

CERVICAL CANCER INQUIRY

Brief of Evidence

Introduction

1. My name is David Christopher Graham Skegg. Since 1980 I have been the Professor of Preventive and Social Medicine at the University of Otago Medical School.
2. Before that I was a Rhodes Scholar, and then Lecturer in Epidemiology, at the University of Oxford. At Oxford I began research in cancer epidemiology with Sir Richard Doll, including a study of risk factors for cervical neoplasia. Much of my subsequent research has been on the causes and control of cancer. At Otago I head a department which contains the largest number of specialists in this field in New Zealand.
3. I was the Foundation Director of the Hugh Adam Cancer Epidemiology Unit in Dunedin, and was formerly the Chairman of the Health Research Council of New Zealand and of the Public Health Commission. Since 1985 I have been a consultant to the World Health Organization in Geneva, in the field of reproductive health, and I currently chair one of its scientific committees.
4. During the 1980s I chaired national working groups on cervical screening and on screening for breast cancer. Since 1994 I have been a member of the Editorial Committee of the *Journal of Medical Screening*, which is the main international journal in this field.
5. I was awarded the OBE for services to medicine in 1990; last year I was awarded the

Sir Charles Hercus Medal by the Royal Society of New Zealand (for advancement of biomedical and health sciences).

The problem of cervical cancer

6. Cervical cancer is the third commonest cancer in women in the world as a whole. In some regions, such as sub-Saharan Africa, Central America, South-central Asia and Melanesia, it is the main cancer affecting women. In New Zealand, as in most developed countries, the disease is much less common. With the incidence rates prevailing in New Zealand in the mid-1990s, the “lifetime” risk (up to the age of 74 years) was just over 1 in 100 women.
7. Our incidence and mortality rates are higher than in most other countries with which we compare ourselves. For example, in comparison with Australia, our incidence rate is about one-third higher and our death rate more than 50% higher. A recent report from the Ministry of Health showed that New Zealand women had the second highest death rate from cervical cancer among 22 OECD countries.¹ The rates are particularly high among Maori women, although the gap between Maori and non-Maori has begun to close rapidly during the last decade.
8. While cervical cancer is much less common than cancers of the breast or bowel, there are two good reasons why it has received so much attention as a public health problem. First, whereas the death rate from cervical cancer had been declining for most of this century, mortality among women under 40 years of age began to increase during the 1970s in several countries including New Zealand. This increase almost certainly reflected generational changes in sexual behaviour, since cervical cancer seems to be caused by sexually transmitted papillomaviruses. Other factors, including the use of oral contraceptives and cigarette smoking, may also have contributed.

9. Observations in other countries have shown that generations of women who experience increased rates of cervical cancer at young ages continue to experience high rates throughout their lives; in other words, a birth-cohort effect is apparent. In a paper reporting these trends in 1986, Dr Brian Cox and I warned that, unless effective control measures were instituted, the numbers of New Zealand women developing and dying from cervical cancer would increase strikingly over the next few decades.²

10. The second reason for focusing on cervical cancer is that an effective control measure is available. We do not know how to prevent breast cancer, for example, but many cases of cervical cancer can be prevented through cytological screening.

The potential of cervical screening

11. The rationale for cytological screening is that detection and removal of pre-invasive lesions - commonly called cervical intraepithelial neoplasia (CIN) - can lead to the prevention of some cases of invasive cancer. The procedure depends on the availability of a suitable test for detecting pre-invasive abnormalities, together with the fact that progression from CIN to invasive cancer usually takes many years. A drawback of screening is that the majority of pre-invasive lesions actually would regress spontaneously; we cannot predict which ones are in this category, so many women must be offered unnecessary treatment.

12. Dr George Papanicolaou and others introduced cytological testing more than half a century ago, at a time when doctors did not appreciate the need to evaluate new medical procedures in experimental studies such as randomized controlled trials. As a result, cervical screening was introduced in many countries (including New Zealand) before its effectiveness had been demonstrated. Pointers to its effectiveness began to accumulate during the 1970s and early 1980s. The most convincing evidence came from studies in different Nordic countries, where staggered introduction and varying

population coverage achieved by screening programmes was followed by corresponding variations in cervical cancer incidence and mortality.

