

**UNDER THE HEALTH AND DISABILITY
SERVICES ACT 1993**

**IN THE MATTER OF THE MINISTERIAL
INQUIRY INTO THE UNDER-
REPORTING OF CERVICAL SMEAR
ABNORMALITIES**

**CLOSING SUBMISSION OF
THE CANCER SOCIETY OF NEW ZEALAND, INC. – PART 2**

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Section 5

TERM OF REFERENCE 3: EVIDENCE OF UNDER-REPORTING IN OTHER AREAS

HFA laboratory review

1. The “Review of Cervical Cytology Practice in New Zealand Community Laboratories 1990-1999 Final Report” (JD/HFA/001) presented by Mr DuRose, Quality Improvement/Audit Coordinator, was offered by the Health Funding Authority as a means by which this term of reference could be addressed.
2. As stated in the executive summary, the overall objective of the review was to “gather enough evidence to establish whether community laboratories in New Zealand were practising within acceptable standards in their reporting of cervical cytology during the period 1990 to 1999”. (JD/HFA/001, page 4)
3. For the evaluation of laboratory practice the report set the following benchmarks for abnormality reporting rates:
 - 3.1 Greater than 0.5% high-grade abnormality.
 - 3.2 Greater than 5% total abnormality: “high grade” + “low grade” (ASCUS included). (JF/HFA/001, page 5)

Expert evidence relating to the HFA review

4. Expert witnesses Professor Skegg and Dr Cox were asked to comment on whether the DuRose review addresses the past or present effectiveness of the screening programme in respect to laboratory reporting of cytology smears.
5. Professor Skegg expressed “some reservations” and did not feel that the evidence presented by Mr DuRose “provides an adequate basis on which to

conclude that the Gisborne experience was exceptional". In his view the review was limited by the following factors:

- 5.1 It is based only on cervical smears, not on women (proportions of smears reported as abnormal can be markedly affected by the patterns of medical practice in different areas).
- 5.2 There is no adjustment in the data for factors such as age or socioeconomic status or ethnicity. (Skegg trans, B/2308)
6. In Professor Skegg's view, Dr Bottrill's laboratory would not have emerged as a "clear outlier" based on the DuRose approach. He noted that: "There were 4 laboratories that had a lower proportion than Dr Bottrill and in terms of his correlation with histology he would be within the range of other laboratories so although one can never say with certainty what would have happened if this had been done in 1994, I am far from convinced that his laboratory would have emerged as a clear outlier". (Skegg trans, B/2311)
7. In Professor Skegg's view, trends in reduced incidence and mortality from cervical cancer in New Zealand indicate that the programme is preventing many cases of invasive cancer. Nevertheless, he was "not comforted" by the evidence presented by Mr DuRose "to the extent that we could deduce that what has happened in Gisborne is totally exceptional and that there might not be some other areas where similar problems could exist". (Skegg trans, B/2319)
8. When asked to comment on the national average of high-grade smears of .8% reported in the HFA review, Professor Skegg did not believe there could be assurance that this is a correct and accurate figure without a full evaluation of the screening programme. (Skegg trans, B/2321)
9. Dr Cox indicated that he agreed with the commentary of Professor Skegg. (Cox trans, B/2594)

10. In Dr Cox's view, the methodology in the practice review does not answer the stated objective for the following reasons:
 - 10.1 The process is not robust enough.
 - 10.2 It is unclear how much can be done retrospectively. (Cox trans, B/2631)
11. Dr Cox was asked to comment on the benchmark of 0.5% high-grade abnormalities used in the review, and also the proposed target that laboratories report not less than 0.5% as high-grade abnormalities in the HFA's draft evaluation and monitoring plan. (JMP/HFA/0042, p 15) Dr Cox stated that this indicator on its own was not robust enough for drawing conclusions. However, if used in combination with others, it may provide useful information. (Cox trans, B/2627-8)
12. Dr Cox also indicated that although there are ways of assuring that laboratories are performing appropriately from this time, it is difficult to establish this as acceptable practice retrospectively. (Cox trans, B/2636-7)
13. According to Dr Cox's reading and interpretation of the study, it leaves the question posed by Term of Reference 3 open. (Cox trans, B/2633)

Implications of the Sydney re-read data

14. Professor Skegg stated that the results of the Sydney re-read showed that the proportion of high-grade abnormalities in the Gisborne smears was higher than the national average in New Zealand. In his view, "... if the Sydney re-read is taken at face value it would have to raise concerns about every laboratory in New Zealand". (Skegg trans, B/2301)
15. Professor Skegg subsequently strengthened his view, stating that: "I don't think we can have any assurance that there isn't systemic under-reporting [throughout New Zealand]. I just don't see how one could exclude that

possibility. Indeed, if all we have is the Sydney results I think it has to be seriously considered". (Skegg trans, B/2306)

Possible ways to address this term of reference

16. Professor Skegg indicated that the issue of under-reporting in other areas would best be resolved by undertaking an audit of the screening histories of women with invasive cervical cancer in these areas. Slides could be re-read by a panel of pathologists. (Skegg trans, B/2434-5)
17. Dr McGoogan also recommended an audit to address this issue. (McGoogan trans, A/1014)
18. Professor Skegg also suggested that further use be made of data on the NCSR, in addition to the national audit. (Skegg trans, B/2319)
19. In particular, Professor Skegg stressed the urgency of the audit to determine "how many women are developing cancer despite having had successive smears reported as normal". (Skegg trans, B/2320)

Conclusions

20. It is the Cancer Society's submission based on expert evidence that the review undertaken by the Health Funding Authority does not establish that the mis-reporting in Gisborne was an isolated case and not a systemic issue for the NCSP.
21. The Society also submits that a national audit by Drs Cox and Richardson must be undertaken with the utmost urgency to address this matter. This critical initiative will be discussed further with regard to Term of Reference 6.
22. The Society is cognisant of the current legal and ethical committee constraints regarding the release of personalised data on the Cancer Registry and the National Cervical Screening Register and urge that these matters be addressed

with urgency. The specific recommendations regarding these matters are set out under Term of Reference 6.

Section 6

TERMS OF REFERENCE 4 & 5: CHANGES MADE OR AGREED TO BE IMPLEMENTED TO ADDRESS ANY RISKS OF UNDER-REPORTING

1. As stated in the Society's submission regarding Term of Reference 2, the reasons for under-reporting are multi-factorial, including both direct and indirect (systems) factors. The systemic issues relate to the NCSP and its deficiencies in not meeting in all respects international criteria for effective screening programmes.
2. Among the most critical failures identified during the 1991-96 period include:
 - 2.1 Failure to implement quality standards for all aspects of the screening pathway.
 - 2.2 Failure to institute routine programme monitoring and evaluation of all aspects of the screening pathway.
3. Some of the key changes made or agreed upon since 1996 to better meet the requirements for effective screening and, in particular for the development of standards and routine monitoring/evaluation, are outlined below as they relate to specific criteria. These include:
 - 3.1 Effective information systems.
 - 3.2 Quality control of both smear taking and smear reading.
 - 3.3 Follow-up systems to ensure all positive cases are treated appropriately.
 - 3.4 An agreed policy and set of objectives for the programme, against which its success can be measured.

- 3.5 A central office or individual responsible for planning, coordinating, monitoring and evaluating the programme.
4. Also described are remaining weaknesses relating to these factors.

National Cervical Screening Register

5. Reconfiguration of the 14 separate registers established at the outset of the programme was completed in early 1997. As a result the NCSR is fully operational as a national register. Advantages include:
 - 5.1 Laboratories in any part of the country can access smear histories of women (formerly the local site could only give histories of women enrolled in their region). (Matcham brief, para 46)
 - 5.2 The register can compare all result recommendations against other information on the database. (Matcham brief, para 49)
 - 5.3 A number of duplications were identified due to movements of women between register sites, and these files could be merged. (JMP/HFA/0015, page 11)
 - 5.3 Laboratory reporting pattern reports are available to all laboratories, and quality reports containing national averages are available to all smear-takers. (Matcham brief, para 86)
 - 5.4 Data at a national level for monitoring and evaluation are readily available, overcoming past problems relating to accessing 14 separate databases.
 - 5.5 Data for statistical reports could be extracted directly from the central register (eg, for the HFA report produced as JMP/HFA/0015).

6. Since the end of 1995 the NCSR has been able to process histology results and attach them to a woman's records. (Matcham brief, para 98) The automatic reporting of cytology and histology results to the NCSR enables the NCSP to assess the accuracy of cytology, monitor whether women with abnormalities are treated and monitor the outcome and assess the effectiveness of treatment.

7. Some of the remaining weaknesses relating to the NCSR are as follows:
 - 7.1 There are delays in histology results being sent to the register, with some labs not sending results electronically. (Matcham brief, para 100) (Matcham trans, B/3553) The effect of the lack of histology results, including the inability to generate correlation reports between cytology and histology reporting, were outlined by Ms Matcham. (Matcham brief, para 101) These issues are also identified in the public submission from the all the regional programmes of the National Cervical Screening Programme and were cited by Professor Skegg. (Skegg trans, A/893)

 - 7.2 The NCSR continues to be a "utilisation register" (women enrolled) rather than a population register. As a result, the denominator of the population is not known; instead, the census is used to determine coverage. Also, the NCSP cannot actively invite women for screening. (Cox trans, B/2590)

 - 7.3 There is limited information available on the quality of data collected by the register. As pointed out by Dr Duggan, a number of the laboratories in the HFA review were shown to have had coding errors. (Cox trans, B/2629) According to Dr Cox, in some areas such errors would be "really critical and others ... less critical". (Cox trans, B/2630)

 - 7.4 Monitoring and evaluation using register data have not yet been established as routine functions. However, one of the current components of the Cox/Richardson evaluation is to look at the

information on the register to ascertain what could be used to provide more information than is currently being produced through statistical reports. (Cox trans, B/2629)

- 7.5 Although women are ‘enrolled’ on the register, they must be allowed to refuse consent for their cytology and histology results to be forwarded to the register on every occasion. (A woman’s consent is required for each test rather than for ongoing participation in the programme.) (Peters trans, B/3471) This requirement is based on the response from the former Health and Disability Commissioner, Robyn Stent, to a consumer complaint, described in JMP/HFA/0043, page 7.
- 7.6 According to Section 74A of the Health Act, women must consent to details being accessed by those reviewing smear history for programme monitoring.
- 7.7 There is no link between the NCSR and the Cancer Registry. According to Professor Skegg, “I find it extraordinary we have spent millions of dollars establishing and maintaining these registers, and we are not using them in the way they could be used to advance the health of women”. (Skegg trans, A/893)

Quality control of both smear taking and smear reading

8. According to evidence before the Inquiry, the document “National Cervical Screening Programme: Standards for Laboratories”, was prepared by the Cervical Screening Advisory Committee in 1995. According to Mr Walker, however, they were never forwarded to TELARC/IANZ. (Walker affidavit, para 3)
9. Evidence given by Ms Sax outlined the work done by the RHAs, together with IANZ and the RCPA, to develop national quality and service standards for medical testing laboratories. The evidence shows that, at 10 June 1997, the

national laboratory standards remained in draft form and were not a formal contractual requirement. (Mellor suppl evid, para 28)

10. The HFA has drafted a comprehensive national policy and quality standards document which includes standards for laboratories. (JMP/HFA/0040) These standards include minimum cytology volumes for laboratories, screeners and pathologists, the rationale for which is outlined in JMP/HFA/0041.
11. The HFA has required, by means of an agreement with labs, that they incorporate the standards in JMP/HFA/0040 and the National Quality Standards for Medical Laboratories 1997. (TM/HFA/0089) Steps are being taken by the HFA to meet a single, nationally consistent contract to include these quality requirements. (Mellor suppl evid, paras 28-38)
12. According to the HFA, all laboratories currently reporting to the NCSP are IANZ accredited. (JD/HFA/001, p 013)
13. The effect of the above is that there appears still not to be a single consistent contract incorporating mandatory quality control for laboratories reporting to the NCSP.

Follow-up systems to ensure all positive cases are treated appropriately

14. A protocol for the management of women with abnormal smears was updated and published as guidelines in 1998. The report acknowledged that “in spite of ideal screening and treatment”, a small number of women will develop invasive cancer, and that such cases **should be the subject of a formal review process** [emphasis as in original]. (JMG/MOH/0050, p 5)
15. One of the present weaknesses identified by Dr Cox is that the NCSP has not collected stage information and some treatment data that would address the European guidelines in terms of management of individuals. (Cox trans, B/2638)

An agreed policy and set of objectives for the NCSP, against which its success can be measured

16. The NCSP policy published by the Ministry of Health in 1996 and produced as RGB/MOH/001 is currently under review and being expanded to include quality standards. (JMP/HFA/0040)

17. Agreed recommendations on the frequency and age for cervical screening were reviewed by a multi-disciplinary group in 1997 and published in 1998 in the *New Zealand Medical Journal*. (JMG/MOH/0049) It is worth assessing whether the recommendations that the group made in 1997 have been implemented.
 - 17.1 In its report the group devoted a substantial section to quality assurance of a cervical screening programme, beginning with the statement that “the implementation and monitoring of quality assurance guidelines is vital if the optimal benefit of screening is to be achieved”.

 - 17.2 The section also listed Europe Against Cancer Programme criteria for a high-quality programme, including targets for coverage, interval to reporting, proportion of unsatisfactory smears, follow-up compliance, treatment compliance, sensitivity, specificity, distribution of invasive cancers and interval cancers.

 - 17.3 The report also recommended that:
 - 17.3.1 The screening history within one and three years of diagnosis of cervical cancer should be determined to identify which parts of the programme need improvement.

