Chapter 11

A SUMMARY OF FINDINGS AND RECOMMENDATIONS

TERM OF REFERENCE ONE

Whether, as alleged in the 'Metro' article, there was a failure adequately to treat cervical carcinoma in situ (CIS) at the National Women's Hospital, and if so, the reasons for that failure and the period for which that failure existed.

1.a **Adequate treatment** of carcinoma in situ is that which is based on generally accepted treatment together with evidence of eradication of the disease. The aim of treatment from the mid-1950s to the present has always been to achieve this, and where there has been a recurrence of the disease, to repeat the treatment. By this standard, there has been a failure adequately to treat a number of patients with cervical CIS at the National Women's Hospital. The outcome of treatment for the majority of women has been adequate, although a significant number were not managed by generally accepted standards over a period of years. For a minority of women, their management resulted in persisting disease, the development of invasive cancer and, in some cases, death.

Follow-up. Any woman who has received a diagnosis of CIS must be treated with the aim of eradicating the disease and must have her condition monitored for life, initially by the hospital or gynaecologist who is responsible for her management and then, when appropriate, by the general practitioner of her choice. These women must be advised of the nature of their condition and of their responsibility to ensure that they have regular smear tests and examinations.

Their general practitioners must be given the same information. Forms currently used for follow-up need redrafting so that the patient and/or her general practitioner receives and sends accurate information.

1.b The reasons for this failure to treat adequately were:

(i) The implementation of the procedures advocated in the 1966 trial.

(ii) Failure to recognise the dangers for patients when procedures were adopted which did not comply with generally accepted standards of treatment at that time.

(iii) Failure to evaluate adequately the risks to patients if the hypothesis on which the 1966 trial was based (that carcinoma in situ is not a pre-malignant disease) was incorrect.

(iv) Failure to note the rising incidence of invasive cancer among the patients included in the trial; and failure to stop the trial and treat the patients as soon as cogent evidence of this risk began to emerge.

(v) Failure on the part of some colleagues and the administration to impinge on clinical freedom and act decisively in the interests of patients' safety.

(vi) Failure to take account of the patients' cultural, social and emotional needs, as well as their physical symptoms of disease, in planning a trial that would lead in some cases to many years of monitoring without definitive treatment.

(vii) Failure to ensure that specialist staff worked as a diagnostic and clinical team.

(viii) Mediocrity of standards and care in some clinical areas and, in particular, in the standard of information offered to patients.

1.c The period for which that failure existed began in the mid-1950s, rising to a peak in the late 1960s and early 1970s, and diminishing from that point. There are still cases to be found where there is inadequate treatment or management.

TERM OF REFERENCE TWO

Whether, as alleged in the 'Metro' article, a research programme into the natural history of CIS of the genital tract was conducted at the National Women's Hospital and, if so:

a) Whether it was approved by any person or body before it was instituted or while it was underway; and

b) Whether patients examined or treated in the course of the programme were aware that they were participants in a research programme?

c) Whether any expressions of concern about the programme were considered and investigated at the time, and if so, by whom?

2.a There was one major research trial (known in this report as the 1966 trial) into the natural history of carcinoma in situ of the genital tract, and some supplementary trials, namely, vaginal swabs in neonatal (newborn) female infants and a study of the histology of fetal cervices from aborted and stillborn infants.

The 1966 trial was discussed and informally approved by the Senior Medical Staff and then formally approved by the Hospital Medical Committee on 20 June 1966. The supplementary trial which involved vaginal swabs of newborn babies was approved by a full staff meeting at National Women's Hospital on 21 October 1963. The other supplementary study on the histology of fetal cervices was not formally approved.

2.b The great majority of patients did not know, except intuitively, that they were participants in the 1966 trial. The formal consent of the parents of the 2244 newborn babies who were swabbed was not sought. No formal consent from parents, or scientific or ethical assessment, was sought for the study of fetal cervices.

