

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

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

BRIEF OF EVIDENCE OF BRIAN COX

**EXPERT WITNESS FOR
THE CANCER SOCIETY OF NEW ZEALAND, INC.**

I, BRIAN COX of Dunedin say:

Part I: Background

Qualifications and experience

1. My name is Brian Cox. I am a registered medical practitioner, specialist in public health medicine and epidemiologist. I am currently employed by the University of Otago as a Senior Research Fellow and I am director of the Hugh Adam Cancer Epidemiology Unit, Department of Preventive and Social Medicine, University of Otago Medical School.
2. I completed a BSc(hons) in mathematics and statistics in 1976 and entered Otago Medical School in 1977 completing the MBChB course in 1981. I worked for two years as a house surgeon at Dunedin Hospital from November 1981 to November 1983.
3. I received a Medical Research Council Training Fellowship in epidemiology in 1983 for 3 years study which I began at the end of 1983.
4. I started training in public health medicine at the beginning of 1984 when enrolled for the Diploma of Community Health at the Wellington Clinical School of Medicine, University of Otago.
5. At the end of 1984 I started a PhD on the epidemiology and control of cervical cancer in New Zealand and continued training in the specialist epidemiology stream of the Australasian Faculty of Public Health Medicine.

- 1 6. I was accepted as a Fellow of the Australasian Faculty of Public
2 Health Medicine in 1989 and became vocationally registered as
3 a specialist in public health medicine in 1990. I received a PhD
4 in epidemiology in 1990 from the University of Otago.
- 5 7. From late-January 1990 I left New Zealand to take up a Training
6 Fellowship in Epidemiology of the International Agency for
7 Research on Cancer (IARC) in Lyon, France, until May 1991.
- 8 8. Occasionally, over the past 15 years, I have been involved in the
9 supervision of students evaluating aspects of cervical screening
10 services and the teaching of medical students about cervical
11 screening and cancer screening in general.
- 12 9. I have had various roles with the National Cervical Screening
13 Programme (NCSP), including membership of the Ministerial
14 Review Committee of the programme in 1989, membership of
15 the Cervical Screening Advisory Committee (CSAC) from 1991
16 to 1996 and being an occasional advisor on specific aspects of
17 the NCSP during the past decade.
- 18 10. Since May 1999, I have been an advisor to the Health Funding
19 Authority in their investigation of the reporting of cervical
20 smears by the pathology laboratory in Gisborne that used to be
21 owned by Dr Bottrill.
- 22 11. I am currently a member of the Public Health Screening
23 Advisory Committee of the Health Funding Authority.
- 24 12. I am conducting, with colleagues at the University of Otago, an
25 evaluation of some aspects of the NCSP under contract to the

1 Ministry of Health. The specific aspects of the NCSP being
2 evaluated are:

3 i. an audit of the
4 screening histories of women with invasive
5 cervical cancer

6 ii. an assessment of
7 the follow-up and treatment for women with
8 abnormal smears

9 iii. an assessment of
10 the capacity of the NCSR to evaluate aspects of
11 the NCSP.

12 13. I am acting as an epidemiologist for a study of the Ministerial
13 Inquiry by its medical advisor.

14 14. I chair the BreastScreen Aotearoa Independent Monitoring
15 Group of the University of Otago which provides monitoring
16 services of the national breast screening programme for the
17 Health Funding Authority under contract.

18 15. I have been a member of the National Health Promotion
19 Committee of the Cancer Society of New Zealand, Inc., since
20 1994.

21 16. I have been a member of a scientific review team for the New
22 South Wales Cancer Registry and Cancer Epidemiology
23 Research Unit.

24 17. I chair the National Cancer Control Steering Committee. This is
25 an adhoc body established in 1997 and supported by various

1 organisations to promote the development of a multi-agency
2 national cancer control strategy for New Zealand. I also chair
3 the taskforce of this committee. This committee is seeking to
4 carry out the recommendations of the Cancer Control 99
5 workshop held in Wellington in August last year.

6 18. I have acted as a consultant for the World Health Organization
7 (WHO) in a review of cancer control in Nauru, represented New
8 Zealand at the WHO Western Pacific Regional Workshop on
9 Cancer Control in the Philippines and attended, by invitation,
10 the WHO 3rd International Workshop on National Cancer
11 Control Programs held three years ago in Sydney.

12 19. I maintain some links with other epidemiologists and specialists
13 in public health medicine in other countries involved in
14 screening programmes and the evaluation of these programmes.

15 20. This brief of evidence is in seven parts. Part I provides a brief
16 introduction and covers some technical aspects of cervical
17 screening programmes. Part II provides a detailed history of the
18 National Cervical Screening Programme from 1989 to 1996
19 focussing on monitoring, evaluation and organisational issues.
20 A brief assessment of the effectiveness of the NCSP will be
21 presented in Part III. Some comments on the interpretation of
22 the proportion of smears reported as high grade or low grade
23 comprise Part IV. Part V briefly reviews international
24 benchmarks for cervical screening programmes. In Part VI
25 future recommendations for the NCSP are made. Part VII
26 recommends the establishment under statute of a Cancer Control
27 Agency for New Zealand.

1 **Some technical aspects of cervical screening programmes**

2 21. The “disease of interest” in screening is the condition that
3 screening seeks to detect and treat. Screening is not just the
4 offer of a screening test to people who do not have symptoms to
5 determine who are most likely to have the disease of interest and
6 who, therefore, require further assessment. Screening involves
7 the organisation of the delivery of each component of the entire
8 “screening pathway” across multiple layers and service
9 providers in the health service. The screening pathway
10 comprises the process of invitation, the taking of the smear, the
11 reporting of the smear, the recall for further smears, the referral
12 process and the treatment of disease detected. Screening needs
13 to be carried out in a structured service to ensure appropriate and
14 timely assessment and needs to be focussed on achieving certain
15 aims and targets. This requires certain organisational and
16 management features and detailed quality assurance, monitoring
17 and evaluation.

18 22. A population-based screening programme is a technical term
19 used in public health medicine. The term “population-based”
20 means that the eligible population is identifiable individually
21 through a list of the population. The closest thing we have in
22 New Zealand to such a list is the electoral roll. In a population-
23 based screening programme the list is used to invite people to
24 participate in the screening programme and usually an
25 appointment time is offered with the invitation. No current
26 cancer screening programmes in New Zealand are truly
27 population-based. It might be argued that the current enrolment
28 of women with the NCSP is estimated to be at such a high level
29 that it is almost population-based. However, a list of newly

1 eligible women for the issuance of personal invitations to join
2 the programme does not exist. The national breast screening
3 programme is essentially an opt-on system, though early pilot
4 studies could be considered close to population-based
5 programmes and one pilot area successfully used the electoral
6 roll for individual invitations to participate. I believe a legal
7 opinion prevented the national breast screening programme from
8 using the electoral roll to invite women to participate.

9 23. There are two terms used in connection with the recruitment
10 process in New Zealand. The first is “opt-on” whereby a
11 woman has to actively give her consent to participate in the
12 screening programme. The second is “opt-off” whereby
13 enrolment with the screening programme occurs automatically
14 unless a woman actively seeks not to participate.

15 24. Cervical screening is possible because there is usually a long
16 time period between the development of neoplastic changes in
17 the cells of the surface of the cervix and the development of
18 invasion from the surface into the deeper layers of tissue of the
19 cervix. There are essentially two types of invasive cervical
20 cancer, squamous cell cancer and adenocarcinoma of the cervix.
21 Cervical screening primarily reduces the risk of squamous cell
22 invasive cervical cancer though early states of adenocarcinoma
23 of the cervix are sometimes discovered through screening
24 [Sigurdsson 1995]. The probability of detecting adenocarcinoma
25 of the cervix by cervical screening is about 42% while for
26 squamous cell carcinoma of the cervix it is between 81% and
27 93% [Sigurdsson 1995].

28 25. For those that develop invasive cervical cancer, the average time
29 between the development of high grade squamous cell

1 abnormalities of the cervix and invasive cancer is about 15
2 years. However, there is quite a range about this average with a
3 very small proportion of women with high grade abnormalities,
4 if left untreated, developing invasive cancer within 3 years while
5 for some women it may take 30 or more years for invasive
6 cancer to develop.

7 26. Once invasion starts the disease becomes invasive cervical
8 cancer and is life-threatening. However, even if invasive cancer
9 is detected through screening at the very earliest stage of
10 invasion, that is microinvasion which is usually asymptomatic,
11 almost all women can be cured. Therefore, the detection of high
12 grade abnormalities of the cervix and even microinvasive
13 cervical cancer by screening can be considered successes of
14 screening. Even when detected at a later stage therapy can
15 result in cure.

16 27. Preinvasive neoplastic changes of the cells of the surface of the
17 cervix represent a dynamic process. The great majority of these
18 changes will regress back to normal. The more persistent the
19 changes are the less likely they are to regress. High grade
20 intraepithelial neoplasia appears to be associated with the
21 integration of human papillomavirus DNA into the human
22 genetic structure of the cells of the cervix. The majority of high
23 grade abnormalities appear to regress to normal if left untreated.
24 It has been estimated that for about 70% of women with high
25 grade abnormalities the condition will regress and that there is
26 considerable scope for over-treatment in cervical screening
27 programmes [Miller et al 1991]. Regression appears more likely
28 in younger rather than older women. However, as there is no
29 clear marker of those women with high grade abnormalities that
30 will regress to normal, high grade abnormalities are all treated to

1 minimise the risk of invasive cervical cancer occurring.
2 Cervical screening policies are required so that the overall the
3 benefits of screening outweigh the side effects and harms.

4 **28. The evidence that well-organised cervical screening is**
5 **effective is overwhelming.**

6 29. A significant reduction over the ten years since the last smear in
7 the risk of invasive cervical cancer follows two negative cervical
8 smears [IARC Working Group on Cervical cancer Screening
9 1986, Miller et al 1991]. However, a history of two negative
10 smears does not abolish the risk of invasive cervical cancer and
11 also the protection diminishes with time since the last negative
12 smear. Signs or symptoms of invasive cervical cancer require
13 prompt clinical investigation irrespective of the result of the last
14 smear.

15 30. From careful assessment of the characteristics of effective
16 cervical screening programmes worldwide, the World Health
17 Organization (WHO) identified the key organisational
18 requirements for effective cervical screening programmes
19 [WHO 1986]. Also, the WHO have provided technical
20 guidelines [WHO 1988] and managerial guidelines for the
21 running of cervical screening programmes [Miller 1992].

22 31. Page 28 of the booklet *Cervical Cancer Screening Programmes:*
23 *Managerial Guidelines* contains advice about the responsibility
24 for cervical screening [Miller 1992]. The following guidance is
25 given.

26 “Responsibility for cervical cancer screening

27 The efficient management of cervical cancer screening in
28 a country or region should preferably be the responsibility

1 of a designated official within a relevant organization. If
2 cancer control has been designated to a special agency in
3 a country, this official should have an appointment within
4 that agency. Alternatively, it would be appropriate to
5 designate an official within the ministry of health.
6

7 In general, it is not appropriate for the director of the
8 cytology laboratory to be made responsible for the overall
9 management of the programme, because the
10 responsibilities for the programme are far wider than for
11 the laboratory, and cover aspects such as the identification
12 of the target group, recruitment, screening, management
13 of any cytological abnormalities detected and evaluation
14 of the impact of the programme.
15

16 The programme manager should be aware that successful
17 cervical cancer screening programmes have a number of
18 common features:
19

20 * They are organized as public health programmes, and
21 not simply as laboratory services for clinical
22 investigations.

