

**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 1**

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Section 1

INTRODUCTION

1. The Cancer Society of New Zealand is a non-profit agency that receives no direct financial support from government.
2. The goal of the Cancer Society is to reduce the number of people who develop or die from cancer and to ensure the best possibly quality of life for those who develop the disease.
3. Consistent with this goal, the Cancer Society has had a long-standing commitment to, and involvement in, the development of an effective National Cervical Screening Programme.
4. It was with this commitment in mind that the Cancer Society of New Zealand began its participation as a party to this Inquiry.
5. Since the beginning, this Inquiry has heard evidence from many witnesses, including government agency and programme staff, epidemiologists, pathologists, clinicians, Maori and consumer representatives, those responsible for accreditation and members of advisory groups. As important is the evidence of women in the Gisborne region whose lives, and whose families' lives, have been affected by the misreading of their cervical smear tests.
6. The National Cervical Screening Programme exists to reduce the burden of cervical cancer in the community, and it has a responsibility to ensure that the best possible efforts are undertaken to maximise the benefits of screening and minimise the risk of harm to women of New Zealand. Throughout the Inquiry, the Cancer Society has kept this principle at the forefront of its involvement.
7. In its involvement in this Inquiry, the Cancer Society has concentrated on certain terms of reference. Its final submission will also focus on those terms.

Section 2

REQUIREMENTS FOR EFFECTIVE SCREENING

1. As this Inquiry has heard, there are particular features of a population-based cervical screening programme which distinguish it from other public health programmes. These include the following specific characteristics:
 - 1.1 First, screening is defined as a process, not just the offering of a test. As such it involves all aspects of what is described as the screening pathway, including identifying and inviting women, taking smears, investigating abnormal results, offering appropriate treatment for abnormalities detected and ensuring that these activities are properly coordinated and carried out to a high standard. (Cox brief, para 21) (McGoogan brief, paras 60-68)
 - 1.2 Secondly, screening requires the involvement of a number of health professionals and administrators across different disciplines. (McGoogan brief, para 63)
 - 1.3 Thirdly, screening involves an invasive investigative procedure rather than therapeutic intervention. It divides people without symptoms into two groups: those likely to have an abnormality and those unlikely to have the abnormality. (Skegg brief, para 17)
 - 1.4 Fourthly, screening results are a measure of probabilities rather than certainties; there will always be some margin of error in the identification of abnormalities (false positives) or the failure to identify them (false negatives). (Skegg brief, para 17)
2. It is from the recognition of these distinguishing characteristics that expert consensus derives on the basic and fundamental requirements of a screening programme which meets its objective of reducing cancer.
3. The WHO guidelines in evidence before the Inquiry formulate criteria to meet

these requirements. (BC/CS/0046) (BC/CS/0047) The Cancer Society draws the Inquiry's attention in particular to the following matters that must be addressed in considering the effectiveness of a screening programme:

- 3.1 Because the screening pathway involves a number of different components and health disciplines, the programme must incorporate clear and efficient systems of organisation, management and accountability. (BC/CS/0047) (JMP/HFA/0031, page 3)
- 3.2 Because the target population is submitting to an invasive procedure where the individual is asymptomatic, the programme must meet specific ethical obligations with respect to ensuring that the benefits outweigh the risks. (Skegg brief, para 16) (McGoogan brief, para 46) (Cox trans, B/2497) (Handiside trans B/3641)
- 3.3 Because there is an inevitable margin of error, the programme must incorporate systems for ensuring that both the target population and the health professionals delivering the service are fully informed not only of the benefits but also of the limitations of screening. (McGoogan brief, para 77) (Peters brief, para 88)
- 3.4 There must be regular monitoring and evaluation of the operation of the programme and of its individual components, measured against specific standards and objectives. (McGoogan brief, para 67) (McGoogan trans, A/1039)
- 3.5 There must be effective systems for response to incidents occurring in the operation and delivery of the programme. (McGoogan brief, para 67)

Section 3

TERM OF REFERENCE 1: WHETHER THERE HAS BEEN AN UNACCEPTABLE LEVEL OF UNDER-REPORTING IN CONSEQUENCE OF MIS-READING AND/OR MIS-REPORTING OF ABNORMALITIES IN THE GISBORNE REGION

1. The question of what constitutes an unacceptable level of under-reporting is one which even in an ideally constituted programme would be difficult to answer definitively. In the absence of any standard criteria for the operation of the programme and its constituent parts, this difficulty is compounded. (Skegg brief, para 59) (McGoogan trans, A/1045)
2. There has been some advocacy before the Inquiry for the adoption of a measure based on comparative findings of high-grade abnormalities from different laboratories. This proposition is not supported by expert evidence.
3. Professor Skegg described this as an “extremely crude approach” for the following reasons:
 - 3.1 It takes no account of the underlying prevalence of the disease among the women who have been screened, which is influenced by factors such as age, ethnic group and socioeconomic factors.
 - 3.2 There is no indication of whether or not the diagnoses were accurate. (Skegg brief, para 60)
4. In his brief of evidence, Dr Cox identified the following additional factors influencing the proportion of smears suggestive of high-grade abnormalities:
 - 4.1 The clinical practice of doctors and other smear-takers (eg, if the smear is repeated, or the colposcopist routinely takes another smear prior to treatment). (Cox brief, para 238)

- 4.2 Further smears being taken if treatment is initially unsuccessful. (Cox brief, para 239)
- 4.3 Underlying level of high-grade abnormalities, which is likely to depend on the exposure to HPV in the population and exposure of the population to factors associated with whether or not the infection persists. (Cox brief, para 240)
- 4.4 The age distribution of the population. (Cox brief, para 241)
- 4.5 The degree of screening already undertaken in the population. (Cox brief, para 241)
5. Dr Cox indicated that the detection rate of histologically confirmed high-grade abnormalities per 1000 women screened would be a better measure of the detection of disease than the proportion of smears reported as high grade. (Cox brief, para 237)
6. In respect of alternative methods for assessing unacceptable levels, there is expert evidence for consideration of the cumulative effect of indicators which, while not individually determinative, may facilitate a “commonsense” conclusion.
7. Dr McGoogan responded to options put before her by Mr Hindle from which she might consider a commonsense approach. These included the following possible approaches: audit of screening histories, positive predictive value for the laboratory; comparison of a sample of slides from Gisborne laboratory with another group of slides; analysis of data on the register; comparison of performance of Gisborne laboratory with that of other labs during this period. (McGoogan trans, A/1096-1111)
8. Dr McGoogan agreed with the proposition that all would be “flags pointing in a particular direction” from which a “commonsense judgment” could be made. (McGoogan trans, A/1111)

9. In response to questions from Mr Grieve, Dr McGoogan also agreed that the professional practices of the lab in question (eg, training, participation in quality assurance programme) could be taken into account in assessing the question, and she addressed these in oral evidence. (McGoogan trans, A/1118-34)
10. Professor Skegg argued that an “ ‘unacceptable level’ of under-reporting is one that leads to a substantial number of cases of invasive cancer that could have been prevented”. (Skegg brief, para 64)
11. Professor Skegg proposed two options to address this: audit and a slide review comparing Dr Bottrill’s slides with similar samples of slides from other New Zealand labs. “I cannot conceive of any other investigation that would provide a reliable conclusion from a scientific point of view or from a legal point of view”. (Skegg trans, A/888)
12. In his evidence, Professor Skegg stated that “the best way in which to assess the scale of the problem would be to conduct a retrospective study of cases of invasive cervical cancer in the Gisborne region”. (Skegg brief, para 65)
13. Dr McGoogan supported this view, indicating she would “wholeheartedly endorse it”. (McGoogan trans, A/1099). She stated that such an audit would help assess the impact of a particular practice on the health of the women in the area and that may help judge whether a level is unacceptable or not. (McGoogan trans, A/1100)
14. However, expert witnesses also concur that, even in the absence of a retrospective study, there is sufficient evidence on which to found a conclusion that there were unacceptable levels of under-reporting. Evidence in respect of the HFA report of the Sydney laboratory (TM/HFA/0087) in particular supports this.

