Ref. No.: 20021940

REVIEW OF PROGRESS TO IMPLEMENT THE RECOMMENDATIONS OF THE GISBORNE CERVICAL SCREENING INQUIRY REPORT; DR EUPHEMIA MCGOOGAN AND THE OFFICE OF THE AUDITOR GENERAL

February 2002

Ref. No.: 20021940

REPORT

BACKGROUND INFORMATION

1 In response to Recommendation 46 of the Inquiry Report, expert cytopathologist, Dr Euphemia McGoogan was engaged by the Minister to provide independent advice on progress to implement the Inquiry Recommendations. Dr McGoogan visited New Zealand for 10 days in October/November 2001 to carry out a review of progress over the first 6 months. This visit involved meetings with over 100 individuals in around 35 separate meetings. To assist Dr McGoogan in her review, the Ministry also supplied full documentation on activity to deliver the Inquiry recommendations. A written report summarising her findings was provided to the Minister on 16th December 2001.

2 In her report, Dr McGoogan made particular mention of the assistance she received to complete her 6-Month Review. She was satisfied that she was able to have frank and open discussion with the groups and individuals with whom she met and noted the immense volume of information obtained during her visit, only 6 months after the release of the Inquiry Report.

3 The Office of the Auditor General provides assurance to Parliament and the public that government organisations are operating and accounting for their performance in accordance with Parliament's intentions. In October 2001 the OAG wrote to the Director General advising her that the OAG intended to carry out a short piece of work to determine what action had been taken to implement the Inquiry Recommendations. A final draft of their report was provided to the Ministry 30 January 2002.

COMMENT

Summary of Key Findings and Ministry Response

4 The OAG found that good progress had been made in setting up structures and systems to address the Inquiry Recommendations. Both the OAG and Dr McGoogan noted the establishment of a Ministry CSI Steering Group for the co-ordination and monitoring of activity to implement the Inquiry recommendations. This group is also responsible for the provision of monthly progress reports to the Minister.

5 Dr McGoogan acknowledged the tremendous effort made by the National Screening Unit (NSU) into improving the quality of the NCSP at all levels. She acknowledged the commitment, enthusiasm and dedication of the staff of the Unit and the tremendous efforts made to improve the NCSP despite a serious shortfall in staff.

6 The OAG also commented that in the course of their review they saw evidence of much determination, particularly among the Ministry staff responsible for the programme that the sad history of the programme would not be repeated again and that recommended changes to the programme would be made.

7 Both the OAG and Dr McGoogan concluded that good progress has been made on implementing quality standards and routine monitoring of performance indicators across the National Cervical Screening Programme (NCSP), including laboratories.

8 The implementation of quality standards and routine performance monitoring has been a priority for the NSU over the last 9 months. Assuming direct control for many aspects of the NCSP delivery, through management of all programme funding and implementation of appropriate contractual arrangements with service providers has also been successfully achieved.

9 As part of her review, Dr McGoogan made a further 24 recommendations for improvements to the NCSP. Of these 24 recommendations, 10 related to workforce issues, 5 related to laboratory coding and reporting, and others related to information systems, monitoring, NCSP Regional Offices, and provision of information to NCSP participants.

10 This brings the total of number of recommendations from the Inquiry and Dr McGoogan to 70. The breadth of these recommendations ranges from relatively small operational improvements, to broad organisational requirements, and to those requiring wider sector and Government support, such as the implementation of new legislation.

11 The NSU supports the recommendations and their intent. However, it must give consideration to prioritisation of its core business activities, (including some recommendations) alongside the guidance provided through other recommendations. Management of the NCSP cannot solely be driven by ongoing emphasis on external recommendations and expectations of immediate delivery where implementation may not be feasible in the short term. The ongoing review of progress by external parties itself generates considerable work for the Unit, which interrupts day to day operations and other project work. The NSU must ensure the ongoing sustainability of its operation. This is difficult to achieve when its activities and staff are exposed to constant review from external parties.

12 Over the last 9 months, in addition to core business, the NSU's priorities have included 19 of the Inquiry recommendations, some of which commenced prior to the Inquiry report and many of which have an ongoing component as part of NCSP operations, including:

- The Audit of Invasive Cervical Cancer. (Recommendation 1 - ongoing)
- Implementation of interim quality standards. (Recommendation 4 – achieved & ongoing - except for smear-takers)
- Legal assessment of NCSP.(Recommendations 5 & 6 – achieved and ongoing)
- Completion of 1996-98 Statistical Report. (Recommendations 7 & 8 – achieved and ongoing)

- Implementation of minimum volumes for laboratories. (Recommendation 9 – achieved and ongoing)

- Implementation of direct contracts with service providers. (Recommendation 12 – achieved and ongoing)

- Input to proposed amendments to Section 74A of the Health Act 1956. (Recommendations 14, 15, 16, 17, 30 - ongoing)

- Completion of Workforce Development Strategy. (Recommendations 28, 40, 41, 42, - achieved and ongoing)

- Provision of information to women. (Recommendation 38 - ongoing)

- Provision of information to smear-takers. (Recommendation 39 - achieved and ongoing)

13 In her report Dr McGoogan's raises concerns related to the available workforce for NCSP operations and implementation of various recommendations. The NSU has taken on board her comments related to the need to identify priorities for the work, and what can and cannot be done in the short to medium term. The NSU is in the process of completing a detailed planning exercise to determine further the priority for the various recommendations proposed by the Inquiry report and Dr McGoogan's review.

14 A summary of the key issues of both reviews is provided at Table 1.0 below.

Table 1.0 Summary

	Key Issue	**Ministry Comment**
a)	Progress Reporting: Criticism regarding the reporting of the status of recommendations as complete or on-track and dissatisfaction with progress on 11 recommendations	Officials recommend that clarification be sought with Dr McGoogan and the OAG regarding their expectations of progress and agreement for measuring progress.
b)	Timetable for Implementation of Recommendations. Dr McGoogan states that the timetable for implementation is 1 year.	Officials recommend that further clarification be sought from Dr McGoogan regarding the basis for the assumed timetable.

	Key Issue	**Ministry Comment**
c)	Audit of Invasive Cervical Cancer Concern that the Audit has not yet commenced. Concern that sufficient expertise has not yet been employed on the Audit.	The NSU advises that it is the data collection (external to Ministry) aspect of the Audit that has not yet commenced. Dr McGoogan states that she is impressed with the work done to date by the NSU's Cancer Audit Project Team in the first two phases of the Audit design and development. Since Dr McGoogan's visit the NSU has made substantial progress in obtaining the expertise to carry out the Audit. This means that the Audit is on target to submit its application to ethics committees in March 2002
d)	Legislative Changes Concern regarding delays and complexities of these changes, as well as concern regarding the use of the discussion document.	Officials have acknowledged the shortcomings of the discussion document given the context of Cabinet decisions and timeframe for its release. Delay to the introduction of legislative changes is also acknowledged, given the extremely tight timeframe, which was unable to be met given the complexity of policy development and legislative drafting.
e)	Ethics Committees Dr McGoogan highlights the difficulties associated with implementing the Inquiry's Recommendations and concludes that progress is unlikely to be made at present.	Officials agree that ethics committees are not in support of the Inquiry Recommendations.

