Chapter 6

TERM OF REFERENCE THREE

I am required to establish

> "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".

While this section of my report is my final account to the Minister of Health pursuant to Term of Reference 3, during the course of the Inquiry I made a number of interim and confidential reports. Those reports are confidential in that they identify individual women and the information is not, therefore, for public consumption.

Procedurally, it is unusual to make interim reports. It could be, and indeed was suggested that it would be, improper for me to form any conclusions and report to the Minister until my enquiries had been concluded. If the evidence and submissions had been completed in the original time span of two and a half months, that might have been possible.

The Inquiry created far more public attention than I had envisaged, more people wished to be heard and the amount of information which was put before me was so great that the initial time estimate was completely inadequate. When this became obvious, I began to consider the need to make interim reports under this Term of Reference to the Minister. I also considered that interim reports containing the names of all women who might need further advice or treatment would enable the Minister to establish procedures for their management before my formal report was published and turned public attention on them. These women are entitled to be treated or advised under conditions which guarantee confidentiality.

If my medical advisers had found no reason for concern about the treatment and advice that women had received when they reviewed the patient files I held, then I could have waited until completing this report. This, however, was not the case. As the information on treatment and advice to patients began to emerge at the hearings, there was some public pressure to begin making interim reports. Professor Richart, the first of the international medical experts to be heard, stressed this in a much publicised part of his evidence. In response to the proposition that patients with persisting disease should be recalled, examined and appropriately treated (a direct reference to his evidence which had criticised the adequacy of treatment procedures at National Women's Hospital) he said,

> *"I would recall them yesterday."*

Well before this, my three medical advisers had developed procedures for identifying any women who might need additional treatment. Although they, with their combined expertise, might be able to advise me on the most up-to-date treatment procedures and definitions of the disease CIS, it was necessary to ensure that the expert medical evidence was adequately explored before making any report to the Minister.

My advisers also confirmed that the delay of a few days or weeks was unlikely to be hazardous for any patient except in the most unusual circumstances. Very early on, two patients were identified as falling into that urgent category. Information on them was immediately given to the Minister and to the Auckland Hospital Board. With this exception, I deferred making further reports until I had heard the evidence of a cross-section of medical opinion.

After hearing the evidence of Professor Ralph Richart, Dr Joseph Jordan, Dr Ellis Pixley,

Dr Sadamu Noda and Dr Minoru Ueki and having read Dr Colin Laverty's brief of evidence, I formulated criteria against which the patients' files I held could be reviewed. These categories were:

1. Patients with persistent or recurrent abnormal cytology following treatment for CIS.
2. Patients who in the past have had a diagnosis of microinvasive carcinoma, and where there was some doubt about adequacy of treatment.
3. Patients whose last operative procedure showed incomplete excision and where there was some doubt about the possibility of ongoing disease.
4. Patients whose only treatment was punch biopsy.
5. Patients who had had treatment for invasive cancer.
6. Patients probably adequately managed, requiring only follow-up cytology.

Using these categories, Professor Eric MacKay, Dr Charlotte Paul and Dr Linda Holloway began classifying patients first from those who had received 'conservative treatment' and who were known as Group 2 in the McIndoe et al paper. Then all other patients with a diagnosis of CIS from 1958 to 1976 inclusive, were similarly classified, and the files of certain patients individually reviewed. The Minister received a list of names with identifying details and brief comments about each patient.

REVIEW OF FILES FROM 1977 ON

From the outset, it had always been possible that it would be necessary to review all files where a diagnosis of CIS had been made from 1977 down to the present time. A sampling of these files at first indicated that there might not be a major problem. My advisers and I had assumed that in more recent years management of patients with a diagnosis of CIS had altered markedly. There was a total of about 3000 files in this period. It was therefore necessary to be sure that the review was essential before committing resources to that end.

For a variety of reasons I asked my advisers to review these files. First, a number of patients whom I had interviewed privately demonstrated that there was cause for concern in more recent treatment and management procedures. Secondly, in the course of reviewing all cases with a diagnosis of microinvasion which had been excluded from the McIndoe et al paper, it became clear that treatment for some patients with microinvasion was very similar to that for some patients with CIS. Microinvasive disease cannot be safely managed in the same way as carcinoma in situ.

It was of great assistance in undertaking this task that, at the same time as advising the Auckland Hospital Board to recommend that the Minister of Health establish an Inquiry under the Hospital's Act, the Superintendent-in-Chief set in place a review of the case records at National Women's Hospital to identify any patients who "are neither discharged from care nor under follow-up".

Drs Jamieson and McIntosh reviewed the case notes of 3037 patients registered as having a pathological diagnosis of carcinoma in situ of the cervix at National Women's Hospital from January 1955 to December 1986. This information provided the base for a further review of all cases diagnosed from 1977 on. It also had the value of helping the Hospital identify those women who required further treatment, or who were lost to follow-up from the Hospital. I was told that immediate steps were taken by the clerical staff to begin tracing them.

