

CERVICAL CANCER INQUIRY

Second Brief of Evidence from Professor David Skegg

Introduction

1. My name is David Christopher Graham Skegg. This is my second brief of evidence for this Inquiry.
2. When I gave evidence on 1 - 2 May 2000, I discussed (from paragraph 58) the significance of the first term of reference: “To determine 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.”
3. I put a proposition 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. In order to assess the scale of the problem, I proposed a retrospective study of cases of invasive cervical cancer in the Gisborne region. A review of the screening histories of women who had developed invasive cervical cancer since 1990 would have indicated how many developed their cancer despite the reporting of smears as normal. In such cases, the smears could have been re-examined according to a scientific protocol.
4. Dr Ann Richardson, together with other colleagues and myself at the University of Otago, had presented an application for such a study to the Tairāwhiti Regional Ethics Committee. A copy of this document was produced as Exhibit DCS/CA/001. I suggested that, assuming the study received ethical approval, it could be carried out

fairly quickly. I hoped to be able to report the findings before the end of the Inquiry.

Correspondence with the Ethics Committee

5. Dr Richardson and I met with a “Fast-Track Committee” of the Tairāwhiti Regional Ethics Committee on Wednesday 3 May 2000 (the day after I completed giving my evidence at the first session of the Inquiry). This was an opportunity to discuss some reservations that had been expressed by the full Ethics Committee at its regular meeting on 28 April.

6. During the course of the meeting I gained the impression that there was some scepticism among the Committee members as to whether the study proposed by Dr Richardson and me might potentially be of importance to the Inquiry. The attitude of at least part of the Committee seemed to be that the investigations being carried out by the Health Funding Authority (HFA) would provide a fully adequate basis for dealing with the first term of reference, so that our study was not really essential. In addition concerns were expressed about Dr Richardson’s role in the proposed study (I refer to this again later in this statement), and about the fact that none of the proposed investigators was based in Gisborne.

7. I was surprised that our proposal was seen as being in some way superfluous to the HFA review. At the time I was not aware that one of the four members of the Committee (Ms Marie Burgess) has been closely involved in a re-reading exercise

carried out by the HFA. I subsequently learned that Ms Burgess was responsible to the HFA for the collection of slides in Gisborne and getting them sent to the Sydney laboratory for re-reading.

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9. The main issue that was raised by the Committee, however, related to access to information from the National Cervical Screening Register and access to the medical records of women who had developed cervical cancer.

10. A potential legal barrier to obtaining access to the National Cervical Screening Register had been discussed during my cross-examination at the Inquiry on 2 May. As I had responded at that time, Dr Richardson and I explained to the Fast-Track Committee that our study would still be possible without access to the National Cervical Screening Register. This is because the relevant information could be obtained from the records of general practitioners and other smear-takers, hospitals, and pathology laboratories.

11. In our application to the Ethics Committee, we had proposed not to approach the women directly, but rather to base the audit on cervical screening records, and medical and laboratory records. We submitted that such disclosure of health records about identifiable individuals would comply with Rule 11 of the Health Information Privacy Code. This provides that disclosure is allowed provided that it is either not desirable or not practicable to obtain authorisation from the individual concerned and that one of a number of other conditions is met. One of these conditions may be that

the information is to be used for research purposes and will not be published in a form that could reasonably be expected to identify the individuals themselves.

12. We explained that we considered that it was not practicable or desirable to approach the women with cervical cancer. Since their diagnosis was made up to 10 years ago, some would have died and others would be untraceable. If consent was not obtained from every individual, the sample would be incomplete and subject to bias. (Suppose, for example, that information could be obtained about only 30 of the 42 patients who developed cervical cancer. It would then be difficult or impossible to draw any firm conclusions relating to the first term of reference.)
13. Dr Richardson and I also stressed the limited time available for the audit. We left the meeting on the understanding that we would be notified of the Committee's decision in due course.
14. I produce copies of the correspondence that has subsequently taken place with the Ethics Committee as follows:
 - (a) On 5 May 2000 the Committee wrote to us to say that it was seeking independent advice. I produce a copy of the letter as DCS/CA/0014. I note that the advice was not made available to either Dr Richardson or me before we received the Committee's decision.
 - (b) On 12 May 2000 the Committee wrote again. I produce a copy of the letter as DCS/CA/0015. The Committee indicated that it was of the unanimous view

that consent of the women concerned would be required to access information through the National Cervical Screening Register, and to access their personal medical records. With respect to the first of these, as I have said we had explained at the meeting that access to the Screening Register details was not absolutely necessary for the study to proceed. With respect to the second, the requirement for written consent from each of the proposed subjects of the study meant that for practical purposes the study could not be completed, and certainly not in time for the results to be of use to the Inquiry.