	Key Issue	**Ministry Comment**
f)	Smear-Takers Dr McGoogan highlights difficulties associated with implementing standards for smear-takers and ensuring appropriate training.	The ability to ensure that smear-takers meet the standards required of NCSP is a concern to the NSU. The main obstacle is the current unavailability of contractual or other mechanisms, including appropriate funding, to ensure standards are met. Development of the most appropriate mechanisms will need to be the subject of ongoing policy development work, pending available resources.
g)	NSU Organisation and Workforce Both reviews highlighted issues related to the available workforce required to implement the recommendations and for the ongoing operation of the NCSP. Structural issues related to the authority of the NSU and the qualifications of the Group Manager are also highlighted.	The NSU acknowledges recruitment and workforce difficulties. The availability of skilled and experienced workforce is limited and requires some time to build up. The NSU will need to re-prioritise work including the Inquiry Recommendations. The NSU acknowledges that the Group Manager does not hold medical qualifications, and intends to recruit two further senior specialist health professionals. . Dr McGoogan, acknowledges the managerial skills, leadership and expertise of the Group Manager despite the lack of medical qualification.
h)	Information to Women Dr McGoogan expresses concern over the need to ensure women are adequately informed regarding the risks and benefits of cervical screening. This relates to the ability of the NSU to provide more timely information and the ability of health service practitioners to discuss aspects of the programme adequately.	The NSU has supplied Dr McGoogan with the full range of available information for women, which were not acknowledged in her report. The NSU acknowledges that a new booklet has taken time to develop. The NSU agrees that information provided to women by health practitioners has not been adequately assessed and relates to the ability of the NSU to mandate standards for primary care in particular.

Progress Reporting

15 Neither the OAG or Dr McGoogan stated in their reports what, in their view, would have represented good progress over the first 6 months for the 46 Inquiry Recommendations.

16 Both the OAG and Dr McGoogan refer to the table included in the 6-Month Summary Report summarising the status of the various recommendations as either complete, underway, on-track or having a revised delivery date.

17 Of the 37 Recommendations reported as Underway in the 6-Month Summary Report, 16 were reported as On-Track and 21 as having Revised Delivery Dates[1]. Dr McGoogan was disappointed that delays had occurred to 21 of the recommendations. She was satisfied that sufficient progress has been made on the implementation of 16 recommendations. She was not satisfied that sufficient progress had been made on 4 of the recommendations with revised delivery dates and on 7 of the 16 recommendations reported as On-Track.

18 An update of the 6-Month Summary table is provided below:

Table 2.0 Status of Recommendations

Status	**Recommendation**	**Total Number (Six Month)**	**Total Number (Updated)**
Complete[2]	4, 5, 6, 9, 10, **11, 12, 13, 25,** 36, 37, 39[3]	8	12
Underway[4]	1, 3, 7, 8, 14, **15,** 16, 17, **18, 19,** 20, 21, 22, 23, 24, 26, 27, **28, 29,** 30, 31, **32, 33,** 34, 35, 38, 39, 40**, 41, 42, 43,** 44, **45,** 46	37	33
On Track[5]	**28, 29,** 31, **32, 33,** 40, **41, 42, 43**, 45, 46	16	11
Revised Delivery Date[6]	**1, 3, 7**, **8**, **14, 15, 16, 17, 18,** 19, **20, 21, 22, 23, 24, 26, 27, 30, 34, 35, 38, 44**	21	22

19 Dr McGoogan was concerned with the terminology used to describe the status of the recommendations, whilst the OAG believed the table was both problematic and valuable.

[1] Revised Delivery Dates refer to amendments to the original timetable proposed by the Ministry in April 2001 rather than any timeframes as may have been specified within the Inquiry Report.
[2] Dr McGoogan is not satisfied that the recommendations highlighted in bold are in fact complete.
[3] Dr McGoogan was concerned regarding delays for the implementation of this recommendation, although it is now complete.
[4] Dr McGoogan is not satisfied that sufficient progress has been made on the recommendations highlighted in bold
[5] Dr McGoogan not satisfied that sufficient progress has been made on the recommendations highlighted in bold.
[6] Dr McGoogan concerned regarding the delays to recommendations highlighted in bold.

20 Dr McGoogan was concerned that the terminology used may not be particularly meaningful for a lay person and in some instances the use of the term complete could suggest that there is no more work to be done, when in fact the actual requirement was an ongoing function or component of a screening programme. The OAG also commented that it was difficult to determine an end-point for implementation of some recommendations.

21 Officials acknowledge that many of the recommendations relate to ongoing requirements to support an improved NCSP and as such there is no specific end point. Further clarification will be sought from Dr McGoogan as to her views on the most appropriate way of reporting the status of the Inquiry recommendations. In addition, the NSU will also seek to highlight those recommendations identified as priority by the Unit, and forming part of its core business and ongoing development.

22 The OAG suggested that the table was problematic because the status of the recommendations is based upon subjective judgements and valuable because it very subjectively generates useful debate on exactly how much progress is being made.

23 Progress to deliver project requirements is measured by the CSI Steering Group on the basis of the achievement of key milestones related to production of specific deliverables, project outputs and decisions. To provide an objective means of measuring progress a milestone plan was formulated by the Ministry based upon the proposed timetable advised to the Minister in April 2001.

24 The April 2001 timetable was developed in advance of more detailed analysis of the Inquiry report and its recommendations and the scope of work needed to deliver them. As the scope of the work has become more evident over the first 6 months a revised timetable has been provided and was included with the 6-Month Summary Report. Further revisions to the timetable may be proposed as the full extent of the work to implement the recommendations, some of it very complex and with dependencies external to the Ministry, is realised. With a very few exceptions the Inquiry Report did not specify timeframes for the implementation of recommendations.

25 Since both Dr McGoogan and the OAG intend to continue monitoring progress it would be appropriate to agree their future expectations of progress and the measures by which progress will be measured. This will need to be considered alongside the NSU's core business activities and other priorities as determined through its ongoing planning exercise.