 - 17.3.2 The stage distribution of cervical cancer should be available.

 - 17.3.3 The use of resources needs to be monitored.

17.3.4 Monitoring should assess:

- number of smears in any three-year period*
- proportion of women with more than one smear during a three-year period*
- coverage by age and ethnic group*
- cytology/histology correlation and the use of colposcopy services
- information from the NCSP, the NCSR and the Cancer Registry to assess the screening service.

17.3.5 Financial gains from increased efficiency should be made available for improvements in other areas of the screening service, including quality assurance, training and treatment.

17.4 Although most of the above recommendations have been addressed in the draft “Policy and Quality Standards for the National Cervical Screening Programme” (JMP/HFA/0040), only those marked with an asterisk [*] have been addressed by the NCSP to date.

A central office or individual responsible for planning, coordinating, monitoring and evaluating the programme

18. Since the Health Funding Authority assumed responsibility for the NCSP and the national unit for the NCSP was moved to Auckland in 1998, there have been major achievements in meeting the above requirement. (Cox trans, B/2620) (Marshall trans, B/3207)

19. Some of the current strengths of the NCSP, as outlined in a letter from the current HFA screening advisory committee, include:

19.1 A public health medicine specialist has leadership responsibility for the programme.

- 19.2 For the first time in the programme's history, responsibility for the NCSR, laboratory services and colposcopy services now come under one unit.
- 19.3 There is a wider range of expertise within one national unit than ever before, including information technology. (EAM/CS/0041)
20. As indicated by Dr Peters, the HFA has acknowledged the need for a "significant number" of additional staff with clinical, epidemiological, public health, contracting and quality assurance and monitoring skills, and they are "progressing these issues". (Peters affidavit, para 6)
21. Remaining deficiencies in fully meeting the WHO requirements for a national unit with the appropriate range of expertise are as follows:
- 21.1 The public health medicine specialist having responsibility for the unit has "quite a burden without necessarily a lot of similar professional support". (Cox B/2618, 3-6)
- 21.2 There is under-resourcing in expertise, qualifications, knowledge and time commitment. (Cox B/2618, 7) (Coney B/2744, 4-12)
- 21.3 The screening coordinators are part-time (divided between two programmes). (Cox trans, B/2618) (Marshall trans, B/3237)
- 21.4 The role and accountability to the national unit of the regional screening coordinators appear not to be clearly defined. No evidence was produced of any job description of a regional coordinator that showed accountability to the national coordinator.
- 21.5 Staff have been "worked off their feet" during the past six months to respond to the Gisborne situation, without increased resources. (Cox trans, B/2621)

- 21.6 There is no provision for the establishment of the unit as a body independent of the Ministry of Health. This is of particular concern in view of the re-absorption of the Health Funding Authority into the Ministry.

Quality standards and programme monitoring/evaluation

22. One of the most critical weaknesses of the NCSP is the absence to date of a detailed set of quality standards developed and implemented within the NCSP. However, a comprehensive document is being developed and due to be finalised shortly. (JMP/HFA/0041)
23. Also, there is no evidence of someone having overall responsibility for NCSP quality assurance.
24. In response to a question from the chair as to “what does it tell you about the New Zealand programme if there were no standards set?” Dr McGoogan replied: “There seems to be a belief that simply doing the work is good enough, not necessarily doing it to a high standard or at least an acceptable standard. Again, I’m very impressed at the effectiveness of the New Zealand cervical screening programme. You have reduced the incidence of cervical cancer in both your Maori population and in the rest of your population, so your screening programme is effective. But without quality standards in place, you cannot evaluate how much more effective it might have been [emphasis added]”. (McGoogan trans, A/1187)
25. Another significant weakness is the absence of programme monitoring on a routine basis. In referring to the initial draft “Evaluation and Monitoring Plan” of the NCSP (JMP/HFA/0023), Dr Peters stated that “There isn’t any routine ongoing monitoring of the NCSP occurring at the moment. This is the purpose of this developmental work, to establish the indicators so that we can do that”. (Peters trans, B/198)

- 26 Evidence before the Inquiry indicates that at present costs associated with the provision of NCSP services to women (excluding costs for the Change Management Team at a national level) are estimated at approximately \$30 million per annum. (Peters affidavit, para 4)
- 27 As stated succinctly by Dr Cox, “If it’s worth spending a lot of money in implementing [the programme], it’s worth monitoring”. (Cox trans, B/2599)
28. Since assuming coordination responsibility for the NCSP, the National Prevention Team has taken important steps in meeting the requirements for monitoring and evaluation. In addition to the drafting of a national monitoring and evaluation plan (JMP/HFA/0042) and finalising the national indicators (Peters affidavit, para 11), the following actions have been undertaken:
- 28.1 Appointment of an independent monitoring group for the NCSP (Peters affidavit, para 11), the concept for which has the support of relevant professionals. (Peters trans, B/201)
- 28.2 Development of a draft format for the NCSP annual statistical report. (JMP/HFA/0036)
- 28.3 A NCSP review. (JMP/HFA/0015)
- 28.4 Draft Health Promotion Plan. (JMP/HFA/0044)
- 28.5 “New Directions for Cervical Screening Education Resources” (an evidence-based review upon which to base revised resources). (JMP/HFA/0043)
- 28.6 NCSP Review of the Current IM Environment. (JMP/HFA/101)
- 28.7 Working draft of a 1996-98 statistical report. (JMP/HFA/0047)

29. In response to questions from the panel, Dr Cox commented on which of the European guideline measures have been, or are currently being, calculated by the NCSP, and which could be calculated using existing data. (Cox trans, B/2510-2521 and B/2615-6) According to his evidence:
- 29.1 Of the 18 tables provided in the guidelines, “there are parts that we have done from time to time but it’s not a routine ongoing thing, and most we do not collect”. (Cox trans, B/2521)
- 29.2 The draft 1996-98 statistical report contains five sets of tables of a similar nature to the guidelines; the remaining 13 tables described by the guidelines as minimal are not yet provided in the statistical reports. (Cox trans, B/2615-6)
- 29.3 Table 11 of the guidelines, which addresses interval cancers, is needed to calculate the sensitivity of the programme. When asked if this calculation would have allowed the programme to detect under-reporting in the Gisborne region, Dr Cox replied that it probably would not have done so at a regional level. (Cox trans, B/2518)
- 29.4 In future, statistical tables in the European guidelines should be included in annual NCSP statistical reports. (Cox trans, B/2588)
30. One of the most significant deficiencies is that to date there has been no full evaluation of the NCSP. (Cox trans, B/2607) However, the Ministry of Health has contracted the University of Otago to evaluate three specific aspects of the NCSP. (Cox brief, para 12) As evidence before the Inquiry has indicated, one of these aspects (audit of the screening histories of women with invasive cervical cancer) cannot proceed due to ethical and legal barriers outlined in Section 7, para 106.

Conclusions

31. Some of the most significant changes made since 1996 to reduce in an indirect way the risks of under-reporting include:
 - 31.1 The establishment of a single dedicated National Cervical Screening Register.
 - 31.2 The development of comprehensive quality standards, including laboratory standards, for the NCSP.
 - 31.3 Responsibility for key elements of the NCSP, including the NCSR, laboratory services and colposcopy services, included in the national unit.
 - 31.4 A public health medicine specialist with leadership responsibility for the programme.
 - 31.5 A wider range of expertise within one national unit than ever before.

32. Some of the most significant weaknesses include:
 - 32.1 The absence (as yet) of a single, nationally consistent contract to include standards for laboratories, including IANZ accreditation.
 - 32.2 The absence of someone in the national unit who has overall responsibility for quality assurance.
 - 32.3 The role and accountability to the national coordinator of regional coordinators is not clearly defined.
 - 32.4 The absence of programme monitoring and evaluation on a routine basis.

- 32.5 The requirement for women to give consent to their personal details being accessed for programme monitoring and evaluation.
 - 32.6 The re-absorption of the NCSP into the Ministry of Health rather than its constitution as independent of this Ministry.
33. These weaknesses are at the heart of the recommendations that this submission outlines under Term of Reference 6.

Section 7

TERM OF REFERENCE 6: PROPOSALS TO AMELIORATE ANY RISKS OF UNDER-REPORTING

1. In this submission the Cancer Society has identified the factors likely to have lead to under-reporting, including both direct and indirect (systems) factors. In so doing, the Cancer Society has identified major weaknesses of the NCSP which, if addressed, may not only reduce the risk of under-reporting but may also result in a programme of a high international standard. As such it would ensure that the best possible efforts are being undertaken to maximise the benefits and minimise the risk of harm to the women of New Zealand.
2. In identifying the proposals that could ameliorate risks of harm to women, the Cancer Society shall focus on the WHO guidelines for the organisation and management of an effective screening programme. In the view of the Cancer Society, minimising the risks of harm can best be achieved by stricter adherence to these guidelines than has occurred in the past.
3. The proposals outlined below relate to the following:
 - 3.1 Central unit responsible for planning, coordinating, monitoring and evaluating the NCSP.
 - 3.2 Advisory committees.
 - 3.3 Sustaining a national programme in a re-structured health system.
 - 3.4 Quality assurance.
 - 3.5 Laboratory standards.
 - 3.6 Protocol for concerns and incidents.
 - 3.7 Programme monitoring and evaluation.

- 3.8 National Cervical Screening Register data issues.
- 3.9 Establishment of a population register.
- 3.10 Linking the Cancer Registry and the NCSR.
- 3.11 Access to personalised data for programme monitoring/evaluation.
- 3.12 Access to Maori women's data as governed by the Kaitiaki Regulations.
- 3.13 Access to Cancer Registry data.
- 3.14 Resourcing of the Cancer Registry.
- 3.15 Routine audit of screening histories of women with invasive cancer.
- 3.16 Information for women.
- 3.17 Information and training for health professionals.
- 3.18 Responsibility and time frame for implementing Inquiry recommendations.

Central unit responsible for planning, coordinating, monitoring and evaluating the NCSP

- 4. The need for a strong central operational unit for the NCSP has been identified consistently in evidence before the Inquiry. (JMG/MOH/0035) (Marshall trans, B/3237) (EAM/CS/0041) (BC/CS/0047) (BC/CS/0046)
- 5. Reflecting upon the evidence identified under Term of Reference 2, we believe the critical importance of such a unit cannot be underestimated.

6. Dr McGoogan reinforced these views in her statement that “the current success of the UK cervical screening programme is in no small measure due to the excellent leadership shown to the programme by the national co-ordinating team and by the national coordinator both in Scotland and England”. (McGoogan, trans A/1129)
7. As emphasised in evidence, the director of the NCSP should be a public health medicine specialist with skills in epidemiology and management. (Cox trans, B/2473) (BC/CS/0047, page 29) (EAM/CS/0041)
8. As identified earlier in this submission, one of the current strengths of the NCSP is that a public health medicine specialist, Dr Peters, has leadership responsibility for the programme. Also, there is a wider range of expertise within the unit than ever before.
9. Nevertheless, considerably greater resources are needed to build upon this expertise and to support Dr Peters in her role. In particular, there is a need to address the risk of staff being over-burdened and inadequately supported as may have been in the past. (Marshall trans, B/3211)
10. According to evidence before the Inquiry, the critical skills needed by the unit include public health medicine, epidemiology, statistics, information technology and cytology. (JMG/MOH/0035) (Coney trans, B/2746) (Coney trans, B/2807) (Cox trans, B/2472-5) (Marshall trans, B/3237) (EAM/CS/0041) (Cox trans, B/2551)
11. Dr Cox also cited the need for a medically trained epidemiologist and a biostatistician. (Cox trans, B/2472-5)
12. Not all of these skills are required on a full-time basis. In the view of the Cancer Society, however, the role of coordinator must be a full-time position. (Cox B/2618, 8) (Marshall B/3237) Dr Cox identified the additional advantage of a coordinator being able to be a medical spokesperson and carry weight in terms of the relationship with medical and other health professionals

providing various aspects of the service of the programme. (Cox trans, B/2618)

13. Evidence has also indicated the need for an appropriate mix of in-house staff and external contractors, with in-house staff needed to support and sustain the knowledge base of the programme. (EAM/CS/0041) (JMG/MOH/35, page 2) (Cox trans, B/2526)
14. Although the HFA may currently be addressing the need for additional staff within the unit, an independent external review should be undertaken to identify specifically what expertise is needed. One possibility would be someone from an overseas programme (eg, the Scottish programme). (Marshall trans, B/3208-9)
15. Innovative ways of attracting and retaining expertise within the unit should also be developed: for example, by establishing joint positions with academic institutions and in-service training opportunities within academic units and overseas screening programmes for staff.
16. The national unit should be responsible for the management, coordination and funding of all aspects of the screening pathway.
17. The role and accountability to the national unit of regional screening coordinators should be clearly defined. Any changes regarding the number of these coordinators should be carefully assessed, taking into consideration the key roles which many of them have in working alongside health professionals within the regions. (Marshall trans, B/3249)
18. Pending the establishment of the unit as an independent body, the director of the national unit should be directly responsible to the Minister of Health.
19. The unit should be secured and operate in a stable environment. (EAM/CS/0041) In the view of the Cancer Society, this can only be achieved if the unit is within a national cancer control agency that is independent of the

Ministry of Health with respect to policy, budget and accountability.

Evidence in support of this recommendation is provided in Appendix A.