23 * They target the age groups at greatest and most
24 immediate risk (i.e. above 35 years of age), concentrating
25 on women who have never had a smear.

26 * They use population registers to identify women in the
27 target group.

28 * The person in charge is named, can be contacted by
29 telephone, and is held responsible for his or her actions.
30

31 In order to run a successful programme, the manager
32 requires skills in the fields of epidemiology, public health
33 and management.”
34

35 **Part II: A history of the NCSP, with emphasis on** 36 **monitoring and evaluation, and organisation**

37 **Discussion of a national cervical screening programme**

38 32. In 1985, the first recommendations for cervical screening were
39 published in the New Zealand Medical Journal. This reviewed
40 the evidence that cervical screening was effective in reducing

1 cervical cancer mortality and incidence and recommended a
2 policy and action to be taken to improve cervical screening in
3 New Zealand. In November 1985, a meeting was called by the
4 Department of Health and the Cancer Society to consider the
5 future needs of cervical screening in New Zealand. Their report
6 of this meeting included a section on how to improve quality
7 control of smears and evaluation and monitoring of the total
8 programme. One of the conclusions of this report was that a
9 NCSP should be designed within 3 to 4 years.

10 33. At this workshop it was recorded that Dr Carol Green stated that
11 70 smears a day was too many for cytoscreeners to cope with
12 and would be unsafe. An acceptable range for the volume of
13 smears per cytoscreener per day is often one of the measures
14 specified in laboratory standards.

15 34. One of the recommendations of the Cartwright Inquiry was the
16 establishment of a NCSP. Work on this by the Department of
17 Health appears to have commenced in 1988 and proceeded in
18 earnest in 1989.

19 **Ministerial Review Committee**

20 35. Due to concerns about the direction of the implementation of a
21 NCSP a Ministerial Review Committee was established. These
22 concerns arose from the lack of involvement of experts and
23 consumers in the development of the programme and the lack of
24 consultation about what was being proposed. This committee,
25 of which I was a member, reported to the Minister of Health in
26 November 1989.

1 36. I understand that the Inquiry has the report of the Ministerial
2 Review Committee. I therefore annex to my evidence only
3 those sections to which I make particular reference. Copies of
4 the sections referred to below are produced as document
5 **BC/CS/0001**. One of the major conclusions of the Ministerial
6 Review Committee (section 1.8a, page 2) was that attention
7 should not be focussed on any particular aspect of the
8 programme and that all aspects of the programme should be
9 developed simultaneously as each was an integral part of
10 achieving success. This recognised that failures could occur in
11 any part of the screening pathway. Inviting women for
12 screening involved a responsibility to ensure a high quality of all
13 parts of the screening process including laboratory performance.
14 This is a consequence of the ethics of screening which differ
15 from usual medical practice. In a statement in section 2.5, page
16 6, the committee expressed concern that the objective of the
17 programme had become that of enrolling the maximum number
18 of eligible women onto the screening register at the expense of
19 other priorities.

20 37. One of the recommendations of the Ministerial Review
21 Committee was that a national cervical cytology register should
22 be established and that one of the uses of such a cytology
23 register would be to provide a method of improving the quality
24 of the screening service provided. Further, the committee
25 considered it essential (section 2.23, page 10) that cytology and
26 histology results for women could be related to one another for
27 two main reasons. The first was to enable an assessment of the
28 overall effectiveness of the programme and the second was to
29 provide a means of assessing the quality and uniformity of
30 smear reading throughout the country.

1 38. Due to concerns regarding the possible delays in the
2 implementation in the NCSP (section 2.24, page 10) it was
3 considered that a cytology register continue as planned, but that
4 an investigation of methods by which histology results could be
5 incorporated should begin immediately.

6 39. The Ministerial Review Committee recommended (section 3.7,
7 page 16) that a full-time National Co-ordinator would be
8 expected to co-ordinate all Area Health Board programmes and
9 ensure that these programmes were adequately monitored and
10 (section 3.7 (viii), page 17) also ensure that adequate monitoring
11 and evaluation systems were established for all aspects of the
12 programme. Section 8, page 52, of the Ministerial Review
13 Committee report concerned smear readers and standards of
14 competency. Section 8.9, page 54, noted that concern had been
15 expressed that the workload of cervical smears in some hospital
16 laboratories was too low for them to be able to maintain
17 competency. This issue is referred to again later in my evidence.
18 Section 8.12, page 55, records that, if consistency in reporting at
19 a national level was to be achieved, systems should be
20 developed further and arrangements such as the analysis of a
21 subset of smears by another laboratory on a regular basis
22 considered. The third recommendation of the committee in this
23 section, page 58, was that a set of guidelines for minimum
24 standards for laboratories and cytologists should be developed
25 and that they would need to be uniformly applied if consistency
26 in the reporting of the results at a national level was to be
27 achieved.

28 40. On page 64, section 9.17, it was also recommended that reading
29 of all cervical smears should fall under the auspices of the
30 NCSP and that this could be achieved by transferring the money

1 budgeted for cervical smears under the Laboratory Benefits
2 Scheme to the NCSP.

3 41. Appendix II of the Ministerial Review Committee report was an
4 overview of Azimuth's cervical screening register. Section
5 II.31, page 83, notes that at that stage no provision had been
6 made for the Department of Health to collect data from the 14
7 Area Health Boards and analyse it, which in effect meant that by
8 installing comparable hardware and software in each Area
9 Health Board, the potential existed to develop a National
10 Cervical Screening Register (NCSR), but the steps required to
11 link the 14 systems still needed to be mapped out.

12 42. Appendix III of the review dealt with register reservations and
13 recommendations. The recommendations in III.41, page 107,
14 briefly outlined that the proportion of women with "abnormal"
15 results should be available and it should be possible to link this
16 to other factors such as previous smear results. Also, it was
17 noted that it was important that issues such as archiving of the
18 register information and how and by whom the information
19 could be accessed should be addressed early in the development
20 stage. The review highlighted the absence of clear and
21 documented requirements in this area.

22 43. Section III.43, page 107, noted that while the NCSR would have
23 to be operational for some time before useful data could be
24 extracted from it and linked with treatment data and data from
25 the Cancer Registry, concern was expressed that these
26 interlinkages had not been thought through sufficiently to ensure
27 that they would be achievable in the future. In recommendation
28 L.1(i), page 108, it was suggested that immediate attention
29 should be given to detailing how the information from the

1 register was to be archived and how it could be accessed. In
2 L.1(iv), page 108, under provisional requirements for links
3 between the NCSR, links with cervical treatment records and the
4 Cancer Registry were also to be given immediate attention.

5 44. Appendix IV of the Ministerial Review Committee's report was
6 titled "Performance Indicators". On page 124, section IV.18, the
7 Committee recommended that comparison between cytology
8 and subsequent histology results should also be monitored as
9 this was ultimately the determinant of the effectiveness of the
10 smear analysis. It also recorded that a further quality control
11 check would be to have a percentage of smears re-read at a
12 different laboratory and to conduct a comparison of the two sets
13 of results.

14 45. Section IV.19, page 124, restated the desire to have performance
15 indicators for laboratories. In advance of these indicators being
16 set the report suggested that interim indicators should include:

- 17 (i) the numbers of smears analysed annually per
18 laboratory,
19 (ii) the average number of smears analysed annually per
20 laboratory,
21 (iii) the average number of smears analysed per FTE
22 cytologist,
23 (iv) the per cent of false negative smears for CIN3 found
24 histologically,
25 (v) the per cent of true positives found at biopsy,
26 (vi) the specificity of the screening procedure and,
27 (vii) the sensitivity of the screening procedure.

1 **46. Progress in implementing the recommendations of the**
2 **Ministerial Review Committee has proved to be slow and**
3 **spasmodic. While a few of the recommendations may have**
4 **proved impossible, many of the recommendations have still**
5 **not been implemented over 10 years later. For example, the**
6 **funding of smear reading does not currently come under the**
7 **NCSP and minimum quality standards for laboratories**
8 **reading cervical smears in the programme have not been**
9 **introduced by the NCSP.**

10 **Expert Group 1990**

11 47. Following the Ministerial Review Committee's report, the
12 Expert Group was established which completed a report in
13 August 1990. I was not a member of the Expert Group. In their
14 report, section 12 titled "Laboratories", gives recommendations
15 to the Department of Health on the issues needed to be
16 considered for determining whether a cytology laboratory should
17 be able to service the NCSP by providing smear reading. The
18 linking of histology results with cervical smear results by the
19 programme was considered an urgent priority. Copies of the
20 sections of the Expert Group's report to which I refer are
21 produced as document **BC/CS/0002** and a copy of a letter to the
22 Minister of Health from the chairperson of the Expert Group
23 dated November 30, 1990, is produced as document
24 **BC/CS/0003.**

25 48. In section 14, page 53, of the report of the Expert Group, titled
26 "Evaluation monitoring", section 14.2.4 lists aspects of the
27 programme which required evaluation, and this included the
28 quality of smear reading at the Area Health Board level. The

1 need for national evaluation of the programme was signalled in
2 section 14.2.5.

3 49. As the NCSR at this time did not exist as a single entity, the
4 Expert Group considered that the Area Health Boards should
5 monitor and evaluate the programme in the first instance,
6 including laboratory performance.

7 50. I was not in New Zealand from late January 1990 until May
8 1991.

9 **Cervical Screening Advisory Committee (CSAC) 1991-1994.**

10 51. In this evidence some of the background papers, correspondence
11 of the CSAC and my correspondence with the Department and,
12 subsequently, the Ministry of Health will be presented. I wish to
13 acknowledge the valuable contribution of the other members of
14 the CSAC in the work that I will now cover.

15 52. The CSAC was established in May 1991. I was a member of
16 this committee but did not attend the first meeting as I was
17 overseas. This committee was established to give advice on the
18 monitoring and evaluation of the NCSP. Several issues that
19 arose from the Expert Group policy were discussed at the first
20 meeting, including: the development of a population-based
21 register and the legislation required for this; the inclusion of
22 histology data on the register; and, the evaluation and
23 monitoring of the programme. I produce copies of minutes of
24 various CSAC meetings from 1991 to 1996 in chronological
25 order as document **BC/CS/0004**. Also, I produce copies of
26 various Department of Health and Ministry of Health reports to
27 the CSAC as document **BC/CS/0005**.

1 53. At this time there was still considerable work being done to
2 include each Area Health Board into the NCSP and the
3 installation of the NCSR in each Area Health Board. Ten of the
4 14 Area Health Boards had the register installed and there was
5 considerable emphasis on factors associated with the
6 participation of women.

7 54. The second meeting of the CSAC was held at a pilot site of the
8 programme in Blenheim on 13 June 1991. The minutes record
9 that the terms of reference for the CSAC were finalised by the
10 committee at this meeting.

11 55. The NCSR consisted of separately maintained registers in the
12 Area Health Boards, using a common software platform and it
13 was not possible to link one to another. At this meeting it was
14 reported by the National Co-ordinator that the Wellington Area
15 Health Board was being very tardy in accepting the register.
16 The issue of accreditation of laboratories was raised. Further
17 work was to be done on this for discussion at the following
18 meeting. The minutes record that the National Co-ordinator
19 considered that there was a need for comprehensive contracts
20 with Area Health Boards.

21 56. At one of the first three meetings of CSAC I recall that the
22 CSAC asked for an outline of the budget and expenditure of the
23 NCSP. The National Co-ordinator checked with the Ministry of
24 Health and reported back to the next meeting of CSAC that this
25 would not be provided to the committee. I do not recall whether
26 a was given.