26 There appears to be confusion regarding the overall timetable to deliver the Inquiry recommendations. In her report, Dr McGoogan made reference to the CSI Committee requiring implementation of the Inquiry Recommendations within 1 year. She acknowledges that 1 year would have been to some extent idealistic. Officials can find no reference in the Inquiry Report to a 12-month timetable for the delivery of all recommendations.

27 In the proposed timetable for the implementation of the Inquiry Recommendations up to 15 recommendations were stated as requiring up to 18 to 24 months or more to implement, given their complexity. Recommendations related to the development and implementation of new information systems were highlighted as requiring longer to implement.

28 A more detailed response to Dr McGoogan and the OAG's detailed review of the implementation of the recommendations is provided below. No comment is provided on recommendations that not specifically highlighted in the reviews.

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.

29 In the Six Month Summary Report, Part 3; The Audit of Invasive Cervical Cancer (the Audit) was noted as representing perhaps the largest and most complex of the projects to implement the Inquiry Recommendations.

30 Both reviews referred to the need for the Audit in order to reassure women of the safety and effectiveness of the NCSP, although Dr McGoogan did conclude that "There has been a major reduction in the incidence of cervical cancer in NZ so what little evidence there is would suggest that the NCSP is doing well

31 The OAG Report also highlighted that between 1987 and 1997, the incidence of women developing cervical cancer fell by 39%, and deaths due to cervical cancer fell by 44%. These reductions occurred against a background of predicted growth in cervical cancer in NZ. ". The Ministry believes that the continued reduction of deaths and hospitalisations from cervical cancer should be highlighted as evidence of the programmes effectiveness.

32 Dr McGoogan was particularly concerned that the Audit had not yet commenced, although acknowledged the work done to date by the NSU's Cancer Audit Project Team, stating that she was very impressed.

33 The Audit design, development and planning work done to date by the NSU Cancer Audit Project Team in Phases 1 and 2 is considered by officials to represent a significant and important part of the Audit work. It is critical that the Audit is designed appropriately to ensure that the work undertaken is of a high quality and achieves its key objective of reassuring NZ women of the safety of the NCSP. Lessons from audits overseas show that these phases are perhaps the most crucial and that the NZ Audit will perhaps be one of the most comprehensive audits ever undertaken by a national cervical screening programme. It is the data collection (information obtained from women's clinical records and in interview) aspect of the Audit that has not yet commenced and will not do so until ethics committee approval is given.

34 The NSU acknowledges the seriousness of the need for the Audit and the project team is working extremely hard to deliver this crucial work. As acknowledged by Dr McGoogan and the OAG, priority is also given to the implementation of quality standards and routine monitoring in an effort to reassure NZ women of the safety and effectiveness of the programme now. The Audit will be examining historical data for women diagnosed with cervical cancer over the last 2 years. Any concerns regarding the safety and effectiveness of the NCSP arising from the Audit will need to relate to the NCSP operations at the time the Audit reports its results. It is crucial therefore that the NSU implement improvements in the NCSP now on the basis of recognised standards and ongoing monitoring in advance of the Audit outcomes in the event that these improvements are shown to be required at the time the Audit reports.

35 In her review, Dr McGoogan highlighted that the NSU had yet to engage an academic epidemiology department to assist with the Audit, following the withdrawal of the University of Otago. She was also concerned regarding the ability to employ experts with experience of population based screening programmes on the Audit.

36 Since Dr McGoogan's visit, the NSU has engaged the services of three epidemiologists from the University of Auckland. In addition, a further public health physician and epidemiologist, Dr Mullin has been appointed as clinical leader for the project. Dr Julia Peters, as project sponsor and clinical director of the NSU, Dr Bernadette Mullin as clinical leader, and Ruth Herbert, as project manager, are all very experienced in the delivery of screening programmes. Dr Bernadette Mullin was recently chair of the Advisory Group on Population Based Screening Programmes and was responsible along with Ruth Herbert for the initial establishment of NZ's Breast Screening Programme.

37 A revised project structure has been set-up and around 24 staff and contractors are in the process of being appointed, in addition to a number of expert advisors. Dr Gabrielle Medley of the Victorian Cytology Service has also been appointed to oversee the Audit's slide review.

38 In her report, Dr McGoogan expressed concern that the Audit may take a further two years to complete. The Audit is a large and complex project and by necessity will take some months to complete its remaining 7 phases. The

current revised project plan estimates that the Audit will be completed by April 2003, assuming approval by ethics committees in March 2002. The NSU has taken the approach that the quality of the audit was of paramount importance, and should not be compromised to meet timeframes that were set before the work was fully scoped.

39 Both Dr McGoogan and the OAG document the issues related to the Audit being carried out under the current legislation in some detail. Dr McGoogan expressed the view that whilst these are complex issues they have been allowed to become more complicated than need be resulting in a great deal of time wasted.

40 Officials acknowledge there have been difficulties and considerable to-ing and fro-ing over the issues. The current legislation does not cope well with the requirements of the NCSP and the necessity to provide for audit. The proposed new legislation addresses these complex issues and provides for effective evaluation, monitoring and audit for the future. The Inquiry Report itself illustrates that the issues related to the Audit are complex and longstanding.

41 Dr McGoogan raised concerns regarding the strained relationship between the Ministry and the University of Otago resulting from previous attempts to conduct the Audit in 1999/2000. The OAG reports that statutory barriers on access to health information meant that the University of Otago was unable to carry out the Audit independently as it would have liked.

42 The OAG report also highlights other issues related to the delays in starting the Cancer Audit, one of which relates to applications to ethics committees. In her report Dr McGoogan notes that 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 as a quality control measure with the assistance of expert agents such as epidemiologists. She notes that this interpretation has been questioned [by ethics committees] 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 publication of academic papers.

43 The NSU values the input of the University of Otago and continues to work closely with the staff of the Hugh Adams Unit in the provision of quarterly performance monitoring of both the NCSP and BSA. The University of Otago's expertise continues to be available to the NSU and more widely across the Ministry through a number of contracts

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.*

44 The OAG and Dr McGoogan expressed concern over the proposed legislative changes. The OAG concluded that changes connected with the effective monitoring, evaluation and audit of the Programme were proving the most intractable and that some of the changes were not straightforward to achieve. Dr McGoogan noted that slippage's in milestones in several areas were mainly due to these proposed changes and was concerned that amendments to the Health Act may not get through Parliament within the next 6 months.

45 The Government's timeframe for the implementation of recommendations to deliver legislative change (Comprehensive Bill), originally proposed to take place before the end of 2001 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. Consideration was given to splitting the Comprehensive Bill into two or more parts, as stated in Dr McGoogan's Report, although more recently it is thought that the Bill may be introduced as originally intended.