20. Central unit responsible for planning, coordinating, monitoring and evaluating the NCSP: recommendations

- 20.1 A strong, central coordination unit responsible for planning, coordinating, monitoring and evaluation the NCSP must be secured.
- 20.2 There must be adequate resources to ensure an appropriate range of expertise to address all aspects of the screening pathway, a sufficient number of staff and continuity of staff.
- 20.3 The unit must be responsible for planning, coordinating, funding, monitoring and evaluating the quality of all aspects of the screening pathway.
- 20.4 The role and accountability to the national unit of regional coordinators should be clearly defined.
- 20.5 Pending the establishment of the unit as an independent body, the director of the national unit should be directly responsible to the Minister of Health.
- 20.6 The unit should be within a national cancer control agency that is independent of the Ministry of Health.

Advisory committees

- 21. Since the inception of the NCSP, Cancer Society witnesses Dr Cox and Ms Marshall have been members of a number of national groups and committees advising on the development and implementation of the programme. Their evidence and that of other witnesses highlights the following:

- 21.1 Frustration that advice, particularly relating to programme monitoring and evaluation, was not being implemented. (Cox trans, B/2571)
- 21.2 Difficulty in knowing where the recommendations were going and whether they were being acted upon. (Marshall trans, B/3232)
22. In Professor Skegg's view, many of the recommendations of advisory committees in relation to the NCSP were clearly not acted on, and he did not believe this Inquiry would be occurring if they had been (Skegg trans, A/900)
23. In contrast to the situation in New Zealand, Dr McGoogan stated that in the United Kingdom, "the role of the advisory group in the cervical screening programme is to take the whole programme in the context of the whole health service, its funding, organisation, what is practical and what is not practical". (McGoogan trans, A/1087)
24. Dr McGoogan also stated that in the United Kingdom the national advisory group has the power "to procure change or to monitor or procure correction if it sees a problem in the programme". In her view, it would be very difficult for the National Health Service (NHS) executive to ignore the advice of a nationally established advisory committee. Furthermore, if its advice were not followed, the committee would have to consider whether it could remain or members could remain. (McGoogan trans, A/1026-7)
25. Some concern was expressed about the current advisory group having to address both the breast screening programme and the NCSP. (Marshall trans, B/3262)
26. In the light of the above issues, the Society submits that there should be a dedicated committee advising on the NCSP and that the committee should report directly to the Minister of Health.
27. In Professor Skegg's view, even when committees advise the Minister, they are often ignored. He indicated that if there were a separate body with a board

of directors, however, that body would be in a better position to give clear advice to the Minister and to the Ministry and would be “a lot more effective”. (Skegg trans, A/900-901) For this reason the Cancer Society recommends that the programme become the responsibility of a separate cancer control body, as outlined in Appendix A.

28. Advisory committees: recommendations

28.1 There should be a single dedicated advisory committee to the National Cervical Screening Programme.

28.2 The committee should be appointed by the Minister of Health and the chairperson should report directly to the Minister of Health.

28.3 The advisory committee should comprise five to seven members to provide high-level strategic advice on the NCSP to the operational unit.

28.4 The committee’s focus should be operational and structural advice.

28.5 The committee should advise when policies need to be reviewed by separate expert policy groups.

28.6 All policies should indicate when they are to be reviewed (eg, every five years unless evidence is strong enough to support more frequent review).

Sustaining a national programme in a restructured health system

29. Evidence has clearly demonstrated the way in which the National Cervical Screening Programme has struggled to survive successive re-structuring and, in particular, to remain a national programme within a system of devolved responsibility for health services and the formal split of accountabilities between personal and public health services.

30. A major achievement of the national coordination unit during the past year has been its success in assuming responsibility for laboratory and treatment services. Until now, these services, along with smear-taking services, have been the responsibility of personal health services within the HFA. As acknowledged by the HFA screening advisory group, bringing these services, along with the National Cervical Screening Register, under the authority of the national team has been a major step in achieving the WHO requirement for one office with responsibility for planning, coordinating, monitoring and evaluating all services within the screening pathway. (EAM/CS/0041)

31. During the Inquiry, concerns have been raised about the current health system restructuring and how this might impact on the NCSP as a national programme. In particular, concerns relate to the potential with 22 district health boards for:
 - 31.1 Fragmentation of the programme. (Coney B/2745) (Marshall B/3285)

 - 31.2 Insufficient expertise or resources in New Zealand to re-duplicate 22 programmes. (Teague trans, B/1474)

 - 31.3 Varying degrees of commitment for the programme within the district health boards. (Coney trans, B/2745)

32. Dr Cox expressed major concerns about the future of the NCSP within the reformed health structure with the 22 district health boards. In his view, the only services that are, and can be, devolved are smear-taking services. (Cox trans, B/2556)

33. These concerns highlight the need for strong national management and coordination within the restructured health system.

34. Also, in the Society's view, responsibilities cannot be devolved to the district health boards in the way that they were devolved to the area health boards at the outset of the programme. As stressed by Dr Teague, "we need a national

programme. It's a national treasure which needs to be held as a national body". (Teague trans, B/1474)

35. Very significant concerns were also expressed about the programme going back into the Ministry of Health, particularly because of:
 - 35.1 The Ministry of Health's history and orientation towards policy rather than operational functions. (Coney trans, B/2745) (Marshall trans, B/3284)
 - 35.2 Experience of the Ministry in the past and lack of confidence that its culture has changed. (Cox trans, 2620)
 - 35.3 The hierarchical and highly politicised environment of the Ministry of Health. (Coney trans, B/2765)
36. As stated by Ms Coney, "I think it's better to keep screening programmes outside that because they're so fragile and easy to damage by people who make the wrong decisions ... not necessarily because they are hostile, they could be un-interested, they could have other priorities". (Coney trans, B/2765)
37. Concerns also relate to the potential loss of experienced staff and institutional memory with the move back into the Ministry. As stated by Ms Coney, "... with every restructuring we've lost really good experienced people and it would be tragic – I just don't know the programme could survive if it had to go through that process all over again". (Coney trans, B/2746)
38. Because of the experience and skills in screening developed by the HFA coordination team in Auckland, the Cancer Society supports the decision to allow the unit to remain in Auckland.
39. As outlined in Appendix A, however, the Cancer Society recommends the establishment of a national cancer control agency and the inclusion of the

NCSP within that agency. The rationale for these recommendations is provided in that appendix.

40. Sustaining a national programme in a restructured health system: recommendations

40.1 The National Cervical Screening Programme must remain a national programme within the reformed health system.

40.2 There should be no distinction between personal and public health services, with all services coming within the jurisdiction of the programme.

Quality assurance

41. As identified in the Cancer Society's response to Terms of Reference 4 and 5 in Section 6, two of the most critical failures in meeting the WHO requirements for effective screening during the 1991-96 period include:

41.1 Failure to implement quality standards for all aspects of the screening pathway.

41.2 Failure to implement routine programme monitoring and evaluation of all aspects of the screening pathway.

42. According to Dr McGoogan, "cervical screening must be run as a system with objectives, criteria to measure progress towards those objectives and standards and targets. Clinical and programme audit is integral to an effective cervical screening programme". (McGoogan brief, para 65)

43. Also, as stated by Dr McGoogan, "to measure and improve the quality of a service, it is necessary to have explicit standards, an information system that allows the necessary data to be collected and a quality assurance system that

allows action to be taken should any part of the programme fail to meet those standards”. (McGoogan brief, para 67)

44. Dr McGoogan identified three types of standards (excellent, minimum acceptable and achievable), emphasising the need to set achievable standards, work toward these, then review them in due course to “assist in the continual pursuit of excellence”. (McGoogan brief, para 125)
45. Dr McGoogan also indicated that in the UK, the cervical screening programme has produced separate guidelines for good practice and quality standards for each component of the screening pathway, with two of the 11 she cited addressing standards for laboratories. (McGoogan brief, para 72)
46. As noted in Section 6, the HFA has made substantial progress in meeting the above requirements by developing quality standards for the NCSP. (MNP/HFA/0042) However, it is not clear who within the HFA team will be responsible for quality assurance within the programme and how this will take place.
47. The British experience as described by Dr McGoogan may provide one model for such a process.
48. According to Dr McGoogan, the NHS Cervical Screening Programme has regional quality assurance teams to monitor and review performance against standards. This process provides a means by which “potential problems are identified, investigated and remedied at an early stage as part of the normal routine of quality assurance, and thus they should not become incidents”. (McGoogan brief, para 142)
49. According to Dr McGoogan, the teams are multi-disciplinary with representatives of all health professionals involved in delivering a cervical screening programme. Each is chaired by a quality assurance chairperson who may be a gynaecologist or a pathologist or a public health doctor. All

professionals involved in delivering the service are represented on the quality assurance team. (McGoogan trans, A/1197)

50. When asked about instances of inappropriate behaviour or poor standards after the Inverclyde Inquiry, Dr McGoogan stated that they “became aware of instances because of our quality assurance programme and because we were critically appraising every aspect of the programme. The harder you look at and the more critically you look at what you’re doing the more likely you are to find examples of deficiencies which can be improved upon”. (McGoogan trans, A/1243)
51. In Dr McGoogan’s view, where there is “gross non compliance with quality standards and a failure at management level to ensure that laboratories comply with good practice, as happened in the Kent and Canterbury situation”, then there is “very little that simply setting standards can do to prevent that sort of situation”. (McGoogan trans, A/1243)
52. According to Dr McGoogan, the critical factor is determining at what point any suspected error rate falls outside acceptable limits and that action may be required. (McGoogan brief, para 132)
53. It is the view of the Cancer Society that a similar process as outlined by Dr McGoogan should be established in New Zealand immediately. Considering the size of this country, it is quite possible that only one quality assurance team would be required.
54. It is also the view of the Cancer Society that the quality assurance team should be independent of the national coordination unit, but coordinated by a staff member, designated as a quality assurance officer, within that unit.
55. Dr McGoogan indicated that the quality assurance process should reflect a partnership of health professionals, funding agencies and women, with all doing their best to achieve a better cervical screening programme.
(McGoogan trans, A/1189)

56. Dr Cox also referred to the team approach of a screening programme when emphasising the need to feed back information being routinely collected to clinicians and participants and other health professionals involved in the programme. In his view, “a lot of screening processes are ... not intellectually challenging. Some of it is, a lot of it is not and it requires a lot of team work between a lot of different players and you need to give them that feedback that what they’re doing is actually useful and helpful”. (Cox trans, B/2522)
57. In the view of the Cancer Society one of the responsibilities of the quality assurance officer should therefore be to feed back to providers and participants the information that is collected routinely.
58. Quality assurance: recommendations
- 58.1 Quality standards for the NCSP should be reviewed regularly.
- 58.2 Processes should be developed whereby lapses in quality are appropriately investigated and appropriate action implemented.
- 58.3 A quality assurance officer should be appointed immediately for the NCSP to coordinate the quality assurance process, including providing feedback to participants and providers.

Laboratory standards

59. The Cancer Society acknowledges the achievement of the HFA in developing NCSP standards for laboratories. The Cancer Society notes with grave concern that mandatory laboratory standards are only now being set in place, when as early as 1986 standards “required for optimal practice and accreditation” based on those made by the American Society of Cytology were presented to the New Zealand Society of Cytology members for consideration. (GRB/MOH/0019)

60. In this submission the Cancer Society wishes to address the issue of a standard specifying minimum cervical cytology volumes for laboratories, citing the expert evidence of Professor Skegg, Dr McGoogan and Dr Cox.
61. As observed by Professor Skegg, as early as 1984 the point was made that some New Zealand laboratories were examining a far smaller number of smears than would be regarded as adequate according to some overseas standards. “After the passage of fifteen years, I am surprised that those responsible for the NCSP have not grasped the nettle and dealt with this problem”. (Skegg brief, para 50)
62. According to a detailed paper on the evidence pertaining to minimum cytology volumes for laboratories, screeners and pathologists produced by Dr Peters as JMP/HFA/0041 and the second draft of the Operational and Policy Quality Standards (JMP/HFA/0040, page 5.12), the HFA has recommended that each laboratory site process a minimum volume of 12,000 smears per annum.
63. As stated in the HFA paper, the minimum volume of 12,000 smears per annum would have “minimal impact on laboratories conducting the majority of cytology for the NCSP”. (JMP/HFA/0041, page 14)
64. According to Dr McGoogan, the NHS Cervical Screening Programme recommends (but does not require as mandatory) that the minimum laboratory cervical cytopathology workload be set at 15,000 cervical smears per annum. (McGoogan brief, para 82)
65. When asked to comment on the HFA’s proposed minimum volume of 12,000, Dr Cox indicated that he “would be reluctant to go with the 12,000 minimum volume” and that his “preference would be 20,000 but I could live with 15,000 possibly moving to 20,000 within a period of time to allow the workforce to adapt”. (Cox trans, B/2544)
66. One of the issues raised in evidence was whether hospital (HHS) laboratories and community laboratories should be subject to the same minimum volume

standards. According to the HFA paper, a minimum volume standard “would preclude HHS laboratories from continuing cytology as their current workloads are too small”. (JMP/HFA/0041, page 12)

67. Dr Peters indicated that one of the main concerns about imposing the same minimum standards on hospital and private laboratories is the impact on education and training if hospital laboratories were excluded because they were not in a position to meet this target. (Peters trans, B/346-7)
68. In Dr McGoogan’s opinion, the same standard should be applied to both as “a cervical smear test is the same screening test whether it is carried out in a community setting, in a hospital setting or in a colposcopy clinic setting”. (McGoogan trans, A/1182)
69. Dr Cox indicated that at least one hospital laboratory should be doing gynaecological cytology, particularly to provide training; however, he would not see this as an adequate reason for not imposing a minimum standard. (Cox trans, B/2545)
70. Laboratory standards: recommendations
- 70.1 It should be mandatory that all private and HHS laboratories reporting to the NCSP process a minimum of 15,000 gynaecological cytology smears per annum.
- 70.2 There should be no deviation from this mandatory minimum volume granted to HHS laboratories.