27 57. Prior to the CSAC meeting of 16 July 1991, I prepared a paper
28 for discussion outlining some steps required for an effective

1 cervical screening programme. This was discussed at this
2 meeting. In that paper, I outlined several issues associated with
3 monitoring and evaluation. The paper was revised by the CSAC
4 and sent to the Associate Minister of Health. A copy of both the
5 paper and the letter is produced as document **BC/CS/0006**.

6 58. The minutes record that the issue of accreditation of laboratories
7 was now being dealt with through the Department of Health
8 policy. Under item 8 of the minutes it is recorded that I sought
9 clarification of the ownership and access to the non-aggregated
10 information held by the Boards. At this time there was a
11 proposal to do a fast-track evaluation of the implementation of
12 the programme in Canterbury. On 20 June 1991 I wrote a brief
13 letter to the National Co-ordinator regarding this evaluation. A
14 copy of this letter is produced as document **BC/CS/0007**. I was
15 concerned that the rate of detection of cervical abnormalities in
16 women who enrolled in the programme was not part of the
17 evaluation.

18 59. For the July meeting, I prepared a paper titled "An outline of
19 areas of evaluation for the NCSP" dated June 27, 1991. A copy
20 of this is produced as document **BC/CS/0008**. I stated that some
21 measurement of the smears taken and the quality of smear
22 reading needed to be undertaken and that valuable information
23 could be gained from reviewing the screening history of women
24 who develop cervical cancer, possibly CIN also, as this would
25 provide clues as to where the service may be deficient. I also
26 indicated that a review of screening histories of women with
27 invasive cancer and CIN3 may be useful to assess any
28 improvement in the cervical screening service as a consequence
29 of the NCSP.

1 60. At this time, there was interest in looking at the proportion of
2 women in the different Area Health Board regions who had not
3 had a smear in the last three years, who had never had a smear,
4 or those who had had one but did not know when. This was
5 calculated from the National Research Bureau survey conducted
6 for the Expert Group, and was presented to the committee in
7 July 1991. However, the survey used telephone interviews and
8 many women, particularly Maori women and relatively
9 unscreened women may not have been approached by telephone.

10 61. From the very limited data available for the Gisborne region in
11 this survey, only 4 of 26 women aged over 20 surveyed did not
12 report a smear in the previous three years. I produce a copy of a
13 table of the some of the findings of this survey as document
14 **BC/CS/0009**.

15 62. At the meeting of the CSAC, 13 September 1991, the minutes
16 record that the issue of discrepancies in the result between an
17 Auckland laboratory and a Rotorua laboratory was discussed.
18 This was in response to a letter from Heather Yamamoto,
19 Programme Planner Cervical Screening, of the Bay of Plenty
20 Area Health Board. Copies of letters relating to this event are
21 provided as document **BC/CS/0010**. I believe this issue may
22 have arisen from the splitting of a smear test by a lay smear
23 taker because of concerns about laboratory reporting in the
24 region. That is, after sampling, the spatula is smeared on two
25 slides and the slides sent to different laboratories. I understand
26 that the splitting of smears is not accepted by pathologists as an
27 appropriate method of assessing laboratory performance.

- 1 63. The minutes of the meeting record that both a New Zealand and
2 overseas referee would investigate the complaint that was made
3 to the New Zealand Society of Pathologists. The issue of
4 TELARC registration of the Rotorua laboratory was discussed
5 and it was explained that TELARC does not continually do
6 quality control but TELARC accreditation involves an
7 assessment that quality control procedures are in place in the
8 laboratory and that TELARC registration was reviewed if there
9 were major staff changes in the laboratory. It is recorded that
10 TELARC accreditation of laboratories was reviewed every two
11 years and more fully every four years. That is, TELARC did not
12 conduct quality control of laboratories but part of accreditation
13 was whether suitable quality control procedures existed in the
14 laboratory.
- 15 64. There was a discussion regarding the number of laboratories that
16 were processing such a low number of smears each year that it
17 might be expected to put their competency in jeopardy. This
18 discussion arose from a paper from the World Health
19 Organization titled "Control of cancer of the cervix uteri" in
20 which a figure of at least 20,000 and preferably 50,000 smears a
21 year was given regarding the annual number of smears which a
22 laboratory should do to maintain cytotechnologists' skills and be
23 cost-efficient [WHO 1986]. It was considered that this was a
24 professional issue of quality assurance for pathologists.
- 25 65. At the meeting there was considerable discussion regarding the
26 nature of the national evaluation of the NCSP. The committee
27 considered that the WHO guidelines would be a good starting
28 point and proposed seven broad areas for evaluation, including
29 quality control in cytology laboratories and the screening
30 histories of cases of symptomatic invasive cancer of the cervix.

1 Just prior to this meeting on 30 July 1991 the health reforms
2 were announced.

3 66. In the Department of Health report to the CSAC for 13
4 September 1991 it was made clear by the National Co-ordinator
5 that the aggregated and non-aggregated data of the NCSR
6 collected by the Area Health Boards was owned by the Crown.

7 67. At the CSAC meeting of 12 December 1991 the minutes record
8 that there was considerable discussion about the accreditation of
9 laboratories. This arose from the follow up of events
10 surrounding a Rotorua laboratory.

11 68. In the follow-up of the complaint about the quality of smear
12 reading at a Rotorua laboratory, a letter to TELARC from the
13 Chair of the Cytology Advisory Liaison Committee (CALC), Dr
14 Clint Teague, was discussed by the CSAC. A copy of this letter
15 is produced as document **BC/CS/0011**. This letter covers the
16 issue of re-screening of negative smears for 10% of negative
17 cervical smears, maximum number of slides read by screeners,
18 checking of abnormal smears, off-site home screening, and
19 external quality control. I believe off-site home screening refers
20 to the practice of reading and reporting smears at home or away
21 from the laboratory. It was noted that there was no entirely
22 satisfactory external quality control programme available in
23 New Zealand at this time. I was not a member of CALC.

24 69. At this CSAC meeting, the committee became aware for the first
25 time that Health Research Services of the Department of Health
26 was developing a national evaluation plan for the screening
27 programme. A draft evaluation paper was tabled. Copies of this
28 paper and an attached memo, an earlier version dated 29 August

1 1991 and another version dated December 1991 are produced as
2 document **BC/CS/0012**. The draft plan consisted of a list of
3 many projects and did not give a great deal of priority to what
4 was needed or what staff resources, training or skills would be
5 required. The draft lacked detail or costs. The draft had been
6 sent out to many people for comment and I believe the CSAC
7 felt that they should have been given the opportunity to
8 comment and refine the plan before wide consultation had
9 occurred. Directing the evaluation plan at this stage was
10 considered by the CSAC to be difficult. I believe CSAC had
11 serious reservations about the process that had been used and
12 expressed these concerns to the National Co-ordinator. The
13 draft did not seem to start from the WHO guidelines as
14 recommended by the CSAC at its 13 September meeting.

15 70. A letter was sent by the CSAC on 13 May, 1991, to the Acting
16 Director General of Health, Ian Miller, to reinforce the need for
17 an up-to-date and accurate Cancer Registry to monitor the
18 effectiveness of the screening programme. Changes in health
19 statistics collection were being made at this time and there was
20 concern that the Cancer Registry may be weakened further by
21 the reorganisation of the Department of Health. A copy of this
22 letter is produced as document **BC/CS/0013**.

23 71. At about this time, a member of Health Research Services was
24 visiting regional co-ordinators to review their procedures for
25 monitoring and evaluation and to seek their contribution to the
26 overall evaluation strategy being proposed by Health Research
27 Services. In the draft national evaluation proposal
28 (BC/CS/0012), it was noted that the lack of interface between
29 cytology and histology in the register inhibited the ability to
30 monitor follow-up of women with abnormal smears. In this

1 document, in Section 5: Minimum information requirements to
2 evaluate the programme, it was stated that laboratory quality
3 could be monitored by collecting information relating to rates of
4 atypical, low grade abnormal and high grade smears on a
5 regional level. I discuss this further later in my evidence. These
6 rates could then be compared to a national standard. The
7 document stated that the information should be generated by the
8 register but until there was an opt-off system, the information
9 should be collected from laboratories wherever possible.

10 72. At the time, the overall concerns of the Department of Health
11 tended to be increasing participation and reaching high risk
12 groups. Comments from various people consulted on the draft
13 evaluation proposal of Health Research Services were also
14 provided to the committee. The committee was clear that its
15 role was to advise on evaluation rather than get into the detail of
16 what was proposed and that the committee would highlight what
17 it saw as important.

18 73. At the CSAC meeting of 14 February 1992 the minutes record
19 that there was considerable discussion about the implications of
20 the health reforms for the NCSP and it was not clear where the
21 programme would be located at a regional level. There was also
22 considerable turnover of programme managers. About this time
23 a new Director General of Health, Chris Lovelace, was
24 appointed.

25 74. The minutes record that the proposed national evaluation of the
26 NCSP by Health Research Services was discussed and Health
27 Research Services agreed to wait for the CSAC's feedback
28 before progressing further with the evaluation. The committee

1 expressed the view that their role would be to monitor the
2 evaluation only.

3 75. It was proposed that a report should be prepared similar to that
4 prepared by the Victorian Cytology Register. The committee
5 again discussed the points listed in the WHO guidelines, which
6 included some aspects of quality control for cytology
7 laboratories.

8 76. It is reported in the minutes that Dr Clint Teague had met with
9 the Department of Health that morning to discuss how national
10 statistics could be provided in regard to laboratories. He would
11 also report back to the committee on information required
12 regarding laboratories.

13 77. The committee agreed to come up with a list of tables and text
14 about what they wanted to be produced from an evaluation and
15 templates on which this should be based.

16 78. The NCSP was officially launched by the Department of Health
17 on 3 September 1991.

18 79. The NCSP newsletter of December 1991 reported that
19 Tairāwhiti had the highest death rate from cervical cancer of any
20 Area Health Board in New Zealand. I produce a copy of this as
21 document **BC/CS/0014**.

22 80. At the cervical screening programme managers meeting of
23 December 4 and 5, 1991, the minutes record that some
24 discussion regarding non-TELARC registered laboratories
25 occurred. I provide a copy of the minutes of this meeting as

1 document **BC/CS/0015**. I was not present at meetings of the
2 programme managers. The programme co-ordinator in the Bay
3 of Plenty sought advice from the National Co-ordinator about
4 how to communicate with GPs about non-accredited
5 laboratories. It is recorded that at this meeting that the CALC
6 recommended that registration of laboratories should be
7 compulsory and, therefore, it was now required that laboratories
8 reporting on the register must be registered. It was reported that
9 the full process of TELARC registration could take up to two
10 years for an individual laboratory.

11 81. Also recorded in the minutes is a discussion about the ethics of
12 transferring data from the regional sites to a central facility. It
13 was recorded that John Brackenbury reported that this capacity
14 had always been incorporated into the register.

15 82. The issue of low smear volumes and lack of registration of
16 hospital laboratories processing cervical smears was reportedly
17 discussed at this meeting. The issue of consistency of reporting
18 of smears and quality assurance across all laboratories was
19 reportedly discussed and it was stated that the issue of outlying
20 laboratories in terms of smear results needed to be addressed. It
21 was also recorded that if 25% of smears were suboptimal, then it
22 was advisable to look at why they were suboptimal.

23 83. The minutes state that there was no good external quality control
24 body except for the Royal College of Pathologists of Australasia
25 based in Sydney.