13. In 1986 a working group of the International Agency for Research on Cancer published an important analysis of data from 7 European countries and 3 provinces of Canada.³ The study confirmed the effectiveness of organised screening programmes. It also enabled comparison of the effects of different screening policies. Screening women every 3 years from ages 20 - 64 was estimated to have the potential to reduce the incidence of cervical cancer by 91%; annual screening offered little extra benefit, while with 5-yearly screening the reduction was by 84%.

14. These estimates apply only to the women who actually follow the screening schedule; even then, the estimates may be optimistic because of the limitations of the non-experimental studies on which they are based. Nevertheless, a study published in 1988 from Finland, a country where screening was repeated every 5 years, was able to estimate that the reduction in incidence due to screening was about 60 - 70%.⁴

15. Few epidemiologists today would question the effectiveness of cervical screening as a cancer control measure. Well-organised screening programmes have also been shown to be cost-effective (in comparison with many other health care interventions) and acceptable to the majority of women.

Characteristics of screening programmes

16. Screening programmes differ in fundamental ways from the usual processes of diagnosis and treatment. First, they involve approaching people who are apparently healthy and urging them to undergo a test. This means that those offering screening have a particular ethical obligation to ensure that the benefits outweigh the risks.

17. A second difference relates to the nature of screening tests, which need to be quick, cheap, and safe. A screening test is used to divide people into two groups: those likely to have the relevant abnormality (a positive screening result), and those unlikely to have the abnormality (a negative screening result). Further investigations are required for those with positive results, to determine whether they have the abnormality or not.
18. No medical test is perfect and, because of their nature, screening tests should never be expected to be as reliable as more elaborate investigations. Hence it is inevitable that some people with positive screening results will turn out not to have the abnormality; we say that their screening result was a “false positive”. Similarly, some people with negative screening results will actually be found to have the disease; their screening result is described as a “false negative”.
19. The terminology relating to cervical screening is potentially confusing, and I have sympathy for anyone new to this field. Part of the problem is that cytological diagnosis is not an exact science, and the diagnostic systems differ between countries and between time periods. The problem is compounded by the frequent use of acronyms, such as CIN, CIS, HGIL, ASCUS, and so on.
20. To avoid confusion, I would recommend that terms could be used in this Inquiry as defined in the Glossary (Appendix 1) of the Cartwright Report (1988) or, if not defined there, in the Glossary of the National Cervical Screening Programme Policy (Ministry of Health, 1996). These glossaries are attached as an appendix. They provide definitions for readers without detailed medical knowledge; I have reviewed them and consider that they are still appropriate.
21. Another aspect of the problem is that some of the concepts used in evaluating screening are actually quite difficult. I shall focus on the concept of the “false negative rate”, because it is crucial to this Inquiry and frequently misunderstood - even by

professionals involved in screening.

22. The Glossary of the Cartwright Report defines the sensitivity of a test as “the proportion of all people who have the disease who are correctly identified as such by the test”. This is sometimes called the “true positive rate”. Of course anyone with the disease who is not identified by the test must be a “false negative”. Hence the “false negative rate” is equal to one minus the sensitivity. Often both values are multiplied by 100 and thus expressed as percentages. A test with a sensitivity of 80% would have a false negative rate of 20%.

23. A related concept is the specificity of a test, which is “the proportion of all people who do not have the disease who are correctly identified as such by the test”. This is sometimes called the “true negative rate”. The “false positive rate” is equal to one minus the specificity. A test with a specificity of 95% would have a false positive rate of 5%.

24. The main purpose of cervical screening is to detect pre-invasive lesions, which usually produce no symptoms. In order to measure directly the sensitivity and specificity of the screening test, one would need to obtain biopsies of the cervix from all women at the same time as taking the cervical smear. Clearly this would not usually be logistically or ethically feasible. Hence various indirect approaches have to be used to estimate sensitivity and specificity. I suspect that the different approaches used may account for part of the large variation in estimates of false negative rates that are cited.