Protocol for concerns and incidents

71. In Section 4, paras 16-18, the Cancer Society identified the absence of any process for reporting and responding to concerns about mis-reporting relating to Patient 1.

72. When Ms Hobbs was asked if the programme needs to have a process in place and an identifiable person so that someone like herself would know to whom to go when they had serious concerns, she replied “very definitely yes, absolutely”. (Hobbs trans, B/3167)
73. As confirmed by Ms Marshall, such a process should be available for anyone wishing to raise concerns about the programme. Also anyone entering into such a process should be assured of confidentiality. (Marshall trans, B/3283-4)
74. In her evidence, Ms Marshall also identified the absence of a standard protocol for responding to concerns of a more widespread nature (an “incident”, as described by Dr McGoogan), which contributed to a delay in the HFA providing a definitive response to the Gisborne situation. (Marshall brief, para 129)
75. According to Dr McGoogan, the NHS CSP document “Guidelines for Managing Incidents in the Cervical Screening Programme” (EM/C A/0002) includes sequence of steps to determine if concerns amount to an “incident”. Once an incident is confirmed, it outlines what action needs to take place. (McGoogan brief, paras 141-147)
76. Protocol for concerns and incidents: recommendations
- 76.1 A protocol should be developed whereby any individual wishing to raise concerns about her smear test or other aspects of the programme can do so with the assurance of confidentiality.
- 76.2 A protocol for managing incidents of a wider nature should also be developed.

Programme monitoring and evaluation

77. As outlined in Section 4, one of the critical failures from the inception of the programme was the failure to establish structures for monitoring and evaluation of the operation of the NCSP and its component services, both clinical and managerial.
78. Considering the cost of the provision of screening services, the NCSP must be fully funded to ensure monitoring and evaluation of all aspects of the screening pathway occurs.
79. In Section 6, the Cancer Society has outlined the significant steps taken by the HFA in meeting the requirements for monitoring and evaluation. The Cancer Society endorses these steps, including the appointment of an independent monitoring group for the NCSP. As indicated by Dr Cox, one of the reasons for having an independent component of monitoring and evaluation is to address the possibility of an organisation “downplaying” the results that are not particularly appealing to the organisation as a whole. (Cox trans, B/2526)
80. Programme monitoring and evaluation: recommendations
- 80.1 With regard to programme monitoring and evaluation, the Cancer Society recommends the following:
- 80.1.1 NCSP statistical reports should be produced annually and include tables similar to those in the European guidelines produced as BC/CS/0044.
- 80.1.2 The 1997 Draft Evaluation Plan developed by Drs Cox and Richardson, which includes an audit of the screening histories of women with cervical cancer, should be implemented in full.
- 80.2 As outlined below, some of the barriers to the implementation to these and other monitoring and evaluation processes relate not only to

apparent limitations in data available but, more importantly, to the restricted access to personalised data on the National Cervical Screening Register and the Cancer Registry. Urgent consideration must be given to these matters.

National Cervical Screening Register data issues

81. The weaknesses relating to the NCSR data which are addressed in the first two recommendations below are identified in para 7 of Section 6.
82. The third recommendation relates to the stance of the former Health and Disability Commissioner that women be given the opportunity to ‘opt off’ the register with every smear test or biopsy (as cited in JMP/HFA/0043, page 70). It is the concern of the Cancer Society that this stance is likely to be having an adverse effect on the completeness of data on the register.
83. National Cervical Screening Register data issues: recommendations
 - 83.1 The director of the NCSP should be charged with the task of addressing the delays and deficiencies in histology results being sent to the NCSR and with ensuring laboratories comply with mandated standards.
 - 83.2 The director of the NCSP should be charged with assessing the quality of data collected by the NCSR and rectifying any deficiencies in data collection.
 - 83.3 A review should be sought from the current Health and Disability Commissioner on whether women should be given the opportunity to ‘opt off’ the register with every smear test or biopsy, with a view to women giving initial consent to being part of the programme, with the understanding that their results will be sent automatically in future unless they choose otherwise.

Establishment of a population register

84. As identified by Dr Cox, the NCSP is not a population-based screening programme in that the eligible population is not identifiable individually through a population register (ie, a list of the population). (Cox brief, para 22)
85. As a result the NCSR has been described as an utilisation register rather than population register. (Cox B/2590) (Marshall, B/3247-8)
86. It could be argued that because of the high level of enrolment of women on the NCSR, that the NCSR is an “equivalent” and that the programme is therefore population-based. (Cox trans, B/2589) (Cox brief, para 22)
87. However, as identified in the document “Evaluation of public health strategies to increase participation in cervical screening: A literature review” (JMP/HFA/0026, page 26), not all eligible women are on the register and many who are on the register are no longer contactable (between 31,000 and 56,000 women, or 3-6% of women on the register).
88. Evidence before the Inquiry indicates that the use of population registers to identify women in the target group is one of the common features of cervical screening programmes. Examples include the WHO booklet “Cervical Cancer Screening Programmes: Managerial Guidelines” (BC/CS/0047) as referred to by Dr Cox (Cox brief, para 31), the report of the Ministerial Review Committee (JMG/MOH/0001) and the Policy Statement of the Expert Group (JMG/MOH/0005).
89. One of the major conclusions of the Ministerial Review Committee was that: “The potential of the cervical screening programme is currently hindered by the lack of such a register. The development in the short term of a cytology register for the purpose of this programme should not therefore be seen as an alternative to the development of a population register, nor as a substitute for the development of a comprehensive health register, but merely an expedient in order to allow the programme to proceed within a reasonable timeframe.”

(JMG/MOH/001, pages 2-3)

90. Both the Ministerial Review Committee and the Expert Group recommended that legislation for a population register needed to be pursued. (BC/CS/0004, pages 2-3)
91. The following two options have been proposed in evidence for development of a population register in New Zealand:
 - 91.1 Development of the NMPI into a complete population listing.
 - 91.2 Use of the electoral roll. (JMG/MOH/0005, page 198) (Cox brief, para 22) (Skegg trans, A1001-2)
92. Professor Skegg described the NMPI as a useful method of linkage of records, although it is not maintained as a register of all people in the country. He also indicated duplication of numbers, “perhaps even more than duplication”. (Skegg trans, A/1001)
93. With regard to programme monitoring and evaluation, one of the key limitations of a utilisation register is its inability to ascertain the denominator of the population to determine coverage; coverage can only be approximated using census data. (Cox B/2589-90)
94. Both Professor Skegg and Ms Marshall expressed support for the establishment of a population register. (Skegg trans, A/988) (Marshall trans, B3247)
95. Professor Skegg acknowledged that the establishment of a population register would require legislative change and he would advocate such a change. (Skegg trans, A/988)
96. The benefit of having such a register for invitation purposes for the breast screening programme was also identified. (Marshall trans, B/3248)

97. Ms Marshall identified the need for consultation and discussion about this issue. (Marshall trans, B/3247)
98. Establishment of a population register: recommendation
- 98.1 Legislation should be passed to provide for a population register in New Zealand.

Linking the Cancer Registry and the NCSR

99. In addition to citing the importance of a cervical screening programme having a population register, the World Health Organization identifies the need for a system of linked records for efficient programme monitoring. (BC/CS/0047, page 27)
100. At present no link between the NCSR and the Cancer Registry exists.
101. In his evidence, Dr Cox identified tables in the European guidelines that could not be produced without the linkage between the Cancer Registry and the NCSR. (B/2616, 18-19) He also indicated that to evaluate cervical screening as a means of reducing incidence of invasive cancer requires the linkage between the Screening Register and the Cancer Registry. (Cox trans, 264)
102. Dr McGoogan also identified the importance of linking the two registers to ensure an effective and high quality service. She commented that she found it “hard to understand why one would collect this information and not make the best use of it”. (McGoogan trans, A/1033)
103. Professor Skegg echoed her sentiments, finding it “extraordinary” that the two registers were not used in the way they could to advance the health of women. (Skegg trans, A/893)
104. Dr Medley stated that in the state of Victoria, legislation has been passed recently which allows a communication between the Cancer Registry and the Screening Register. (Medley trans, 264)

105. Linking the Cancer Registry and the NCSR: recommendations

105.1 Linkage between the Cancer Registry and the National Cervical Screening Register should be established with urgency.

105.2 Should legislation to establish such a link be required, such legislation should be pursued with urgency.

Access to personalised data for programme monitoring/evaluation

106. Evidence before the Inquiry has identified restrictions on access to personalised data as follows:

106.1 According to Section 74A of the Health Act, personalised information on the NCSR cannot be accessed without the permission of individual women.

106.2 Personalised data on the Cancer Registry cannot be released without ethics committee approval. (One of the key issues of concern to ethics committees relates to consent.)

107. As a result, critical components of programme evaluation, such as the audit of the screening histories of women with cervical cancer, cannot proceed.

108. In the context of consent relating to the release of data on both the NCSR and the Cancer Registry, the chair raised with several witnesses the possibility of a change in legislation to enable inferred or implied consent. In such circumstances consent could be sought from women for the release of data from the NCSR and the Cancer Registry for quality assurance, monitoring and evaluation purposes at the time a woman has a smear test.

109. In their responses, Ms Coney and Ms Marshall identified the following limitations of this approach:

- 109.1 “Burdening women” when they are having a smear (ie, seeking their consent for access to data should they develop cancer). (Coney trans, B/2777) (Marshall trans, B/3272)
- 109.2 Uncertainty about what would happen at the point of interaction between GP and women. (Coney trans, B/2778)
110. According to Professor Skegg and Dr Cox, one of the limitations of this approach would be its exclusion from any research and evaluation of women who are not part of the programme. (Skegg trans, B/2322) (Cox trans, B/2645)
111. Dr Cox highlighted the fact that issues relating to access to personalised data apply not only to cervical screening but also to other aspects of monitoring and evaluation of any other screening programme. (Cox trans, B/2609-10)
112. Professor Skegg indicated he was unsure whether implied consent would be accepted by ethics committees. Also, in his view, requiring doctors to advise women when they have a smear would be a “bureaucratic barrier”. (Skegg trans, B/2322)
113. Finally, a “special arrangement “ for cervical cancer would “seem ... to support the position taken by the ethics committees at the moment that privacy considerations should preclude us from proper quality control”. Also there would be a “delay of months or perhaps several years before it could be considered that enough women had given such implied consent to be monitored”. (Skegg trans, B/2324)
114. The need for women to have information about the use of their data for monitoring and evaluation purposes was nevertheless endorsed. (Marshall trans, B/3273)
115. With regard to the need for a legislative solution to address this matter, Ms Coney and Ms Marshall referred to their experiences in identifying problems

with the opt-on system of enrolment adopted initially by the NCSP and seeking support among women for the opt-off legislation through community consultation. (Coney trans, B/2760-62) (Marshall trans, B/3246)

116. Both witnesses stressed the need for consultation should any changes to the legislation be required. As Ms Coney stated: “I’m a believer in undertaking that kind of process when you want to make changes because I believe in the common sense of the public and that once they understand that wisdom of taking a particular direction that they will support it. They support things that are in their interests once they have them explained to them.” (Coney trans, B/2761) Also, “I believe that people will see the sense of changes that are wanting to be made so that better monitoring and evaluation of the programme is possible.” (Coney trans, B/2762)
117. According to Ms Coney, because of consultation prior to opt-off legislation, she is not aware of any complaint regarding its implementation. (Coney trans, B/2779)
118. When Ms Hobbs was asked, based on her involvement with the women affected, whether women would object to their information on the Cancer Registry and the Screening Register being matched to ensure the programme was working properly, she replied, “No, I believe they would not object in my opinion; all these women would not wish this experience on any other woman”. (Hobbs trans, B/3618)
119. In the Cancer Society’s view, this matter must be addressed urgently, not only to access data for the purposes of this Inquiry but also to ensure access for the purposes of ongoing programme monitoring and evaluation.
120. The Society endorses Mr Corkill’s submission that the New Zealand Public Health and Disability Bill provides an opportunity to deal, on an urgent basis, with the problems relating to Section 74A. It is the Society’s view that in the absence of a ruling from the High Court, an amendment is needed so that it is

clear beyond doubt that regulations can be promulgated to Section 74A to enable access to personalised data for monitoring and evaluation purposes.

121. Access to personalised data for programme monitoring/evaluation: recommendation

121.1 Issues relating to Section 74A of the Health Act regarding the release of personalised data must be addressed urgently, not only to access data for the purposes of this Inquiry but also for the purposes of ongoing programme monitoring and evaluation.

Access to Maori women's data as governed by the Kaitiaki regulations

122. Issues arising from the Kaitiaki regulations and their impact on access to aggregated data concerning Maori women are outlined in Appendix B. In the Society's view these issues need to be addressed to ensure the monitoring and evaluation of the effectiveness and acceptability of the NCSP for Maori women.

123. Access to Maori women's data as governed by the Kaitiaki regulations: recommendations

123.1 As outlined in Appendix B, mechanisms, including the possibility of regulations to the Health (Cervical Screening (Kaitiaki)) Regulations 1995, should be considered to provide the following:

- 123.1.1 Criteria for the group to judge applications for aggregated Maori data; responses to applicants should reflect these criteria.
- 123.1.2 An appeal process for applicants.
- 123.1.3 Membership which includes someone with research expertise.