46 Progress on the legislative changes 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 May 2002.

47 Dr McGoogan and the OAG were critical of the discussion document regarding intended changes to the Health Act, which was approved for release by Cabinet in May 2001. [Ref. CAB Min (01) 15/6]

48 Dr McGoogan suggested that the basis of the consent issues, the intentions behind the Audit and the type of approach planned was not made clear to people whose opinions were being canvassed.

49 The OAG suggested that the discussion document was an example of poor communication with women about the NCSP and OAG concluded that the document was inadequate because:

- it communicated intentions rather than proposals;
- it did not explain these intentions clearly or in sufficient detail;
- it did not provide details of the Audit and what women's information would be used for; and
- it implied that information might be used more widely than only by the clinical reviewers employed by the Ministry.

50 The OAG recommends that in future the Ministry needs to more clearly specify the intention of its documents. The OAG notes that by using the term "discussion document" the Ministry set-up an expectation with the reader that the proposed changes were by no means final. In addition, the OAG suggested that communicating with women's groups prior to the document going out for comment would have encouraged a more informed debate.

51 Dr McGoogan was concerned that the "external" audit suggested for the Audit has mistakenly been portrayed as similar to financial audits. The OAG also comments on the use of the term auditors and suggests that use of this term has resulted in misunderstandings as to the role of auditors. The OAG suggests the term clinical reviewers should be used instead.

52 Officials acknowledge the shortcomings of the discussion document which was issued in the context of a decision by Cabinet that:

- Agreed that regulatory and legislative changes are required to facilitate access to identifiable personal information held on the NCSP-R for researchers studying cancer and for audit of the NCSP. [CAB (00) M35/4 (a)];
- There is a need to seek public input on the implementation of the government's decision to provide for access to identifiable personal information held on the Register for use by researchers studying cancer and for audit of the NCSP. [CAB (00) M35/4 (c(i))]

53 As stated in the foreword of the discussion document the purpose was "to inform women of the changes the Government proposes to make. The language was kept simple and focussed on the key messages, which

included the need to assure women that their information would be protected. As the Minister had publicly accepted all of the Inquiry's recommendations and had stated an intention to implement all of them, the justification for the changes was limited to that already provided in the Inquiry report.

54 A further difficulty with drafting of the document was that the protocol for the Audit was still under development, and decisions on the protocol effectively determined the detail of the legislative changes. This made it impossible for the Ministry to be more specific about the detailed use of the information. The law changes are in fact highly complex [refer EHC Min (01) 10/1 and CAB Min (01) 27/27].

55 It was not possible to delay the release of the discussion document until the Audit protocol was more fully developed in view of the timeframe set by Cabinet. Cabinet invited the Minister to report to EHC and Cabinet in late August 2001 on the form that the proposed legislative and regulatory change will take. [CAB Min (01) 15/6]

56 After analysis of public submissions, a draft cabinet paper on the amendments to the Health Act 1956 was considered by the Cabinet Education and Health Committee 28 August 2001. This resulted in further consultation on recommendations concerning access to women's clinical records. 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, with the requirement to seek consent to disclose medical records to those engaged to evaluate or Audit. [CAB Min (01) 27/17 refers] The OAG notes that this Cabinet requirement is contrary to the Inquiry's recommendations

57 Subsequent to Dr McGoogan's visit and the OAG's review, the proposals for consent to disclose medical records have been further clarified to require only those records obtained from GPs to require consent. Hospital records would be able to be made available to clinical reviewers without consent. [Ministerial Briefing 20011603]

58 Dr McGoogan's Report mistakenly identifies the NSU as now leading the work to amend the Health Act. The NSU has and continues to provide expert technical advice for this work, in respect of the delivery of high quality cervical screening programmes. The NSU lacks the necessary policy and legislative resource and capacity required to lead and implement the legislative changes. This lead currently sits with Sector Policy Directorate, and there is consideration being given to shift it to the Public Health Directorate

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

59 Cabinet 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. The OAG comments that issues surrounding access to Maori women's data are even more complex and progress to address the Inquiry's concerns are slow.

60 Since Dr McGoogan's visit and the OAG review, officials have met with a National Kaitiaki Focus Group (past and present Kaitiaki Group members) to discuss a draft discussion document in preparation for 10 regional hui planned for March 2002. A number of options for the role of the Kaitiaki Group are proposed for consultation at the hui.

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.

61 As for the proposed changes to the Health Act, there have been delays to the implementation of these recommendations linked to the introduction of the proposed Health Professionals Competency Assurance (HPCA) Bill, and

amendments to the Health and Disability Commissioner Act 1994. These legislative changes are now likely to be introduced into Parliament in May 2002.

62 Dr McGoogan suggests that until this legislation is introduced, 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 NSU has met with representatives of ACC and the Health and Disability Commissioner to discuss the sharing of information in advance of the new legislation. Both departments have agreed to work with the NSU to establish Memorandum of Understanding or protocols to assist in the sharing of information where possible. (Refer also Recommendation 24)

63 Royal assent was received for the Injury Prevention and Rehabilitation Act in Mid September 2001. This legislation includes legal obligations on the ACC to share information on medical misadventure claims with the Health and Disability Commissioner, registration bodies, employers and the Director-General of Health. Thus in the Seventh/Eighth Monthly Report, Recommendation 36 was reported as complete. However the sections that put in place the information-sharing obligation on the ACC do not come into affect until April 2002.

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.

64 Dr McGoogan comments that current systems are inadequate to ensure that health professionals are not inhibited from expressing concerns about the competency of other health professionals. The Cabinet Education and Health Committee has agreed the HPCA Bill will contain provisions to address these concerns. [EHC Min (01) 9/8]

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.

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.

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

65 Dr McGoogan's Report highlights the difficulties associated with implementing the Inquiry's Recommendations regarding ethics committees. Dr McGoogan concludes that progress is unlikely to be made at present and she expresses concern that regional ethics committees are at risk of taking an entrenched position.

66 Recommendations 18 and 20 are being addressed through the Operational Standard for Health and Disability Ethics Committees. Release of the Standard has been delayed to allow some additions to the content of the document to address concerns raised by Hon Tariana Turia about its adequacy in relation to Maori issues. Consultation on the resulting changes is now being completed, and it is hoped that the Standard will be released during February. Recommendations 19, 21 and 23 will be addressed by the National Ethics Committee, which has, as its first task, the requirement to carry out the review referred to in recommendation 19. Members of the Committee have now been appointed.

67 Dr McGoogan recommends that a mechanism be put in place without delay to standardise the approach taken by ethics committees with respect to research and audit projects for the NCSP specifically.