There is a reference in the letter to the fact that one woman involved had “previously declined access”. I do not know what the basis of this assertion is. Certainly neither Dr Richardson nor I (nor, as far as I am aware, anyone else associated with our proposed study) has ever approached any of the women that might be involved. I can only assume that the Committee was referring to someone who had been approached in relation to a different study of some sort.

Finally, the Committee’s letter referred to its “disquiet” in relation to Dr Richardson’s role as lead investigator in the proposed study while she also held the position of “... Medical Adviser to the Committee of Enquiry (sic)”

- (c) On 19 May 2000 there was a follow-up letter from the Committee, a copy of which is produced as exhibit DCS/CA/0016. In effect the letter confirmed the decision requiring informed written consent. Again Dr Richardson’s position was referred to. The Committee continued to express disquiet in relation to

her “dual” role. The whole purpose of the study was to obtain information that might assist the Inquiry in meeting its obligations. I thought that this would have been clear to the Committee from our application and during the meeting we had on 3 May.

In any event, as a result of the Committee’s insistence on the matter, Dr Richardson and I asked Mr Hindle as Counsel Assisting the Inquiry to reply to the Committee on our behalf.

- (d) Mr Hindle did so on 23 May 2000. I produce a copy of his letter as DCS/CA/0017. A further letter was sent by Mr Hindle to the Committee on 16 June 2000. I produce a copy of that letter as DCS/CA/0018.

- (e) The Committee replied on 16 June 2000. A copy of its letter to Mr Hindle is produced as exhibit DCS/CA/0019. A copy of its letter of the same date to Dr Richardson and me is produced as Exhibit DCS/CA/0020. The letter to Dr Richardson and me had with it a copy of a letter the Committee had received from the Minister of Health (DCS/CA/0021), as well as a copy of Mr Hindle’s letter to the Committee dated 23 May 2000 (DCS/CA/0017).

The Committee’s letter refers to advice from Professor David Seedhouse. The Committee has now asked that we (Dr Richardson and I) clarify Mr Hindle’s status in relationship to the proposed study.

(f) A copy of Mr Hindle's response to the Committee's letter is produced as exhibit DCS/CA/0022.

(g) Subsequently the Committee replied to Mr. Hindle on 30 June 2000, a copy of which is produced as exhibit DCS/CA/0023.

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16. In the result, however, the decision has been that written consent must be obtained from each of the proposed subjects of the study before the commencement of the research. The Committee has also required to see and approve the format of a written information sheet and consent form, which it would have been prepared to consider at a meeting on some date after 7 June 2000 (refer exhibit DCS/CA/0016).

Implications of the Ethics Committee decision

17. On 26 May I consulted the Director-General of Health, Dr Karen Poutasi. In her reply dated 31 May 2000 (a copy of which is produced as DCS/CA/0024), she advised that the Ethics Committee must approve access to individual medical records. There was no ability for the Minister of Health to intervene in this matter. For completeness I also produce a copy of my reply to the Director General as exhibit DCS/CA/0025.

18. After consultation with the Counsel Assisting the Inquiry, we regretfully concluded that there was no possibility of completing any adequate audit within a time-frame that would be helpful to this Inquiry. It is worth emphasising that the real value in the study we proposed could only come from a careful analysis of all relevant medical

records.

Continued failure to audit the National Cervical Screening Programme

19. The difficulties that we have encountered may seem surprising, since the proposed audit would be a routine component of quality control in many countries. In her evidence to the Inquiry, Dr Euphemia McGoogan explained that in Scotland there is “a public health audit of the women who develop invasive cancer” (8 May 2000, page 1121, line 8).
20. In my first brief of evidence, I was critical that earlier proposals for such evaluation in New Zealand had not been acted upon. 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. Hence the situation that appears to have developed in Gisborne could have been detected at an early stage.
21. A group had been contracted in January 1997 to prepare an evaluation plan for the National Cervical Screening Programme (NCSP), and they submitted a detailed plan in May 1997. When I first gave evidence, I was critical of the fact that only recently had some limited parts of this evaluation been started.
22. Regrettably I must report that even this limited project has faltered. The team that has been commissioned by the Ministry of Health to undertake this work is based in our Department at the University of Otago. Their application to proceed was received by the Otago Ethics Committee by 18 November 1999. Seven months later, ethical

approval for the review of invasive cancer cases has still not been granted.

23. I believe that the continued failure to monitor adequately the quality of the NCSP is entirely unacceptable.

24. When I last gave evidence I referred to legal advice dealing with the question of the limitations on access to information from the National Cervical Screening Register. I mentioned this in paragraph 56 of my first brief and again at page 912 of the transcript (2 May 2000). I received a copy of this advice in my capacity as Head of the Department responsible for the evaluation of the NCSP. I now produce it as exhibit DCS/CA/0026.