25. While everyone strives to keep them to a minimum, false negatives and false positives will inevitably occur - with any medical investigation, and especially with a screening test. It needs to be emphasised that error by a pathologist (or cytological screener) is only one of the possible reasons for a false negative cervical screening test. Other reasons may be that the smear was not taken adequately or that, even though the smear was taken correctly, no abnormal cells were included. There are inherent limitations

- of the test, quite apart from the frailties of the professionals involved.
26. In most cervical screening programmes today, false negative results are not the main reason for failures of screening to prevent cancers from occurring. Much more important factors are failure to screen women at risk - either at all, or often enough - or failure to take appropriate action in response to abnormal results.
27. It is important to recognise that, as the screening coverage of the population improves, the proportion of cancers occurring in women who have been screened (with false negative results) will increase.
28. It may seem paradoxical that, as a population-based cervical screening programme becomes more effective - with a consequent reduction in the number of cancers - the proportion of false negatives will increase. Consider the analogy of cigarette smoking and lung cancer. Let us assume that 90% of lung cancers in our society at present are attributable to smoking. As we persuade people not to smoke, the number of lung cancers will decline but the proportion that involve non-smokers will increase. This should lead no-one to doubt that avoidance of smoking reduces the risk of lung cancer. Yet critics of screening sometimes point to the occurrence of cancers in women who have been screened recently, in the mistaken belief that this demonstrates that screening does not work.
29. As pathologists and their staff strive to avoid false negatives, there is a danger that the proportion of false positives will increase. In other words, there may be a trade-off between the false negative rate and the false positive rate. In 1995 *The Lancet* invited me to write a Commentary⁵ to accompany a paper from Bristol,⁶ in which the authors reported excessive diagnosis of smear abnormalities. Overdiagnosis not only wastes resources, by leading to unnecessary procedures, but also increases the number of women who have to experience the grief of believing that they may be developing a potentially fatal illness.

30. The authors from Bristol attributed their overdiagnosis to fear of litigation or pillory by the media. They wrote:

“In the past 10 years there have been well-publicised incidents related to reading of smears and many threatened court cases. If a smear shows anything that an expert witness could in the future claim to be a missed abnormality, then the safest thing is to err on the side of caution. The desire to avoid overdiagnosis, which in the past kept the detection rates low, has now been outweighed by the need to avoid any possibility of being held responsible for missing a case.”

31. The Bristol group had become generally pessimistic about the value of screening, and I questioned the scientific grounds for several of their conclusions. But I was impressed by their account of living in a state of fear of being blamed for failing to prevent cases of invasive cancer.

32. Clearly such an atmosphere, which will inevitably be to the detriment of women who participate in screening, is more likely to arise if there have been unrealistic claims about the benefits. Women may sometimes have been given the impression that, if they participate in regular screening, they can be assured of not developing cervical cancer. Even with the most effective programmes, that is not the case.

33. The atmosphere described could also be engendered by formal inquiries such as this one, together with all the media publicity and potential litigation that surrounds it. No-one would dispute that steps must be taken to protect women from any incompetence or negligence on the part of health professionals. Such problems should be detected and addressed routinely, however, as part of the regular monitoring of the screening programme.

34. Whatever is determined about the practice of Dr Bottrill, the fact that this Inquiry

needs to be held points to a failure on the part of the screening programme. This is a separate issue from the failure or inability of those involved in disciplinary proceedings to consider the safety of other patients apart from the original complainant whose management was reviewed.

Cervical screening in New Zealand

35. The first efforts to introduce systematic cervical screening in New Zealand were made by general practitioners during the 1960s. These organised initiatives were short-lived, and screening tended to be applied in a sporadic and piecemeal fashion over the next two decades. Scepticism among doctors about the value of cervical screening persisted longer here than in most countries, because of circumstances at the National Women's Hospital which were documented in the Cartwright Report.