68 The Ministry will raise this issue with regional ethics committees. However, given the importance the committees attach to allowing each committee to raise the impact of research on its community, it is unlikely they would be willing to agree to a standardised approach towards NCSP projects. The implementation of Recommendation 22, that a national ethics committee should be established for the assessment of multi-centre or national studies, would facilitate ethical review of NCSP projects. Regional committees opposed this recommendation, and the Minister has referred it to the National Ethics Committee to consider as part of its review.

NCSP Operations

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.*

69 Dr McGoogan was concerned regarding delays to the delivery of recommendations to produce statistical information from the NCSP-R and NCR in a timely manner.

70 The NSU intends to produce annual statistical reports. The first of these reports, covering the period 1996-98 will be published March 2002. The second, covering the period 1999-2000 will not be published until December 2002.

71 It is anticipated that future reports will be provided up to 18 months after the period for which they report. Dr McGoogan is concerned that it is taking too long for the publication of Annual Statistical Reports and that these need to be provided in a more timely manner.

72 Workforce issues and the lack of available epidemiological expertise within the NSU are preventing the completion of these reports more quickly. Heavy reliance is placed upon experts' external to the NSU to complete and peer review these reports. These experts may not always be available for this work as required given their other commitments. The NSU has attempted to recruit a permanent epidemiologist, but has been unsuccessful. There is a shortage of good epidemiological expertise in NZ and these experts are in high demand.

73 Three NCSP Independent Monitoring Group (IMG) reports have now been published. Dr McGoogan and the OAG noted good progress had been made on the routine monitoring of performance indicators across the programme, including laboratories.

74 The publication of the IMG reports, as noted by Dr McGoogan, generate a huge amount of activity for the NSU, IMG and providers. The reports are provided in draft for checking prior to publication. Dr McGoogan notes that this process is not without its difficulties and that providers can be "very uptight and stressed" regarding the reporting. She recommends that more work needs to be done by all parties to ensure a better understanding of the respective positions and the need for reporting.

75 Officials advise that this would involve work with up to 13 laboratories, 21 DHBs and their gynaecologists and Regional Office staff, 9 Independent Service Providers and numerous professional groups. Representatives from some of these organisations and groups are already members of the IMG. Other than through the already scheduled contact with these groups, the NSU is unable to allocate further resource to this activity.

76 Dr McGoogan also suggests that whilst quarterly IMG reporting is reasonable at present, it should be possible to reduce the frequency of publication to six monthly and even annually. Reducing the frequency of reporting may assist in smoothing some of the difficulties in the current process and relieve pressure on provider and NSU staff.

77 In relation to laboratory reporting, Dr McGoogan made specific recommendations regarding improvements to the reporting of unsatisfactory smears, duplicate smears at colposcopy, liquid based cytology, and the introduction of the new Bethesda 2001 and revised SNOMED coding systems. The NSU does not have the workforce to address these issues in the short term. It is unlikely that Dr McGoogan's recommendations will be followed up prior to a review of the NCSP Interim Operational Policy and Quality Standards planned to commence before 2003. (Refer Recommendations 11.27 and 26 and 32)

78 Dr McGoogan noted in her report that many laboratories receive smears from across the country influenced by a variety of commercial and organisational factors. Dr McGoogan concludes that no useful information about the regional population can be derived from a laboratory's data and it is not possible to correlate information about regional variations in the incidence of cervical cancer with local laboratory reporting patterns. Dr McGoogan recommends

that another means of evaluating this laboratory reporting must be found. The NSU has examined this requirement together with the University of Otago and has found that there is no straightforward way to deliver this aspect of Recommendation 8 given the current configuration of laboratory services. The NSU may need to consider contracting with laboratories on a regional basis to ensure that this reporting can be provided in the future. It will not be possible, however, to report retrospectively.

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.

79 Dr McGoogan stated that she was satisfied that sufficient progress had been made in the implementation of these recommendations. The OAG notes the implementation of the minimum volume standards for laboratories and the incorporation of the NCSP Interim Operational Policy and Quality Standards within provider contracts. These recommendations were reported as complete in the 6-Month Summary Report.

80 The two public hospital laboratories providing cervical cytology services have recently alerted the NSU to the possibility that they may not reach the required minimum volume of cytology cases as required, despite their best endeavours. A briefing will be provided to the Minister following further meetings with the hospitals and an examination of other options for shifting volume from other laboratories.

81 In the 6-Month Summary Report officials identified that further work is needed with regard to implementation of standards for smear takers. Dr McGoogan highlights in her report that in the past GPs had no ownership of the NCSP and are burdened with the administrative requirements to support the NCSP without recompense.

82 Whilst she recognises that support for the NCSP by GPs may be improving she notes that many of the previous obstacles remain. These obstacles may prevent women from accessing the NCSP and receiving good information about the NCSP. These obstacles also make it difficult for the NSU to implement standards for smear-taking and ensure fail-safe follow-up by GPs. Dr McGoogan notes that coverage rates for the NCSP in NZ are not high and participation in the NCSP must be further improved.

83 The difficulties associated with NSU implementing standards for smear-takers is covered in some detail in the legal assessment provided to the NSU in response to Recommendations 5 and 6. Further policy development work is required to examine the various options for implementing standards for smear-takers. The lack of available internal workforce is preventing the NSU from progressing this work at this stage.

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

84 Dr McGoogan stated that she was satisfied that sufficient progress had been made in the implementation of Recommendation 27, but that insufficient progress had been made to implement Recommendation 32.

85 Laboratory coding standards will be developed in line with the review of the Policy and Quality Standards due for completion in 2003. Lack of workforce prevents the NSU from addressing this requirement any sooner.

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.

86 Recommendations 10, 11, 12 and 13 were reported as complete in the 6-Month Summary Report and discussion within the body of the report highlighted where these recommendations had been implemented. Whilst satisfied that progress has been made in the implementation of Recommendation 10, Dr McGoogan states that she is not satisfied that Recommendations 11, 12 and 13 are in fact complete.

87 Dr McGoogan reports three main areas of concern regarding the NSU, its governance, its management and its manpower resources.

88 The NSU was only recently established in November 2000 as a separate business unit within the Public Health Directorate of the Ministry of Health. As a business unit, the NSU has its own budget for the delivery of New Zealand's two organised population-based screening programmes. The manager of the NSU has the delegated authority to manage the Unit, having due regard to Ministry policies and public sector rules and expectations regarding financial management, human resources, and use of capital and facilities management.

> *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.*

89 The actual requirement for the NSU to have its own budget and contract directly with providers was largely implemented from 1 July 2001. Dr McGoogan, however, reports that the NSU is not seen as being "independent" as stipulated in Recommendation 11.12 and that generic Ministry rules may constrain the ability of the manager to run the NSU in the optimal way. She comments that the NSU must be allowed to function as intended without pressure or undue influence from other sections of the Ministry or politicians. Dr McGoogan intends to review this situation on her next visit and the OAG considers that it would be a useful exercise to review the operation of the present arrangements to determine whether or not these concerns have substance. Linked to these comments, one of Dr McGoogan's

particular concerns relates to difficulties experienced by the NSU attracting and retaining expertise.