15. Led by Dr Duggan, Dr Farnsworth commented on three indicators of under-reporting which, when considered in combination, indicated a “very high level of under-reporting” of Dr Bottrill’s laboratory. (Farnsworth trans, B/1870). Data for these calculations were found in TM/HFA/0087, Tables 5.3 and 5.4 (pages 49 and 50). The indicators are as follows:

15.1 *Detection rate of Dr Bottrill’s laboratory as compared with the Sydney re-read results* (Farnsworth trans, B1844-49) According to the data, 37 out of 72, or 51.3% of, women with high-grade cytology (high-grade abnormalities and cancer) diagnosed by Dr Bottrill had this result confirmed on biopsy. Comparable figures for the Sydney laboratory were 50.7%, or 132 out of 260. According to Dr Farnsworth, although the confirmation rate was the same for both labs, Sydney had 3.5 times more than the number of smears confirmed as high grade by Bottrill’s laboratory. In her view this difference represented under-reporting by Dr Bottrill’s lab. (Farnsworth trans, B/1851)

15.2 *False positive reporting* (Farnsworth trans, B/1851-63) According to the data, Dr Bottrill’s laboratory had a very low false positive rate (3.9%) compared with the Sydney laboratory’s re-reading rate of 28.9%. In answer to the question of whether, with a low false positive rate, there was a greater likelihood of under-reporting, Dr Farnsworth replied “absolutely”. (Farnsworth trans, B/1859) She concluded that this measure represents one possible measure for under-reporting. (Farnsworth trans, B/1859)

15.3 *Cytology confirmed by histology* (Farnsworth trans, B/1862-66) According to the data, of the 216 biopsies that were cancer or high grade, 17 % (37 out of 216) were correctly predicted by Dr Bottrill’s laboratory, compared with 61% (132 out of 216) correctly predicted by the Sydney laboratory. Dr Farnsworth confirmed that this measure indicated under-reporting. (Farnsworth trans, B/1866)

16. During his second appearance before the Inquiry, Professor Skegg cited Table 5.6 (TM/HFA/0087, page 52) as providing information of particular relevance in addressing this term of reference. In his view, it was “the most important from an epidemiological point of view in this report”. (Farnsworth trans, B/2292)

17. Professor Skegg made the following statements based on his analysis of this table:
 - 17.1 16 results had all been reported as either normal or low grade or ASCUS by Dr Bottrill and all reported as high-grade abnormalities or cancer by Sydney. “I believe that that does indicate a substantial level of under-reporting”. (Skegg trans, B/2297) When asked if a “very substantial level of under-reporting” was unacceptable, he replied “yes” (Skegg trans, B/2298). He was hesitant to say “unacceptable” as has not been defined in the terms of reference (Skegg trans, B/2306) and he expressed his preference for a pathologist to provide an opinion. (Skegg trans, B/2307)

 - 17.2 “Many of those 16 women who developed cervical cancer in the two latter periods might well have avoided getting cancer if the programme had had an evaluation system in place that had drawn attention to the problems of this laboratory while Dr Bottrill was still practicing”. (Skegg trans, B/2298)

 - 17.3 “... if there had been an evaluation of cases of cervical cancer as they occurred it might well be that some or a large proportion of the 16 women who’ve developed cervical cancer, and of course now we have to add a number of other women, given that it’s clear that their cancers developed after false reassurance from normal smears or low grade smears, I think it’s worth noting that some of those cancers could have been avoided”. (Skegg trans, B/2298)

18. Asked to comment on the analyses of other tables in the document raised with Dr Farnsworth and outlined in 15 above, Professor Skegg indicated that the data show a very substantial degree of under-reporting of serious histological abnormalities. (Skegg trans, B/2306)
19. Based on his analysis of the data provided in TM/HFA/0087, Professor Skegg indicated that because the situation was “worse than anticipated”, he no longer believed that the audit he proposed was essential to answer Term of Reference 1. Nevertheless the information would be “highly desirable”, especially in answering Term of Reference 2. In his view, the audit could still identify other factors “that are just as important or more important in the occurrence of avoidable cancers”. (Skegg trans, B/2300)
20. In comparing the lab results of Gisborne and Sydney found in TM/HFA/0087, Table 5.6 (page 52), Dr Wain stated that 30% of women who developed cancer had their smears read by Dr Bottrill’s laboratory as cancer or high grade. From this table alone, he indicated that the level of under-reporting was “extreme”. (Wain trans, B/1950) He added that on a ten-point scale, he gave it a ten: “completely unacceptable”. (Wain trans, B/1950)
21. Another approach to this term of reference was provided by Dr Brian Cox, who provided an estimation of the laboratory sensitivity of the original and the re-read laboratories for a mixture of screening and diagnostic reporting. (BC/CX/050) Based on his calculations, Dr Cox concluded that there was an unacceptable level of under-reporting in Dr Bottrill’s laboratory. (Cox trans, B/2565)
22. The Cancer Society submits that the above evidence supports the conclusion that there was an unacceptable level of under-reporting in consequence of mis-reading and/or mis-reporting of abnormalities in cervical smears in the Gisborne region.

Section 4

TERM OF REFERENCE 2: FACTORS LIKELY TO HAVE LED TO UNDER-REPORTING IN THE GISBORNE REGION

1. In the view of the Cancer Society there are both direct and indirect factors which have led to under-reporting in the Gisborne region. Direct factors include the practice of Dr Bottrill; indirect factors at both a regional and national level are those which contributed to under-reporting by not enabling the situation to be identified at an earlier stage. These include systemic issues relating to the National Cancer Screening Programme (NCSP) and its deficiencies in not meeting in all respects international criteria for cervical screening programme effectiveness.

PART 1: REGIONAL ISSUES

2. In this part of its submission, the Cancer Society addresses the following issues relating to the operation of the NCSP in the Gisborne region:
 - 2.1 Practice of Dr Bottrill as sole pathologist.
 - 2.2 Volume of slides read in Dr Bottrill's laboratory.
 - 2.3 Reliance by medical practitioners and patients on screening as sole indicator of abnormality.
 - 2.4 Absence of system within the region for reporting and responding to incidents.
 - 2.5 Absence of audit within the region of patients who developed cervical cancer.

Practice of Dr Bottrill as sole pathologist

3. There is no challenge to evidence that Dr Bottrill operated as a sole pathologist with no cytoscreener, no external quality assurance and no accreditation of his laboratory.
4. With regard to internal quality control, Dr McGoogan stated that “it is difficult in a situation where there is only one person for that individual to quality control themselves and while it is not impossible to maintain quality service under those circumstances it would be extremely difficult and would require exceptional measures to be put in place by the individual to ensure competence and a quality service”. (McGoogan trans, A/1016)
5. Dr McGoogan identified six measures which a small laboratory with one pathologist could put into place to ensure competence and quality. These included:
 - 5.1 Frequent and good interaction with pathologists in another laboratory whereby there was exchange of work between the two laboratories.
 - 5.2 Well documented processes and data collected for internal quality control.
 - 5.3 Biopsy smear correlation.
 - 5.4 Frequent participation in external quality assurance.
 - 5.5 Frequent attendance of meetings of cytologists with cytological topics pertaining to cervical screening.
 - 5.6 External accreditation. (McGoogan trans, A/1017)
6. Through cross examination by Mr Grieve, Dr McGoogan agreed that Dr Bottrill did not comply with five (and possibly six) of these criteria, which she identified as being essential to give women whose slides were being tested any

form of confidence that they were getting accurate results. (McGoogan trans, A/1133)

7. Asked whether she thought it good practice for the programme to be structured in such a way that someone within the programme allowed a pathologist practicing in such a way to read smears for the purpose of the programme, she replied “no it was not good practice”. (McGoogan trans, A/1128)
8. During cross examination, Dr Wain was asked the following question: “Well would you be confident of using a laboratory to read pap smears which is being run by a pathologist doing primary screening as the only pathologist who did not participate in any external quality assurance programme and ... apart from the general ethical requirements that all registered medical practitioners have to adhere to, it was not subject to any other mandatory requirements?” He responded: “No I wouldn’t be at all happy with that in the year 2000 or 1995 or 1990 or 1985. Those principles have been in place for a long time regardless of how you define them in terms of accreditation or whatever else. The accreditation process has always been conceptually against that approach.” (Wain trans, B/2000)

Volume of slides read in Dr Bottrill’s laboratory

9. This is an issue in both regional and systemic contexts, on which expert evidence has been heard. Essentially, that evidence suggests that the volume of smears read by Dr Bottrill’s laboratory was insufficient to enable him to maintain a competent and reliable standard of accuracy in reporting.

Reliance by medical practitioners and patients on screening as sole indicator of abnormality

10. Evidence regarding the clinical management of individual patients indicates a lack of understanding on the part of both health professionals and women affected on the role and purpose of screening. Evidence shows some women had smear tests which failed to show any abnormality, yet they either

presented with symptoms or had bleeding at the time the smear was taken, but were not referred for assessment.