Access to Cancer Registry data

124. The key issue relating to the Cancer Registry concerns the requirement for ethics committee approval for the release of personalised data. These issues and the following recommendations are addressed in Appendix C of this section.
125. Access to Cancer Registry data: recommendations
- 125.1 An independent review of the membership and processes of ethics committees is required.
- 125.2 Ethics committees require clearer guidance regarding weighing up harms and benefits in assessing the ethics of observational studies.
- 125.3 Ethics committees require guidance regarding the application of the Health Information Privacy Code. Ethics committees must be informed that interpretation of the code is the legal responsibility of the agency holding the data, not of ethics committees, and that a breach of the Health Information Privacy Code only occurs if the release of information can be shown to be injurious to an individual in some way.
- 125.4 The Society calls for the establishment of a national ethics committee for the assessment of multi-centre or national studies. This national ethics committee should be independent in process to, and membership from, the regional ethics committees.
- 125.5 The process for seeking a second opinion from the HRC Ethics Committee needs to be reviewed.
- 125.6 As the HRC Ethics Committee is the body accrediting regional ethics committees, it is considered that members of the HRC Ethics Committee should not be members of the regional ethics committees.

Resourcing of the Cancer Registry

126. Problems associated with the Cancer Registry identified in evidence before the Inquiry are outlined in Appendix A, para 5.7
127. Resourcing of the Cancer Registry: recommendations
- 127.1 High priority must be given to resourcing the Cancer Registry to ensure the timely, accurate and complete collection and analysis of data.
- 127.2 The Cancer Registry should be the responsibility of a national cancer control agency.

Routine audit of screening histories of women with invasive cancer

128. Many of the barriers to effective NCSP monitoring and evaluation outlined above have been identified through evidence of the process undertaken by Drs Cox and Richardson to begin a national audit of the screening histories of women with cervical cancer.
129. Described by Dr McGoogan as a “powerful tool” and by Dr Teague as a “gold standard by which the programme could be evaluated”, such an audit was cited as being of critical importance by a number of witnesses at the Inquiry. (McGoogan trans, A/1070) (Teague brief, para 23.2) (Cox trans, B/2502-3) (Coney B/2776) (Skegg brief, para 55) (Medley trans, B/2705-6)
130. As stated by Dr McGoogan, “We can never prevent all women developing invasive cancer but by looking at those women that the programme has failed to stop developing invasive cancer allows us to target areas for improvement”. (McGoogan trans, A/1068)
131. The need for such an audit has been identified by a number of experts and advisory groups as outlined in Section 4, paragraphs 82 and 83.

132. As indicated in evidence, a paper outlining the importance and methods by which such an audit could be undertaken was prepared by Dr Cox and was discussed at a CSAC meeting on 27 and 28 February 1996. The document was produced by Dr Cox as BC/CS/0036.
133. As confirmed by Ms Handiside, she and Ms Glackin were recorded as being present at the above CSAC meeting. (Handiside trans, B/3676) Ms Handiside also confirmed that Dr Cox's paper made reference to the fact that women with invasive cancer could be identified from the Cancer Registry and that "the Act sets guidelines for the release of data and that ethical approval for the approach outlined would be required". (Handiside trans, B/3677)
134. Ms Handiside stated that she had discussed the methodology described in the above paper with several managers and had included it in her annual business plan. However, the audit was given low priority and was not funded in her time as coordinator. (Handiside brief, para 40).
135. Ms Handiside recalled Dr Cox's frustration that the audit which he proposed did not proceed at that time, and that he resigned from CSAC after the meeting at which the decision not to proceed with the audit was discussed: "Yes, he did resign after that meeting and I think that helped to catapult him to retire". (Handiside trans, B/3678)
136. Routine audit of screening histories of women with invasive cancer: recommendation
- 136.1 An audit of the screening histories of all women who develop cervical cancer in New Zealand should be undertaken on a routine basis as an essential part of programme evaluation.

Information for women

137. As outlined in Section 4, Appendix A, some of the issues identified in the evidence of women affected which highlight the need for women to be more fully informed about screening are:
- 137.1 Belief in the infallibility of cervical screening.
- 137.2 Misunderstandings concerning cervical abnormalities, the screening programme/register and the recommended frequency of smear tests.
138. After reviewing evidence of women affected, Dr Wain concluded that “in some aspects there are apparent misunderstandings about cervical screening, particularly the difference between preinvasive and invasive disease, suggesting that public education programs about screening have not been as successful as one may have hoped”. (Wain brief, page 27)
139. The evidence suggests that New Zealand, like the UK, has been successful in “selling” the benefits of screening. As Dr McGoogan stated, however, “we have been less successful and conscientious about explaining and defining the limitations of a single smear test”. (McGoogan brief, para 75)
140. Also, as Professor Skegg stated, “people who have been keen to exalt women to take up screening” may have given women the “misleading impression” that it prevents all cancers. (Skegg trans, A/990)
141. Evidence also supports the need for information and reassurance to women that a three-yearly screening interval (as opposed to annual) is safe. (Marshall trans, B/3260)
142. Information for women: recommendations

- 142.1 The Cancer Society supports the recommendations of the Women's Health Action Trust regarding women's information needs. These include the endorsement of:
- 142.1.1 The comprehensive recommendations of the document "New Directions for Cervical Screening Education Resources" (JMP/HFA/0043) prepared by the Trust.
 - 142.1.2 The need for the programme to adopt an approach that enables consumers to make informed decisions about screening and to provide information regarding potential risks and benefits.
- 142.2 It is also recommended that women be informed that:
- 142.2.1 Any symptoms (to be specified) should be checked by a doctor, regardless of the smear result.
 - 142.2.2 Screening will not necessarily detect and therefore prevent adenocarcinoma of the cervix.
 - 142.2.3 Their data on the NCSR will be used for monitoring/evaluation purposes to ensure a high-quality service for themselves and for other women.

Information and training for health professionals

143. Evidence of the women affected as analysed in Section 4, Appendix A also identifies deficiencies in the understanding and training of health professionals relating to cervical screening. These have resulted in poor practice, poor management and patterns of over-screening.
144. One of the most critical issues relates to evidence of poor management of women with symptoms. As stated in the "Recommendations for Cervical

Screening”, 1997 (JMG/MOH/0049) which were published in the *New Zealand Medical Journal*, “the cervical smear will be part of the investigation of women with signs and symptoms of cervical cancer. It is not sufficiently sensitive, however, for a negative result to override clinical concern”. (page 94)

145. When asked about poor management of women with symptoms, Mr Jones agreed there is a need for updating or retraining with regard to recognising and acting on symptoms, even if the result of smears is negative. (Jones trans, B/1622)

146. Patterns of over-screening also suggest the need for information and reassurance to health professionals that a three-yearly screening interval (as opposed to annual) is safe. (Marshall trans, B/3260)

147. Information and training for health professionals: recommendation

147.1 Strategies should be developed to address the information and training needs of health professionals regarding cervical screening.

Responsibility and time frame for implementing Inquiry recommendations

148. Having been a party to the Cartwright Inquiry, the Cancer Society of New Zealand is concerned about the process of implementation of the recommendations of the Inquiry and the time frame for these.

149. The Society notes that according to Dr McGoogan, the majority of the recommendations for the Inverclyde Inquiry were put in place within the first 24-36 months. (McGoogan trans, A/1039)

150. Responsibility and time frame for implementing Inquiry recommendations: recommendations

150.1 The Cancer Society supports the recommendation of Mr Corkill that:

- 150.1.1 The Minister of Health appoints a person to monitor, on a long-term basis, the implementation of the recommendations of this Inquiry.
- 150.1.2 Professor Skegg be appointed and that he report directly to the Minister.
- 150.1.3 A time frame for implementation be established by the Inquiry.

Section 6: Term of Reference 6 – Appendix A
CANCER CONTROL

The need for a control strategy in New Zealand

1. According to evidence before the Inquiry cancer control is a systematic approach to the reduction of the burden of cancer. “Cancer control recognizes that the disease can not be completely eradicated but its effect can be minimised. This includes reducing the incidence and mortality of cancer, ensuring gains in the treatment and management of the disease are maximised within the resources available and reducing the suffering of those who develop the disease. It involves a prospective systematic and coordinated approach to ... prevention, earlier diagnosis and screening where this has been shown to lead to a better outcome, anti-cancer treatment and symptom control, rehabilitation and palliative care”. (DCS/CA/0008)
2. The World Health Organization recommends to countries that they establish national cancer control programmes or strategies. (Cox trans, B/2555)
3. A cancer control strategy would provide a systematic and coordinated approach across multiple agencies to the cancer burden in New Zealand. (Cox brief, para 254)
4. In 1989 Professor Skegg wrote an editorial pointing out that New Zealand was not following these WHO recommendations to develop such a strategy. (DCS/CA/0007)
5. The need for a cancer control strategy has been identified by a number of groups in New Zealand over a number of years. (DCS/CA/0008)
6. In August 1999 participants from a wide cross-section of groups at a national workshop in Wellington unanimously recommended the development of a national cancer control strategy for New Zealand. (Cox brief, para 254)

7. The workshop also identified the need for an organisation or agency to be charged with the responsibility for developing a national cancer control strategy in New Zealand. (Skegg trans, A/981)
8. According to Dr Cox, the participants unanimously recommended the establishment of a cancer control secretariat through a consortium of agencies. They did not favour a secretariat developed in the Ministry of Health or in one of the funding agencies. (Cox trans, B/2553)
9. The role of the secretariat would be to develop a national cancer control strategy to reduce the impact of cancer. Through the process of developing the strategy, different agencies would develop an investment in the final strategy, which would be reflected in their business plans and other aspects of their work. (Cox trans, B/2553)

The need for the NCSP to be a part of such a strategy

10. According to Professor Skegg, other countries such as Australia and the United Kingdom have made great strides in developing cancer control strategies or programmes, and cervical screening is always part of one of those. (Skegg trans, A/980)
11. Evidence provided by Professor Skegg as DCS/CS/0008 states that while screening programmes in New Zealand such as the NCSP have been supported by government, they do not appear to be part of a national cancer control strategy systematically developed and coordinated to address the six components of cancer control.
12. As an example, Professor Skegg cited reference in this article (DCS/CS/0008) to unacceptable delays - for example, in colposcopy investigations of women with abnormalities. (Skegg trans, A/982)

13. Other evidence and witnesses support the view that the National Cervical Screening Programme should be part of such a national strategy. (JMP/HFA/0016, page 3) (Marshall brief, para 131) (Cox brief, para 257)

The need for a separate agency for cancer control outside the Ministry of Health

14. Witnesses identified the need for a separate agency to be responsible for cancer control. (Skegg trans, A/981) (Coney trans, B/2744)
15. According to Dr Cox, "... whatever New Zealand national cancer control strategy is developed needs to be owned by somebody or an organisation who has some dedication to seeing that through, and the best way I believe to ensure that happens is to have a national cancer control agency". (Cox trans, B/2551-4)
16. "If there were a separate body with some sort of board of directors that body would clearly be responsible to the Ministry of Health but it would be in a better position to give clear advice to the Minister and to the Ministry and I believe would be a lot more effective." (Skegg trans, A/901-2)

The need for the NCSP to be in a separate cancer control agency

17. Witnesses also identified the need for the National Cervical Screening Programme to be part of such a separate agency. (Skegg trans, A/979) (Cox trans, B/2556) (Coney trans, B/2744) (Marshall trans, B/3287)
18. "One of the reasons why I would favour ... a separate agency [to be responsible for the NCSP], which as I said could possibly cover other aspects of cancer control and could contain the Cancer Registry, is that I believe that sort of organisation would be better able to obtain advice in a timely way and also to ensure that that advice is acted on appropriately". (Skegg trans, A/979)
19. According to Professor Skegg, "... the Ministry of Health is not an ideal place in which to place responsibility for a programme like this ... it's a very large

organisation, it has a wide variety of functions and responsibilities, and it's also subject to the day to day guidance of ministers. (Skegg trans, A/901)

20. According to the World Health Organization Managerial Guidelines produced by Dr Cox as BC/CX/0047, if cancer control has been designated to a special agency in a country, then the person responsible for cervical screening should have an appointment within that agency. The guidelines state that "alternatively, it would be appropriate to designate an official within the ministry of health". Dr Cox noted that the way in which this recommendation is stated implies that a ministry of health would not be the first choice. (Cox trans, B/2618)
21. According to Ms Coney, a separate stand-alone agency with separate accountability would give stability to the programme: "stability ... which this programme has lacked over the last 10 years with all the changes that have occurred". (Coney trans, B/2744-5)
22. Ms Coney emphasised the importance of the programme retaining its identity within a cancer control agency and not adding to women's perceptions that cervical screening is testing for cancer. (Coney trans, B/279-5)

The role of a cancer control agency

23. One of the roles of a separate cancer control agency would be to have responsibility for screening programmes, including the NCSP. (Cox brief, para 257)
24. The need for a cancer control agency to have responsibility for other aspects of cancer control was also identified by Dr Cox (Cox brief, para 257) and Professor Skegg. According to Professor Skegg, "There has been a lot of focus in this inquiry on the deficiencies of the cervical screening programme but I'm sad to say this is one of the best parts of our health system. It has been given tremendous attention. If one looks at cancer more generally New

Zealanders have an exceptionally high rate of death from cancer.” (Skegg trans, A/901)

25. Other identified responsibilities for a cancer control agency include monitoring and evaluation, aspects of treatment guidelines and assessment of survival after diagnosis. (Cox trans, B/2552)
26. According to Dr Cox, “A cancer control agency also would co-ordinate some of the activities of different agencies that are all involved in different aspects of cancer control from primary prevention through screening, treatment, rehabilitation and palliative care; identify where improvements might be or resources might be best focused ... in terms of reducing the burden of cancer and the suffering of people after diagnosis.” (Cox trans, B/2552)
27. Referring to past and current inadequacies of the Cancer Registry, witnesses identified the need for the registry to be part of a cancer control agency. (Skegg trans, A/901-3) (Cox brief, para 257)
28. The Cancer Registry as essential in determining the effectiveness of the NCSP and as a starting point for ongoing audit of the programme was identified in evidence before the Inquiry. (Cox brief, para 70) (Skegg trans, A/904) (Marshall brief, para 77)
29. Problems associated with the Cancer Registry were identified by evidence during the Inquiry, including the following:
 - 29.1 In 1990 the expert group wrote to the Minister of Health expressing concerns about the Cancer Registry and recommended as a matter of urgency that it be resourced with equipment, staff and legislative framework to provide such information. (Marshall brief, para 77)
 - 29.2 A list of selected CSAC correspondence relating to its concerns about the Cancer Registry are included in the committee’s 1994 report. (JMG/MOH/0035, pages 24 and 25)