36. In 1984 the Department of Health and the Cancer Society asked a working group to make recommendations on cervical screening. This group (which I chaired) published its report in the *New Zealand Medical Journal* in 1985.⁷ We concluded that there was now "compelling evidence that cytological screening is an effective preventive measure", and made recommendations for routine screening.

37. In 1987 the Cancer Society published a professional bulletin in which Dr Charlotte Paul summarised the recommendations and offered guidelines for screening programmes in general practice. Many general practitioners established very good systems for inviting and recalling their own patients for screening, but calls for a population-based screening programme were not acted on by health authorities.

38. In the Report of the Cervical Cancer Inquiry (1988), Judge Cartwright recommended that a nationally planned population-based screening programme should be implemented urgently. This galvanised the Department of Health into action, but sadly

several of Judge Cartwright's key recommendations were ignored. These included the need for full consultation with consumer groups and relevant health professionals. In fact a computer consultancy firm was hired to develop proposals for the programme.

Planning continued behind closed doors, and both medical organisations and consumer groups expressed concerns about the direction of the scheme.

39. In 1989 I wrote a leading article for the *New Zealand Medical Journal*, entitled: "How not to organise a cervical screening programme".⁸ Apart from the lack of consultation, I was concerned about the plan to require women to give written consent for information to be placed on the cervical screening register, rather than providing them with the right to opt out of the programme. I predicted that millions of dollars could be wasted on a complex but incomplete computer system that would probably achieve little.

Unfortunately this proved to be the case, until an "opt-off" register was implemented from 1993 onwards.

40. In the meantime the Minister of Health, Helen Clark, had responded to some of the concerns by establishing a Ministerial review committee and then (in December 1989) an Expert Group to advise on policy and oversee the implementation of the National Cervical Screening Programme (NCSP). The NCSP was implemented following the appointment of the first national coordinator, Gillian Grew, in June 1990.

Perspectives on the National Cervical Screening Programme

41. The first decade of the NCSP has coincided with a period of unprecedented turmoil in the New Zealand health system. Few major health initiatives in New Zealand have an uncomplicated birth, but the NCSP has had to contend with an almost constant process of organisational change. That it has survived at all is a remarkable feat, which probably reflects the high political sensitivity of the subject.

42. I understand that other witnesses will give detailed accounts of the NCSP. I have not been involved directly (except while Chairman of the Public Health Commission), although several of my colleagues have played significant roles. I will therefore confine myself to some limited perspectives that have a bearing on the present Inquiry.
43. My first point is that, despite many false starts and interruptions, the NCSP has achieved a great deal. There is now a much greater awareness among women and health providers of the need for cervical screening; a high proportion of the population at risk have been screened and included on the register; access has been improved by involving a wider variety of health workers in screening; and guidelines have been developed for taking smears and for dealing with women who have abnormal results. The whole system is under-pinned by numerous dedicated staff at the local level.
44. Secondly, improvements in cervical screening before and since the establishment of the NCSP already appear to be saving many women from serious illness and premature death. I have already mentioned the unfavourable birth-cohort trend that was noted in the 1980s. In 1992 Dr Brian Cox and I published projections of cervical cancer mortality and incidence in New Zealand over the next two decades.⁹ It was clear that both mortality and incidence rates would increase if screening services were not improved.
45. In absolute terms, the projections indicated that the then current 100 deaths per year could increase to about 148 deaths per year, while there could be a much larger increase in incidence from 235 new cases per year to about 440 per year. Such estimates are inevitably imprecise, but it was concluded that plausible improvements in cervical screening were likely to be accompanied by only small changes in the burden of cervical cancer; if screening services were not improved, on the other hand, there would be striking increases in both mortality and incidence.

46. In the event, the numbers of deaths and new cases of cervical cancer have both declined during the 1990s. In 1997 there were only 73 deaths from cervical cancer, the lowest number (and mortality rate) for at least half a century. In 1995, the latest year for which incidence data are available, there were 231 women registered with cervical cancer. In terms of mortality, we have already achieved a public health target set for 2005. The decline in mortality and incidence rates is believed to reflect improvements in cervical screening since the mid-1980s.