11. According to Dr Cox, signs or symptoms of invasive cervical cancer require prompt clinical investigation irrespective of the result of the last smear. (Cox brief, para 29) The need for such investigation was stressed consistently in the reports of the 1985, 1991 and 1997 working groups on recommendations for routine cervical screening. (GRB/MOH/0007, page 636) (JMG/MOH/0010, page 292) ((JMG/MOH/0049, page 94)
12. According to Dr Wain, who reviewed the evidence of patients 1-10, although there was no consistent pattern of poor clinical behaviour or management, there appeared to be some misunderstandings about cervical screening. (Wain brief, para 27)
13. The analysis by the Cancer Society of evidence of women affected (included as Appendix A) also indicates poor management by doctors of women presenting with symptoms whose smear test results were normal.
14. When asked to comment on why, in two specific cases, there appeared to be a clinical reliance on smear tests in the presence of obvious cancer, Mr Jones stated that he would have expected all doctors to be able to recognise a malignant cervix. (Jones trans, B/1620-1)
15. When asked to comment on bleeding at the time of sampling, Dr Cox stated that it is a clinical sign and should have triggered a referral for assessment. (Cox trans, B/2500)

Absence of system within the region for reporting and responding to incidents

16. According to her evidence, Ms Reid documented her observations of an increase in high-grade abnormalities in the Gisborne region in a report she produced for a NCSP managers meeting on 18/19 June 1997 as JMG/MOH/0062, page 68. However, she did not report such observations to

anyone in her region. (Reid trans, B/782). When asked to whom she could have reported such matters, she indicated her managers; when asked what she thought they might have done, she replied “I wouldn’t have a clue”. (Reid trans, B/783)

17. Ms Reid also stated that, when she became aware of the mis-reading of smears of patient 1 in 1997, she did not think it was her role to do something actively to bring it to the attention of other people within Tairawhiti Health Limited or of the National Coordinator. (Reid trans, B/752) She “hoped that it was an isolated incident and that if it wasn’t then certainly bigger people than me were going to bring it out into the open”. (Reid trans, B/751-2)
18. The evidence of Janice Hobbs testifies to the absence of any process for reporting and responding to incidents of mis-reporting. Having discussed the mis-reading of four smears of patient 1 with Ms Reid (but without identifying the patient’s name), Ms Hobbs assumed that “those who could have been alerted to a problem were aware of that problem”. (Hobbs trans, B/3167)

Absence of audit within the region of patients who developed cervical cancer

19. Having been asked to look at evidence of patients 7 and 8, Dr Cox stated that had there been an audit of their cases, especially as they occurred within a small region within a relatively short period of time, it would have triggered further investigation. (Cox trans, B/2656) No such audit ever occurred however.
20. According to Mr Jones, if the audit of cases of cervical cancer recommended on numerous occasions and described in the *Guidelines for the Management of the Abnormal Cervical Smear* 1998 (JMG/MOH/0050, p 5) had occurred, this inquiry would not be taking place”. (Jones brief, para 10)
21. According to Mr Jones and others, such a review can and should be undertaken by the treating gynaecologist in association with other clinicians

(eg. cytopathologists and histopathologists). (Jones trans, B/1546) (Cox trans, B/2657)

22. According to Dr Beer, his laboratory has regular meetings with the gynaecologists in the area to review all of their positive diagnoses of invasive cervical cancer. (Beer trans, B/1063)
23. According to Dr Cox, an audit could also have been undertaken by the programme, assuming access to medical records could have been obtained. (Cox trans, B/2657)

PART 2: SYSTEMIC ISSUES

Failure of the national cervical screening programme to meet fully internationally recognised requirements for effective cervical screening programmes

24. Systemic failures in the NCSP which led to under-reporting in Gisborne have been the subject of a considerable volume of evidence before this Inquiry, and will be the subject also of extensive submissions. The Cancer Society endorses the submissions of both Mr Corkill as counsel for the women affected and of Mr Kirton and Ms Coney on many of these issues, and will not cover in detail matters which they address.
25. Evidence shows that during the 1990-96 period the NCSP did not meet in all respects the key organisational requirements for effective screening programmes outlined in documents before the Inquiry. A listing of these requirements, which is included in the 1994 CSAC report (JMG/MOH/0035, page 3), includes the WHO requirements for effective screening produced as BC/CS/0046 and the managerial guidelines for the running of cervical screening programmes produced as BC/CS/0047.
26. In his evidence, Dr Cox stated that World Health Organization documents were developed after careful assessment of the characteristics of effective

cervical screening programmes worldwide (Cox brief, para 30). With regard to the managerial guidelines, he stated that they represented an unusual step by the WHO, in that it “does not like to get down to dictating ... how a service should be provided within a specific country because it usually respects the autonomy of countries”. He stated that the document was produced because of experience gained overseas, particularly in Europe, North America and Scandinavia, about “what can go wrong and what’s needed”. (Cox trans, B/2618)

27. Critical failures from the inception of the programme to comply with the above requirements included:
 - 27.1 Failure to establish a fully resourced central unit with strong identifiable leadership, stable and appropriately qualified staff and clear lines of accountability.
 - 27.2 Implementation of opt-on register with 14 separate sites.
 - 27.3 Failure to implement systems for regular collection and analysis of reliable data.
 - 27.4 Failure to establish at the outset structures for monitoring and evaluation of the operation of the programme and its component services, both clinical and managerial.

28. Ultimately, the evidence points above all to political factors as the consistent background to the continuing inadequacies of the NCSP. Those factors, recorded throughout documentary and oral evidence, were particularly:
 - 28.1 Vulnerability of the NCSP to successive periods of restructuring of health care services according to the policies of changing governments, with consequent instability of service structures — including unsuccessful attempts to manipulate the structure, location, funding and staffing of the NCSP to make it “fit” a devolved system with a

formal split of accountabilities between personal and public health services.

- 28.2 Inertia and resistance by Department (later Ministry) of Health officials to the advice of professional experts committed to the establishment of a properly constituted NCSP operating in accordance with recognised international standards..
29. Evidence before the Inquiry demonstrates repeated calls for the NCSP to meet established criteria for effective programmes:
- 29.1 ‘Towards a More Effective Screening Service for Women in New Zealand’. (EAM/CS/0012)
- 29.2 “The Case for a National Cervical Screening Programme; A Report to the Expert Group, 29 May 1990”. (EAM/CS/0031)
- 29.3 Straton review of the NCSP. (JMG/MOH/0004)
- 29.4 Policy Statement of the NCSP Expert Group. (JMG/MOH/005)
- 29.5 CSAC report: “Monitoring and evaluation of the NCSP: The First Three Establishment Years” (JMG/MOH/0035).
30. Evidence also confirms the failure of the DOH/MOH to recognise the importance of these criteria. (Coney trans, B/2807-8)

Failure to establish a fully resourced central unit with strong identifiable leadership, stable and appropriately qualified staff and with clear responsibility for programme planning, coordination, monitoring and evaluation

31. The need for strong leadership to develop, coordinate and maintain the NCSP was identified by Judge Cartwright as essential to the success of the programme. In her report, Judge Cartwright identified concern among

women's health groups that the Department of Health might leave the responsibility for screening to area health boards. For this reason she stressed the need for a programme that was centrally organised, thereby avoiding dilution through regionalisation. (Cartwright Report, pages 207-8)

32. Evidence before the Inquiry shows that there has never been an independent fully resourced central office responsible for the functions outlined above, particularly programme monitoring and evaluation. (Marshall brief, para 36)
33. This was due in part to a failure to commit adequate funding and other resources to management of the programme. (JMP/HFA/0027) (Handiside trans, B/3789)

Inadequate staff levels and appropriate levels of expertise

34. An inevitable consequence of inadequate financial resourcing was inadequacy of staffing levels and of appropriate levels of expertise. (Cox trans, B/2538 and 2663) (Teague trans, B/1247) (Cox brief, paras 91, 96, 120, 129, 133, 142, 164, 166, 177, 179 and 187) (Marshall brief, paras 69-74) (JMG/MOH/0004, p 56)
35. While the MOH did not have the expertise or staff, it also was reluctant to "unbundle a piece of money from their budget" for someone else to do programme monitoring/evaluation. (Cox trans, B/2671)
36. Examples of limited or no action on expert advice due to insufficient staff with the appropriate expertise and skills included:
 - 36.1 Limited action in implementing the Ministerial Review Committee's recommendations on monitoring/evaluation (Cox trans, B/2662)
 - 36.2 Lack of response to variations in laboratory practices identified by the first two statistical reports. According to Dr Cox, "Issues of this nature which are relatively serious and of a clinical nature, they would have

needed some sort of medical input into interpreting the information and what might be done about it”. He confirmed that someone without medical expertise might not have realised the importance of this issue. (Cox trans, B/2495)

36.3 Inaction on “wake-up calls” for the programme, which included:

36.3.1 The NCSP newsletter article on patients in a Sydney hospital whose previous smear tests on review showed malignant cells. (BC/CS/0022) (Cox brief, para 114, and B/2668, 18)

36.3.2 The NCSP newsletter article and CSAC discussion regarding several failures in screening programmes in the UK. (BC/CS/0029) (Cox brief, para 151, and B/2668, 19-24)

36.3.3 Legal case in Australia. (Cox para 167, B/2668-9)

37. In Dr Cox’s view, “... there has been the difficulty ... over a long period of time because of the relative lack of expertise and experience of screening within the Ministry ... the Department of Health and I must say within the Health Funding Authority now to fully appreciate the importance of some pieces of information over and above other pieces of information and if you like see the wood from the trees”. (Cox trans, B/2496)