90 Certainly the NSU has experienced difficulty in attracting expertise over the last 12 months. When the Unit was formed in November 2000 approval was given for an establishment of 33 full time positions covering both the NCSP and BreastScreen Aotearoa (BSA). At the time there were only 7 staff in post and a further 26 staff would need to be appointed before the NSU would be fully operational. The 26 new positions did not include staff for developmental projects such as the workforce development project, cancer Audit project, CSI recommendations' projects, and IT projects.

91 In March 2001, 1 month before the release of the Inquiry Report, there were only 9.4 staff in post covering both the NCSP and BSA – refer Table 2.0 below:

Table 2.0 National Screening Unit Workforce

National Screening Unit Structure	Staff in Post March 2001 (FTEs)	Staff in Post February 2002 (FTEs)	Vacancies February 2002	Total Establishment
Group Manager & Support	1.0	2.0	0	2.0
Clinical Director	1.0	1.0	0	1.0
Communications	0	1.0	0	1.0
NCSP	1.5	4.0	1.5	5.5
Maori Health Screening Development	0.8	2.0	0	2.0
BSA	1.5	5.0	0.5	5.5
Quality Monitoring Audit and Analysis	0.6	5.4	0.6	6.0
Information Systems Support (NCSP and BSA)	3.0	5.0	1.0	6.0
Contracts and Finance	0	4.0	0	4.0
TOTAL	9.4	29.4	3.6	33.0

92 Some positions have been difficult to fill despite repeated attempts in NZ and overseas. NZ does not have a well skilled and experienced workforce to call on with regard to screening.

93 More than half of the NSU's staff have been in post less then 5 months. All new staff require extensive training and guidance in screening activities and services and in working within the Ministry. The burden of this falls to only two or three staff within the Unit; the same staff working to manage and deliver key NSU projects. Dr McGoogan expresses concern that the necessary experience and expertise is lacking and must be addressed quickly. Unfortunately obtaining available experience and expertise in NZ is difficult and finding such people may take some time. Dr McGoogan recommends that an external review of recruitment issues be considered.

94 Recruitment difficulties were highlighted by the NSU in April 2001. The NSU suggested a more proactive response and Ministry wide approach to resourcing through targeted recruitment, long term secondments, performance payments and more attractive remuneration, and relaxation of the internal transfer policy.

95 Even where assistance has been sought from recruitment agencies, the Group Manager and Clinical Director have both spent considerable time in interviews and recruitment activities over the last 10 months on top of day to day work to deliver the two programmes.

96 Dr McGoogan comments that the NSU is severely under-resourced, particularly at this early stage when so much work is required over a short timeframe to implement the Inquiry recommendations. She highlights the need to fill two vacant key management posts and views the "*role of the Clinical Director to be severely over-stretched"*. Dr McGoogan recommends that two additional Clinical Leader positions be provided for in NSU in order to improve the level of clinical input and experience within the Unit. The NSU intends to seek candidates for the Clinical Leader positions for both NCSP and BSA. It would be preferable if these positions were filled with people experienced in the delivery of screening programmes, which will necessitate the Unit looking overseas for suitable candidates.

97 In September, November and December 2001 the NSU further highlighted workforce issues identifying difficulties in meeting key project deliverables and timeframes as well as issues related to core activities, the requirement to meet Ministry and Ministerial reporting, and respond to political and media attention.

98 The NSU is clearly in a developmental stage. Additional resource may be required over and above that required for core activity to enable many developmental projects to be delivered including the Inquiry recommendations. Some of these projects may be resourced using contractors where they can be found, although this still places a burden on core staff to manage contractor activity, and provide expert input as required. Dr McGoogan recommends that the NSU identify as soon as possible what can and what cannot be done utilising the available resource. The NSU is currently carrying out detailed planning in an effort to determine workforce requirements and work priorities and timeframes for the next 2 years.

99 In addition, later in her report, Dr McGoogan recommends that consideration should be given to organisational development of the NSU.

"A balance needs to be achieved between undertaking pieces of work, all members of the Unit pulling together and building up internal expertise and the NSU developing as an organisation"

100 In its first year the NSU has had little time to focus on the requirements of developing a new organisation, strategic and business planning. These requirements are recognised as key aspects of the Unit's development and greater attention will be paid to these in the coming months. Attention to this development as a priority, however, will place a strain on the Units ability to deliver other work.

101 Both the OAG and Dr McGoogan reports highlight that Recommendation 13 has not been implemented as envisaged by the Inquiry. The NSU's Group Manager does not hold specialist medical qualifications in public health or epidemiology.

102 The National Screening Unit retains its emphasis on maintaining strong clinical leadership for the programmes with Dr Julia Peters, a specialist in public health medicine as the clinical leader for the NSU's two screening programmes. 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, a budget of $60m, and contractual relationships with up to 70 service providers, necessitates this type of approach. The OAG report comments that this arrangement whereby a person with management skills and experience is employed to free up the time of the clinical leader to allow them to undertake clinical rather than managerial work, is operated in some health services overseas.

103 Dr McGoogan, however, whilst acknowledging the managerial skills, leadership and expertise of the current Group Manager, and the good working relationship with the Clinical Director, expresses concern that a system dependent upon personalities for the smooth running of the Unit is likely to fail in the long term. The OAG report highlights the concerns reported by Dr McGoogan that the Clinical Director has a direct line management relationship to the Group Manger, which she [Dr McGoogan] considers to be unusual, and that this arrangement runs the risk that clinical input to the NSU could be sidelined and the Clinical Director excluded from decision making.

104 The Clinical Director is a member of the NSU's Senior Management Team and as such is included in all critical decision making. The Clinical Director also has day to day contact with the Group Manager and other senior managers providing clinical and technical oversight of all work across both NCSP and BSA. Unfortunately due to the need for the Clinical Director to also cover the vacant Quality Manager's position, there is a limit to her ability to provide this oversight at present.

105 Recommendations 5, 6, 11, 12 and 13 relate to the finding by the Inquiry Committee under Term of Reference Three that there had been a failure to provide strong centralised leadership with the appropriate qualifications and authority to initiate action. In summary the Inquiry Committee found:

- Split leadership function between the central agency (Department/Ministry of Health) and regional agencies (area health boards/regional health authorities).

- The central agency did not have direct control over some aspects of the programme's delivery.

- Leadership functions of the central agency were further split between its various business units.