26 84. Brief quarterly reports from the screening programme were
27 produced giving the percentage of smears in different categories
28 for each Area Health Board. A bundle of copies of these are

1 produced as document **BC/CS/0016**. However, because of the
2 low coverage of the screening programme at this time and the
3 relative infrequency of abnormal reports, the figures for
4 relatively rare occurrences such as cytology reports suggestive of
5 CIN2 and CIN3 were not very comparable from one period to
6 another or from one Area Health Board to another.

7 85. On 31 January 1992, a meeting discussing the opt-off register
8 was held in the Department of Health. The Department of
9 Health report to the CSAC records that one of the issues
10 discussed at that time was the power of the CALC to enforce
11 accreditation of laboratories and whether a consumer
12 representative on the CALC was required.

13 86. At the CSAC meeting of 3 April 1992 the minutes record that
14 there was considerable discussion about where the NCSP would
15 fit into the new structures of the health reforms. It was
16 considered that quality assurance issues needed to be
17 emphasised and built into the management of the screening
18 programme within the new health structure. The committee
19 considered that good quality assurance mechanisms were
20 essential for the effectiveness of the programme.

21 87. At the meeting of 17 August 1992 the minutes record that the
22 first statistical report of the NCSP was discussed. I, John
23 Brackenbury and Clint Teague were authors of this report [Cox
24 et al 1993]. I wish to acknowledge the assistance of two CSAC
25 members, Theresa Green and Claire Salmond, who provided
26 helpful comments on an earlier draft of this report. John
27 Brackenbury was managing the NCSR implementation in the
28 Area Health Boards and collected the data centrally and
29 analysed the data using the statistical package SAS and sent me

1 tables of aggregated data for the further work needed to produce
2 this report. This report analysed data to May 1992 and was
3 provided to the Ministry of Health in August 1992. This was the
4 first time laboratory results had been compared nationally and
5 this generated some interest. It meant that there was at last some
6 quantitative measure of laboratory variation and processes to
7 address this could be developed. The report was set out as a
8 basic template for future reports. At the time I was aware that
9 subsequent reports would be able to significantly extend the data
10 analysis and the information available from the programme.

11 88. The recommendations for a Kaitiaki group covering access to
12 the NCSR were also discussed. This was described as a lock out
13 system for Maori data at this meeting. The issue of the accuracy
14 of ethnicity recorded by the screening register was discussed and
15 a view was put that, if it was not accurate, then it should not be
16 collected.

17 89. A similar lock out system for Pacific Island women's data held
18 on the NCSR was also being explored at this time.

19 90. The minutes record that the issue of the opt-off register for
20 laboratories was discussed, and it was explained that
21 participation in the opt-off register by laboratories was
22 voluntary. It was also suggested that making participation by
23 laboratories compulsory was not possible and that it may be
24 advantageous to not accept smears from a laboratory if they
25 were performing poorly. The effect of not accepting smears
26 from a poorly performing laboratory was unclear. Presumably it
27 would have meant that all smears of both women in the NCSP
28 and outside of the NCSP processed by a poorly performing

1 laboratory would not be reimbursed by the Department of Health
2 under the Laboratory Benefits Scheme.

3 91. At this time, the National Co-ordinator was no longer working
4 full time on the NCSP.

5 92. The minutes record that discussion of the statistical report took
6 place and limited circulation of the report was approved. There
7 was some concern that the report may be misinterpreted or
8 misused and there was a suggestion that the release of the report
9 should be delayed for six months. I believe this was mainly to
10 allow CALC to consider the results. At this time, laboratories
11 and government were establishing contracts for services with the
12 new health service organisations. The issue of quarterly
13 reporting was again discussed at this meeting. I believe attempts
14 to address the issues of variations in reporting rates and
15 reporting practices identified in the Victorian screening
16 programme were also being addressed in Victoria, Australia.

17 **93. From the time that the first statistical report of the NCSP**
18 **was published in August 1992 it became possible to conduct**
19 **inter-laboratory comparisons of cytology reporting of the**
20 **results for women in the NCSP. However, this required**
21 **extraction of data from the separate screening registers and**
22 **its collation on one computer for analysis.** Because data was
23 not supplied by the Wellington Area Health Board before the
24 analysis for the first report, data from Wellington was not
25 included in the first statistical report. I recall that it was reported
26 by the National Co-ordinator that the Wellington Area Health
27 Board ethics committee considered the release of even the
28 aggregated data from the NCSR in their region to be a breach of
29 privacy. I believe there was some correspondence between the

1 Department of Health and the Wellington Area Health Board
2 about this at the time.

3 94. With the resignation of the national cervical screening co-
4 ordinator and the restructuring of the health service, it became
5 important for CSAC to lobby for the maintenance of a central
6 national cervical screening unit for the NCSP.

7 95. In 1992, there became a distinct separation between public
8 health services and personal health services, and this was
9 reflected in the restructuring of the Department of Health and
10 the establishment of the Public Health Commission (PHC).
11 **This formal split of accountabilities made the delivery of the**
12 **public health activity of a cervical screening service across**
13 **the public health and personal health service divide more**
14 **difficult to co-ordinate and organise.**

15 96. At this time, issues of laboratory services were seen as part of
16 personal health services, while the co-ordination of the NCSP,
17 the screening register, the recruitment strategies, and the
18 activities of the regional co-ordinators were considered public
19 health activities. The accountabilities for the various aspects of
20 the programme were unclear. As I recall the CSAC decided that
21 it would take considerable time for the reformers to get down to
22 the level of deciding how the NCSP should be parcelled.
23 Therefore, the CSAC decided on a proactive approach and
24 indicated where it thought the NCSP should fit to maximise its
25 chances of surviving through at least the initial stage of the
26 reforms. This proved a very difficult task. For at least two years
27 the place of the NCSP was unclear and it did not fit easily into
28 the new structures of the Department and then the Ministry of
29 Health. This was a most unsettling time for all involved. I

1 believe staff turn over was high but I think there was a personal
2 commitment from many people involved to try to fully
3 implement the NCSP.

4 97. On 15 February 1993 I wrote to the Chairperson of the National
5 CSAC, Betsy Marshall, regarding concern about the decision
6 making processes of the Department of Health during the
7 transition to the restructured health service. I produce a copy of
8 this letter as document **BC/CS/0017**.

9 98. I stated that it is desirable that monitoring and evaluations were
10 the responsibility of a separate body and that the resolution
11 between the Department of Health and the PHC regarding the
12 application of the Statement of Accountabilities to the NCSP did
13 not occur either at the December 10 or January 13 meetings as
14 had been expected by the CSAC.

15 99. I also expressed concern that since the restructuring of the
16 Department of Health in October 1992 the interests of the
17 Department of Health appeared to have become more dominant
18 than the provision of a good NCSP to women and that the last
19 time this occurred so strongly was in 1989 and resulted in the
20 ministerial review of the NCSP.

21 100. Colposcopy was also seen as part of the treatment services
22 associated with personal health services. In addition, the
23 Department of Health was moving away from the provision of
24 services and restricting itself to policy and regulation. In that
25 environment, a national cervical screening unit with a service
26 component associated with the cervical screening register did

1 not easily fit. In the end it came under the auspices of the public
2 health group within the Ministry of Health.

3 101. In the restructuring, issues of who was providing what, and
4 who was accountable for what, were all being revisited, both
5 within the Department of Health, the Regional Health
6 Authorities, and the major provider organisations. At this point
7 it was not clear whether the PHC would be taking over
8 responsibility for monitoring and evaluation of the cervical
9 screening programme, or whether that would, either continue to
10 reside within the Department of Health, or whether the national
11 cervical screening unit would be maintained. Performance
12 indicators for the programme now needed to be an integral part
13 of the contract specifications with providers.

14 102. The term of the CSAC was extended until June 1994 with
15 slightly modified terms of reference. At the CSAC meeting of
16 11 February 1993 the minutes record that there was further
17 discussion regarding the first statistical report and it was agreed
18 that the report should be sent to the Minister with a summary
19 statement. The report was finally released publicly in August
20 1993 a year after its production. It was also agreed that regular
21 and timely statistical reports were required.

22 103. The minutes record that there was a discussion of the status of
23 the NCSP in the regions and it was reported by the National Co-
24 ordinator that although some managers were no longer
25 employed, someone in each Area Health Board was responsible
26 for the programme, although the programme was often only part
27 of their duties.

1 104. In discussions regarding possible reconfiguration of the NCSP
2 through the new structures of the health service the CSAC was
3 rarely represented. A major issue was how Regional Health
4 Authorities were to purchase local co-ordination of the
5 screening programme.

6 105. There was further discussion of the inclusion of histology onto
7 the NCSR and reports were commissioned by the Department of
8 Health regarding what was required for this to be achieved.

9 106. At this time, proposals to consolidate the cervical screening
10 register were prepared by the Department of Health. On 5
11 March 1993, the CSAC wrote to the then Associate Minister of
12 Health, Katherine O'Reagan, outlining concerns about the
13 NCSP. A copy of this letter is produced as document
14 **BC/CS/0018**.

15 107. With the new health structures and the changed role of the
16 Department of Health, the role of the PHC and future options for
17 the cervical screening register, there was concern that the key
18 elements of an effective cervical screening programme as
19 outlined by the World Health Organization may be difficult to
20 establish in the reformed health system. This was partly
21 reflected in my letter commenting on the NCSR Options for
22 Change document prepared by the Department of Health that
23 had been widely circulated. A copy of my letter to the
24 chairperson of the CSAC is provided as document **BC/CS/0019**.

25 108. At the CSAC meeting of 29 April 1993 the minutes record that
26 further discussion on monitoring and evaluation took place and
27 it was suggested that the statistical report should be repeated at
28 that time and again 14 months later. This would then bring the

1 reporting in line with an annual reporting cycle. Linkage of the
2 NCSR with Cancer Registry data was also proposed yet again.

3 109. Concern was expressed that the advent of the opt-off
4 legislation becoming effective from 1 July 1993 would result in
5 an increased need for local co-ordination of the programme just
6 at the time when local co-ordination was being reconfigured in
7 the new health service structures.

8 110. On 19 March 1993, the committee wrote to Katherine
9 O'Reagan, the Associate Minister of Health, strongly
10 recommending against the establishment of four regional
11 cervical screening registers, which were unlinked, as the CSAC
12 felt that this would result in four separate screening
13 programmes. Also, the CSAC indicated that if this option was
14 adopted, the efforts to establish an effective national programme
15 would have been in vain, and the CSAC members would no
16 longer wish to be associated with the programme. The same
17 letter was also sent to the Director General of Health, Chris
18 Lovelace. A copy of these letters are produced as document
19 **BC/CS/0020**.

20 111. The committee's paper on the options for change to the NCSP
21 registers reiterated the WHO requirements for an effective
22 programme. A copy of the CSAC's paper is produced as
23 document **BC/CS/0021**. The committee again emphasised the
24 need to identify accountabilities for the different aspects of the
25 programme and reiterated that the Department of Health had had
26 limited control over the ongoing development of the Area
27 Health Board registers of the screening programme. Problems
28 associated with local co-ordinators not having on-line direct

1 accountability to the National Co-ordinator in the Department of
2 Health were raised in this document.

3 112. The committee strongly advised against the NCSR being
4 contracted to an agency outside the Ministry or the PHC as its
5 implementation phase had not been completed. Ongoing
6 development of software was required and the mechanism for
7 including histology results was still being developed.

8 113. The committee was strongly of the view that there should be
9 only one register for the NCSP, with its own staff, so that
10 consistency could be maintained and ongoing software
11 development and modification could be easily implemented. It
12 was also recommended that if the register had its own staff it
13 would not have to rely on consultancy with private companies.
14 This was considered to be costly and did not allow expertise to
15 develop within the programme.