38. In a covering letter to the Minister of Health accompanying CSAC’s report on monitoring and evaluation (JMG/MOH/0035), the committee identified the need for paid staff with expertise from several disciplines. Asked to comment on the Minister’s response (JMG/MOH/0036), Dr Cox described it as “vastly inadequate”. (Cox trans, B/2540)

39. Other staffing issues included:

39.1 Absence of a national coordinator at the start of the programme.

- 39.2 During the 1991-94 period there were two national coordinators. There were also two five-month periods of time when the coordinator's position was vacant. (Marshall brief, para 98)
- 39.3 High turnover and shortage of support staff. (Marshall brief, paras 69,70, 71 (Grew trans, B/4119) (Marshall brief, para 95)
- 39.4 Reliance on contracted skills rather than developing in-house expertise, resulting in a high use of resources and loss of opportunity for in-house expertise. (JMG/MOH/0035)

Instability in siting coordinator due to internal restructuring

- 40 High turnover and shortage of support staff were consequences not only of inadequate resourcing, but also of instability due to internal restructuring within the Department/Ministry of Health. (Marshall brief, para 73)
41. According to Professor Skegg, restructuring in the Department/Ministry of Health "has been a ... problem for the staff working in the Ministry over the last 12 years". (Skegg trans, A/918) "Staff were subject to an extraordinary degree of organisational change – it would be restructured or refocused, essentially a lot of people had to reapply for their jobs and it's hard in that climate to expect people to take definite actions perhaps to make themselves unpopular by taking a stand on matters like cervical screening so it has been quite difficult for the Ministry to function in some of these areas". (Skegg trans, A/918)

The low status of coordinator

41. The low status of the national coordinator was acknowledged in GRB/MOH/0014 and Boyd brief, paras 151-3.

42. Professor Skegg noted that because of the low status of the position, the national coordinator was not in a position of authority to secure change “other than by influence, discussion and lobbying”. (Skegg trans, A/892)
43. Professor Skegg described the Ministry of Health as a “very hierarchical organisation which has a large mix of responsibilities ... one has to ask the question as to whether the programme was as well served by having a coordinator at a relatively low level in a very large organisation as opposed to having a separate focus for the NCSP”. (Skegg trans, A/892)
44. “The difficulty with having a unit such as this in the Ministry of Health is that the people who are on the advisory committees are actually not meeting with the people making the decisions, they are advising coordinators who then have to lobby within the Ministry of Health for something to be done”. (Skegg trans, A/917)
45. With regard to addressing the risk of responsibility for monitoring/evaluation being split between different agencies, Professor Skegg said “if there had been strong central leadership for the NCSP, I would have expected that someone would have been drawing attention to this ambiguity and that the matter should have been clarified as to which organisation did have the responsibility for ensuring quality control”. (Skegg trans, A/899)

Inadequate accountability to the national unit

46. One of the issues identified in evidence is the absence of clear lines of accountability between different aspects of the programme and the national coordination unit.
47. When Dr McGoogan was asked to comment on an early diagram of the programme (JMG/MOH/0040, Appendix 1) as an illustration of the complexity of programme accountabilities, she replied that “if she were a pathologist working in this system” she “would find it extremely difficult

knowing to whom I was actually responsible for delivering my part of the programme”. (McGoogan trans, A/1086)

48. As Dr Lambie indicated, there also were no direct lines of accountability between the area health board programme managers and the NCSP coordinators. As a result the national coordinator had no contractual or regulatory authority over them. (Lambie trans, B/3976)
49. Dr McGoogan observed that she would have expected some line of accountability to the area health board programme managers, some direct line moving between the programme managers and the area health board managers. (McGoogan trans, A/1090)
50. As CSAC noted in its 1994 report, lines of accountability become further fragmented when various aspects of the NCSP conceptually became the responsibility of the Ministry of Health, Public Health Commission and Regional Health Authorities. (JMG/MOH/0035, page 5)
51. As Ms Coney noted, not only were accountabilities divided, but there was also the funder/provider split which resulted from the 1991 health reforms. (Coney trans, B/2772)
52. In response to the 1996 Review of Accountabilities outlined in JMG/MOH/0040, CSAC stressed the need for one national programme with strong national operational leadership, rather than four programmes run by four RHAs.

Implementation of opt-on register with 14 separate register sites

53. Until July 1993 the NCSR was restricted to those women giving written consent. A number of witnesses were critical that early advice for an “opt-off” register, described by Professor Skegg as a “fundamental lynchpin” for the programme, was not implemented. (Skegg trans, A/907) (Skegg brief, para

39) (Cox brief, para 85) (Coney brief, para 19.1, paras 164-185) (Coney trans, B/2760)

54. Limitations of an opt-off system include:

54.1 Enrolment relied on smear-takers informing women of the register and its purpose, thereby limiting enrolment and the number of smear results included. (According to the first statistical report with smear results up to May 1992, only 12.8% of eligible women were registered nationally, excluding the Wellington Area Health Board.) (JMG/MOH/0026) (Cox trans, B/2491)

54.2 Under an opt-on system, data was not only limited in quantity but also could not be taken as a representative sample of the population as a whole. (Teague brief, para 18.3)

54.3 According to Professor Skegg, "One would expect the proportion of smears showing for example severe abnormalities would be different among the women on the register compared to other women. Those differences could vary in different parts of the country. It makes interpretation very difficult". (Skegg trans, A/909)

55. The ramifications of having fourteen separate register sites, as described in the 1994 CSAC report, were:

55.1 Those responsible for the management of regional registers were accountable to their board and not to the Department/Ministry of Health.

55.2 Because the Ministry had no authority (or staff or resources) to directly monitor local registers, variations of procedures and data coding between areas occurred.

- 55.3 There were difficulties with gathering uniform national data for statistical and quality control purposes, as well as substantial problems in retrieving data necessary for inclusion in a national data set.
- 55.4 One site required the approval of the local ethics committee before releasing the data to the Ministry of Health. (JMG/MOH/0035, page 4)
56. As the CSAC report stated, restricted enrolment of women and the existence of 14 separate registers had profound implications for obtaining national data essential to national monitoring and evaluation.
57. For example, as cited by Dr Teague, the opt-on system was providing relatively low numbers of smear results to 14 different registers, “making statistical evaluation of laboratory performance extremely difficult given the relatively low incidence of significant abnormalities”. (Teague brief, para 19.3)

Failure to implement systems for regular collection and analysis of reliable data

58. In 1990 the Expert Group recommended to the Minister of Health that in the absence of a national population-based register, the objectives of the programme could only be achieved through three linked registers: a national cytology register, a population register and a histology register. The group acknowledged that each of these registers was “integral” to the programme; each therefore “is a potential weak link”. (CAT/RCPA/004, page 123)
59. Despite the fact that the Expert Group’s advice confirmed previous advice of the Ministerial Review Committee that it was essential that both cytology and histology results be recorded, (JMG/MOH/001, para 2.23) legislation requiring notification of histology to the register was not passed until 1993.

60. According to Professor Skegg, “it is of fundamental importance and it is inexcusable that several years elapsed before this was done”. (Skegg trans, A/893)
61. Without histology results on the register the NCSP was unable to:
- 61.1 Assess the accuracy of cytology
 - 61.2 Monitor that women with abnormalities were treated
 - 61.3 Monitor the outcome and assess the effectiveness of treatment. (Cox brief, para 37 and 71)
62. In addition to the absence of systems to collect histology information, no process was developed at the outset for the routine collection and analysis of data from the 14 separate registers. As cited by Dr Cox, “the potential existed” to develop a national cervical screening register, but the steps required to link the 14 systems “still needed to be mapped out”. (Cox brief, para 41)
63. The need for linkage of the Cancer Registry and the NCSR was also identified during the initial development of the programme, with the Ministerial Review Committee expressing concern that linkages between the NCSR with treatment data and data from the Cancer Registry “had not been thought through sufficiently to ensure that they would be achievable in the future”. (JMG/MOH/0001, page 107) The report recommended that immediate attention be given to requirements for linkage between the NCSR, cervical treatment records and the Cancer Registry. (page 108)
64. In his brief Dr Cox referred to discussion at the CSAC meeting of 11 June 1993 regarding the need for linkage, citing his understanding that a legal opinion provided to the Department of Health suggested that linkage of the two registers may not be possible. (Cox brief, para 121)

65. The importance of comprehensive data being collected and analysed routinely was emphasised in 1991 by the working group which reviewed the routine recommendations for cervical screening. In the conclusion of their report published in the New Zealand Medical Journal, the group stated that, “It is extremely important that by the time the next review of the screening recommendations is due there should be sufficient information available to evaluate the success of the screening programme. Comprehensive cytology registers linked to histology must be developed, and the National Cancer Registry must be improved. If we are to convince all women to put up with the inconvenience and minor discomfort of a cervical smear every three years for the sake of their future health, we need to ensure that such screening does indeed benefit them”. (JMG/MOH/0010, p294)