2.c From 1966 to 1987 there were many and varied expressions of concern about the 1966 trial, both within New Zealand and overseas. The trial was reviewed by the Hospital Medical Committee in 1975, but not formally ended. Some health professionals expressed concern about the vaginal swabbing of newborn babies. That study was abandoned shortly after it began in 1963. However, the taking of vaginal swabs continued until 1966. The study of fetal cervices began in 1964 and was abandoned around 1967. I have no evidence that any concern was expressed about this study.

TERM OF REFERENCE THREE

Whether there is a need to contact women who have been referred to or treated for CIS at the National Women's Hospital with a view to providing further advice or treatment or both to them?

3.a The names of 123 women have been reported to the Minister of Health starting in September 1987 and concluding in June 1988. This list included some women with microinvasive disease. Suggestions to assist follow-up treatment or advice have been made. They include recommendations concerning cultural, social, emotional and medical matters. I have reported that a special duty is owed to these women who must be offered optimal management.

TERM OF REFERENCE FOUR

Whether the procedures observed at the National Women's Hospital for the approval of research and/or treatment and for its surveillance are adequate, and, in particular, whether they ensure that the rights of patients are protected?

4.a **Procedures observed at National Women's Hospital for the approval of research.**

The Ethical Committee at National Women's Hospital has operated for over 10 years. Most research conducted at the Hospital during that period would have been assessed by it. Many projects funded by independent groups will also have received ethical approval from that Committee. In the main, those projects will have been scientifically assessed independently of the Ethical Committee. Projects not so funded, appear not to have received adequate scientific assessment in all cases, and the Ethical Committee lacks proper procedures for ensuring that this is undertaken.

The Committee has a poor record for ensuring that informed consent to inclusion in a trial is properly sought, and lacks the appearance of impartiality. Although it has recently increased its lay representation, it is heavily weighted with medically trained personnel. The Committee appears to have a limited understanding of ethical principles and their application to research projects.

4.b **Procedures observed for the approval of treatment.**

New treatment procedures are not systematically reviewed by the Ethical Committee but will be considered if put to it. Treatment protocols in gynaecological malignancy have not been developed systematically by the Hospital Medical Committee.

4.c **Procedures for surveillance of research or treatment.**

(i) Research: Few approved projects appear to be reviewed by the Ethical Committee. The publication of results is not encouraged or enforced.

(ii) Treatment: Peer review is almost non-existent except at an informal level. The Tumour Panel discusses difficult or unusual cases, but there is little other systematic, ongoing review of treatment.

4.d **The rights of patients.**

The lack of the systematic seeking of consent to inclusion in research or treatment (except for operative procedures) and the inadequate procedures for approval and surveillance of research and treatment, pose a serious risk to patients' rights.

TERM OF REFERENCE FIVE

What steps, if any, need to be taken to improve the protection of patients in respect of whom research and/or treatment is conducted at the National Women's Hospital?

5.a **Treatment**

(i) Treatment protocols for gynaecological disease should be developed and maintained. These protocols will provide the basis for communicating information to various health professionals and for verbal communication with patients.

Visual and written material should be prepared using the protocol as the starting point. This material will help the patient understand the need for screening for disease, the nature of her condition and the procedures she will be offered in managing it.

(ii) Significant shifts in treatment or management of gynaecological malignancy should receive both ethical and scientific assessment and approval.

(iii) In-hospital audit procedures should be encouraged and external audit of clinical standards seriously considered. Quality assurance programmes involving the patient should be developed.

5.b **Research**

(i) Scientific assessment of in-hospital research projects and ethical assessment for all research projects must be developed to meet modern standards. National Women's Hospital has not succeeded in developing and maintaining scientific and ethical standards and in achieving impartiality. The Auckland Hospital Board (or Area Health Board), under the supervision of the Director-General of Health, should develop one or more ethical committees for assessment of all research projects in its institutions. The Ethical Committee at National Women's Hospital should be disbanded.