16 114. The NCSP newsletter of January-February 1993 reviewed the
17 staff changes of the national cervical screening unit within the
18 Department of Health and contained a short article on the
19 accuracy of smear tests related to 237 women referred to the
20 Royal Hospital for women in Sydney for invasive cervical
21 cancer. A copy of this newsletter is produced as document
22 **BC/CS/0022**. It reported that a worrying aspect of the study,
23 which was published in an Australian journal, was the number
24 of patients whose previous Pap smear on review showed frankly
25 malignant cells, but was originally reported as normal.

26 115. It was recorded in the newsletter that, by the end of 1993, all
27 laboratories reading cervical smears would be required to be

1 registered with TELARC and at this time nearly 70% of
2 laboratories were registered.

3 116. The newsletter reported the appearance of a newspaper article
4 where it was acknowledged that one in ten smears in women
5 with an abnormality could be reported as negative.

6 117. At the meeting 11 June 1993 the minutes record that the
7 termination of the CIT cytopathology training course was
8 discussed. This resulted from a letter to the National Co-
9 ordinator from the Dean of the Faculty of Science and Health
10 Sciences at the Central Institute of Technology in Wellington. A
11 copy of this letter is produced as document **BC/CS/0023**. I
12 recall that it was reported that the course was not being fully
13 supported by all the pathology laboratories in the country and, as
14 a consequence, there were insufficient numbers of students to
15 justify continued funding of the course by the Department of
16 Education. The committee considered the proposal for
17 providing funds for the CIT training course but felt that it was
18 inappropriate for the programme to fund this given that, without
19 the full support of all laboratories, it was unlikely that the course
20 would ever have enough students to be self-supporting.

21 118. The CSAC minutes record that the place of the cervical
22 screening register in the reformed health sector was discussed.
23 Also, it was reported by the National Co-ordinator that an
24 interim Kaitiaki group had been established to protect Maori
25 data on the cervical screening register, and that Pacific Island
26 women had also approached the Minister about their own data,
27 and that this would be considered in the future.

1 119. It was reported by the National Co-ordinator that a further
2 statistical report was not going to happen immediately as the
3 Department needed to buy the appropriate SAS software for the
4 analysis but also that the second statistical report was to be
5 completed by 30 December 1993 and mechanisms for ongoing
6 evaluation of the programme would be completed by 30 June
7 1994.

8 120. It was also reported by the National Co-ordinator that the
9 changes in the health sector were making the roles and
10 responsibilities of national co-ordination more complicated.
11 The committee expressed concern that without adequate
12 resourcing of the national cervical screening unit, the
13 committee's ability to fulfil its monitoring and evaluation role
14 could be jeopardised. It was agreed that the Chair of the
15 committee would write to the Director General of Health and the
16 Associate Minister of Health to identify some concerns
17 regarding resourcing of the national cervical screening unit. In
18 particular, the committee was concerned that the complexity of
19 the programme was underestimated by the Department of Health
20 and that this jeopardised the effectiveness of the programme.

21 121. In discussion regarding monitoring and evaluation the minutes
22 record that the issue of linking the Cancer Registry with the
23 cervical screening register was raised yet again. I now believe
24 that about this time a legal opinion was obtained by the
25 Department of Health which suggested that linkage of the two
26 registers may not be possible. If a legal opinion was sought at
27 this time, I do not recall it being provided to the CSAC.

28 122. Despite repeated requests by the CSAC for annual statistical
29 reports, the Department of Health report to the CSAC for 11

1 June 1993 indicated that the next statistical report would be
2 deferred until the following financial year.

3 123. In the screening programme's review of laboratory services of
4 June 1993, it was recorded that 12 hospital laboratories
5 processed 8% of the smears of the programme, while 92% were
6 processed through community laboratories [Norton 1993]. It
7 was reported that only four of the hospital laboratories
8 participated in the Royal College of Pathologists of Australasia
9 quality assurance programme. Eighteen of the 19 community
10 laboratories responded to the survey questionnaire. Thirteen of
11 18 community laboratories reported participating in this quality
12 assurance programme. Of 19 community laboratories offering
13 cervical cytology, five community laboratories were processing
14 less than 10,000 smears a year, as were 11 hospital laboratories.
15 In total, there were 14 laboratories processing 10,000 or more
16 smears a year at this time. It was estimated that about 37% of
17 all smears processed by laboratories in New Zealand were from
18 women enrolled in the NCSP.

19 124. On 2 June 1993, I wrote to the cervical screening unit,
20 Population Health Service, Department of Health, regarding the
21 histology requirements for the screening programme. A copy of
22 this letter is produced as document **BC/CS/0024**. The letter
23 records that, since the records of the Cancer Registry contain the
24 NMPI number for women, linkage between the cervical
25 screening register and the Cancer Registry may be possible once
26 annually, and that this may improve both record systems and
27 allow tabulation of the number of women diagnosed with
28 cervical cancer for each stage of the disease within and outside
29 the NCSP. I suggested that an attempt to do this as a trial could
30 be undertaken in 1994.

1 125. The letter states that feedback reports needed to be improved
2 immediately so that feedback of histology and correlations
3 between cytology and histology would be just another essential
4 layer for smear takers and laboratories. It would improve and
5 maintain quality. I also pointed out the programme may need a
6 formal process to handle wildly discordant results, both between
7 smear takers and laboratories, and between cytology and
8 histology results. I also considered that feedback to laboratories,
9 smear takers and women about the programme results was
10 needed.

11 126. On 1 July 1993 I sent a copy of the second report of the
12 Committee of Public Accounts on Cervical and Breast
13 Screening in England to the National Co-ordinator. Copies of
14 this letter, the report and a letter of confirmation are produced as
15 document **BC/CS/0025**. This was part of a process of review by
16 the Auditor General in England which had been obtained by the
17 previous National Co-ordinator on my recommendation in 1992.
18 I pointed out that many of the reports and responses of
19 professional and other bodies contained in the minutes of
20 evidence in the report were not peculiar to England and I
21 considered them very relevant to New Zealand.

22 127. These items were also brought to the attention of the PHC in
23 my letter of 21 July 1993. A copy of this letter is produced as
24 document **BC/CS/0026**.

25 128. Following the CSAC meeting of 5 November 1993, the
26 committee wrote to Bruce Slane, Privacy Commissioner,
27 regarding interpretation of the Health Amendment Act 1993 in
28 relation to the enrolment procedure for the NCSR. This was
29 done because some medical practitioners were unsure about

1 whether the Privacy Act or the Code of Health Practice
2 Principles overrode the Health Amendment Act, and an article
3 had appeared in the New Zealand Medical Association
4 newsletter with a proforma for a consent/objection form for use
5 by general practitioners. A letter to the Privacy Commissioner
6 is produced as document **BC/CS/0027**.

7 129. In a letter to Katherine O'Reagan, Associate Minister of
8 Health, 24 September 1993 from the Chair of the Committee,
9 the committee was pleased to acknowledge that steps were being
10 undertaken to enhance the number and expertise of the staff
11 involved in the national cervical screening unit, and noted that
12 there should be benefits from enhancing the expertise of the unit
13 through a reduction in the costs associated with consultancy
14 with private companies, and that it would ensure greater
15 continuity of expertise within the programme. A copy of this
16 letter is produced as document **BC/CS/0028**. The committee
17 also noted that the Australian cervical screening programme had
18 a medical spokesperson for the programme.

19 130. At the meeting of the CSAC 11 March 1994 the minutes
20 record that the National Co-ordinator reported that 0.5 FTEs had
21 been withdrawn from the national cervical screening unit in the
22 Ministry of Health. The Director General of Health had decided
23 that the national co-ordination of the NCSP should remain
24 within population health services within the Ministry of Health.
25 It was reported that there was a greater awareness of the
26 problems of an operational programme within a policy group but
27 that the status quo was to remain. It was reported that the
28 structure of the Ministry of Health sometimes did not allow
29 national co-ordination of operational and financial management
30 to occur easily.

1 131. Several reasons were proposed for this decision, one being that
2 the screening programme was still in a developmental phase and
3 therefore would benefit from close association with national
4 policy development. Also, it was indicated that the placement
5 of the national co-ordination functions would be reviewed again
6 in two years.

7 132. The report of the Ministry of Health to the CSAC suggested
8 that a major review of evaluation and monitoring was being
9 undertaken by the Ministry at this time.

10 133. The committee expressed the need to ensure that someone was
11 responsible to collect, oversee and analyse information to
12 evaluate the NCSP. The minutes record that it was stated that
13 both the Ministry of Health and the PHC had responsibility for
14 monitoring and evaluation, but the ultimate responsibility rested
15 with the Ministry of Health. The committee felt that such a
16 person should be able to discharge the Ministry of Health's
17 responsibility to gather information and produce a quarterly
18 report on a routine basis. The Ministry of Health needed
19 someone of at least statistical ability to ensure this was done.

20 134. The minutes record that the committee re-examined its terms
21 of reference and confirmed that it had general terms of reference
22 about monitoring and evaluation. In reality, the committee had
23 been providing operational advice and had been keen to oversee
24 monitoring and evaluation but the year had been difficult in
25 terms of changes in the health sector. The future role of the
26 committee was discussed.

27 135. The meeting advised the National Co-ordinator there needed to
28 be a second statistical report before the regional registers were

1 combined into one entity as the first report raised issues about
2 which there appeared to have been no follow-up. I recall
3 laboratory variation was specifically raised in this context.

4 136. The CSAC also raised the need for a second statistical report.
5 The National Co-ordinator stated that a second statistical report
6 was not planned for this financial year because of resource
7 constraints, changes to the enrolment procedure and the health
8 reforms. The committee stressed the importance of measuring
9 the effects of opt-off and that resources to do a second statistical
10 report should be made available provided this did not
11 compromise the other projects within the screening programme.

12 137. The CSAC repeated their endorsement of the need for a
13 statistical report on an annual basis. The meeting expressed
14 concern that any monitoring and evaluation should involve
15 professional groups to ensure feedback would be relevant to
16 their needs and it was reported that laboratories had already been
17 consulted about monitoring and quality assurance.

18 138. The committee considered that regular quarterly information
19 from the local programmes would assist in their monitoring and
20 evaluation function. There was general discussion regarding the
21 relationship between national co-ordination and the 14 NCSP
22 sites.

23 139. The committee noted there was no direct accountability and
24 the chief accountability was through the contract arrangements
25 between the Crown RHAs and providers. However, the
26 National Co-ordinator felt that the lines of accountability were
27 stronger than in the old Area Health Board system.

1 140. The committee noted that there was no formal way to measure
2 whether the lines of accountability were sufficient for the
3 screening programme to run effectively.

4 141. There was concern expressed by the CSAC that resource
5 constraints were occurring nationally while local evaluations of
6 varying quality were happening on an ad hoc basis.

7 142. The report of the Ministry of Health to the CSAC confirmed
8 that difficulties in filling positions in the national cervical
9 screening unit had caused delays in several of the projects of the
10 unit. The needs of the CSAC regarding monitoring and
11 evaluation were again expressed. Members of the PHC also
12 joined for this discussion on monitoring and evaluation.

13 143. The lack of intermediate measures of performance was
14 highlighted and that most of the data coming from the screening
15 register was associated with enrolment figures. The CSAC felt
16 that intermediate measures of performance needed to go back to
17 providers of services and that professional groups should be
18 involved in determining these. Examples of intermediate
19 measures of effect would be similar to those first proposed by
20 the Ministerial Review Committee such as the detection rates of
21 abnormalities per 1000 women screened. Other examples
22 would be the proportion of smears considered unsatisfactory and
23 the proportion of women who have had a high grade smear who,
24 after being referred for treatment, had normal smears between
25 six months to two years after referral. The CSAC recommended
26 that the National Co-ordinator work with the PHC and others on
27 intermediate processes for the monitoring and evaluation of the
28 screening programme.