Limited analysis of data collected

66. During the period up to 1996, the NCSP undertook limited analysis on a national basis of data being collected by the screening register. The primary analyses included the following statistical reports:
- 66.1 “The First Statistical Report” published in August 1993 provided analysis of data up to May 1992. (JMG/MOH/0026)
- 66.2 “The Second Statistical Report” published in October 1995 provided analysis of data up to June 1994. (JMG/MOH/0027)
67. The Cancer Society supports the submission by Mr Corkill, based on an analysis of the evidence of the history and contents of these two reports, that these did not amount to a basis for monitoring and evaluation. (Corkill submission, para 174)
68. In addition, the evidence highlights that although the data may have been limited in some areas, what was collected could have been subjected to more detailed analysis. When commenting on the second and third statistical

reports, Dr Cox commented that “the programme had not done the sort of analysis, extensive analysis that ... the data was begging for I might say in terms of providing information that would be useful in terms of monitoring and evaluation”. (Cox trans, B/2506)

69. As further highlighted by Dr Duggan in cross-examination of Dr Cox, some of the information which would have been required to meet all the parameters set out in the European Guidelines for Quality Assurance in Cervical Screening (BC/CS/0044) was not available during the early period of the programme. Nevertheless, there was quite a bit of monitoring/evaluation which could have been conducted with what was available. (Cox trans, B/2646)
70. Dr Cox also confirmed that the two statistical reports established wide variability between laboratories. However, there was no comment in the second report as to what had been done in the previous two years and what was anticipated in the future to address this issue. (Cox trans, B/2494)

Failure to establish at the outset structures for monitoring and evaluation of the programme and its component services

Programme monitoring and evaluation

71. As identified by Mr Corkill in paragraph 134 of his submission, various definitions of monitoring, evaluation and audit were provided in evidence.
72. In distinguishing between monitoring and evaluation, Dr Cox referred to his current role as chair of the independent monitoring group for the breast screening programme. Within the programme there is a national monitoring data set, collected by the NZHIS from the providers of the programme. The group’s role is to analyse the data and produce figures which are then compared against the national targets and indicators. By comparison, evaluation is more thorough and therefore is too exhaustive to be carried out on an ongoing basis. It is done intermittently to achieve a more thorough understanding of a particular issue. (Cox trans, B/2606)

73. In Dr Cox's view, evaluation is part of the quality control/assurance process. Audit is a "thorough review of processes ... most of which would not be measured through monitoring. When an indicator is breached, it triggers a thorough assessment of the processes behind that particular performance parameter, and that I would call an audit". (Cox trans, B/2608)
74. According to Dr Cox, research involves "a priori hypothesis and a specific study design to test a particular hypothesis". (Cox trans, B/2609)
75. Mr Murray indicated that monitoring could have different meanings depending on the stage of the health system (eg, monitoring and evaluations of organisations who were funding providers). (Marshall trans, B/3226) It is within this context that Dr Lambie described the role of the Performance Management Branch of the Ministry of Health as monitoring RHA performance in delivering service obligations as laid out in funding agreements. The Ministry's role was not, however, to monitor provider performance. (Lambie brief, paras 51-53)

Programme monitoring and evaluation – what was recommended

76. According to the WHO guidelines for effective screening published in 1986, a cervical screening programme should not be initiated prior to the establishment of adequate evaluation procedures. (BC/CS/0046, p614)
77. In Appendix IV of its report, the Ministerial Review Committee acknowledged that effective monitoring of the programme would require a wide range of performance indicators, which together would provide an overall indication of performance. (JMG/MOH/0001, page 117) The report included listings of suggested indicators for all aspects of the screening pathway. As stated by Dr Cox, progress in implementing these and other recommendations of the Review Committee "has proved to be slow and spasmodic", and "many have still not been implemented over ten years later". (Cox brief, para 46)

78. In their report published in the *New Zealand Medical Journal*, the 1991 working group to review the cervical screening recommendations called for “quality control of all aspects of cervical screening and formal evaluation of all components of the screening process, from recruitment and recall of women to management of women with abnormal smears”. (JMG/MOH/0010. p 294)
79. Other recommendations or references to monitoring/evaluation in policy include:
- 79.1 Straton review recommendations:
- evaluation function of the register should be developed
 - suitably qualified register coordinator be appointed to manage its monitoring function
 - need to incorporate an evaluation component into planning of future cervical screening projects, including service delivery, with such evaluation ideally being coordinated nationally. (JMG/MOH/0004)
- 79.2 Expert Group Policy:
- performance indicators were to be developed for AHBs
 - aspects of the programme which required evaluation, including quality of smear reading
 - Department of Health was to establish epidemiological information available from the register and ensure economic evaluation. (JMG/MOH/0005)
- 79.3 1991 and 1993 Government Policies for the NPHC
- reiterated key monitoring/evaluation needs identified in Expert Group Policy (JMG/MOH/0015) (JMG/MOH/0027)
- 79.4 Cervical Screening Advisory Committee 1991-1994

- Appendix 3 of CSAC's final report provides a four-page summary of committee documents and recommendations on monitoring/evaluation over its three-year term. (JMG/MOH/0035)
- CSAC appended to its report tables from European Guidelines for Quality Assurance of Cervical Screening. (BC/CS/0044) (Cox trans, B/2508)
- In his brief of evidence, Dr Cox identifies CSAC discussions/recommendations in minutes of meetings. (65, 71, 75, 108,143,145,177,186)

80. The 1994 report of CSAC recommended an annual statistical report, regular feedback to smear-takers and laboratories re quality, routine monitoring of waiting time for colposcopy and annual expenditure report. (JMG/MOH/0035, page 2) In Dr Cox's view, these measures could have been implemented at the latest in 1993, though "there were many opportunities before that for many of those matters". (Cox trans, B/2537)
81. Dr Cox sent a full copy of the European Guidelines for Quality Assurance in Cervical Cancer Screening to CSAC, the national coordinator and the Public Health Commission Monitoring and Evaluation Section. (Cox brief, para 186) According to Dr Cox, these are an international benchmark which the programme could have begun implementing in 1995. (B/2535) The importance of the guidelines was also recognised by CSLAC. (Cox trans, B/2534)

Audit of women with cervical cancer

82. The need for an audit of the screening histories of women with invasive cancer has been identified by a number of experts and advisory groups for a number of years. Referring to minutes of CSAC meetings, Dr Cox cites in his brief of evidence discussions and recommendations for such an audit in paragraphs 65,

144, 163, 195, and 207. CSAC also raised the matter in correspondence with Katherine O'Regan. (EAM/CS/0042, pages 9 and 13)

83. The recommendation for such an audit was also made in an outline of evaluation for the NCSP which Dr Cox prepared for CSAC in 1991 (BC/CS/008) and in the report of the working group of which he was a member, which was published in the *New Zealand Medical Journal* in 1997. (JMG/MOH/0050)
84. As yet no programme audit has been undertaken.

Performance indicators

85. Evidence shows that there were few performance indicators for the programme which had to be reported to the Ministry of Health for the purposes of national programme monitoring and evaluation. According to Ms Glackin, those which were required from area health boards included:
- colposcopies per 1000 women
 - women waiting longer than six months for colposcopy
 - percentage of women on the NCSR who had had a smear in the last three years
 - percentage of cervical cancer detected at stage one of the disease.
- (Glackin brief, para 287)
86. In her evidence Ms Handiside confirmed that for 1993/94 and 1994/95, the only "accountability indicators" for the NCSP in the funding agreements between the Crown and the RHAs related to colposcopy waiting times (colposcopy patients waiting > 6 months and colposcopy patients with CIN-3 waiting > 4 weeks). (Handiside trans, B/3647 and B/3650) This was confirmed by Dr Lambie. (Lambie brief, para 58)
87. Evidence shows that some consideration was given to developing a performance indicator requiring RHAs to indicate the number of laboratories contracted for cervical screening services. A specific performance indicator

was not developed, however. (Lambie brief, para 61) (JMG/MOH/102)
 Instead, the issue of TELARC accreditation was listed with other cervical screening services within funding agreements, with RHAs to undertake “reasonable endeavours” to ensure labs were TELARC registered. (Lambie trans, B/3895)

Monitoring/evaluation reports

88. According to the CSAC final report, up until 1994 monitoring and evaluation of the NCSP was undertaken on a project/one-off approach and on a contractual basis, rather than on a routine basis. (JMG/MOH/0035)
89. According to a literature review undertaken by Women’s Health Action for the NCSP and HFA, between 1990 and 1994 a number of evaluations and projects were carried out on women’s understandings of cervical screening and their educational needs. (Coney brief, para 216)
90. In her evidence, Dr Peters provides a list of eight reports carried out by the Ministry of Health and held at the HFA office. She indicates that although they provide “valuable information for those working in the NCSP they are not the type of monitoring and evaluation reports that I would require for the purpose of detecting potential failures within the screening programme. (Peters affidavit, para 10).
91. Dr Cox provided the following comments on other reports not addressed by Dr Peters as follows:
- 91.1 Straton report (JMG/MOH/004): “an overview...of the implementation where improvements could be made”. (Cox trans, B/2648)
- 91.2 Norton Laboratory Review (JGM/MOH/0025): not monitoring/evaluation. (Cox trans, B/2648)