Submission

25. As a result of these circumstances (and my general experience), I wish to make the following submission to the Inquiry Panel.

26. Unfortunately the problems I have described are not isolated or unusual incidents. Unless such problems can be resolved, it could be argued that New Zealand should consider abandoning national programmes such as those for the control of cervical cancer and breast cancer. It seems unethical to exhort apparently healthy people to undergo medical procedures, when adequate steps cannot be taken to monitor the quality of the process or the outcomes achieved.

27. Over recent years I have continually heard of public health research projects that could not proceed because of privacy considerations.
28. The Privacy Commissioner has sometimes expressed exasperation about misuse of the Privacy Act in order to block steps that are in the public interest. In fact the Privacy Act asks the Commissioner to have “due regard for the protection of important human rights and social interests that compete with privacy”, in the exercise of powers under the Act. The Privacy Act makes specific exemption from the restriction on disclosure of information when the disclosure is for research purposes. Furthermore the Health Information Privacy Code, 1994, includes specific provisions for disclosure for research purposes, including that an ethics committee has approved the research. In the commentary to the Code, the matters which an ethics committee might need to address are outlined. The Health Research Council of New Zealand has also developed guidance notes for researchers and ethics committees on the interpretation of the Code.
29. Thus the law in New Zealand already provides for the public interest to be taken into account in research involving health information. The basic problem seems to be that ethics committees tend to take a highly restrictive view regarding the use of health information for research. This has the effect of preventing many initiatives that could benefit the public health.
30. Health researchers who are doctors or nurses have strict professional obligations to maintain confidentiality. Other health researchers also have an impeccable record in this regard. Indeed I am not aware of a single breach of confidentiality that has

occurred during any research project. Hence proposals that have been properly assessed by ethics committees should pose no material risk of any breach of confidentiality.

31. Despite this consideration, it must be admitted that there is a small loss of privacy or autonomy when it is decided that it is either not desirable or not practicable to seek specific consent from individuals for the use of medical records. The key question is: how important is that small loss of privacy, when balanced against the health and well-being of our fellow citizens?

32. Sir Douglas Black, who chaired a British working group on confidentiality of health records, commented that this “is a subject in which autonomy and beneficence clash head on”.¹ He continued: “Not once but many times I learnt that absolute autonomy, as advocated by the self appointed proxies for patients, is a veritable boomerang, though it is a perverse one in that it damages not the proxies but present and future patients.”

33. Most New Zealanders are aware that our health expectations have fallen behind those of many developed countries. The fact that New Zealand women are reported to have the sixth highest death rate (adjusted for age) from all cancers combined, out of 173 countries, is a vivid example.² Our capacity to solve these problems will be partly limited by economic factors: New Zealand is now poorer than some of the countries with which we like to compare ourselves. But why do we make privacy considerations a further barrier to developing and maintaining health services of an international standard?

34. Ethics committees often make a distinction between audit and research. They accept that some forms of audit are unavoidable, but do not make a similar allowance for research involving health records. In fact, however, the ethical principles would appear to be the same. In both cases there is no risk to the individual, apart from a small loss of privacy, while the benefits will apply to other patients or citizens.
35. Even audit is considered by some to be acceptable only if it is carried out by the “care-givers”. This may be practicable within one general practice or hospital service, but how then could one audit a screening programme (as in the Tairāwhiti region) or services over a wider sphere?
36. If we confine audit or evaluation to care-givers, the substandard parts of our health system will continue to be undetected. As a hypothetical example, consider the treatment of breast cancer. According to a recent report from the Ministry of Health, New Zealand women have the second highest death rate from breast cancer out of 22 OECD countries.³ I believe that a partial explanation for this state of affairs could be that, because of the piecemeal organisation of treatment services, some women are not receiving the benefits of advances in breast cancer treatment. It would hardly be realistic to expect the “care-givers” themselves to identify these deficiencies, and indeed only an evaluation involving many care-givers could provide the information that is needed. Yet no-one is likely even to propose such an audit of breast cancer treatment in New Zealand, because access to the required health information would not be approved.

37. While privacy and autonomy are important considerations, I do not believe that most New Zealanders would consider that they should always over-ride the interests of their fellow citizens. Unless there is some reconsideration of the balance between privacy and the health of the community, I have no confidence that the kinds of problems that led to the present Ministerial Inquiry will be any less common in the future.

Professor David Skegg

Date

REFERENCES

1. Black D. Access to records for epidemiological research. British Medical Journal 1992; 304: 987.
2. International Agency for Research on Cancer. GLOBOCAN 1: Cancer Incidence and Mortality Worldwide (computer package). Lyon: International Agency for Research on Cancer, 1998.
3. Ministry of Health. Cancer: New Registrations and Deaths 1995. Wellington: Ministry of Health, 1999.