29.3 Professor Skegg, who described the Registry as in a “fairly marginal state of health”, identified the following issues relating to the Registry at the Inquiry:

- gaps in data collection (eg, staging of cancer)
- missing data
- poorly funded
- lacking professional leadership
- recent priorities mainly management issues and the administration of the health system. (Skegg trans, A/901-3)

29.4 Professor Skegg also described the approach of the Ministry of Health to the Registry as:

- according it very low priority
- initially opposing legislation introduced as a private members bill to make cancer registration compulsory. (Skegg trans, A/903-4)

29.5 Dr Cox also cited a time lag between diagnosis and reporting of diagnosis of invasive cancer to the Cancer Registry identified in 1995. (Cox brief, para 189)

Overseas models for cancer control and cancer registries

30. According to Dr Cox, the cancer councils in Victoria and New South Wales have responsibility for a national cancer control strategy. (Cox trans, B/2551)

31. These are set up under statute by their local state departments of health and have boards, which report to the Minister. Both have responsibility for the cancer registry. (Cox trans, B/2552)

32. Professor Skegg stated that in most countries there would be a director of the cancer registry who would probably be a medically qualified person, trained in cancer epidemiology. According to Professor Skegg, this is the model in Australia where there are “very good cancer registries”. (Skegg trans, A/902)

Recommendations

33. The Cancer Society recommends that a national cancer control strategy be established in New Zealand.
34. The implementation of such a strategy should be the responsibility of a national cancer control agency that must be independent of the Ministry of Health.
35. The Cancer Society also recommends that the central offices for the National Cervical Screening Programme and the breast screening programme, the databases of these programmes and the Cancer Registry should be placed in this agency.

**Section 7: Term of Reference 6 – Appendix B:
KAITIAKI REGULATIONS**

Involvement of Maori women in the development of the NCSP

1. In her report Judge Cartwright identified that “special duties are owed” to Maori women within a national cervical screening programme, citing the higher incidence of cervical cancer among Maori as compared with non-Maori women. (Cartwright report, p 217)
2. Since the inception of the NCSP, Maori women have played a major role in many aspects of the programme. Their contribution to and achievements in the NCSP are acknowledged in *A Brief Narrative on Maori Women in the National Cervical Screening Programme*, produced by Ms Earp as LRE/MOH/0002.

Available analyses of NCSP data concerning Maori women

3. Ms Earp produced the first statistical report of data regarding Maori women on the NCSR as LRE/MOH/0004. The report covers data up to 31 December 1995 and was published in 1999.
4. Dr Peters produced an analysis of data from the NCSR for the years 1994-1997 (NCSP Review), which includes a section on Maori women, as JMP/HFA/0015. Although the full draft of this report was completed in March 1999, it was finalised only recently. (Peters brief, para 96)

Importance of analysis of Maori data

5. Evidence before the Inquiry has highlighted the importance of analysis of Maori women’s data.
6. As stated by Professor Skegg, research is needed to identify why Maori women have a higher mortality rate than non-Maori. In his view it is essential

for Maori women that specific evaluations using Maori data are undertaken in relation to the overall working of the programme. (Skegg trans, B/2448)

7. The need for Maori data to ensure acceptable and appropriate services for Maori was identified by the authors of the first Maori statistical report: “Statistical data [of Maori women enrolled on the register] are important in determining where and why services need to be introduced or expanded to provide an acceptable and appropriate means for Maori women to participate in the cervical screening programme.” (LRE/MOH/0004, p1)
8. According to Dr Cox, because Maori women are over-represented among those affected, there is a “greater prerogative” for monitoring/evaluation to minimise failures of the screening service for Maori and Pacific women. (Cox trans, B/2604)
9. The Working Group for the Evaluation of Maori Women’s Data, advising the HFA on the development of the 1999 review, identified the need for regular analysis of Maori data at a more detailed level than the overall national targets for the programme. (JMP/HFA/0015, p 108, 7.5.8)
10. Some of the key issues identified by the working group in the 1999 review include:
 - 10.1 The Tairāwhiti NCSP has the best enrolment and coverage rates for Maori women in the country.
 - 10.2 There has been a decline across all regions in number of Maori women enrolling on the register each year.
 - 10.3 There has been lower enrolment rates among Maori women than for all women.
 - 10.4 There has been a lower overall coverage rate for Maori women than for all women.

- 10.5 The highest rate of short-interval rescreening is among Maori women.
(JMP/HFA/0015, 81-83)
11. Some of the implications of these findings as identified by the working group include:
- 11.1 There are lessons to be learnt from the Tairāwhiti area which could be applied elsewhere.
- 11.2 Further evaluation is needed to identify reasons for lower enrolment and coverage rates.
- 11.3 Consideration of extra funding is needed to reduce disparity in accessing services by Maori women.
- 11.4 Investigation of reasons for short-interval rescreening is needed.
(JMP/HFA/0015, 107-8)
12. In her evidence, Dr Peters identified the need for such information as that included in the NCSP review to be made available in a timely way to those in a position to act on data (eg, smear-takers and health promoters). (Peters trans, B/339)

Key issues for Maori women concerning data

- 13 As outlined in a history of the involvement of Maori women in the development of the programme, one of the key issues of concern to Maori women was the development of the NCSR and the need to reassure Maori women that the data collected would only be used for their benefit.
(JMG/MOH/0047, p72-74)
14. As stated by Ms Earp, one of the main concerns of Maori women about the protection of Maori data relates to their belief in the sanctity of Te Whare

Tangata and the need for information about it be afforded special protection.
(Earp brief, para 22)

15. Ms Earp also cited an element of whakama (humility or embarrassment) associated with screening. (Earp brief, para 23)
16. According to Ms Earp, concerns about the protection of and access to Maori women's cervical screening data were raised early in the development of the NCS (eg, at the Porirua Workshop in 1988). (Earp brief, para 28)
17. In reply to a question regarding the concern of Maori women to access to Maori data for the purpose of research, Ms Earp replied that the concern relates to "the way in which Maori like to see themselves revealed in research data". (Earp trans, A/847)

The National Kaitiaki Group

18. As stated by Ms Earp, the National Kaitiaki Group was established under the Health (Cervical Screening (Kaitiaki)) Regulations 1995 to provide appropriate protection for Maori women's summary data on the NCSR. (Earp brief, para 27)
19. A brief history of the development of these regulations is produced in Ms Earp's brief (paras 27-30) and in JMG/MOH/0047, pages 72-74.
20. According to the regulations, Maori women's summary data on the register can only be obtained by special application to the National Kaitiaki Group. (Earp brief, para 23) In some cases this arrangement has been referred to as a "lock-out" system. (Earp trans, A/846) (Huriwai trans, B/3856) (Cox brief, para 88)
21. As stated by Ms Earp, the National Kaitiaki Group "has the challenging role of balancing the tension between access to Maori women's health information (on cervical screening) to enable research which contributes to informed

programme and service decision-making, and protecting the personal information and intellectual property rights of Maori women on the Register”. (Earp brief, para 32)

22. According to the current convenor, Ms Huriwai, the group is not concerned with the actual use of the data in a medical sense but whether those receiving the data understand the importance of the data to Maori. (Huriwai trans, B/3858)
23. According to Ms Huriwai, the group has statutory existence and authority. (Huriwai trans, B/3863) There is an absence of evidence, however, as to whether, in administrative law terms, a decision to decline access would be open to review. (Huriwai trans, B/3863)
24. Members of the National Kaitiaki Group are appointed by the Minister of Health, and they can be removed by the Minister. (Huriwai trans, B/3868)
25. Employment positions of current members include a tutor, regional council member, smear-taker and health promoter, lawyer and coordinator of a well-women health service. (Huriwai trans, B/3853/4)
26. Current membership qualifications do not include epidemiology or skills in statistics/statistical analysis. (Earp trans, A/843) Yet the Kaitiaki regulations under Section 74A solely apply to the release of aggregated data such as would be used in a statistical report.
27. It does not appear that membership includes those with particular experience in research, monitoring or evaluation. (Cox trans, B/2608)
28. In Dr Cox’ view, lay members may have a different perspective or particular focus (eg, improving access to and cultural appropriateness of service delivery) than epidemiologists, whose focus would be improving the quality assurance process. (Cox trans, B/2603)

Concerns about timeliness of Maori data

29. One of the concerns identified in evidence regarding the process of requiring National Kaitiaki Group approval for the release of Maori data is the timeliness of such data once it is published. These concerns applied to both the first Maori statistical report and the NCSP review identified in paragraphs 3 and 4 above.
30. According to Ms Handiside, the application for release of information for the Maori statistical report was made prior to August 1996. (Handiside trans, B/3775) However, approval does not appear to have been given prior to November 1998. (Huriwai trans, B/3865)
31. When asked as the Deputy Director General, Maori Health, to comment on this delay, Ms Earp indicated that the reasons were unclear. (Earp trans, A/852) She later suggested, however, that the membership of the group [at the time of application] may have been a factor. In her view the current National Kaitiaki Group has “interpreted the legislation requirements in a different way to the previous committee in which case the issue of maintaining and balancing that tension is better managed than it perhaps was in the past”. (Earp trans, A/856) According to Ms Earp, the members of the previous group had resigned, having seen their brief as being “far wider perhaps than the legislation itself”. (Earp trans, A/857)
32. In Ms Earp’s view, the issue of timeliness relates to the administration of the group rather than a matter requiring a change to the regulations. (Earp trans, A/858)
33. Delays encountered by the Health Funding Authority in releasing the NCSP review in 1999 (JMP/HFA/0015) were cited by Dr Peters. (Peters brief, para 95) (Peters trans, B/194) (Peters trans, B/333)
34. Key factors contributing to the delay was the objection of the National Kaitiaki Group to the way some of the data had been presented, despite the

appointment of the working group of Maori women to oversee the analysis and writing of the recommendations. (Peters brief, para 96)

35. In its recommendations within the review, the working group itself identified the need to review the process for obtaining and analysing Maori data “to enable timely and responsive use of Maori data for planning to benefit Maori women”. (JMP/HFA/0015, page 108)
36. Dr Peters considered the delays regrettable as the report could not be circulated to the Kaimahi group (Maori women working in the programme). (Peters trans, B/336)
37. Although the HFA experienced no delays in the release of data for 1996-1998 and 1999 statistical reports, Dr Peters acknowledged that there could be a problem in future in terms of yearly reports. (Peters trans, B/337)
38. When asked about delays, Ms Huriwai stated that there had been a backlog of applications prior to November 1988, and that this had been cleared by the current group. (Huriwai trans, B/3867) She also indicated that there had been a “change of approach” by the Kaitiaki Group since 1998 to the release of data on Maori women. (Huriwai trans, B/3853)
39. However, as the size of this backlog was not revealed, it is difficult to determine if the delay could be considered reasonable.

Other issues relating to Kaitiaki regulations/Kaitiaki Group

40. Dr Cox stated that one of the problems for the researcher is that the reasons for an application being declined are not always clear. (Cox trans, B/2601)
41. Dr Cox also stated that the reasons an application is declined do not always appear consistent to the applicant. (Cox trans, B/2601)

Potential future problems

42. In response to questions from the panel, Dr Peters acknowledged the inherent delays resulting from those using the data having to report back to the Kaitiaki Group before releasing a report, especially in light of the group meeting a limited number of times a year.
43. Dr Peters also acknowledged that such delays may have a particular impact on routine programme monitoring. (Peters trans, B/341)
44. Ms Huriwai acknowledged that although the current group was dealing with applications in a timely fashion, changed membership could result in delays in processing applications. (Huriwai trans, B/3868) Changed membership could also take a different interpretation of the legislation. (Huriwai trans, B/3873)

Conclusions

45. Analysis of Maori data is essential to monitor the effectiveness, acceptability and accessibility of the NCSP to Maori women.
46. The process of approval for release of Maori data under the Kaitiaki regulations has resulted in unacceptable delays in the publication of analyses of Maori data.
47. The way in which applications are processed appears to depend on the membership of the group.
48. Membership of the National Kaitiaki Group does not include anyone with research expertise.
49. There does not appear to be an appeal process for those whose applications are rejected.

50. There does not appear to be a clear timeframe and clear criteria consistently applied by which the group judges applications.

Recommendations

51. Mechanisms, including the possibility of regulations to the Health (Cervical Screening (Kaitiaki)) Regulations 1995, should be considered to provide the following:
 - 51.1 Criteria for the group to judge applications for aggregated Maori data; responses to applicants should reflect these criteria
 - 51.2 An independent appeal process for applicants
 - 51.3 Membership which includes individuals with research expertise.