- 91.3 CSAC 1994 report (JMG/MOH/0035): no monitoring/evaluation (Cox trans, B/2648)
92. According to Dr Cox, some evaluation occurred at the area health board level regarding enrolment and recruitment. “I think that’s where most of the evaluation money was spent.” (Cox trans, B/2577)
93. When asked about the evaluation plan which he had developed with Dr Richardson in 1997 (JMG/MOH/0047) and which was not implemented because the budget exceeded the funding available (Glackin brief, para 369), Dr Cox replied: “I believe the legacy of the one-off cost was because things had not been done in a staged manner in the earlier years and so that it hit someone’s annual budget as a large item”. (Cox trans, B/2485)
94. When Dr Cox was asked about the development of the 1997 plan and why some parts and not all were selected by MOH, he replied that “it was very important [for full evaluation plan to proceed] and I think almost all aspects of the programme needed evaluation at that time”. (Cox trans, B/2484)
95. If you leave paths of the screening pathway unmonitored, they are likely to come back to haunt you. When asked, he confirmed “That’s what has happened”. (Cox trans, B/2647, 18-19)
96. When asked his views on the fact that the Cox/Richardson evaluation study had not been completed, Mr Jones said that it is “a terrible indictment on New Zealand’s health service”. (Jones trans, B/1624)
97. In Professor Skegg’s view, “better procedures for evaluation could have drawn attention to any major problem in Gisborne many years ago, when remedial action could have been taken”. (Skegg brief, para 54)

Quality control of smear reading as a service component of the programme

98. In its report, the Ministerial Review Committee indicated the need for performance indicators for laboratories. In advance of these indicators being set, the report suggested interim indicators. (Cox brief, para 45) (Section IV. 19, page 124)
99. As stated by Dr Cox, minimum quality standards for laboratories still have not been produced by the National Cervical Screening Programme. (Cox brief, para 46)
100. In Professor Skegg's view, "ideally of course most of these criteria ought to have been in place before there was a national programme ... I would not have been in favour of delaying the programme for several years while these matters were attended to but I would expect them to be attended to as soon as possible and some could have been dealt with almost immediately". (Skegg trans, A/926)
101. Although there were no NCSP standards for laboratories, the need for laboratories servicing the programme to have TELARC accreditation was identified in a number of NCSP policy statements, as outlined by Mr Corkill in para 125 of his submission.
102. Although CALC had made recommendations to TELARC in 1991 regarding criteria for accreditation, these applied only to the labs that sought accreditation. (Marshall trans, B/3227)
103. During this period monitoring of smear taking and smear reading was left to local programmes. (JMP/HFA/27)

Vulnerability of NCSP to health service restructure and devolution

104. Professor Skegg described the changes to which the NCSP was subjected since its inception as follows: "The first decade of the NCSP has coincided with a period of unprecedented turmoil in the New Zealand health system. Few major health initiatives in New Zealand have an uncomplicated birth, but

the NCSP has had to contend with an almost constant process of organisational change. That it has survived at all is a remarkable feat, which probably reflects the high political sensitivity of the subject.” (Skegg brief, para 41)

Programme designed/modified to fit the health system of the time

105. One of the inevitable requirements of restructuring was the need to make cervical screening fit the health system model of the day. (Skegg trans, A/890)
106. Lead responsibility given to was given to the Department [Ministry] of Health, which had a predominant focus on policy/regulation, rather than service provision. (Cox brief, para 100) (Marshall trans, B/3232) As a result, the NCSP with its operational functions did not fit well in the Ministry of Health (Handiside trans, B/3642) (Coney trans, B/2773), with some describing the programme in the Ministry as a “square peg in a round hole”. (Handiside trans, B/3642) (Teague trans, B/1468)
107. According to Dr Cox, during the changes which began 1991, “issues associated with the screening programme I believe got a much lesser priority than the need to appear to reform the programme into a new model”. (Cox trans, B/2583) He observed that for at least two years, the place of the NCSP was unclear and that it did not fit easily into the new structures. (Cox brief, para 96)
108. There is also clear evidence that the NCSP did not fit well with the funder/provider split. (Cox trans, B/2584) (JMG/MOH/0035, page 5) According to Dr Cox, “this formal split of accountabilities made the delivery of the public health activity of a cervical screening service across the public health and personal health service divide more difficult to co-ordinate and organise”. (Cox brief, para 95)

109. At the same time, because of the NCSP's political profile, any major changes "would have resulted in an outcry in certain ... quarters". (Cox trans, B/2584)
110. At response to the MOH's 1996 review of accountabilities of the NCSP, CSAC acknowledged that the NCSP did not fit in the reformed health sector, and that this was not "the first attempt to make it fit". (Marshall brief, para 112)

Devolution of responsibilities

111. In Professor Skegg's personal opinion, "there has been a tendency for central government to want to devolve responsibility for the NCSP for obvious reasons. Because of inquiries like this one." (Skegg trans, A/890)
112. According to Ms Coney, "the ideology of devolution resulted in a lack of commitment to a national programme and serious deviations from WHO screening programme guidelines". (Coney brief, para 255)
113. As discussed elsewhere in these submissions, one of the most critical results of devolution was the establishment of 14 separate registers. Having 14 separate registers resulted in a "cumbersome approach" to collect data from the registers for the first statistical report. (Cox trans, B/2490)
114. "It was quite attractive to the government at the time to leave the responsibility for running the register to AHBs rather than accepting that as a responsibility for the department of Health or setting up a central agency. But there must have been strong reasons because this decision was taken in the face of very consistent strongly presented advice from both experts and screening and consumer groups." (Skegg trans, A/890)
115. When asked about the decision to allow 14 regional registers to be developed, Dr McGoogan replied that she found it "incredible to be quite frank that 14 different areas were organising programmes in their own area". (McGoogan trans, A/1028)

116. Along with devolution of responsibilities, the Ministry of Health had few absolute requirements by way of performance indicators for RHAs with regard to their purchasing. Asked, for example, why more performance indicators were not set out in funding agreements with the RHAs, Ms Handiside said that one of the directives to her was to “try and make our service obligations as short as possible”. (Handiside trans, B/3655)
117. According to Ms Handiside, funding agreements did specify that the programme was to be purchased according to national policy. For this reason she attempted to include in the 1996 policy as many standards as possible. (However, these were not translated into performance indicators for which the Ministry of Health required reporting from RHAs for programme monitoring and evaluation purposes.) (Handiside trans, B/3657-8)

Process of health system restructuring

118. As indicated in the 1994 CSAC report, soon after the committee was formed its attention was diverted from making recommendations on essential requirements for programme monitoring and evaluation to working towards improving the structural arrangements for the NCSP in the restructured health system. (JMG/MOH/0035, page 6)
119. In his evidence Dr Cox identifies some of the CSAC committee discussions regarding health reform issues and how the programme could fit within the new system. (Cox brief, paras 73, 86, 96, 97, 99, 101, 104, 111, 118, 120 and 130)
120. Dr Cox observed that “... since the restructuring of the Department of Health in October 1992 the interests of the Department of Health appeared to have become more dominant than the provision of a good NCSP to women”. He noted that “the last time this occurred so strongly was in 1989 and resulted in the ministerial review”. (Cox brief, para 99) Health restructuring resulted in “a great deal of anxiety within various organisations ... with the focus of the

Department of Health on what it got to keep and what it got to lose”. (Cox trans, B/2583)

121. Health system restructuring also resulted in a turnover in staff both regionally and centrally, resulting in a loss of institutional memory to the day-to-day operation of the NCSP. (Cox trans, B/2671) (Cox brief, para 177) (Coney trans, B/2746) “With every restructuring we’ve lost really good experienced people”. (Coney trans, B/2746)

Fight for programme survival

122. Witnesses commented that the programme survived because of the commitment of many, including advisory committees and through staff who “have worked tirelessly for the programme”. (Marshall brief, paras 37 and 38)
123. Advisory committees had to fight for the survival of the programme during health system restructuring. (Marshall brief, paras 93 and 110) She notes that “during the years when advisory committees should have been focused on the effective implementation and operation of the NCSP, we were unable even to rely on its continued existence”. (Marshall brief, para 113)
124. Consumer organisations also spent a considerable amount of time fighting on behalf of the programme. As stated by Ms Coney, “... there was just an endless stream of where are we going to put it, PHC, Ministry, all of which did not add to the strength of the programme and actually weakened it, so that there was this continual diversion into things that were completely peripheral to the programme but actually damaged its health”. (Coney trans, B2766)
125. Others who felt they were continually having to argue for the survival of the programme included regional coordinators and national staff. (Marshall trans, B/3210)