In their initial review of the Jamieson/McIntosh information on post-1976 diagnoses of CIS, my advisers initially identified 251 cases where examination of individual files would be necessary. Following an examination of these files, they reported that many of those

women had already been located and procedures set in place to treat them. From this review, however, names of certain women diagnosed with microinvasive disease were reported to the Minister. From the review of files from 1958 to 1986 inclusive, 123 names were given to the Minister in interim reports, the first dated 23 September 1987 and the last, 10 June 1988. A summary of the manner in which the information was collated and the results of the review of all files may be found in Appendix 3.

WHAT ACTION IS NOW NEEDED?

My advisers have only had the opportunity of reading the files as they have been made available from National Women's Hospital. They have not reviewed the pathology or examined the patients. They have, however, carefully reviewed the notes. The time has come for these women to be located, examined, where necessary treated, and given appropriate advice which allows them to understand the nature of their condition and to co-operate in future treatment plans. I believe that the medical profession and I have a special duty to these women. In my opinion the following principles must be borne in mind when their cases are considered.

1. Locating the patient

Some of these women have lost contact with National Women's Hospital. In normal circumstances, I would accept that the patient shares a responsibility to ensure that she returns for treatment and advice. The responsibility cannot be said to rest solely with her doctor. In the present instance, however, there is a small group of women who lost contact with National Women's Hospital without ever having received adequate treatment for their condition. These women were being followed-up while continuing to have positive smears. I am concerned that they did not know they were included in a trial which involved withholding generally accepted treatment. They may be quite unaware that they are still at high risk.

There are also other women who, following treatment, can no longer be located. There is some uncertainty about the adequacy of their treatment or follow-up. So few of the women whom I have met have accurate information about their condition, or adequate information on which to base decisions about their own health care, that each and every one of these women must be located and given this information. I am hopeful that many of them will have received adequate information and definitive treatment at other hospitals.

2. Treatment

The best available treatment must be offered to this group of women. In his evidence, Dr Jordan set out criteria for follow-up of patients known to have had carcinoma in situ or microinvasive carcinoma in the past. He said:

a) *"All patients treated for carcinoma in situ and microinvasive carcinoma should have lifelong follow-up by cytology.*

b) *"Any patients with persistent abnormal cytology following treatment should be reviewed by colposcopy and cytology (to include an endocervical cytology specimen or endocervical curettage) with a view to intervention if persistent abnormality is suspected.*

c) *"Any patient who has been treated, has had negative follow-up cytology and subsequently develops abnormal cytology in the future, should be reviewed by colposcopy and cytology (to include an endocervical cytology specimen or endocervical curettage) with a view to intervention if a new lesion is suspected.*

d) *"If these procedures are already being adopted, then there is no indication to recall such patients for reassessment. Those patients who are not being followed in this way should be recalled.*

"Patients who have, in the past, had a diagnosis of microinvasive carcinoma —
All case records should be reviewed by the Hospital Authorities to assess first, if treatment has been adequate and is the patient thought to be free of disease, and second, is further intervention required.

"Patients with a histological diagnosis of carcinoma in situ and who continue to have positive cytology during follow-up —
These patients should all be reviewed, as a matter of urgency, by a colposcopist.

"Patients with a histological diagnosis of carcinoma in situ who were managed by punch biopsy and cytology follow-up —
The case records of all of these patients should be reviewed and if there is any suspicion that there may be ongoing abnormality, then the patient should be reviewed by a colposcopist.

"Patients with a histological diagnosis of carcinoma in situ who had post-operative abnormal cytology and were subsequently subjected to a second operative procedure which showed incomplete excision on the second operative specimen, of carcinoma in situ —
These records should all be reviewed and if there is any doubt about adequacy of treatment the patients should be recalled and reviewed by a colposcopist.

"Patients who had a second operative procedure because of ongoing abnormal cytology, and in whom excision of the lesion was shown to be complete at the second operative procedure —
These records should be reviewed and if there is any doubt about the possibility of ongoing disease, the patient should be recalled and assessed by colposcopy.

"Patients with a histological diagnosis of carcinoma in situ in whom the initial operative procedure showed incomplete excision of carcinoma in situ but who subsequently had negative follow-up smears —
These records should be reviewed and if there is any suspicion that the immediate follow-up period did not include colposcopy and adequate cytology, then the patients should be recalled.

"Finally, many women treated at the Hospital since the late 1950s will undoubtedly wonder if they are harbouring further disease. They should be reassured that there is no dispute about the adequacy of treatment in the majority of instances. But, if any women do have doubts, then they should be offered a consultation with a view to giving final reassurance."

Dr Jordan also stated, and I accept, that if there is any uncertainty over the follow-up of these patients, then they must be located and treated. If they have been discharged or there is uncertainty over follow-up arrangements, the responsibility is on National Women's Hospital to ensure that they are receiving adequate treatment elsewhere. I am aware that there is a heavy and mounting workload for cytologists, pathologists, colposcopists and gynaecologists. However, these women must be given priority.