1 144. The CSAC made some recommendations to be taken to the
2 PHC from the CSAC, including that there should be routine
3 examination by the PHC of every case of invasive cancer, with a
4 review of screening history. The committee noted that this was
5 a matter of urgency.

6 **145. From 1991 to 1994 the advice of the CSAC regarding**
7 **monitoring and evaluation appeared to be in opposition to**
8 **many of the internal decisions of the Ministry of Health.**

9 146. The NCSP newsletter of March/April 1994 announced that the
10 review of the policy of the NCSP had begun in February 1994 so
11 that the revised policy could be promulgated around August
12 1994. A copy of this newsletter is produced as document
13 **BC/CS/0029.**

14 147. In the newsletter the National Co-ordinators trip to the cervical
15 screening programme in British Columbia was outlined. This
16 programme was established in the 1950's and was centralised in
17 Vancouver, Canada. The programme was entirely government
18 funded and all smears were sent to a government funded
19 laboratory.

20 148. This trip occurred in conjunction with a trip by other Ministry
21 of Health staff to the World Health Organization 2nd
22 International Workshop on National Cancer Control Programs
23 held in Banff, Canada, which was also attended by the National
24 Co-ordinator.

25 149. The then Director General of Health, Chris Lovelace, had
26 appointed an advisory committee in 1992 or 1993 to report on
27 the benefits of a national cancer control programme for New

1 Zealand. I believe the report of this committee has not been
2 published. I was not a member of this advisory committee.

3 150. In the newsletter there again appeared a small article on the
4 location of national co-ordination of NCSP. A report on this
5 had been received from Peat Marwick who conducted the work
6 under contract to the Ministry of Health.

7 151. On the last page of this NCSP newsletter, there was a brief
8 report on several failures of the screening process that had
9 occurred in Great Britain. In particular, a group of 2000 women
10 were recalled in Greenock where smears had been wrongly read
11 for 5 years in a laboratory described as under-staffed, antiquated
12 and isolated. I believe this was the Inverclyde Hospital
13 investigation. I recall that the CSAC advised the National Co-
14 ordinator that this type of event could occur in New Zealand and
15 that appropriate quality assurance was needed to minimise the
16 risk of such an event occurring.

17 152. Also, in this article of the newsletter, it was stated that the
18 Department of Health was also considering ways to improve
19 internal quality control of laboratories perhaps by retesting a
20 fixed proportion of slides or by swapping slides between
21 screeners. Wide variations in local practices in Britain were
22 reported and a position of National Co-ordinator of Cervical
23 Screening was to be created in Britain.

24 153. A draft report reviewing cervical screening evaluations
25 produced by Health Research and Analytical Services dated 7
26 March 1994 was provided to the CSAC. The final report was
27 produced in April 1994. As had often been the case, the review
28 tended to concentrate on enrolment, the number of cervical

1 smear tests completed, smear taker characteristics, and the
2 inclusion of groups of women considered at higher risk.

3 154. The 11 March 1994 report of the Ministry of Health to the
4 CSAC records that in December 1993 the National Cervical
5 Screening Co-ordinator visited Melbourne. Her visit included
6 the Victorian Cytology Register, laboratories, TELARC and
7 some of the Australian Cancer Councils.

8 155. The Director General of Health made the decision to keep the
9 NCSP within the population health services section of the
10 Department of Health and acknowledged that the programme
11 did not fit perfectly within the Ministry and that there was a lack
12 of organisational elegance about the programme. This was
13 acknowledged in his letter to Dr Gillian Durham, CEO of the
14 PHC, dated 4 February 1994. A copy of this letter is produced
15 as document **BC/CS/0030**.

16 156. In March 1994 the PHC published its advice to the Minister of
17 Health with regard to cervical cancer [PHC 1994]. Aspects of
18 the primary and secondary prevention of cervical cancer were
19 summarised in this document.

20 157. The PHC proposed that RHAs continue to purchase cervical
21 screening services of a high quality. The PHC proposed that
22 RHAs purchase services that would maintain ongoing
23 monitoring and evaluation of the laboratory's performance to
24 ensure the accuracy of screening and diagnosis for abnormal
25 cytology.

26 158. The Government policy for national cervical screening
27 updated October 1993, [Ministry of Health 1993] section 3.1.2,

1 page 3 records that one of the objectives of the NCSR was to
2 monitor the quality of smears and in Section 3.1.10, page 4, that
3 the NCSR would generate reports on the quality of smears.

4 159. In section 4.1.2 page 5, it was recorded that all cytology
5 laboratories servicing the NCSP should be registered with
6 TELARC or other recognised authority, but that a reasonable
7 period of time would be allowed for laboratories to obtain
8 registration.

9 160. In section 4.1.3, page 6, it records that the Ministry of Health
10 would be responsible for confirming that those laboratories
11 carrying out cytology screening and histology for the NCSP
12 meet the requirements set out in 4.1.4. The criteria in 4.1.4
13 were:

- 14 (i) the reading of a minimum number of smears a year,
15 (ii) employment of suitably qualified staff,
16 (iii) maximum workloads for each cyto-screener,
17 (iv) adequate in-service education,
18 (v) satisfactory participation in both internal and external
19 quality assurance procedures,
20 and, (vi) provision of cytology reports to the cytology
21 register.

22 161. In section 7.1.4, page 8, it records that the National Co-
23 ordinator would be responsible for ensuring that the NCSP was
24 monitored and evaluated nationally. It was also stated that
25 evaluation of the projects and services nationally will be co-
26 ordinated by the Ministry of Health.

1 162. In section 8.1.2, page 8, one of the main responsibilities of the
2 Ministry of Health was to co-ordinate monitoring and evaluation
3 of the programme. Responsibility for purchase and delivery of
4 cervical screening services rested with the RHA.

5 163. At the CSAC meeting of 15 June, 1994, the minutes record
6 that false negative results were discussed. The investigation of
7 the screening history and slides of women with invasive cervical
8 cancer was again proposed by the CSAC.

9 164. The minutes record that the National Co-ordinator confirmed
10 that 0.5 FTE for a support person had been reinstated within the
11 screening unit since the committee's last meeting and that the
12 committee was asked to continue with its current terms of
13 reference until the 30th September 1994 by Katherine O'Reagan.

14 165. It was reported that some laboratories were under imminent
15 threat of closure and until these issues were sorted out between
16 the laboratories and the RHAs, the screening programme may
17 have problems getting laboratory results.

18 166. The report of the Ministry of Health to the CSAC stated that,
19 because specialist computer skills were scarce, implementation of
20 one NCSR would be delayed until the register co-ordinator
21 position was filled.

22 167. It was confirmed that the Ministry of Health was one of
23 several groups working on standards for quality assurance in
24 laboratories at this time. At this meeting there was further
25 discussion of the false positive and false negative rates for
26 cervical screening. This had become the major issue for
27 laboratories because of a legal case in Australia and the National

1 Co-ordinator agreed to look into the issue of the information
2 provided to women, specifically that cervical smear test results
3 were not always reliable, especially when there were symptoms
4 or signs of cervical cancer.

5 168. Again, it was proposed that there should be a review of the
6 slides of women who developed invasive cervical cancer. The
7 National Co-ordinator agreed to investigate this proposal.

8 169. The report of the Ministry of Health to the CSAC, 15 June
9 1994, records that the Ministry hoped to contract with Health
10 Research and Analytical Services for analysis and report writing
11 in the 1994 and 1995 year.

12 170. Some delay was reported in obtaining the appropriate data
13 because some sites were at least three months behind in their
14 data entry.

15 171. It was noted in this report that the CALC would meet at the
16 end of June and items for discussion at that meeting would
17 include review of the national policy, quality assurance and
18 terms of reference for the committee.

19 172. At the CSAC meeting on 29 September 1994 the minutes
20 record that there was some discussion regarding the Association
21 of Community Laboratories recommendation that laboratory
22 reports state that there was a significant false negative rate from
23 cervical smears. The National Co-ordinator had obtained a legal
24 opinion and the Ministry of Health had asked the PHC
25 programme managers to check all education and promotion
26 materials to ensure they did not give women false reassurance
27 that smear tests were infallible.

1 173. It was reported by the Ministry of Health to this meeting that
2 one national register with remote access would be implemented
3 over one-and-a-half financial years with all Area Health Board
4 data on a single national register by late 1995 or early 1996.

5 174. Problems with the register in the Auckland area were reported
6 to be continuing and that the Ministry staff were assisting
7 Auckland as much as possible. I believe this was mainly due to
8 a backlog of paperwork that required to be entered onto the
9 NCSR and obtaining complete information for the NCSR.

10 175. The meeting discussed the release of Wellington data which
11 was being held up again by security protocols of the Wellington
12 Ethics Committee and until this occurred the Ministry would not
13 produce a second statistical report. I recall that the CSAC felt
14 that the second statistical report should proceed without the
15 Wellington region as had occurred in the first statistical report.
16 The CSAC confirmed an earlier legal opinion that the data was
17 owned by the Crown and suggested that the Ministry's legal
18 advisors write to the Crown Health Enterprise (CHE) general
19 managers to advise them accordingly.

20 176. This was the CSAC's last meeting and a considerable part of
21 the meeting involved finalising the committee's final report
22 entitled "Monitoring and Evaluation of the NCSP - the first
23 three establishment years". This report was produced because
24 the CSAC considered it important to document various
25 recommendations it had made and to re-emphasize to the
26 Minister and the Ministry of Health what it thought was required
27 to improve the NCSP so that it could be compared with
28 international benchmarks for cervical screening programmes.
29 Barriers to effective monitoring and evaluation were outlined in

1 this document. The final report of the CSAC was sent to the
2 Minister on 2 November 1994.

3 177. I recall that the desire of the CSAC to produce this report arose
4 from the frustration the committee had felt regarding the
5 implementation of the programme and the limited progress on
6 monitoring and evaluation that had been achieved. It is my
7 opinion that the repeated changes of staff and restructuring
8 throughout the health sector meant that institutional memory of
9 the programme was rapidly being lost to the day-to-day
10 operation of the NCSP. I recall that the CSAC felt it important
11 to record its work and advice in case the NCSP was further
12 weakened or even abolished.

13 178. The CSAC also undertook to write to Sonya Easterbrook-
14 Smith, the Manager of Population Health Services in the
15 Ministry of Health, regarding the CSAC experience in the
16 development of a NCSP which it believed to have relevance to
17 the development of other screening programmes in New
18 Zealand. Several key points were made. In particular, that
19 quality control issues and the necessary information systems
20 should be addressed before clients were actively recruited. A
21 copy of this letter is produced as document **BC/CS/0031**.

22 179. In the report of the Ministry of Health to the CSAC of 29
23 September 1994 it was reported that the National Co-ordinator
24 position was vacant. It was reported that the Health Research
25 and Analytical Services section of the Ministry had been
26 contracted to produce the next statistical report and that the
27 CALC had met at the end of June.

1 180. The report of the Ministry of Health mentioned that a
2 laboratory disclaimer on the cervical screening programme
3 enrolment form and draft standards for cytology laboratory
4 assistants were discussed by CALC and that nominations for the
5 new laboratory advisory committee were reported to have been
6 sought from appropriate professional organizations.

7 181. The report of the Ministry of Health to the Programme
8 Managers meeting of 8-9 September 1994 noted that the CALC
9 had provided advice for the redrafting of laboratory standards
10 for TELARC accreditation. I believe that the laboratory
11 standards of TELARC permitted home-screening under certain
12 circumstances.