- Central agency officials lacked appropriate qualifications and expertise to appreciate fully the implications of programmes design and implementation.

- The National Co-ordinator did not have the necessary power to ensure the programme's effective management and co-ordination and no authority to require action to be taken or to impose sanctions when nothing happened.

- The National Co-ordinator had to operate within the framework of the central agency's management structure and as a fourth tier manager her ability to advance issues depended upon her ability to identify them, make a case for action, and influence colleagues. The Inquiry suggested that a medically qualified manager would have been in a better position to outline to more senior persons the dangers of inaction.

- In evidence the Inquiry Committee heard that recommendations in 1988 to set-up an executive group with decision making power to control the programme and the provision of specific and separate funding for the programme were not implemented by the then Government. The Committee agreed with further evidence supplied at the Inquiry that the programme needed a chief executive in whom sufficient power was vested to ensure that the programme was run properly.

106 Leadership functions are now retained by the Ministry of Health within the NSU with direct control, through the contracting mechanism, for many aspects of the programme delivery (excluding smear-taking and private gynaecology services). The NSU now manages all programme funding and has the ability to take action and/or apply various sanctions for failures in programme service delivery and quality.

107 The Group Manager still needs to operate within the framework of the central agency's management structure, albeit from a third tier position. The Group Manager's ability to identify issues is reliant upon the full range of expertise and capability within the NSU, including the Clinical Director, in addition to recommendations of the Advisory Group, IMG, information from ACC and HDC, and from providers, consumer and professional groups. The Group

Manager's ability to recognise risk issues and make a case for action is consistent with that of an experienced health service manager, utilising available advice, particularly that of medically qualified staff.

108 In the Committees view the programme needs to be managed by someone who has the authority and the means available to do whatever needs to be done. . The authority of the NSU's Group Manager are those which reflect the organisation's powers as vested in the Director General and as exercised through Ministry policies and guidelines at other levels of the organisation. The Ministry established the unit as a "separate business unit" at the end of 2001. The powers, delegations and responsibilities of a separate business unit and its manager will be reviewed by the Ministry later this year to ensure the adequacy of the arrangements to ensure accountability as well as provide sufficient autonomy to act effectively. The Ministry notes that the overall approach by government is to consolidate state sector agencies, rather than fragment them.

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.

109 Whilst Dr McGoogan expresses concern regarding progress on Recommendations 28, 41, and 42, she acknowledges that a colossal amount of work has gone into this area over the past few months by the NSU as part of the its Workforce Development Strategy project. The implementation of the NSU's Workforce Development Strategy will take some time to achieve and the Unit acknowledges that it will not be possible to implement these Inquiry recommendations in the immediate to short term.

110 In particular, Dr McGoogan comments on the need to raise the profile of practice nurses and lay smear-takers in the NCSP. There are several initiatives in the NSU's Draft Workforce Development Strategy, which relate to raising the profile of smear taking within the primary care setting.

111 Dr McGoogan notes that lack of specific funding for smear-taking training may act as a barrier to ensuring that all practice nurses are adequately trained. The Draft Workforce Development Strategy does not allocate funds for individuals to undertake smear-taker training, however incentives are recommended for consideration for some groups

112 Dr McGoogan expressed concern over the inability of the NCSP to audit the quality of smears taken by nurses who have not undergone formal training. There are no specific initiatives regarding credentialling only those who have undergone specific smear-taker training or for routinely auditing information held on the NCSP-R to determine quality of smear taking. Information regarding nurses taking smears without having undergone smear-taker

training is difficult to ascertain. The Workforce Development Project Team endeavoured to locate this information also, but to no avail. However the Project Team was anecdotally informed by several sources, that this practice does not occur frequently as the majority of nurses consider themselves accountable for their practice. The impact of the enactment of the Health Professionals Competency Assurance Bill on nurses' scopes of practice and ongoing education is acknowledged within the Draft Workforce Development Strategy, although nurses are legally responsible for all aspects of their practice under the current Nurses Act.

113 Dr McGoogan recommends that 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. Training should also be funded and easily accessible. Due to the fact that smear-takers are not currently contractually obligated to the NCSP, there are no Workforce Development initiatives that **require** specific training and ongoing education. However, several initiatives relate to the development of formal training courses and continuing professional development. It is noted in the Workforce Development background document that undergraduate medical training consists of an approx. 60-90 minute lecture and the undertaking of 1-5 vaginal examinations, during which a cervical smear is taken.

114 Dr McGoogan expressed concern regarding the unplanned introduction of thin-prep methodology in laboratories. The Workforce Development Strategy does not specify any initiatives related to liquid-based cytology. It is acknowledged in the strategy and in the background document that training is provided by the manufacturer and that approximately 15% of cervical smears are currently processed in this manner.

115 Dr McGoogan raises a number of concerns regarding laboratory participants in External Quality Assurance (EQA) programmes. In particular, she is concerned that there is no obligation on the part of laboratories to declare any "poor" performance to the NSU. The RCPA provides a Quality Assurance Programme (QAP) for laboratories and it is a contractual requirement that NCSP laboratories take part in this or a similar programme (refer pg 5.11of NCSP Interim Standards). This is also linked with IANZ accreditation. Dr McGoogan suggests that the NSU needs to consider developing a NZ EQA scheme for individual laboratory staff with a facility to break anonymity if there is a persistent poor performer. The Workforce Development Strategy identifies the possibility of introducing a New Zealand proficiency-testing regime for those who process and interpret cervical smears.

116 Dr McGoogan notes the concern expressed by laboratories regarding the introduction by the NSU of the new laboratory quality standards and that these have resulted in fewer cytology laboratories and fewer opportunities to train junior pathologists. It was suggested to Dr McGoogan that training agreements are incorporated within laboratory contracts to address this.

117 Pathology registrar training is the responsibility of the Clinical Training Agency (CTA). The Project Team is working closely with CTA and a member of the

CTA was on the Workforce Development Steering Group. The CTA and the NSU are aware of the political issues surrounding the desire of private laboratories to receive CTA funding for registrar training and the cost implications thereof. The CTA continues to work on strategies for managing this as it does not solely relate to cytology.

118 Another concern of Dr McGoogan's is the lack of availability of cervical cytology update courses for pathologists in NZ. The lack of availability of NZ cytology courses for pathologists and for technical staff is highlighted within the Draft Workforce Development.

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.

119 Dr McGoogan was satisfied with progress on Recommendation 37 but not satisfied that enough progress has been made implementing Recommendation 43.

120 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.