(ii) General information on therapeutic or non-therapeutic research should be offered to all patients whose permission is sought for inclusion in a trial. Their written consent must be sought on all occasions when interventionist clinical or non-therapeutic research is planned. The consent of the guardian or guardians of any child to be included in similar trials must be obtained.

Information should be available in the first language of the person whose permission is sought, and adequate time provided to allow consideration or consultation with whanau or family. The patient advocate must be advised of all patients whose consent is being sought for inclusion in a trial.

5.c The system for protecting patients involved in research and/or treatment at National Women's Hospital has failed in significant areas. A system focused on the protection of patients and independent of the Hospital should be set in place.

(i) **The patient** or her near relatives should have access to:

(a) an advocate in the Hospital whose only duty is to protect her and to ensure that she receives full information and the opportunity to consent to all procedures in which she will be involved;

(b) the Medical Superintendent, as at present;

(c) a Committee of the elected representatives of the Auckland Hospital Board (or Area Health Board) and to the Board administration when she is concerned about a lack of information or has other concerns or grievances;

(d) the disciplinary body established pursuant to the Medical Practitioners Act 1968;

(e) a Health Commissioner appointed under the Human Rights Commission Act 1977.

(ii) **A patient advocate** responsible to the Director-General of Health should be employed at National Women's Hospital

(a) to ensure that patients who are included in research or teaching, or undergoing treatment, are protected;

(b) to help develop material for the information or, where appropriate, for the education of patients; and

(c) to provide the patient with a means of obtaining more information.

The patient advocate need not be employed full-time at National Women's Hospital. She should be an independent and powerful advocate for the patient. Her reports to the Director-General of Health should also be given to the Health Commissioner and to the Auckland Hospital Board. She should have the power to refer complaints to the disciplinary body established pursuant to the Medical Practitioners Act 1968,

to a Health Commissioner, or to the Hospital Board on behalf of a particular patient or class of patients. Before research involving patients is undertaken she must be informed of those who are to be included and afforded the opportunity to comment. Where possible, she should be a member of the ethical committee which assesses projects involving patients of National Women's Hospital.

(iii) **The Board.** Elected representatives to the Auckland Hospital Board (or Area Health Board) should take greater responsibility for the patients' welfare. They should ensure that the duty to safeguard the patients' health is the administration's paramount consideration at all times. The administrative and elected representatives of the Board should receive reports from time to time from the patient advocate and from the ethical committee assessing research at National Women's Hospital. Where appropriate, a sub-committee of elected representatives should have the power to seek further information from the ethical committee.

(iv) **The Human Rights Commission Act 1977** should be amended to provide for a statement of patients' rights and to provide for the appointment of a Health Commissioner. The Commissioner's role would include

(a) negotiation and mediation of complaints and grievances by patients;
(b) heightening the professionals' understanding of patients' rights;
(c) the entitlement to seek a ruling or sanctions from the Equal Opportunities Tribunal on behalf of a patient or class of patients.

The Commissioner should have the power to accept complaints from, or refer complaints to the patient advocate or the Board. The Commissioner should have access to the disciplinary procedures pursuant to the Medical Practitioners Act 1968. Adequate resources to service the increased work of the Human Rights Commission should be provided.

(v) **The Director-General of Health** should

(a) continue to give urgent consideration to the improvement of ethical standards in National Women's Hospital;
(b) monitor progress and encourage improvements in ethical committees by heightening the awareness of the importance of strong ethical principles in research and new treatment or management;
(c) ensure that the patient advocate role is reviewed and developed and that her independence from the administrative structures of the hospital is maintained at all times;
(d) ensure that lay representation on the ethical committee approximates one half of the membership; and
(e) encourage the development of better procedures for scientific and ethical assessment.