13 182. Assorted reports from regional screening managers were
14 provided and were attached to the minutes to indicate some of
15 the work that regional co-ordinators conducted for the
16 programme at this time.

17 183. The reports indicated that National Co-ordinator visited
18 Tairāwhiti from June 22 to June 24 1994. The Southland
19 cervical screening programme manager expressed concern about
20 some of the disparities between laboratories and the proportion
21 of smears reported as satisfactory or satisfactory but limited. I
22 do not recall what action was taken by the National Co-ordinator
23 in this regard.

24 184. In August 1994 the Associate Minister of Health decided to
25 continue to receive advice from an advisory committee and at
26 the September meeting the proposed terms of reference of the
27 new advisory committee were discussed.

1 185. The initial proposal from Health Research and Analytical
2 Services for the second statistical report of the programme was
3 prepared in May 1994 for the National Co-ordinator.

4 186. In July 27, 1994 I sent a copy of the European Guidelines for
5 Quality Assurance for Cervical Cancer Screening to members of
6 the Advisory Committee, the National Co-ordinator and the
7 Monitoring Evaluation Section of the PHC [Europe Against
8 Cancer Programme 1993]. I pointed out that the tables in the
9 appendix of this document may be a good place to start for yet
10 again stating what needs to be evaluated. A copy of this letter is
11 produced as document **BC/CS/0032**.

12 187. On November 8, 1994 the minutes of the CSAC meeting
13 record that the Chair of the CSAC reported to members that she
14 had sent letters to the Associate Minister of Health, the Deputy
15 Director-General of Health and the manager of Population
16 Health Services of the Ministry of Health, with copies of our
17 final report. The issue of employing appropriate expertise was
18 emphasised in both these letters. A copy of the letter to the
19 Associate Minister of Health is produced as document
20 **BC/CS/0033**.

21 **Cervical Screening Advisory Committee (CSAC) 1995-1996**

22 188. In May 1995 the new CSAC met with new terms of reference.
23 A copy of the initial terms of reference is produced as document
24 **BC/CS/0034**. The Ministry of Health report to this meeting
25 indicated that discussions were ongoing with the RHAs on the
26 government policy. It was recorded that the review of the
27 national policy had been delayed due to staff changes at this
28 time and that work was in progress on the production of a

1 statistical report for the 1993-94 period and that there had been
2 some difficulty getting data from all sites for this report.

3 189. In May 1995 the screening programme had approached the
4 Cancer Registry to determine how long the time lag was
5 between diagnosis and reporting of diagnoses of invasive cancer
6 to the Cancer Registry and it was indicated that they had no way
7 of monitoring this. It was estimated that 1993 information
8 would be finished around September 1995. A copy of an e-mail
9 confirming this is produced as document **BC/CS/0035**.

10 190. In the minutes of the CSAC meeting of 1 August 1995 it is
11 recorded that it had been proposed by CSAC that the new
12 Cervical Screening Laboratory Advisory Committee (CSLAC)
13 should be extended to include a consumer representative,
14 general practitioners, gynaecologists and programme managers.

15 191. The CSAC also discussed issues relating to the evaluation and
16 monitoring of laboratories. I recall one option expressed at the
17 time was for the committee to have its own laboratory
18 subcommittee.

19 192. At this meeting, it was noted that there was no longer a
20 problem with access to the Wellington data for the production of
21 statistical reports. I do not know how this matter was finally
22 resolved.

23 193. A report on the progress of the second statistical report was
24 given at that meeting. Also, a Maori statistical report of the
25 programme was being considered by the Kaitiaki at this time.

1 194. It was also reported that the CSLAC agreed to the inclusion of
2 laboratory statistics in the 1993-1994 statistical report. I was not
3 aware that CSLAC approval had been required for the
4 production of the statistical reports.

5 195. The issue of conducting an audit of women who developed
6 cervical cancer who were part of the screening programme was
7 again discussed at this meeting.

8 196. The availability of public health medicine expertise for the
9 ongoing evaluation and monitoring of the programme was
10 discussed again at this meeting. The CSAC again outlined
11 priorities identified by the committee for the programme.

12 197. In the Ministry of Health's report attached to the minutes of
13 this meeting and dated July 1995, it was noted that an analysis
14 of laboratory statistics and protocols for feedback of information
15 to laboratories and smear takers on quality had been discussed
16 by the CSLAC on July 24, 1995.

17 198. A working party to review the cervical screening
18 recommendations was set up at this time. I was a member of
19 this working party.

20 199. A brief paper for the audit of the screening history of women
21 developing cervical cancer that I prepared for the committee was
22 discussed. A copy of this paper is produced as document
23 **BC/CS/0036**.

24 200. The CSAC met again on 27 and 28 February 1996. The report
25 of the Ministry of Health indicated relocation of the cervical

1 screening programme to the prevention policy section of the
2 public health group in November 1995.

3 201. Draft objectives for the revised policy of the programme that I
4 had prepared were provided as a background paper for the
5 meeting. A copy of this paper is produced as document
6 **BC/CS/0037**.

7 202. Continuing problems at the Auckland screening programme
8 site were highlighted. A time frame for the reconfiguration of
9 the screening register to one national register was altered due to
10 delays.

11 203. At the meeting of 27 and 28 February, 1996 the minutes record
12 that Druis Barrett was welcomed to the CSAC and Judy Glackin
13 was introduced as the new manager to the prevention policy
14 section of the public health group in the Ministry.

15 204. Three separate contracts for the delivery of the screening
16 programme in Auckland were described, and it was reported that
17 the laboratories not registered to TELARC and not performing
18 adequately according to TELARC standards would have their
19 funding cut by the RHA.

20 205. The terms of reference for the CSLAC and the CSAC were to
21 end on 30 June 1996.

22 206. It was also reported at this meeting that the second statistical
23 report would be published following approval by the Minister
24 and work had begun on the third statistical report in conjunction
25 with the Public Health Intelligence section of the Ministry of

1 Health. It was recommended by the CSAC that information on
2 the statistical report should be available up to the date of opt-off,
3 which was 1 June 1993, and after opt-off.

4 207. There was some discussion about access to the NCSR for
5 information from the register about coverage and other statistics
6 by ethnicity. It was considered that this would be useful in the
7 statistical reports as these groups were identified as a priority for
8 the programme. There was discussion by the CSAC at this
9 meeting, yet again, regarding an assessment of the screening
10 histories of women enrolled on the screening programme who
11 developed cervical cancer. It was suggested that one option
12 would be to establish regional peer review groups to investigate
13 the screening history of women in the programme who
14 developed invasive cervical cancer and that these peer review
15 groups could meet two to three times a year. They would then
16 contact the women's gynaecologists, pathologists, and general
17 practitioners. The benefits of such a process were listed.

18 208. Also at this meeting, links between the cervical screening
19 programme and the developmental work of the breast screening
20 programme were discussed. There was a view amongst
21 members of the committee that the experience of the committee
22 and others in the development of the NCSP would be useful to
23 those involved in the planning of a national breast screening
24 programme.

25 209. At this meeting it was announced that funding was available
26 for the evaluation and monitoring strategies of the screening
27 programme and that the Public Health Intelligence section
28 would produce a scoping paper by the end of the financial year.

1 This involved the preparation of an evaluation plan which may
2 involve one or two more discrete projects.

3 210. It was decided that the second statistical report would be sent
4 to the CSAC including age breakdowns for enrolments by
5 region. It was proposed that the third statistical report would be
6 forwarded to the CSAC for comment and indicated that the
7 screening programme intended to produce subsequent statistical
8 reports by calendar year.

9 211. In late-March or early-April I was asked to comment on the
10 draft proposal on the Ministry of Health for the third statistical
11 report. The draft proposal and my comments are produced as
12 document **BC/CS/0038**. I cannot trace the letter to the Ministry
13 of Health submitting my comments but I believe my comments
14 were sent. I was disappointed with the 2nd and 3rd statistical
15 reports as I felt there was considerable scope to extend the
16 analysis of the first statistical report.

17 212. It was recommended by the CSAC that the Ministry of Health
18 take note of the Europe Against Cancer Programme guidelines
19 for the evaluation of cervical screening programmes summarised
20 in the tables at the back of this document.

21 213. It was reported that the Associate Minister of Health would be
22 considering extending the CSAC's terms of reference for one
23 more year, and that future needs included monitoring and
24 evaluation, liaison with the Royal College of Obstetricians and
25 Gynaecologists about quality assurance and there was discussion
26 about augmenting the committee with representation of the
27 Royal College of Obstetricians and Gynaecologists and the
28 RHAs, but no firm decision was reached.

Resignation from the CSAC

1
2 214. At this time I felt that despite numerous attempts by the CSAC
3 to ensure appropriate monitoring and evaluation of the cervical
4 screening programme this had not been completed.

5 215. I felt that the Ministry of Health appeared to want to manage
6 the NCSP for political reasons rather than making sure it was
7 effective.

8 216. I was involved as a member of the working party reviewing the
9 cervical screening policy and had made comments on the draft
10 proposal of the Ministry of Health for the third statistical report.

11 217. My assessment was that there was insufficient expertise within
12 the Ministry of Health for good evaluation and monitoring of the
13 programme to ever be achieved and that measurement against
14 the international benchmark of the Europe Against Cancer
15 Programme for cervical screening programmes was technically
16 beyond the capacity of the Ministry of Health.

17 218. I tendered my resignation of the CSAC to the Chairperson of
18 the committee on May 6, 1995. It was brought to my attention
19 that, as the CSAC was appointed by the Minister, my letter of
20 resignation should be sent to the Associate Minister of Health.
21 This I did on June 10, 1996. Copies of these letters are
22 produced as document **BC/CS/0039**.

Other involvement since 1996

23

1 219. I was a member of the working party reviewing the cervical
2 screening policy for New Zealand.

3 220. I was asked to attend a one-off meeting of experts that was
4 held on 13 May 1998. Some of the background documents
5 provided to participants for this meeting are provided as
6 document **BC/CS/0040**.

7 221. This meeting was initially called while the NCSP was in the
8 Ministry of Health. However in the weeks prior to this meeting,
9 responsibility for the programme transferred to the HFA.

10 222. This meeting discussed a wide range of issues but focussed
11 mainly on laboratory issues including inter-laboratory variation.
12 During this meeting there was considerable discussion about the
13 quality assurance programme of the Royal College of
14 Pathologists of Australasia and about the number of laboratories
15 reporting what was internationally considered to be a relatively
16 small number of cervical smears a year. Some very limited
17 information regarding the reporting from hospital and
18 community labs according to their size was provided at this
19 meeting. After considerable discussion, the meeting decided
20 that, if a cut-off for the number of smears that should be
21 processed a year by a laboratory for it to be included in the
22 screening programme was chosen, 10,000 smears a year was
23 probably the most acceptable cut-off for New Zealand.

24 223. At the time of the meeting, it was indicated that such a group
25 may meet on an annual basis to discuss various issues of a
26 technical nature such as laboratory reporting for the cervical
27 screening programme.

1 224. On receipt of the draft minutes of this meeting I responded to
2 the National Co-ordinator rejecting the minutes as a record of
3 the meeting because they were incomplete. I pointed out that, if
4 another group was to meet in a year's time, it was very
5 important that a record of the meeting was available to them to
6 inform their discussions. I can not locate my copy of this letter.
7 A copy of the draft minutes that I received is produced as
8 document **BC/CS/0041**. I did not receive any revision of the
9 minutes of this meeting.