47. The largest reduction in the incidence of cervical cancer during the 1990s has been among Maori women. Nevertheless, much more work needs to be done to close the gap between Maori and non-Maori.

48. Given the recent achievements of cervical screening in New Zealand, we must hope that the present Inquiry does not damage confidence in the NCSP to an extent that women or health providers reduce their commitment. Of course this does not mean that we should fail to address any deficiencies or ways in which the scheme could be improved.

49. Several laboratory advisory committees have advised the NCSP, and I expect that other witnesses will describe the advances that have occurred in the training of laboratory staff, accreditation of laboratories, and participation in external quality assurance programmes. Certainly these aspects have improved immeasurably from the general situation described at a meeting I attended in Wellington in November 1985. In the published proceedings of that meeting,¹⁰ there was a brief reference to the particular problems of small laboratories. One of the speakers asserted that, in some smaller centres, “staff are inadequately trained and/or supervised and to a large extent are unsure of what they are doing”.

50. At the time of the discussions of our working group in 1984 and 1985, the point was often made that several New Zealand laboratories were examining far smaller

numbers of smears than would be regarded as adequate according to some overseas standards. It is believed to be very difficult to maintain high quality cytological practice under such circumstances. After the passage of 15 years, I am surprised that those responsible for the NCSP have not grasped the nettle and dealt with this problem.

51. Cervical smears are easily transported by courier. I am aware of one Dunedin laboratory that processes smears from Otago, Southland, Canterbury, the Kapiti Coast, Wanganui-Manawatu, and the Hawke's Bay. Although I would not go as far as those who advocate dedicating only one laboratory for the whole programme, I would question the wisdom of having smears examined in about 20 separate laboratories.

52. Another disappointing aspect of the NCSP has been its inadequate investment in research and evaluation. Perhaps this is typical of the New Zealand health system, and indeed of our society as a whole. When one urges apparently healthy people to undergo a medical procedure, there is surely an obligation to monitor the quality of the process and the outcomes achieved.

53. There have been repeated calls for better evaluation of the NCSP, but too little action. For example, the Ministry of Health issued a request for proposals for development of an evaluation plan in August 1996. A group was contracted in January 1997 to prepare the evaluation plan; after wide consultation they submitted a detailed plan in May 1997; yet only recently have some limited parts of this evaluation been started.

54. Better procedures for evaluation could have drawn attention to any major problem in Gisborne many years ago, when remedial action could have been taken. Consider, for example, these recommendations in a 1994 report from the Cervical Screening Advisory Committee on Monitoring and Evaluation:

“False negative reports need to be defined and ascertained. The rates of discordant

histology/cytology results need to be ascertained and these need to be reported.”

“It is possible to identify the number of women with cervical cancer who are on the NCSR. The committee has recommended this be undertaken (see Appendix 3, 1.16) along with a review of their screening history, as a matter of urgency. Such a review should include all cases of cervical cancer, not only those on the NCSR. This should be done on an ongoing basis as cases are diagnosed.”

55. As I have already mentioned, there are only about 200 new cases of cervical cancer in New Zealand each year. It should not be a difficult task to review these cases; to find out whether or not they were screened; whether the smears were reported as normal; or whether there was a failure to respond adequately to abnormal results. Dr Keri Ratima, of Whakatohea, while a postgraduate student in our Department at the University of Otago, conducted such an audit of cervical cancer in Maori women throughout Aotearoa. This was published in the *New Zealand Medical Journal* in 1993.¹¹

56. Such an approach, applied as a routine, could have identified any major tendency for a laboratory to issue false negative reports that were leading to cases of invasive cancer. Moreover the advent of the national cervical screening register (NCSR) should have greatly facilitated such an exercise. Yet I have been told that the main reason for inaction is that lawyers advised that linking the Cancer Registry and the NCSR would contravene privacy legislation.