Constant changes and instability in structures resulted in inaction

126. In response to a question as to why TELARC registration did not become compulsory until 1997, Professor Skegg responded that “the first reason relates to the changes occurring during the 90s ... there were bodies created/abolished, accountabilities were being transferred on a regular basis ... it was a very unusual decade”. (Skegg trans, A/933)

Inertia and resistance by government health officials

Failure to understand complexity

127. Evidence before the Inquiry identifies the urgency with which NCSP developed and lack of understanding about the complexity of the task.
128. In her review of the NCSP, Dr Straton stated that the political impetus to establish the programme as soon as possible without regard to the complexity of the task led to unrealistic deadlines. (JMG/MOH/0004) Ms Coney, Dr Cox and Ms Marshall also commented on the unrealistic time frame and the establishment of the programme before everything was in place. (Coney trans, B/2737) (Cox trans, B/2658) (Marshall trans, B/3217)
129. Other witnesses confirmed that the Department of Health underestimated the complexity of the programme. (Handiside trans, B/3718) (Grew trans, B/4138-9) (Coney trans, B/2737)
130. According to Dr Cox, this underestimation jeopardised its effectiveness. (Cox trans, B/2670, 15 and Cox brief, para 120)
131. In its report, the Ministerial Review Committee identified the importance of all aspects of the programme being developed simultaneously, with each being an integral part of achieving success. (JMG/MOH/0001, page 2) At the same time, the committee acknowledged that the programme would need to be implemented, despite not having everything in place. Examples of outstanding issues included defined performance measures, including those for laboratories, absence of histology results, absence of an opt-off register.

Lack of Department/Ministry of Health Commitment to the NCSP

132. Department of Health ambivalence towards the NCSP. (Marshall brief, para 78-87)
133. Department of Health reservations about the need for a nationally coordinated programme. (Marshall brief, para 81)
134. Adherence by some in the Department of Health to the principle of devolution of all health services to area health boards. (Marshall brief, paras 83 and 84)
135. “Foot dragging and lack of commitment to the programme” [by the DOH/MOH]. (Coney trans, B/2744/12-14)
136. In Dr Cox’s view, at the start of the programme the Department of Health did not particularly want the initiative of a national cervical screening programme and “it was imposed through a ministerial inquiry ... I don’t think the Ministry took the implementation of a NCSP as a public health initiative for New Zealand on board to the extent that they should have”. (Cox trans, B/2665)
137. Dr Cox noted, however, that the political nature of the NCSP helped ensure its survival. “The programme has always been highly political and in many ways if it hadn’t been it probably would have died”. (Cox trans, B/2571) “It also would not have been left as untouched as it was by the health reforms”. (Cox trans, B/2571)
138. Several witnesses were asked to comment on Ministry of Health responses to recommendations regarding programme monitoring and evaluation.
139. When asked whether the Minister or any official in the MOH had challenged any of the recommendations or contradicted the descriptions given in the 1994 report, Dr Cox said:

139.1 “the manner of reply tends to be in the nature of excuses rather than contradiction, particularly from the national coordinators who I actually think at a personal level wanted this thing to be successful and proceed”. (Cox trans, B/2538)

139.2 “the difference between what was required and what they were able to provide was so wide that excuses tended to be used”. (Cox trans, B/2538)

139.3 “We are doing this and we’re doing a bit of that and it is getting better and please hang in there”. (Cox trans, B/2539)

140. “So the evaluation was always able to have a lower priority and was delayed. And that’s when I mean there was a lack of commitment to moving it on”. (Handiside trans, B/3703)

Department of Health resistance to advice

141. In Professor Skegg’s view, “... many of the recommendations of advisory committees in relation to this programme were clearly not acted on and I don’t believe this inquiry would be occurring if they had acted”. (Skegg trans, A/900)

142. The response of departmental officials to proposals which they did not wish to implement, was to recommend the abolition of the advisory bodies making the proposals:

142.1 “... the very existence of the committee [CALC, CSLAC] was questioned and whether the committee should continue in existence ... it would be put to me that we could perhaps abandon the laboratory advisory committee, sometimes for cost rather than a clear appreciation of the work of the committee”. (Handiside trans, B/3726)

142.2 "... the Expert Group which I was on continually had to set up direct channels of communication with the Minister of Health because we couldn't rely on the Department correctly conveying our recommendations in a timely fashion, that they actually seemed to want to sabotage what the Minister wanted and what we were trying to do at every turn ... it was like being in a Kafka novel". (Coney trans, B/2767-8)

142.3 Memo: Department of Health to Katherine O'Regan, Associate Minister of Health, January 1991: "It is recommended that you: ... (2) Note the Department's concerns with the current Expert Group. (3) Reconstitute the Expert Group and form a new cervical screening advisory group". (JMG/MOH/105)

Desperation of advisors

143. Faced with the combined effects of under-resourcing, restructuring, departmental inertia and resistance, committee members felt frustrated and some felt ethically compromised:

143.1 "There were a number of issues in which there was a degree of frustration. I suppose with frustration I could go public, as I did once with the training programme. I could walk away from it, and I think some people have at times. I believed it was more important to hang in and try and improve it and get it going." (Teague trans, B/1464)

143.2 "... one of the frustrations is that nobody rejected it [our advice], nobody said we're not going to do this". (Teague trans, B/1358)

144. When asked to comment on CSAC's inclusion of a chronology of committee correspondence, documents and recommendations regarding programme monitoring and evaluation in its 1994 report (JMG/MOH/0035), Dr Cox replied, "I think its completeness and extent was a direct consequence of the

frustration and the degree of frustration that the advisory committee had experience over the entire duration of its existence”. (Cox trans, B/2571)

145. In commenting on why the CSAC report was written, Dr Cox stated: “We were driven spare ... members of the committee I think were becoming increasingly uncomfortable with the lack of progress on monitoring and evaluation of the programme and to the point where some of us feeling professionally unsafe and we were aware of incidents that had occurred overseas and that something somewhere was gonna happen possibly to the extent that an inquiry such as this would eventuate and we took the opportunity at the end of this particular time of this particular committee to write an extensive report and lay out all the things that we had tried to do and tried to get established through the Department of Health and Ministry of Health over the period of our existence”. (Cox trans, B/2536-37)
146. Dr Cox spoke of his ethical responsibility as a public health medicine specialist in giving advice: ”The fact of just giving good advice that wasn’t acted on I don’t think in the end allows you to feel comfortable that you’ve discharged your professional responsibilities, although at times it’s difficult to see what else you could do. And so at that point, if there was a failure of the NCSP and I continued to be involved I felt that would reflect on my competence as a public health medicine specialist”. (Cox trans, B/2570)
147. Ms Coney also spoke of her ethical dilemma of continuing to promote the programme knowing that without monitoring and evaluation, programme quality couldn’t be guaranteed: “Women expected the programme would deliver what they had been promised and ... for those of us who had concerns, we couldn’t guarantee that was so”. “It was putting us increasingly in a difficult ethical position in that women were expecting that they were getting a good quality programme but without the monitoring and evaluation we really couldn’t guarantee that”. (Coney trans, B/2740)
148. Referring to a letter she wrote to the Minister of Health in November 1998 (para 430), Ms Coney said “a certain amount of desperation was setting in” as

the national evaluation had not yet proceeded. (Coney brief, para 430) (Coney trans, B/2741)

149. "...Dr Cox, when he resigned, said he resigned because he didn't want to have blood on his hands because there would be a calamity like this, and it has happened". (Handiside trans, B/3703)

Conclusions

150. As a result of all these factors, the Cancer Society submits that the evidence establishes the existence of profound and significant systemic flaws in NCSP from the outset which compromised and undermined its effectiveness and would have led inexorably to the events in Gisborne, if not elsewhere.