Section 7: Term of Reference 6 – Appendix C
ETHICS OF SCREENING AND ETHICS COMMITTEE ASSESSMENT OF
AUDIT, MONITORING, EVALUATION AND RESEARCH

Ethical principles of screening

1. There is not a clear distinction between audit, monitoring, evaluation and research.
2. The requirement for ethical review depends on what is proposed in an investigation and not what term is used.
3. Dr Cox described the difference between the ethical responsibility associated with screening and usual clinical practice, as stated by Cochrane and Holland (1971). (Cox trans, B2497) The following is a quote from their paper: “We believe there is an ethical difference between everyday medical practice and screening. If a patient asks a medical practitioner for help, the doctor does the best he can. He is not responsible for defects in medical knowledge. If, however, the practitioner initiates screening procedures he is in a very different situation. He should, in our view, have conclusive evidence that screening can alter the natural history of disease in a significant proportion of those screened.” (Cochrane & Holland, *British Medical Bulletin* 1971: 27: 3-8)
4. Ensuring that the benefits of screening outweigh the harms requires monitoring and evaluation.
5. The requirement for the proper collation of information in order to conduct audits was emphasised at the Cartwright Inquiry. (Evans trans, B3946)

The balance of benefits and harms in considering the ethics of a study

6. Ethics committees are required to weigh up the potential benefits and potential harms when assessing applications.

7. This is clearly outlined in several documents. The National Standard for Ethics Committees (1996) lists, among other objectives, to:
 - 7.1 Safeguard the rights of health and disability support services consumers and participants in health research and protect them from harm.
 - 7.2 Facilitate the excellence of health- and disability-related research for the wellbeing of society.
8. The Royal College of Physicians of London, Guidelines on the Practice of Ethics Committees (1990), states: “In achieving these objectives [of protecting the subjects of research from harm] Ethics Committees should remember that research benefits society and they should take care not to hinder it without good cause”. (Evans brief, para 37)
9. The CIOMS international guidelines for ethical review of epidemiological studies (1991) include the statement: “The purpose of ethical review is to consider the features of a proposed study in the light of ethical principles, so as to ensure that investigators have anticipated and satisfactorily resolved possible ethical objections, and to assess their responses to ethical issues raised by the study. Not all ethical principles weigh equally. A study may be assessed as ethical even if a usual ethical expectation, such as confidentiality of data, has not been comprehensively met, provided the potential benefits clearly outweigh the risks and the investigators give assurances of minimising risks. It may even be unethical to reject such a study, if its rejection would deny a community the benefits it offers. The challenge of ethical review is to make assessments that take into account potential risks and benefits, and to reach decisions on which members of ethical review committees may reasonably differ”.
10. The primary responsibility for the ethical conduct of monitoring, audit, evaluation and research rests with the investigators involved. It is most

appropriate that their ethical judgement is reviewed by a suitably constituted ethics committee adhering to an appropriate code of practice.

11. Professor Evans referred to the Nuremburg Code of 1947 when reviewing ethics committees' decisions about the Investigation of Cervical Screening Histories of Women Diagnosed with Invasive Cervical Cancer in Tairawhiti from 1990-1999 (GIS 00/03) and the evaluation of the National Cervical Screening Programme commissioned by the Ministry of Health. (Evans brief, para 24)
12. This is inappropriate and implies that the regional ethics committees consider the review of medical records or interviews with women with invasive cervical cancer to be a form of damaging human experimentation.

The Declaration of Helsinki (1989)

13. Professor Evans also referred to the World Medical Association Declaration of Helsinki (1989). (Evans brief, para 37) The declaration is a statement of “recommendations guiding physicians in biomedical research involving human subjects”, originally formulated in 1964. It includes the following statement, under a section headed “Non-Therapeutic Biomedical Research Involving Human Subjects”: “In research on man, the interests of science and society should never take precedence over considerations related to the wellbeing of the subject”.
14. An uncritical application of the Helsinki declaration to observational as opposed to human experimental research is misguided for several reasons:
 - 14.1 Firstly, weighing up benefits and risks is not the same as having benefits taking precedence over risks.
 - 14.2 Secondly, the risk being considered in the case of the audit under review is a small loss of privacy, not the overriding of the wellbeing of the subject.

- 14.3 Thirdly, the type of risks to wellbeing envisaged in the statement, as in the original 1964 Helsinki Declaration, relate to “human experimentation”. The other clauses under this section of the Declaration make it clear that it is experimental research that is being discussed here (such as Phase 1 drug trials): eg, “the subjects should be volunteers – either healthy persons or patients for whom the experimental design is not related to the subject’s illness”.
15. It is not appropriate to apply the Helsinki Declaration to observational (not experimental) studies based on medical records or interviews. The difference between observational and experimental studies was recognised in the Cartwright Report (page 62).

The Health Information Privacy Code

16. The matters that an ethics committee should take into consideration in approving a study protocol that entails the disclosure of personal health information without the prior authorisation of the individuals concerned are also spelt out in the Health Research Council “Health Research and Privacy guidance notes for health researchers and ethics committees”.
[<http://www.hrc.govt.nz/ethguid9.htm>] (Evans brief, para 42)
17. This document, which was developed by a working party for the Ethics Committee of the HRC, gives guidance on discretionary matters in the interpretation of the Health Information Privacy Code and ethical guidance for good practice. The most relevant sections are 3(b)(ii) collection of information from health records; 3(c) recommended good practice; 4(b)(i) and 4(b)(ii), 4(c) and 5(c).
18. The main point of 3(b)(ii) is that the use of health records for research without the authorisation of the individual concerned should only be undertaken under two conditions:

- 18.1 The reason for not seeking consent should be justified to the ethics committee. Reasons may be scientific, practical or ethical.
- 18.2 The potential benefits of the research must be described to the ethics committee, which must weigh up these potential benefits against the loss of privacy.
19. The HRC guidelines on good practice include guidance on the approach to an individual (if relevant), on storage and security, retention and disposal, the responsibilities of researchers, etc.
20. It appears that the HRC “Health Research and Privacy guidance notes for health researchers and ethics committees” have not been used by the ethics committees in the recent circumstances.

Were the benefits overlooked?

21. Professor Evans stated that the regional ethics committees agreed unanimously that the study proposed in Tairāwhiti and the national audit were considered very important (Evans brief, para 25); however, it is difficult to reconcile this statement with the decisions, or lack thereof, of the ethics committees.
22. Professor Skegg highlighted this when he stated: “ I think they [ethics committee members] often don’t see the cost of not doing things. They see the problems in doing them, but not the cost of not doing them. I’ve thought about this issue with the national evaluation [ie, the audit in question] and I hope this doesn’t sound emotive, but about 80 women die from cervical cancer in NZ each year. Now I believe it would be a very conservative estimate to assume that at least 10 of those deaths could be prevented by detecting the sort of problems that have emerged in Gisborne and doing something about them”. (Skegg trans, B2324)
23. It is the view of the Cancer Society that considerably more than 100 women over the past 10 years would not have died from cervical cancer had the NCSP

been monitored, including ongoing audit of women with invasive cervical cancer, with remedial action as deficiencies were identified.

24. If ethics committees were very much aware of the benefits of audit or research in terms of saving lives, as spelt out by Professor Skegg, the fact that they have held up such audit or research is a much more serious charge than if they had been unaware of the benefits.
25. The Cancer Society considers it totally unacceptable that both the proposed study in Tairāwhiti for the Inquiry and the properly constituted national audit of women with invasive cervical cancer have been thwarted by the decisions of regional ethics committees. This appears to deny those responsible for the NCSP the ability to meet their ethical responsibilities to women for appropriate monitoring and evaluation.
26. It is the Cancer Society's view that the Inquiry recommends an appropriate resolution to this issue.
 - 26.1 In doing so, the Society asks that rather than specific resolution of this issue for the NCSP, a more generic solution is proposed so that the evaluation and monitoring of other screening programmes and public health activities can be conducted.
 - 26.2 Moreover, the processes which have led regional ethics committees to take the stand they have need to be reviewed and changed.

Ethics committees' confusion regarding matters of law

27. The national audit of the NCSP has highlighted confusion by the regional ethics committees about the Privacy Act and the Health Information Privacy Code (HIPC).
28. Professor Evans said that the regional ethics committees did not consider that the responses of the Minister of Health regarding the application of the HIPC

to the release of individually identifiable data from the Cancer Registry (Exhibits DME/REC/014 and DME/REC/0015) have sufficiently reassured them that the release is legal. (Evans trans, B3903 & B3912-13).

29. The Cancer Society notes that the Minister of Health clearly indicated that the government considered it lawful.

Reasons for disclosure of information without the individual's consent

30. The regional ethics committees have proposed that first contact with patients should be made by the Cancer Registry. There are several reasons why this is inappropriate.
31. As discussed above, the HRC Health Research and Privacy guidance notes state that the reasons for not seeking consent should be justified to the ethics committee, and that the reasons may be scientific, practical or ethical. These are discussed below.

Scientific reasons

32. For scientific reasons, to avoid bias, data that are as complete as possible are required about cancer cases. If data were released only after patients had been contacted, the data would be incomplete, for reasons explained below.

Practical reasons

33. It is unrealistic to expect that the Cancer Registry could contact all patients to seek their consent to release their information to the investigators. Many patients will have changed address and some will have died. The Cancer Registry does not have the staff time to follow up changes of address or to contact non-responders. Moreover, it would be against the policy of the NZHIS for its staff to undertake such a task.

Ethical reasons

34. Even if the Cancer Registry were prepared to approach patients, the Society believes this would be undesirable, for several reasons.
- 34.1 The request for release of information would be sent on Cancer Registry letterhead from a government official. This is a much less personal way of approaching a person who has been diagnosed with cancer than a letter from a doctor in a medical school.
- 34.2 Unfortunately, it is also the case that misclassification does occur, so that some women noted on the registry files as having cancer may not have cancer. This is likely to be a particular problem with cervical cancer, as registrations of carcinoma-in-situ are also recorded in the Cancer Registry. In addition, some women have equivocal pathological results that require further investigation. Before contacting patients recorded with cancer, it is the usual policy of investigators to double-check pathology reports and to consult the patient's own medical advisors.
35. The Cancer Society believes that the best way to approach patients is to make initial contact with the woman's medical advisors in order to determine the appropriateness of the investigators approaching the woman directly. This allows the woman's doctor to discuss the issue with her if necessary, and avoids causing distress. It also avoids an extra, preliminary, letter from the Cancer Registry being sent to women who may be very sick or dying, or to their recently bereaved families.

Lack of appreciation of the practical aspects of audit or research by ethics committees

36. Contrary to the view expressed by Professor Evans on behalf of the regional ethics committees (Evans trans, B3920), agencies bring in epidemiologists and specialists in public health medicine to establish the cause of deaths or

illnesses not only in situations that are not considered epidemics but also to establish whether causes of illness discovered overseas also occur in New Zealand.

37. The Tairāwhiti ethics committee did not suggest that the Cancer Registry first approach patients for the Tairāwhiti study in their letter to the investigators (exhibits DCS/CA/014-016), but this requirement was made of the national audit.
38. The practical aspects of conducting audit and research were not appreciated by regional ethics committees. (Evans trans, B3909-12 & B3921-26) This was exemplified in the cross-examination of Professor Evans, when he was asked about tracing slides held in a laboratory. It would be most unlikely that a woman's slides could be retrieved without knowing her name and probably her date of birth also. (Evans trans, B3911)
39. Professor Evans implied that it was less unethical for the Cancer Registry to approach people for consent and then overrule them if they refused than to release their names to the investigators. (Evans trans, B3924) This seems inappropriate, as asking for consent implies the women have a choice about their participation.

The process of ethics committees

40. Now (September 2000), it is more than 10 months since the original application for ethical approval for the national audit of the NCSP was submitted to the regional ethics committees. This audit has still not been approved or declined by the Otago Ethics Committee on behalf of all regional committees.
41. The investigators can only lodge a complaint with the Otago Ethics Committee or seek a second opinion from the HRC ethics committee once a decision is received. Since no decision has been received, the regional ethics

committees are wrong to imply that the investigators could seek a second opinion from the HRC Ethics Committee (Evans trans, B3953).

42. Appendix 1 of the Guidelines for Completion of Application Form EA 06/99 of the National Application Form for Ethical Approval of a Research Project describes the multi-centre research proposal application process. Point 6 states that: “Where the primary committee disagrees with the concerns raised by a secondary committee, the Chairs of the respective committees will speedily resolve the issue.”
43. In the case of the national audit of the NCSP, the decision to approve or disapprove the audit of invasive cervical cancers has not been made speedily.

Primary ethics committee for multi-centre studies and the role of the HRC ethics committee

44. The regional ethics committees come under the aegis of the Ministry of Health and accreditation of the committees is determined by the Health Research Council.
45. The process involving primary committees for multi-centre or national studies has proved unworkable in delivering timely decisions, and regional variations in the interpretation of applicability of ethical principles have not always been resolved through the chairs of regional ethics committees.
46. When decisions are made by consensus it is possible for an individual who is a member of a regional ethics committee, and also of the Committee of the Chairs of Regional Ethics Committees and the HRC Ethics Committee (the committee to be consulted for a second opinion and which accredits ethics committees) to have undue influence on the approval process.
47. The HRC Ethics Committee membership as set out in Section 26 of the Health Research Council Act (1990) does not need to contain members of regional

ethics committees. The Cancer Society considers that it should not contain such members.

48. The Committee of the Chairs of the Regional Ethics Committees is composed entirely of lay people since the National Standard for Ethics Committees (Section 2.5) determines that the chair of an ethics committee shall be a lay person. (DME/REC/009) This means that the Committee of the Chairs of the Regional Ethics Committees could not contain the skills and expertise that should be available to an ethics committee described in the standard (Section 2.6). (DME/REC/009)
49. The Committee of the Chairs of the Regional Ethics Committees could not be considered to meet the standard for ethics committees, and it is the view of the Cancer Society that it should not have a role in assessing applications.