121 The NSU acknowledges that a number of laboratories still appear to be concerned regarding the public nature of the monitoring reports prepared by the IMG and NSU. Some of these concerns relate to the commercial nature of their operations and the use of this information by other laboratories as a marketing tool to persuade smear-takers to send smear tests to them. Some

laboratories have not responded well to the NSU following up some of the recommendations contained within the IMG reports and are unhappy about providing further explanation of their reporting and performance.

122 The NSU continues to monitor this situation on a case by case basis maintaining contact with the College over specific issues where appropriate. As laboratories become more used to this monitoring we may see a shift to a more open-minded approach. The new Community Laboratory Agreements currently being prepared by the NSU contain more explicit requirements regarding audit and monitoring. Any laboratory not wishing to comply with these requirements in negotiation with the NSU will not be contracted to provide cervical cytology for the NCSP.

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.*

123 Dr McGoogan is not satisfied with progress to implement this recommendation.

124 The NSU contracted Women's Health Action (WHA) to develop a new, more detailed booklet for women regarding the NCSP including the benefits and risks of screening. This detailed booklet will be published in July 2002. Its publication will **not** now await the introduction of changes to the legislation as noted in Dr McGoogan's report. A further revision will be published once the legislation is in place.

125 Dr McGoogan implies in her reporting that this booklet is the only resource produced by the NSU providing basic information regarding the NCSP. The NSU has recently sent Dr McGoogan the whole range of resources for her review, including:

- General pamphlet: Have you had a cervical smear in the last 3 years?
- Cervical Screening. Understanding Cervical Smear Test Results.
- Colposcopy. Information for women who have abnormal cervical smear results.

- Maori pamphlet: Atawhaitia Te Wharetangata. Cervical Screening.

- Pacific Islands Series pamphlets (currently being reviewed): the following pamphlets translated into 7 Pacific languages:

  The Cervical Screening Register
  Facts about Cervical Screening
  Understanding Cervical Screening Results

126 Basic information about the NCSP for smear-takers, gynaecologists and women is available through a range of pamphlets and brochures. These resources are distributed by the programme's regional offices to practitioners and in correspondence with women. In addition, the NSU is also currently preparing a tear-off information pad for use by practitioners in their consultation with women. This will be available around March 2002.

127 The NSU also has a user-friendly website www.healthywomen.org.co.nz as well as an 0800 number to give easy access to women.

128 Dr McGoogan comments that there is a high level of ignorance about the risks, benefits and limitations of cervical screening programmes amongst the public and healthcare professionals. Women are either being encouraged to participate in the programme with no clear understanding of the benefits or are badly informed and opt-off the programme without fully understanding the risks incurred by doing so.

129 She also highlights potential misunderstandings amongst healthcare professionals. In her report she comments that Gynaecologists use smear tests for reasons other then screening where the cervical smear is a screening test and not a diagnostic test. This potentially results in the recording of duplicate smear tests on the NCSP-Register with the possibility of skewing laboratory reporting rates. As part of the review of the Interim Standards, the NSU will consider further policy development regarding this gynaecological practice.

130 The NSU's intention is that the detailed booklet to be published in July 2002 will be used by health professionals to inform both themselves and women about the risks and benefits of cervical screening. Women will be able to retain the booklet for future reference.

131 The Royal College of General Practitioners has also just published its own detailed booklet on Cervical Screening ' Information and Practice Review Activities to Aid in the Provision of Quality Cervical Screening in General Practice, 2001, for smear-takers and includes reference to the NCSP Interim Standards as an appendix. A copy of this booklet will also be sent to Dr McGoogan.

132 From the recent IMG reporting, Dr McGoogan also suggests that smear-takers and gynaecologists fail to understand the economics of the screening interval, advocating early recall at great expense but little benefit to many women. The NSU estimates that the high short-interval screening rate in NZ costs an additional $2m or more in the processing of cervical cytology, not to

mention the unnecessary expense for women and the potential for unnecessary anxiety and intervention. High rates of short-interval screening are also being examined in Australia and the NSU continues to monitor developments there.

133 Dr McGoogan recommends that more work must be done to develop and promote an understanding of clinical audits as an integral part of good quality healthcare delivery. Greater understanding of the benefits in participating in a screening programme with comprehensive audit built in must be promoted amongst women. The safety checks built into the NCSP, such as those offered by the Audit, are there to protect women, who should be demanding, not merely consenting to the process.

Information technology

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

134 Dr McGoogan is not satisfied that this recommendation is complete as stated in the 6-Month Summary Report. She raises concerns that 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.

135 The NSU and Cancer Registry have now agreed upon a regular data assurance process between the NCSP-Register and the Registry to be performed monthly. This process has been refined and enhanced since the first trial in 2001. The new process requires some programming and is due to commence in March 2002. Within this process, the Cancer Registry reviews information that it holds, and is able to obtain missing data directly from the source laboratories rather than the NCSP-Register to update and correct Cancer Registry information. In addition, by checking all the cancers reported to NCSP-Register, the Cancer Registry is now able to inform NSU of which cancers are cervical primary and this important information is now recorded in the Register.

136 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, were identified. Phase 2 has therefore been discontinued. This decision was further reviewed in the development of the regular Monthly Data Assurance process. It has been agreed that this process has been automated as far, as is desirable, as it is imperative that individual discrepancies are manually checked and agreement reached on any corrections that are made. It is intended to give the Cancer Registry

read-only access to the NCSP-Register and this will be implemented once the NCSP-Register network is migrated to the Health Information Network, due for full completion by June 2002.

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.

137 Dr McGoogan expresses disappointment with the delays to implement this recommendation.

138 Officials report that 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. 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.

139 Performance standards for the NCSP-Register have been incorporated into DHB Agreements. The NCSP-Register Operating Protocol Version 2.0 has been released in the first week of January 2002.

140 Further work on performance standards will be incorporated within the NSU's work to review the NCSP Interim Standards, for completion in 2003. Lack of available resource prevents the NSU from undertaking this work any sooner.

Other Issues

141 In relation to Recommendations 25, 26 and 32, Dr McGoogan also raises concerns regarding the need for 14 NCSP Regional Offices. In particular, Dr McGoogan is concerned about the staffing of these offices and their role and responsibilities. The Inquiry Report did not provide specific recommendations relating to the role of NCSP Regional Offices.

142 The NSU is currently carrying out a funding review of the Regional Office services. The NCSP-Register component of these services will also be reviewed as part of the NSU's Information Systems Strategy development. Given the available resources it is unlikely that the NSU will be able to consider a full cost effectiveness review of the Regional Offices and the re-organisation of their services before 2003.

143 Dr McGoogan also suggests that a national cervical smear request form be implemented to reduce the effort by Regional Offices to improve patient identification data provided by smear-takers to laboratories. The NSU does provide a standard NCSP form to smear-takers, although is unable to mandate its use by smear-takers.