3. Independent assessment

Some of these women may prefer to receive advice or treatment from gynaecologists who are not associated with National Women's Hospital. If this is so, their requests must be

honoured. More recent examples of delay in diagnosis and treatment of CIS and invasive cancer have led me to the view that independent review of treatment offered to these women at National Women's Hospital must be put in place. I am not confident that the standard of management offered is always of the highest order.

4. **Contacting the patient**

Many of these women will be disturbed to learn that they need follow-up treatment or advice. Some may be reluctant to co-operate in treatment because of the public controversy which has focused on the Hospital over the last year. Therefore they must be offered sensitive care. During the course of the hearings, I received a wide variety of suggestions on how this contact should be made. I accept the following general suggestions:

a) Any patient who requires follow-up treatment or advice must be contacted direct. Her general practitioner, where known, also ought to be contacted and advised.

b) Attention should be paid to ensuring that colposcopy facilities are available with skilled colposcopists, so that all women who require follow-up treatment have immediate access to a colposcopic examination.

c) Women's groups and Maori women with strong links to the Maori community should be asked to advise the Minister on various aspects of follow-up. Maori women in particular will need personal contact.

d) An appropriately trained counsellor or medical social worker should make the initial personal contact and should be available to those women who require further treatment or advice. Cultural considerations must be taken into account.

e) This group of women must have immediate access to their own files should they wish to read them personally or seek further specialist advice.

5. **Cases reviewed during the Inquiry**

During the course of the Inquiry the files of many NWH patients with a diagnosis of CIS or invasive disease of the genital tract were discussed. In some cases, the notes were reviewed and comment made by overseas authorities who gave evidence at the hearings. It is my opinion that any woman whose case has been discussed or reviewed by my medical advisers, should have the right to the information if she so desires. I have therefore arranged that a comprehensive list be prepared so that any patient may ask for a copy of comment made during the evidence. The Minister of Health and Commission offices each hold a copy of this list which includes the details of all women whose names have been reported to the Minister pursuant to this Term of Reference. The list includes details of women who have died of invasive cancer and who appear not to have received generally accepted treatment. The information is, of course, confidential and should be made available only to the woman herself, or on her authority to some other person or, if she has died, to a near relative.

6. **All other patients who have been treated for CIS of the cervix**

In addition to the women who require a review because of doubts about the adequacy of their treatment, I am concerned about all the other women who have been treated at National Women's Hospital for CIS of the cervix. Many of these women will understandably be anxious that their treatment may have been inadequate in view of the publicity given to this Inquiry and to my comments in this report. Moreover, there is evidence that some of these women and their general practitioners were not informed by the Hospital when they were discharged from the clinic that they must undergo regular, annual smear tests. The women also were not told that they need to know the results of the smear

and to ensure that some action is taken if those results were abnormal. I therefore recommend that all women who have had a diagnosis of CIS of the genital tract at National Women's Hospital receive written information about the nature of their condition and the need for follow-up smears.

7. Women who had CIS with microinvasion

Women who have had a diagnosis of CIS with microinvasion form a special category. These women should be told of their diagnosis as there is some evidence that they were not aware that they had early invasive cancer. The appropriate follow-up treatment and management must be explained to them so that they too can share the responsibility with their general practitioners or gynaecologist for their future health care.

8. Dysplasia

In the time available, my advisers have not attempted to identify those women who have received a diagnosis of mild or moderate dysplasia (CIN 1 or 2 in modern terminology). These are the abnormalities preceding CIS. Nor have they attempted to advise me on the adequacy of treatment of this group of women. Dr Holloway told me that the current assumption about dysplasia was that "the implication of the dysplasia – CIS terminology, is that only those lesions classified as the latter are at the doorstep of invasive carcinoma, and therefore dysplasia must progress to CIS before invasion of the stroma is imminent." She stressed, however, that present knowledge cannot allow a confident assumption to be made that dysplasia always progresses to CIS. Since there is that possibility, however, management of patients with the diagnosis of dysplasia must be carefully undertaken. A review of this category of patients and their management is recommended.

Patients referred to the Minister of Health pursuant to this Term of Reference

Period of first admission	Category	Number
1955-76	Persistent or recurrent abnormal cytology following treatment	20
	Patients with a diagnosis of microinvasive cancer and doubt about adequacy of treatment	13
	Only treatment punch or wedge biopsy	5
	Patients with incomplete excision and some doubt about possible ongoing disease	13
	Other special needs	17
	(Of these 68 referrals, 3 related to CIS vagina and 65 to CIS cervix)	68
1955-76	CIS vagina (additional case)	1
1977-86	CIS cervix	19
	Microinvasive cancer	32
1977-86	CIS vagina	1
1983-86	CIS vulva	2
	TOTAL	123