, NSU Judy Glackin, PFH Grant Adam, Chief Legal Advisor Warwick Gilchrist, Analyst, NSU Caroline Greaney, Analyst, PFH Adele Plummer, Health Legal	31.10.01 11am-12pm	Wellington
9	**Laboratory Technologists Board**	Harold Neal (Dr) Phil Saxby (Secretariat)	31.10.01 12.30pm- 1.30pm	Wellington
10	**Audit of Invasive Cervical Cancers**	Ruth Herbert, Project Manager Julie Macdonald, Analyst Keri Ratima, Analyst John Edwards, Legal Sue Crengle, Maori Research, General Practice Anne Alan-Moetaua, Pacific Island Advisor Peter Bethwaite (Dr) – Pathology	31.10.01 2pm-4pm	Wellington
11	**Comprehensive Project Team**	Helen Wyn, Sector Policy Judy Glackin, PFH Sheila Swann, Analyst Marilyn Goddard, Analyst Caroline Greaney, Analyst	1.11.01 9am-10am	Wellington

Dr Euphemia McGoogan's NZ Visit

October/November 2001

MEETING ATTENDEES

	MEETING	ATTENDEES	DATE / TIME OF MEETING	WHERE
12	**Ethics Project Team**	Judy Glackin, PFH Helen Wyn, Sector Policy Carol Algie, Analyst PFH Eric Harris, Analyst PFH Barbara Burt, Analyst Sector Policy	1.11.01 10am-11am	Wellington
13	**Regional Ethics Committee Representatives**	Professor Donald Evans, Chair Otago EC Barbara Beckford, Chair, West Coast EC Kaye Worrall, Chair, Auckand EC	1.11.01 11am-12pm	Wellington
14	**Royal College of Pathologists**	Andrew Tie (Dr) Peter Bethwaite (Dr) Pathologist Karen Wood (Dr) Pathologist, cytology	1.11.01 12.30pm-2.30pm	Wellington
15	**IT Recommendations**	Dean Martin – Acting Group Manager, NZHIS Vicky Sheldon – NZHIS Jim Frazier – Chief Analyst, NZHIS Catherine Scollay – IS Manager, NSU	1.11.01 3.15pm-4.15pm	Wellington
16	**Auditor Director-General's Office**	Helen Chandelle, Director Special Audits & Studies Deborah Mills, Project Auditor Angela Hands, Project Auditor	1.11.01 4.30pm-5pm	Wellington
17	**University of Otago**	David Skegg (Prof) Charlotte Paul (Prof)	2.11.01 11.30am-2.30pm	Dunedin
18	**Independent Monitoring Group**	Brian Cox (Dr) Mary-Jane Sneyd (Dr)	2.11.01 2.30pm-4.30pm	Dunedin
19	**NSU, National Cervical Screening Programme**	Jane McEntee, Acting Manager Aroha Harris, Manager Maori Health Screening Development Sally Hughes, Co-ordinator, Health Promotion Anne Allan-Moetaua, Analyst Pacific Advisor Warwick Gilchrist, Analyst Kathy Gilbert, Executive Assistant	5.11.01 9am-10am	Auckland
20	**NSU, Quality, Monitoring, Audit & Analysis**	Julia Peters (Dr), Manager Simon Baker (Dr) Public Health Medicine Specialist Madhu Chatterji (Dr) Public Health Medicine Specialist Rockshan Creado, Executive Assistant	5.11.01 10.30am-11.30am	Auckland
21	**Women's Health Action**	Sandra Coney, Executive Director	5.11.01 1pm-2.30pm	Auckland
22	**Workforce Development Team**	Allison Nichols-Dunsmuir, Project Co-ordinator Helen Potaka, Project Co-ordinator Victoria Smith, Research Analyst Julia Peters	5.11.01 3pm-5pm	Auckland
23	**Druis Barrett**	Druis Barrett Julia Peters, Karen Mitchell	6.11.01 9am-11am	Auckland
24	**Cancer Audit**	Prof Rod Jackson, Julia Peters	6.11.01 11am-12pm	Auckland

Dr Euphemia McGoogan's NZ Visit

October/November 2001

MEETING ATTENDEES

	MEETING	ATTENDEES	DATE / TIME OF MEETING	WHERE
25	**Diagnostic Medical Laboratory (visit)**	Tony Bierre (Dr) Elizabeth Pringle, Manager	6.11.01 1pm-2pm	Auckland
26	**NCSP Regional Office (visit)**	Tracey Monehan, Manager NCSP	6.11.01 3pm-4pm	Auckland
27	**Kaitiaki Group Chair (teleconference)**	Te Miringa Huriwai	6.11.01 6pm-6.30pm	Teleconference
28	**Cancer Society**	Betsy Marshall	7.11.01 9am-10am	Auckland
29	**LabPlus – Auckland District Health Board (visit)**	Ian Smelton – cytopathologist Gwenda Lawerence – charge cytotechnologist George Chan – Clinical Director Justine Tringham – Contract Manger, ADHB	7.11.01 11am-12pm	Auckland
30	**Screening Advisory Group**	Dr Peter Bethwaite, Acting Chair, Pathologist Terry Green, Health Economist, Statistician Betsy Marshall, Health education Peter Sykes, Gynaecologist Barbara Robson, Consumer Representative Alison Denyer, GP - General Practice Prof Bruce Arroll – Public Health Medicine Jo Barnaby, Maori Consumer & Nursing Rep	Wed 7.11.01 1-3pm	Auckland
31	**Communications Advisor**	Karen Mitchell, Kallon Basham, Communications advisor	Wed 7.11.01 3.30pm – 5pm	Auckland
32	**Gisborne Event (visit)**	Minister, Associate Minister, Karen Poutasi, Peter Abernethy, Karen Mitchell, Julia Peters, Aroha Harris, Kallon Basham Gisborne women and families, Public meeting	8.11.01 11am-3pm	Gisborne
33	**Debrief with Don Matheson, Karen Mitchell, Julia Peters**	Don Matheson Karen Mitchell Julia Peters	9.11.01 9am-10am	Auckland / teleconference
34	**Final Meeting with NSU staff**	Auckland: Karen Mitchell, Julia Peters, Fiona Gilhooly, Christine Cole, Barbara Phillips, Rod Brown, Andrew Palmer, Warwick Gilchrist, Aroha Harris, Sally Hughes, Simon Baker, Madhu Chatterji, Rockshan Creado, Jacki Downey, Kathy Gilbert, Esther Blomfield Wellington: Catherine Scollay	9.11.01 10am-10.15am	Auckland
35	**College of Practice Nurses**	Terri Lambert	9.11.01 1.30pm-2.30pm	Wellington