(vi) **The University of Auckland** should

(a) improve the teaching of ethical principles and communication skills at all levels of the medical degree;
(b) take some responsibility for encouraging community debate on medical ethical topics;
(c) ensure that academic staff members are encouraged to take part in ethical or scientific assessment committees;
(d) ensure that properly planned research is conducted at National Women's Hospital;
(e) acknowledge that the paramount consideration in teaching or research which involves patients is the welfare of those patients.

TERM OF REFERENCE SIX

Whether patients at the National Women's Hospital are properly informed of the treatment and options available to them and, if not, the steps that need to be taken to see that they are?

6.a Patients have not always been properly informed of the treatment and options available to them.

6.b **Steps that need to be taken:**

(i) There must be greatly improved communication with all patients and improved information available in the first language of those attending the Hospital for in-patient or out-patient treatment or management. Interpreters must be provided wherever possible. Development of visual formats to present information will greatly enhance communication with patients.

(ii) Prior written consent must be sought from patients

(a) for all procedures conducted under anaesthesic, be they for the benefit of that patient and/or for teaching purposes. No more than two students (present with the patient's consent) may participate in a vaginal examination on an individual patient;

(b) for significant departures from generally accepted treatment of gynaecological malignancy.

A written record should be maintained of a patient's refusal to undergo a recommended procedure, or of her choice from among options for treatment (based on generally accepted management procedures) and particularly where there are significant risks or benefits to her. Except in cases of serious emergency, the patient's autonomy and the right to participate in decisions concerning her treatment or management must be honoured.

(iii) Except in an emergency, verbal consent for procedures or a management programme should be sought from conscious patients after adequate information has been provided.

(iv) A statement of the patient's rights, including the right to have her consent sought to any vaginal examination or other invasive procedure under anaesthetic, should be enacted in an amendment to the Human Rights Commission Act 1977.

(v) Full information on patients' rights and responsibilities should be freely available to all patients of National Women's Hospital.

(vi) Sanctions including disciplinary measures should be set in place for failure on the part of a health professional to comply with these obligations to patients.

TERM OF REFERENCE SEVEN

7.a What training has been and is being given at the National Women's Hospital to medical students and medical practitioners in relation to the proper detection and treatment of cervical cancer and pre-cancerous conditions of the genital tract?

Teaching on gynaecological malignancy has largely been orthodox except where it concerns:

(i) The invasive potential of CIS.

(ii) The value of cytology and the need for a population-based cervical screening programme.

7.b Should steps be taken to improve this training, or to inform previous trainees about the proper detection and treatment of cervical cancer and precancerous conditions of the genital tract?

Teaching on these topics needs improvement, particularly:

(i) The significance of carcinoma in situ, its invasive potential, its incidence and its treatment.

(ii) The significance of microinvasive disease and its treatment.

(iii) Teaching students the importance of informing women patients about smear tests as a preventive health measure. Teaching should include the international evidence on the value of organised screening for 'at risk' women.

(iv) Practical teaching involving patients requires far higher standards, and should comply with standards which will protect the woman's dignity and treat her with humanity. Formal teaching throughout the undergraduate and postgraduate courses should include ethical concepts and improved communication skills.

There should be dissemination of:

(i) Information given to this Inquiry, including the views of patients on questions of consent, inclusion in teaching procedures or trials, their right to be involved in treatment or management decisions, and their right to be treated with dignity and humanity.

(ii) Information, to general practitioners in particular, on generally accepted views of the significance of carcinoma in situ as a cancer precursor and the importance of offering smear tests to all at risk women and in particular Maori women. The Royal NZ College of Obstetricians and Gynaecologists has a responsibility in this area, as has the Royal NZ College of General Practitioners.

(iii) The international and accurate New Zealand views of the value of population-based screening for cervical cancer and cancer precursors, so all medical practitioners have adequate information and will co-operate in a population-based programme.

(iv) This report, and the material accumulated from expert medical, ethical, diagnostic and cultural authorities, should be accessible to all health professionals in training.

TERM OF REFERENCE EIGHT

The nature of the relationships between the academic and clinical units at the National Women's Hospital.