Evidence that ethics committees have impeded research

50. Professor Evans quoted an article written by Associate Professor Paul in support of the workings of ethics committees (Evans trans, para 33); however, half the researchers surveyed in the article reported occasions where ethics committees had unnecessarily impeded research.
51. It should be noted that researchers were concerned not only about wanting research to proceed unimpeded. Some were also concerned that risks in experimental or intervention research were not being adequately recognised.

Audit by “insiders” only

52. During cross-examination of Professor Evans, some discussion occurred about whether current ethics committee rulings regarding access to medical records for audit, monitoring, evaluation or research would have precluded the assemblage of material by McIndoe et al that was necessary for the independent assessment of Professor Green’s research. (Evans trans, B3934-48) Professor Evans, representing the regional ethics committees,

misunderstood the role of Drs McIndoe, Jones and McLean at National Women's Hospital with respect to women who were the subjects in Professor Green's experiment.

53. Mr Rennie, counsel for the Royal College of Pathology of Australasia, was able to clarify that these doctors were not involved in the care of the women and this was accepted by the parties to the Inquiry, including counsel for the regional ethics committees. (Evans trans, B3939-40 & B3941-42)
54. In the Cartwright Report, Professor Bonham referred to McIndoe et al as reviewing cases "belonging to other consultants" without approval, both in a letter in 1982, and in evidence at the Inquiry. (Cartwright Report, page 92) Professor Bonham, as Chairman of the Ethical Committee, disapproved of the work undertaken by McIndoe et al. (Cartwright Report, page 93)
55. An important conclusion of the Cartwright Inquiry was that those in charge – even of ethics committees - could behave badly.
56. It is possible that Professor Evans was confusing the physical proximity of the medical records to Drs McIndoe, Jones and McLean, who worked in the same institution as Professor Green (and who were accessing records with ethics committee approval).
57. It is the Cancer Society's view that as doctors not participating in the care of all the patients involved, Drs McIndoe, Jones and McLean would have had to invoke rule 11 of the HIPC to gain access to the medical records without the women's consent. It would not have been possible to collect sufficient data for the study if they had to write to each individual patient or their next of kin and, if they had been required to do so, Professor Green may have been able to prevent the study.

Professor Skegg's expertise or knowledge of the ethical assessment of research

58. The regional ethics committees, through Professor Evans' brief, attempted to denigrate Professor Skegg's expertise and knowledge of the ethics of audit and research. (Evans brief, para 16)
59. The Department of Health appointed Professor Skegg advisor to the Steering Committee for the CIOMS International Guidelines for Ethical Review of Epidemiological Studies, and he is named in the resulting document. In addition, he is a past member of the Ethics Committee of the HRC. He has a long involvement with the consideration of the ethical issues in epidemiological research, including preparing applications for ethics committee review.

Conclusions

60. There is considerable evidence that confusion exists among ethics committees about the application of the Health Information Privacy Code.
61. There is considerable evidence that the appropriate weighing up of benefits and harms that is required of ethics committees in considering the ethics of audit, monitoring, evaluation or research has not occurred.
62. There is evidence that the Committee of Chairs of the Regional Ethics Committees has no formal status.
63. There is evidence of confusion by regional ethics committees about the impact their current decisions would have had on the study of McIndoe et al that lead to the Cartwright Inquiry.

Recommendations

64. An independent review of the membership and processes of ethics committees is required.

65. Ethics committees require clearer guidance regarding the weighing up harms and benefits in assessing the ethics of observational studies.
66. Ethics committees require guidance regarding the application of the Health Information Privacy Code. Ethics committees must be informed that interpretation of the code is the legal responsibility of the agency holding the data, not of ethics committees, and that a breach of the Health Information Privacy Code only occurs if the release of information can be shown to be injurious to an individual in some way.
67. A national ethics committee for the assessment of multi-centre or national studies should be established. This national ethics committee should be independent in process to, and membership from, the regional ethics committees.
68. The process for seeking a second opinion from the HRC Ethics Committee needs to be reviewed.
69. As the HRC Ethics Committee is the body accrediting regional ethics committees, it is considered that members of the HRC Ethics Committee should not be members of the regional ethics committees.

Section 8

CONCLUDING SUBMISSIONS

1. Cervical screening saves lives. The National Cervical Screening Programme operating in New Zealand has succeeded in doing this.
2. The success of the National Cervical Screening Programme has been compromised, however, because it has failed in many respects to meet international standards for effective screening programmes. The result of these failures has been the events in Gisborne, which have led to unnecessary suffering and loss of life and culminated in this Inquiry.
3. This Committee of Inquiry now has the opportunity to make recommendations which, if implemented, could confer on New Zealanders the benefit of an NCSP of high international standard to minimise the risk of these events occurring again.
4. To achieve this outcome, the Cancer Society of New Zealand submits that the following minimum requirements must be met:
 - 4.1 Establishment of a national cancer control agency, independent of any government department, fully funded from an annual budget allocation within Vote Health.
 - 4.2 The central unit for the National Cervical Screening Programme and the breast screening programme, the databases of these programmes and the Cancer Registry should be the responsibility of the National Cancer Control Agency.
 - 4.3 The National Cancer Control Agency, including the National Cervical Screening Programme with all of its component services, must comply with all relevant international guidelines promulgated for such agencies and programmes, and in particular with guidelines published by the World Health Organization.

- 4.4 This Committee should in its report provide a time line for the implementation of all the steps required to achieve its recommended outcomes.

- 4.5 This Committee should recommend a mechanism for ensuring the implementation of its report, if necessary by recommending the appointment of one individual with authority to direct and coordinate that process.

Section 9

SUMMARY OF RECOMMENDATIONS

Strong central coordination unit

1. A strong, central coordination unit responsible for planning, coordinating, monitoring and evaluation the NCSP must be secured.
2. There must be adequate resources to ensure an appropriate range of expertise to address all aspects of the screening pathway, a sufficient number of staff and continuity of staff.
3. The unit must be responsible for planning, coordinating, funding, monitoring and evaluating all aspects of the screening pathway.
4. The role and accountability to the national unit of regional coordinators should be clearly defined.
5. Pending the establishment of the unit as an independent body, the director of the national unit should be directly responsible to the Minister of Health.
6. The unit should be within a national cancer control agency which is independent of the Ministry of Health with respect to policy, budget and accountability.

Advisory committees

7. There should be a single dedicated advisory committee to the National Cervical Screening Programme
8. The committee should be appointed by the Minister of Health and the chairperson should report directly to the Minister of Health.

9. The advisory committee should comprise five to seven members to provide high-level strategic advice on the NCSP to the operational unit.
10. The committee's focus should be operational and structural advice.
11. The committee should advise when policies need to be reviewed by separate expert policy groups.
12. All policies should indicate when they are to be reviewed (eg, every five years unless evidence is strong enough to support more frequent review).

Sustaining a national programme in a restructured health system

13. The National Cervical Screening Programme must remain a national programme within the reformed health system.
14. There should be no distinction between personal and public health services, with all services coming within the jurisdiction of the programme.

Quality assurance

15. Quality standards for the NCSP should be reviewed regularly.
16. Processes should be developed whereby lapses in quality are appropriately investigated and appropriate action implemented.
17. A quality assurance officer should be appointed immediately for the NCSP whose role is to coordinate the quality assurance process, including providing feedback to participants and providers.

Laboratory standards

18. It should be mandatory that all private and HHS laboratories reporting to the NCSP process a minimum of 15,000 gynaecological cytology smears per annum.
19. There should be no deviation from this mandatory minimum volume granted to HHS laboratories.

Protocol for concerns and incidents

20. A protocol should be developed whereby any individual wishing to raise concerns about her smear tests or other aspects of the programme can do so with the assurance of confidentiality
21. A protocol for managing incidents of a wider nature should also be developed.

Programme monitoring and evaluation

22. With regard to programme monitoring and evaluation, the Cancer Society recommends the following:
 - 22.1 NCSP statistical reports should be produced annually and include tables in the European guidelines produced as BC/CS/0044.
 - 22.2 The 1997 Draft Evaluation Plan developed by Drs Cox and Richardson, which includes an audit of the screening histories of women with cervical cancer, should be implemented in full.

National Cervical Screening Register data issues

23. The director of the NCSP should be charged with the task of addressing delays and deficiencies in histology results being sent to the NCSR and with ensuring laboratories comply with mandated standards.

24. The director of the NCSP should be charged with assessing the quality of data collected by the NCSR and rectifying any deficiencies in data collection.
25. A review should be sought from the current Health and Disability Commissioner on whether women should be given the opportunity to 'opt off' the register with every smear test or biopsy, with a view to women giving initial consent to being part of the programme, with the understanding that their results will be sent automatically in future unless they choose otherwise.

Establishment of a population register

26. Legislation should be passed to provide for a population register in New Zealand.

Linking the Cancer Registry and the NCSR

27. Linkage between the Cancer Registry and the National Cervical Screening Register should be established with urgency.
28. Should legislation to establish such a link be required, such legislation should be pursued with urgency.

Access to personalised data for programme monitoring/evaluation

29. Issues relating to Section 74A of the Health Act regarding the release of personalised data must be addressed urgently, not only to access data for the purposes of this Inquiry but also for the purposes of ongoing programme monitoring and evaluation.

Access to Maori women's data as governed by the Kaitiaki Regulations

30. Mechanisms, including the possibility of regulations to the Health (Cervical Screening (Kaitiaki)) Regulations 1995, should be considered to provide the following:
 - 30.1 Criteria for the group to judge applications for aggregated Maori data; responses to applicants should reflect these criteria.
 - 30.2 An independent appeal process for applicants.
 - 30.3 Membership which includes individuals with research expertise.

Access to Cancer Registry data

31. An independent review of the membership and processes of ethics committees is required.
32. Ethics committees require clearer guidance regarding weighing up harms and benefits in assessing the ethics of observational studies.
33. Ethics committees require guidance regarding the application of the Health Information Privacy Code. Ethics committees must be informed that interpretation of the code is the legal responsibility of the agency holding the data, not of ethics committees, and that a breach of the Health Information Privacy Code only occurs if the release of information can be shown to be injurious to an individual in some way.
34. A national ethics committee for the assessment of multi-centre or national studies should be established. This national ethics committee should be independent in process to, and membership from, the regional ethics committees.

35. The process for seeking a second opinion from the HRC Ethics Committee needs to be reviewed.
36. As the HRC Ethics Committee is the body accrediting regional ethics committees, it is considered that members of the HRC Ethics Committee should not be members of the regional ethics committees.

Resourcing of the Cancer Registry

37. High priority must be given to resourcing the Cancer Registry to ensure the timely, accurate and complete collection and analysis of data.
38. The Cancer Registry should be the responsibility of a national cancer control agency.

Routine audit of women with cervical cancer

39. An audit of the screening histories of all women who develop cervical cancer in New Zealand should be undertaken on a routine basis as an essential part of programme evaluation.

Information for women

40. The Cancer Society supports the recommendations of the Women's Health Action Trust regarding women's information needs. These include the endorsement of:
 - 40.1 The comprehensive recommendations of the document "New Directions for Cervical Screening Education Resources (JMP/HFA/0043) prepared by the Trust.
 - 40.2 The need for the programme to adopt an approach that enables consumers to make informed decisions about screening and to provide information regarding potential risks and benefits

41. It is also recommended that women be informed that:
 - 41.1 Any symptoms (to be specified) should be checked by a doctor, regardless of the smear result.
 - 41.2 Screening will not necessarily detect and therefore prevent adenocarcinoma of the cervix.
 - 41.3 Their data on the NCSR will be used for monitoring/evaluation purposes to ensure a high quality service for themselves and for other women.

Information and training for health professionals

42. Strategies should be developed to address the information and training needs of health professionals regarding cervical screening.

Responsibility and time frame for implementing Inquiry recommendations

43. The Cancer Society supports the recommendation of Mr Corkill that:
 - 43.1 The Minister of Health appoints a person to monitor, on a long-term basis, the implementation of the recommendations of this Inquiry.
 - 43.2 Professor Skegg be appointed and that he report directly to the Minister.
 - 43.3 A time frame for implementation should be established by the Inquiry.

Section 10

VISION FOR THE FUTURE OF THE NATIONAL CERVICAL SCREENING PROGRAMME

A clearly defined national operational unit with a director of the NCSP

- ?? The unit will be lead by a public health medicine specialist.
- ?? The tasks of the unit and expertise required will be specified.
- ?? The unit will include a quality assurance officer.
- ?? Expertise within the unit will include public health medicine, epidemiology, biostatistics and information technology.

An independent monitoring group that works closely with the operational unit

- ?? The group will have a close working relationship with the unit, thereby enabling ongoing improvements of performance measures and timely monitoring reports.
- ?? Programme monitoring will be maximised through the appropriate analysis of data and reports.

An expert NCSP advisory committee

- ?? The committee will be appointed by the Minister of Health and the chairperson will report directly to the Minister of Health.
- ?? The advisory committee will comprise 5-7 members to provide high level strategic advice on the NCSP to the operational unit.
- ?? The committee's focus will be operational and structural advice.
- ?? The committee will advise when policies need to be reviewed by separate expert policy groups.
- ?? All policies will indicate when they are to be reviewed, eg. every five years unless evidence is strong enough to support review sooner.

An independent quality assurance process linked to QA of the colleges

?? A multi-disciplinary quality assurance team, with a quality assurance officer, will address cytology, pathology, gynaecology, information technology, administration and consumer issues.

A stable workforce

?? This will be necessary for sufficient expertise and critical mass to be established to fulfil the multi-disciplinary requirements of running the NCSP.

The NCSP as part of a National Cancer Control Agency

?? The central unit for the National Cervical Screening Programme and the breast screening programme, the databases of these programmes and the Cancer Registry will be the responsibility of a separate National Cancer Control Agency which is independent of the Ministry of Health.