10 225. As a member of the National Health Promotion Committee of
11 the Cancer Society I have a letter dated 17 September 1996 from
12 the then Executive Director of the Cancer Society, Jeff Brown,
13 to Dr Gillian Durham, the general manager of the Public Health
14 Group, Ministry of Health, and her reply. Copies of these letters
15 are produced as document **BC/CS/0042**.

16 **Part III: Effectiveness of the NCSP**

17 226. The NCSP is New Zealand's first national cancer screening
18 programme. It is a very important public health programme and
19 has been largely responsible for driving improvements in the
20 organisation of the cervical screening service to women.

21 227. The NCSP can be improved and with some appropriate
22 modifications, such as clearer accountability, more direct
23 budgetary control, appropriate management and supervision, and
24 appropriate monitoring and evaluation it will become a cervical
25 screening programme of international standard. In my opinion
26 these changes are able to be achieved. There have been
27 considerable improvements as a consequence of the programme.

1 228. Cervical screening has had an impact on the incidence and
2 mortality of cervical cancer in New Zealand [Cox & Borman
3 1994].

4 229. Provisional data for 1997 indicate that 214 women developed
5 invasive cervical cancer and 73 died of it in New Zealand. The
6 most conservative prediction in 1992 was that without
7 improvements in cervical screening, on average about 332
8 women would develop invasive cervical cancer and about 112
9 would die from it each year from 1994 to 1998 [Cox & Skegg
10 1992]. That is, there has been at least a 35% reduction in
11 incidence and mortality from cervical cancer compared to what
12 was expected. Even further reductions can be anticipated due to
13 the NCSP.

14 230. From a theoretical standpoint, if all women received three-
15 yearly screening, invasive cervical cancer may be reduced by
16 about 91%.

17 231. Well-organised cervical screening programmes have been
18 shown to achieve reductions in invasive cervical cancer
19 incidence and mortality by 70-80% in the general population.

20 232. Well-organised programmes are population-based and have
21 the characteristics outlined by the WHO. The technical term
22 “population-based” means that the invitation and recall to
23 screening is made from a listing of the entire eligible female
24 population. In the New Zealand the electoral roll is the closest
25 thing we have to that but about 5% of eligible women may not
26 be listed on the electoral roll.

1 233. Screening programmes that are not population-based are
2 almost always less effective than those that are population-
3 based.

4 234. As the proportion of eligible women enrolled in the NCSP is
5 estimated to be over 90% it is possible to consider that the
6 programme is close to a population-based cancer screening
7 programme.

8 235. Women who have had precancer detected by screening and
9 successfully treated can be considered successes of cervical
10 screening. However, the treatment of high grade abnormalities
11 can have very serious side effects which, from a population
12 perspective, need to be balanced against the risk of dying of
13 invasive cervical cancer.

14 **Part IV: Some comments on the proportion of** 15 **smears reported as high grade or low grade.**

16 236. The assessment of cervical cytology specimens is subjective
17 and requires considerable training and experience. There is
18 dependence on appropriate sampling by the clinician and
19 transportation of the specimen taken from the cervix of the
20 woman to the laboratory.

21 237. One process measure of the screening programme is the
22 detection rate of high grade abnormalities in women. That is,
23 the detection rate of histologically confirmed high grade
24 abnormalities per 1000 women screened. This is a better
25 measure of the detection of the disease of interest than the
26 proportion of smears reported as suggestive of high grade
27 abnormalities. The proportion of smears that are suggestive of

1 high grade abnormalities can be influenced by many factors.
2 Some of these are outlined below.

3 238. For a woman with a high grade abnormality of the cervix one
4 or more smears may be taken before treatment is instituted.
5 Therefore, the proportion of smears reported as suggestive of a
6 high grade abnormality may reflect the clinical practice of
7 doctors and other smear takers. For example, if the smear is
8 repeated, or the colposcopist routinely takes another smear just
9 prior to treatment, this will influence the proportion of smears
10 processed that are reported as suggestive of a high grade lesion.

11 239. If treatment is initially unsuccessful, further smears which are
12 reported as suggestive of a high grade lesion may eventuate until
13 treatment is successfully completed and normal smears are
14 returned.

15 240. The underlying level of high grade abnormalities in the
16 population will underpin the proportion of smears reported as
17 suggestive of a high grade abnormality. This is likely to depend
18 on the exposure to relevant human papillomavirus in the
19 population and the exposure of the population to factors that
20 appear to be associated with whether or not the infection
21 persists.

22 241. As the prevalence of high grade abnormalities varies
23 considerably with age [Miller 1992], the age distribution of the
24 population screened can be expected to alter the detection rate of
25 high grade abnormalities in the population.

26 242. The degree of screening already undertaken in the population
27 may alter the prevalence of high grade abnormalities. In a

1 heavily screened population a greater proportion of women who
2 had high grade abnormalities may have had these detected
3 already and successfully treated whereas this would not be the
4 case where the previous detection of high grade abnormalities
5 through screening had been low.

6 243. Some similar considerations are required for the interpretation
7 of rates of reporting of other cytological abnormalities.

8 **Part V: International benchmarks for cervical** 9 **screening**

10 244. In 1986 WHO produced guidelines for laboratories processing
11 cervical smears for cervical screening programmes.

12 245. The Europe Against Cancer Programme published quality
13 standards for cervical screening programmes in 1993 [Europe
14 Against Cancer Programme 1993]. These have been used to
15 assess the highly successful screening programme in Iceland
16 [Sigurdsson 1995]. A brief summary of these minimum
17 monitoring parameters is shown in Table 1.

1 Table 1. Parameters for the monitoring a cervical screening programme
 2 [Europe Against Cancer Programme 1993].

3	Time scale	Parameters
4		
5	For monitoring effectiveness	
6	<i>Long term</i>	Mortality rates
7		Incident cancers
8	<i>Short term</i>	Coverage
9		Interval to reporting of smears
10		Proportion of unsatisfactory smears
11		Follow-up compliance
12		Treatment compliance
13		Sensitivity and specificity
14		Stage distribution of cancers
15		Interval cancers
16	For monitoring resource use	
17	<i>Long term</i>	Cost-effectiveness analysis
18	<i>Short term</i>	Number of smears each year by age group
19		and abnormality
20		Proportion of smears by screening history and age group
21		Excess use of smears
22		

23 246. These have been repeatedly put forward to the Ministry of
 24 Health as an appropriate international benchmark for the NCSP.

25

Part VI: Future recommendations for the NCSP

1
2
3 247. In my opinion, stricter adherence to the WHO guidelines for
4 the organisation of an effective cervical screening programme is
5 required. In particular the need for a central suitably staffed
6 office with an individual who is responsible for the NCSP is
7 essential. The WHO managerial guidelines should also be
8 adopted. In my opinion this central office should no longer be
9 in the Ministry of Health.

10 248. In my opinion obstacles to the appropriate monitoring and
11 evaluation of the NCSP need to be overcome. This includes
12 obstacles to the monitoring and evaluation for Maori and Pacific
13 women. Amendments to legislation or the promulgation of
14 regulations to enable such monitoring and evaluation to occur
15 should be carried out. The Europe Against Cancer Programme
16 guidelines should be used as a guide to what is required for the
17 monitoring and evaluation of the NCSP.

18 249. In my opinion the current health system changes announced by
19 government involving devolution to local health boards should
20 not be allowed to weaken the NCSP.

21 250. In my opinion the external quality assurance of laboratories
22 should be reviewed by a multidisciplinary body to assess
23 whether it is appropriate for the NCSP.

24 251. Cervical cytology should be conducted in laboratories
25 processing sufficient numbers of cervical smears for sufficient

1 skills of the screeners, cytotechnicians and cytopathologists to
2 be maintained. The WHO guidelines appear to be appropriate.
3 If necessary, regulations for minimum laboratory standards for
4 cervical cytology should be introduced.

5 252. In my opinion evaluation of the treatment of neoplastic
6 cervical abnormalities detected at screening is required. Quality
7 assurance processes for the treatment of women with abnormal
8 smears should be reviewed by the NCSP.

9 **Part VII: The need for a Cancer Control** 10 **Agency for New Zealand**

11 253. New Zealand has the 6th highest overall cancer mortality rate
12 for women and the 33rd highest overall cancer mortality rate for
13 men in the world [Ferlay et al 1998]. Cancer is predicted to
14 become a much greater cause of morbidity and mortality in New
15 Zealand in the ensuing decades.

16 254. In my opinion, and unanimously agreed by the 110 participants
17 from a wide cross-section of interested groups at the Cancer
18 Control 99 Workshop held in Wellington last year, a systematic
19 and co-ordinated approach across multiple agencies to the
20 cancer burden in New Zealand society is required.

21 255. In my opinion a Cancer Control Agency for New Zealand
22 should be established. The statutes, governance and structures
23 for a Cancer Control Agency for New Zealand should be
24 developed after assessment of the structures of the Cancer
25 Councils in states of Australia.

1 256. This agency should have a statutory responsibility for cancer
2 control in New Zealand.

3 257. As a minimum, the central offices for the NCSP and the
4 national breast cancer screening programme, the databases of
5 these programmes and the Cancer Registry should be placed in
6 this agency. This agency must be independent of the Ministry of
7 Health with respect to policy, budget and accountability.

8 **References**

9 Cox B, Borman B. Cervical cancer in New Zealand: national and
10 regional trends. *NZ Med J* 1994; 107: 323-6.

11 Cox B, Brackenbury J, Teague C. *The First Statistical Report of the*
12 *NCSP*. Wellington: Ministry of Health, 1993.

13 Cox B, Skegg DCG. Projections of cervical cancer mortality and
14 incidence in New Zealand: the possible impact of screening. *J*
15 *Epidemiol Comm Health* 1992; 46: 373-377.

16 Europe Against Cancer Programme. European guidelines for quality
17 assurance in cervical cancer screening. *Eur J Cancer* 1993; 29A
18 (suppl 4): S12-S15.

19 Ferlay J, Parkin DM, Pisani P. *GLOBOCAN 1: Cancer Incidence*
20 *and Mortality Worldwide*. Lyon: IARC Press, 1998.

21 IARC Working Group on Cervical Cancer Screening. In: Hakama
22 M, Miller AB, Day NE, (eds). *Screening for cancer of the uterine*
23 *cervix*. Lyon: IARC, 1986.

24 Miller AB, et al. The natural history of cancer of the cervix, and the
25 implications for screening policy. In: Miller AB et al., eds. *Cancer*
26 *screening*. Cambridge, Cambridge University Press: 141-152, 1991.

27 Miller AB. *Cervical Cancer Screening Programmes: Managerial*
28 *Guidelines*. Geneva, World Health Organization, 1992.

29 Ministry of Health. *Government Policy for National Cervical*
30 *Screening: Updates October 1993*. Ministry of Health, 1993.

31 Norton V. *The National Cervical Screening Programme's review of*
32 *Laboratory Services*. Report of the National Cervical Screening

- 1 Programme, prepared by Health Research and Analytical Services
2 of the Department of Health. June, 1993.
- 3 PHC. *Cervical Cancer: The Public Health Commission's Advice to*
4 *the Minister of Health*. Public Health Commission, 1994.
- 5 Sigurdsson K. Quality assurance in cervical cancer screening: the
6 Iceland experience 1964-1993. *Eur J Cancer* 1995; 31A: 728-734.
- 7 WHO. *Cytological screening in control of cervical cancer:*
8 *technical guidelines*. Geneva, World Health Organisation, 1988.
- 9 WHO. Control of cancer of the cervix uteri. *Bull WHO* 1986: 64:
10 607-618.