8.a Relationships have been poor in the past and from time to time have contributed to the failure to put patients' health and welfare first. The structure for formal communication exists, but has not always been effective. More effective monitoring should be developed by the University of Auckland and by the Auckland Hospital Board (or Area Health Board) to ensure that the primacy of the principle of patients' welfare is observed.

TERM OF REFERENCE NINE

Any other matter which in your opinion is relevant to the detection and treatment at the National Women's Hospital of cervical cancer and precancerous conditions of the genital tract, or to the foregoing terms of reference or to both.

9.a **A nationally planned population-based screening programme** should be imple-

mented urgently. There should be full consultation with consumer groups, including women's health groups, the Ministry of Women's Affairs, the Health Department and all relevant health professionals to ensure that:

(i) Administrative problems are kept to a minimum.

(ii) Optimum numbers of women who are or have been sexually active are reached by the programme.

(iii) Cultural, privacy and financial considerations are taken into account, so that screening is acceptable and available to all women. Given the difficulties in establishing an efficient programme and the likely marked increase in numbers of women suffering from disease of the genital tract, this is an urgent priority.

9.b **A specialist oncology unit** with gynaecological oncology, radiotherapy and appropriate support staff and equipment should be developed at National Women's Hospital for the treatment of invasive cancer of the genital tract. Alternatively, all radiation therapy, both external and intra-cavitary, should be conducted at Auckland Hospital where specialist services exist. A gynaecologist should be available to assist in that treatment. There is inadequate liaison over patients' care between the two hospitals and lack of some essential specialist services at National Women's Hospital. Additional resources must be provided to the relevant hospital to develop or extend its oncology unit.

9.c **The histological and other material** held at National Women's Hospital, particularly that which resulted from the 1966 trial and its supplementary trials, should be available for properly planned and approved research and teaching.

9.d **Special duties are owed to:**

(i) All those women (123) whose names have been reported to the Minister of Health pursuant to Term of Reference 3.

(ii) Maori women who have a three times greater risk of contracting invasive cancer than other women in New Zealand.

(iii) All women in New Zealand who are or have been sexually active. Each year 200 women are diagnosed as having invasive cancer of the cervix and about 100 die of the disease. One in 80 women can expect to develop invasive disease before the age of 70. If present trends continue the incidence of this disease will rise and one in 28 women born around 1957 may contract the disease before the age of 70.

9.e **These duties can be discharged by:**

(i) Providing optimal medical and support facilities for those 123 women who may need further treatment and advice. The facilities must be independent of National Women's Hospital, if that is what these women wish. Colposcopic examination should be provided where necessary as should culturally and emotionally appropriate contact and support services.

(ii) Developing a programme in consultation with Maori women, which is sensitive to their needs, which will inform them of the nature of the disease and ensure that adequate screening, treatment and advice is readily accessible.

(iii) Disseminating clear and accurate information to the public through the media, general practitioners, Family Planning Clinics, the Ministry of Women's Affairs and by any other appropriate means about
   a) the nature of CIS and the nature and symptoms of invasive cancer
   b) the need for regular smear tests
   c) the need to co-operate in a nationwide screening programme.

(iv) Establishing a population-based screening programme.

(v) As a parallel measure, attention must be paid to ensuring that cytology, pathology and colposcopy facilities are able to meet an increased workload and that

a) **Cytology**
- a common nomenclature is developed for use by all New Zealand laboratories;
- training for cytotechnologists is developed;
- quality assurance programmes are developed;
- continuing education is encouraged.

b) **Pathology**
- more pathologists with expertise in both cytology and histopathology will be needed;
- more training positions for pathologists should be established to meet this demand and replace those retiring.

c) **Colposcopy**
- facilities for expert colposcopic examinations be expanded as a matter of urgency throughout New Zealand.

(vi) Appropriate training for those health professionals who treat disease of the genital tract to help them deal with seriously or terminally ill patients.