Section 4: Term of Reference 2 — Appendix A
ISSUES ARISING FROM THE EVIDENCE OF WOMEN AFFECTED

For the purposes of this analysis we have not obtained access to the full medical notes of each patient, which we understand were filed. Although the analysis is not comprehensive, it identifies issues which suggest the following:

Evidence of poor practice by health professionals

1. No covering while patient having colposcopy; person tried to enter room during examination. (Patient 16 brief, paras 7 and 8)
2. False reassurance by nurse. (Patient 5 brief, para 12)
3. Inadequate explanation of abnormalities. (Patient 6 brief, paras 12 and 14) (Patient 11 brief, paras 14 and 18) (Patient 20 brief, para 12)
4. No explanation of apparent regression of abnormalities. (Patient 19 brief, para 16)
5. Women told of results over the phone for:
 - CIN III result (Patient 12 brief, para 4)
 - possible invasive disease (Patient 12 brief, para 14)
 - cancer (Patient 17 brief, para 14)
6. Length of wait (three hours) for pre-admission for surgery for invasive cancer. (Patient 12 brief, para 25)
7. Length of wait for surgery (all day). (Patient 14 brief, para 10)
8. Lack of follow-up for surgical after-care from National Women's Hospital to local health professionals. (Patient 12 brief, paras 32 and 34)

9. Inappropriate comments by gynaecologists during colposcopy. (Patient 13 brief, para 8) (Patient 14 brief, para 4)
10. Doctor implying woman had invasive disease when she did not. (Patient 16 brief, para 21)

Evidence of poor management by health professionals or by programme staff

11. Length of wait for colposcopy/specialist assessment not according to guidelines. (Patient 1 brief, para 6) (Patient 7 brief, para 9) (Wain brief, Patient 7, page 15) (Patient 12 brief, para 6)
12. Length of wait for treatment of invasive cervical cancer (three weeks), requiring involvement of patient advocate. (Patient 12 brief, para 23)
13. Length of wait for follow-up treatment following cone biopsy. (Patient 16 brief, para 12)
14. Evidence of poor management of women with symptoms. (Patient 1 trans, 29) (Wain brief, Patient 4, page 12) (Wain brief, Patient 7, pages 14 and 15) (Patient 7 brief, para 4) (Patient 7 trans, 25-29) (Wain brief, Patient 9, page 19) (Patient 9 medical records, F-1) (Patient 11 brief, paras 4-8) (Patient 16 brief, para 3)
15. Inadequate response of programme manager to patient concerns. (Patient 4 brief, para 17) (Patient 4 trans, 48)
16. Woman poorly screened despite multiple interactions with gynaecologists and other doctors. (Wain brief, Patient 8, page 17)
17. Absence of screening history audit by treating gynaecologist. (Jones trans, B/1558)

18. Failure by smear-taker to inform woman of smear result requiring repeat in three months. (Patient 12 brief, para 40)
19. Advice to have ovaries removed at time of hysterectomy because “ovarian cancer was very hard to detect and once it was it was usually fatal”. (Patient 13 brief, para 11)
20. Patient not told about follow-up requirements, including the need for vault smears, following hysterectomy. (Patient 16 brief, paras 23 and 30)

Belief of women that screening was infallible

21. Understanding smear tests to be “foolproof” or “100% accurate”. (Patient 5 brief, para 2) (Patient 7 brief, para 4) (Patient 11 brief, para 3) (Patient 12 brief, para 2) (Patient 13 brief, paras 2 and 16) (Patient 19 brief, para 11) (Patient 20 brief, para 4)
22. “At no time while I was having smears was I told there was a chance of under-reporting”. (Patient 13 brief, para 25)
23. “I had my smears regularly and understood that the results were reported correctly”. (Patient 16 brief, para 16)

Misunderstandings of abnormalities by women

23. Evidence suggests that women were not adequately informed about a number of issues relating to cervical abnormalities.
24. In some cases women assumed:
 - 24.1 Mildly abnormal results always precede more serious results. (Patient 1 brief, para 5) (Patient 2 brief, para 2)

- 24.2 The progression of abnormalities (from normal to low grade to high grade) takes many years and that a high-grade result shortly after a normal or low-grade result is unusual and/or means aggressive disease. (Patient 2 brief, para 3) (Wain brief, Patient 2, page 8) (Patient 3 brief, trans 40)
25. In some cases women did not understand the difference between CIN III and invasive cancer. (Patient 2 brief, para 14) (Patient 2 trans, 35-36) (Wain brief, Patient 2, page 8) (Patient 11 brief, para 25)
26. In one instance a woman understood cervical cancer to have a familial basis (ie, that she was more likely to develop it because a relative had it). (Patient 4 brief, para 2)
27. In one instance a woman thought CIN III was less serious than CIN I and that it was a common occurrence in women. (Patient 5 brief, para 13)
28. In one instance a woman did not understand that there is a difference between squamous cell cancer and adenocarcinoma of the cervix and that screening is less effective in preventing adenocarcinoma of the cervix. (Patient 4 brief, para 17)

Patterns of over-screening

31. According to evidence, many women appeared to have had smears more frequently than every three years, despite apparent normal results. In some cases evidence suggests a view by smear-takers of “while you’re here, have a smear”. (Wain brief, Patient 1: 6 smears in 6 years) (Patient 4 brief, paras 13-14: normal smears in 1986, 1987, 1988, 1989) (Patient 12 trans, B/3026, and Patient 12 brief, para 25: normal smears in 1/1991, 8/1991, 1992) (Patient 20 affidavit, page 8: normal smears in 11/1993, 7/1994, 6/1995, 9/1996, 1/1998, 4/1998, 4/1999)

Patient 12: “When I went to see the doctor for other matters, for example taking the children for an injection, I was always asked if they could take a smear just to see if everything was all right down there. I was told it was better to be safe than sorry. To the best of my knowledge, my smear results were always normal. I was not told otherwise.”

30. Some health professionals questioned the adequacy of three-yearly smear tests, as well as the starting age for screening. (Van de Mark brief, para 49) (Exhibits of daughter of Patient 9, tab D, para 6)
31. Some women stated their expectation that yearly smears afford better protection. (Patient 1 trans, A/24) (Patient 2 brief, para 1)
32. Some women stated their belief that it was a matter of personal choice how frequently to have a smear. (Patient 11 trans, B/3026)
33. Evidence regarding over-screening is consistent with an HFA analysis of national data provided in the NCSP review. (JMP/HFA/0015, page 82, 5.5.3)
 - 33.1 The review states that short-interval re-screening:
 - has been increasing steadily to 11% in 1997
 - provides little extra protection against cervical cancer and will incur extra costs and unnecessary investigations.
 - 33.2 Possible reasons for over-screening cited by the HFA analysis:
 - women requesting smears more frequently (due to taking the prevention message on board or feeling more at risk due to a family member with cervical abnormalities)
 - smear-takers suggesting smears at shorter intervals
 - women and smear-takers being increasingly unsure of the timing and results of their last smears.
 - 33.3 The report recommends that short-interval re-screening be minimised for the programme to be cost-effective. (page 106, 7.4)

- 33.4 The report also cites that Maori women had the highest rate of short-interval re-screening with 11% in 1997 and that the reasons for this need to be investigated. (page 108, 7.5.7)

Lack of understanding about the programme/register among women

34. A number of women indicated a lack of understanding of the programme and the register and expressed uncertainty about whether they were enrolled on the register. (Patient 5 trans, 64-65) (Patient 13 brief, para 3) (Patient 14 brief, para 2) (Patient 17 brief, para 2) (Patient 20 brief, para 4)

Inadequate explanation of treatment

35. One patient understood her second LLETZ procedure was required because of delay, which is not necessarily the case. (Wain brief, Patient 3, page 9)

Inadequate understanding of progression of abnormalities by health professionals

36. Understanding that mildly abnormal results always precede more serious results. (Patient 2 brief, para 2)
37. Assumption that a high-grade result shortly after a normal or low-grade result means aggressive disease. (Patient 2 brief, para 3)

Impact of mis-read smears on women's families and their lives

38. "I still could not believe that after having regular smears the outcome was that I was to be robbed of my right to have children and in the worst case scenario even my life". (Patient 12 brief, para 19)

39. “I feel very let down with the health system ... she [mother] did everything by the book. Cervical cancer is supposed to be able to be detected and cured. She was a nurse and was vigilant about smears. She should never have died”. (Statement by daughter of Patient 9, para 18)
40. Strain on relationships with partners and children. (Patient 14 brief, para 11)
(Patient 12 brief, para 44)
41. “Because of this disastrous botch up the goal posts in our lives have been moved, without consultation or permission from John or me.... I feel I have lost my womanhood because I cannot do what is my right, to produce children”. (Patient 12 brief, paras 42 and 44)
42. “I had an active and productive life before October 1999. I was an active walker and reasonably fit. I was looking forward to at least a further fifteen years of good health”. (Patient 15 brief, para 22)
43. One woman had a two-day old baby at time of diagnosis of invasive cancer and had to have treatment immediately following the birth. (Patient 17 brief, para 19)
44. “How do we tell the children that we can trust the medical profession?”
(Patient 17 brief, para 30)

Conclusions

45. Without a full clinical audit of the histories of the women with invasive cancer, it is not possible to come to definitive conclusions regarding poor clinical management of patients 1-20. A full audit should therefore be undertaken of the records of all women who developed cervical cancer.
46. It is likely that those women who had smears more frequently than every three years and whose results were normal would have felt they were being better protected as a result.

47. Women were let down by the programme. Despite following advice to be screened regularly (some “with vigilance”), some developed cervical cancer. “My mother did everything that was asked of her by the health system” .
(Statement by daughter of patient 9, para 18)