57. If this was the case, steps should have been taken to have the Health Information Privacy Code or other relevant regulations amended. The audit that I have described could be performed with strict safeguards for confidentiality, and I am confident that women would want such quality control. Unfortunately considerations of privacy are often used to reject proposals that would advance the public health. Professional health

researchers, in this country and overseas, have an impeccable record for maintaining confidentiality. Privacy is an important right but, considering issues such as avoidable failures of cervical screening, one wonders how many New Zealanders have to die for it.

The first term of reference

58. Turning now to the terms of reference for this Inquiry, I note that the first term of reference is crucial. Several of the other terms of reference depend on the determination as to “whether there has been an unacceptable level of under-reporting in consequence of mis-reading and/or mis-reporting of abnormalities in cervical smears in the Gisborne region”.

59. As an epidemiologist, I have wondered how this question will be addressed. As I have already made clear, some level of under-reporting (and over-reporting) is inevitable in any screening programme. What, therefore, is an “unacceptable level” of under-reporting?

60. Even to determine whether the level of under-reporting in the Gisborne region was higher or lower than the average is not a simple matter. Sometimes much is made of comparisons of the proportions of all smears that are reported by different laboratories as abnormal, or as showing high grade abnormalities. This is an extremely crude approach. First, it takes no account of the underlying prevalence of disease among the women who have been screened in different regions. This will be influenced by factors such as age, ethnic group, and socioeconomic status. Secondly, it does not indicate whether or not the diagnoses were accurate. I have no expertise in cervical cytology: however, if I were given a pile of slides and told that I was expected to report 1% as showing high-grade abnormalities, I am sure that I could oblige. The problem is that they would not be the correct 1%!

61. This hypothetical example illustrates why one should not over-state the concept of a trade-off between the false negative rate and the false positive rate. An incompetent pathologist might produce results with both a high false negative rate and a high false positive rate. In contrast, an expert might be able to keep both of these rates relatively low.
62. Another comparison has involved the results reported by the Gisborne laboratory and those reported by a Sydney laboratory after smears had been re-read. I presume that such re-reading was arranged for the sake of women who might need further investigation and treatment, rather than for any scientific assessment of the degree of under-reporting in Gisborne. While the results that have been announced certainly give cause for concern, they do not allow any firm conclusions to be drawn.
63. There is no a priori reason why we should assume that the results from Sydney are more reliable than those from Gisborne. Had the intention been to assess the performance of the Gisborne laboratory, it would have been preferable to send its slides to several other laboratories for comparison. Moreover, I understand that slides from other New Zealand laboratories were not sent to Sydney. If the results from Sydney were taken at face value, it might be concluded that under-reporting is a problem at most New Zealand laboratories.
64. It needs to be remembered that the purpose of cervical screening is to prevent invasive cancer, not merely to identify CIN in women who have no symptoms. I have already mentioned that the progression from CIN to invasive cancer usually takes many years. Since many cases of CIN will regress spontaneously, the ideal would be to diagnose CIN as late as possible in the natural history of the condition - at a time when it can still be treated effectively, without putting the patient at risk. Under-reporting of smear abnormalities that are indicative of CIN may betray poor performance as a pathologist, but the women who have been harmed are those who have gone on to develop

invasive cancer. As far as the others are concerned, one hopes that either their condition will have regressed to normal or their abnormality will be detected at the time of the next cervical smear. Hence I would argue that an “unacceptable level” of under-reporting is one that leads to a substantial number of cases of invasive cancer that could have been prevented.

65. In my view, the best way in which to assess the scale of the problem would be to conduct a retrospective study of cases of invasive cervical cancer in the Gisborne region. According to the National Cancer Registry, about 40 women in the Tairāwhiti area have been diagnosed with invasive cervical cancer since 1990. A review of the screening histories of these women would indicate how many developed their cancer despite the reporting of smears as normal. In such cases, the smears could be re-examined according to a scientific protocol.

66. In conjunction with Dr Ann Richardson, who is assisting the Inquiry, my colleagues and I have been exploring the feasibility of such a study. Assuming that it receives ethical approval, we believe that the investigation could be carried out fairly quickly. I hope that it might be possible to report its findings before the end of this Inquiry.

Professor David Skegg

Date

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