

Chapter 5

ADEQUATE MANAGEMENT OF CIS

My first Term of Reference requires me to find out:

“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.”

From time to time throughout the hearings and submissions, various parties expressed concern that ‘adequate treatment’ for carcinoma in situ would be defined by 1987 standards and knowledge, rather than by the standards and medical knowledge available at any particular time over the past 20 years. The evidence of eight overseas authorities, as well as the evidence of a large number of highly qualified gynaecologists and pathologists from New Zealand, ensured that there was little risk of this happening.

From an early stage it also became essential to reach a broad definition of adequate treatment for carcinoma in situ so that I could begin making reports to the Minister under Term of Reference Three which required me to advise him:

“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.”

In establishing a definition for the purposes of that Term of Reference, I have limited myself to a definition which incorporates 1987 standards, medical knowledge and procedures. My medical advisers could then measure the existing treatment or condition of all women treated for carcinoma in situ at National Women’s Hospital since 1955 against that norm.

In answering Term of Reference One, however, it has been necessary to retrace medical knowledge from 1966 to the present time. In reaching my conclusions about the appropriate standard of treatment for carcinoma in situ at any time since 1966, greater emphasis has naturally been placed on the views of visiting overseas authorities.

Arguments and submissions on Term of Reference One

Some Counsel argued that Term of Reference One should be restricted in its interpretation. In summary, these arguments were:

1. That the only allegations of inadequate treatment that could be considered under Term of Reference One related to those which had been raised in the ‘Metro’ article.

This submission in essence, argues that Term of Reference One must be read in isolation from the preamble and from the other Terms of Reference so that the words “as alleged in the Metro article” narrow the enquiry to those patients whose identity can be ascertained from the article itself.

I do not accept the validity of this argument. In my view, Term of Reference One must be read in the context of the entire document which established the Committee of Inquiry. The title of the Committee of Inquiry is:

“Appointment of Committee of Inquiry into allegations concerning the treatment of cervical cancer at National Women’s Hospital and into other related matters.”

CERVICAL CANCER REPORT

The preamble says:

"Whereas Sandra Coney and Phillida Bunkle have made ...allegations concerning the treatment of cervical cancer at the National Women's Hospital; and whereas it is desirable that inquiries should be made into the treatment of cervical cancer at that hospital;...."

The heading and the preamble clearly set out the Minister's intention which was to inquire into the treatment of cervical cancer at National Women's Hospital. In that context I do not accept that Term of Reference One ought to be restricted only to those allegations made in the 'Metro' article.

2. A definition of adequacy of treatment should be based on the long-term outcome of a patient's management; that is, whether that patient developed invasive cancer.

This argument implies a finding that if a patient undergoing treatment for carcinoma in situ develops invasive cancer, then she has been inadequately treated. Alternatively, if she does not develop invasive cancer, then her treatment has been adequate. There are two problems with this approach. First, in spite of management by currently acceptable methods, a very small percentage of patients might still subsequently be diagnosed as having invasive cancer of the cervix or vagina. Dr Coppleson said:

"[In the 1960s] a treatment such as hysterectomy had to be regarded as adequate, but it was no guarantee that in exceptional circumstances, that the condition might not recur."

The second problem encountered when defining adequate treatment by the outcome, relates to the time which elapses before invasive cancer develops from carcinoma in situ. Invasive cancer may take many years to develop from CIS. As one counsel said:

"If the patient has as of 1987 continuing CIS following various procedures administered over a number of years which would not be regarded as generally accepted treatment, but has not developed invasive cancer, it makes no sense to suggest that she has been adequately treated."

In this context, an outcome-oriented test taken to its logical conclusion would require waiting until the patient's death from invasive cancer or from another cause before deciding whether or not she had been adequately treated for carcinoma in situ. In my view, if the gynaecologist **intends** to treat the patient diagnosed with CIS **using currently acceptable methods**, then regardless of outcome, and in the absence of any negligence or change of intention, that patient has been adequately treated.

3. Undue weight must not be given to the retrospective criticism of the experts who presented evidence to the Committee of Inquiry.

Some of the overseas authorities who gave evidence were invited to carry out case studies of selected patient files independently of each other. Their conclusions on patient management in each case demonstrated a remarkable degree of unanimity. Professor Bonham criticised these case analyses on the grounds that any person not present at the time the treatment was administered, could not evaluate the adequacy of that treatment.

Implicit in that criticism is the suggestion that the case notes might not be full enough to disclose all relevant information on which a decision was reached. For example, a patient might have elected not to have a hysterectomy. Information of this kind is of such importance that it ought to be included in case notes. Generally speaking, the case notes I have reviewed and those that the independent overseas authorities reviewed were full and had ample material in the form of clinical, pathology and colposcopy reports to follow the clear line of management in each case. In her submissions Counsel Assisting said:

"Judgements can always be validly made about events that have passed, as long as they are intelligently made and the evaluator is seized of sufficient

relevant facts. On the latter point, much evidence was heard from past and present personnel of the National Women's Hospital on the meticulous tradition of the CC Clinic in keeping detailed file histories of patient treatment. If Professor Bonham's criticism on this matter were to be given serious consideration, it would mean that lessons could never be learned from the past."

Counsel Assisting called Dr Joseph Jordan as an independent expert in this field. It was suggested that he was too young to speak from personal experience and therefore authoritatively on medical practice in the 1960s. Personal and direct experience however, has never been the sole factor in determining the expertise of a witness. Dr Jordan's expertise was unchallenged in any other regard. His levels of achievement and prominence in the field of medicine entitles him to make retrospective judgement about matters within his field of special knowledge. In any event, his views were very similar to those of Professor Richart, Professor Kolstad and Dr Coppleson, all of whom were world leaders in their fields by the 1960s and were publishing authoritatively at that time.

4. Counsel for the Hospital Board submitted that if as the result of the review undertaken by two gynaecologists practising at National Women's Hospital (Drs Jamieson and Mackintosh), a particular patient's treatment had not been criticised by 1987 standards, then "as a matter of logic, it cannot be criticised as being inadequate by the standards of the time".

The review conducted by Drs Jamieson and Mackintosh of patients at National Women's Hospital who had an initial diagnosis of carcinoma in situ of the cervix between the years 1955 and 1986, identifies 71 patients who had a subsequent diagnosis of invasive cancer of the genital tract. Although this review would suggest that the outcome was the measure of the adequacy or otherwise of the treatment, at the very least, the identification of 71 patients with a diagnosis of invasive cancer following an initial diagnosis of CIS raises the question of adequacy of treatment for those women.

Other counsel suggested that Term of Reference One should be interpreted liberally and in particular should not be limited to considering adequacy of treatment in the strict medical sense.

1. In common with many other diseases, treatment for CIS relies on a diagnosis of the disease. Counsel for the Ministry of Women's Affairs submitted that because the medical system operates on a model which focuses on illness and disease rather than wellness and health, it is possible that adequate treatment may be beyond the capabilities of the system as it stands.
2. Counsel for the authors of the 'Metro' article and Fertility Action submitted that Term of Reference One was wide enough to enable 'treatment' to be interpreted as including the management of patients overall; and that such matters as the existence or absence of informed consent and the inconvenience for patients required to return for many years for examination and/or treatment, could be dealt with under this Term.

Questions of the protection and rights of patients must be addressed later. I do, however, accept that treatment implies overall management of the patient's condition.

EXPERT OPINION

During the course of this Inquiry I have been privileged to hear the evidence of those who have been described as some of the 'high priests' of gynaecological expertise. The sum total of their knowledge was of pivotal importance to this Inquiry and will be valuable to the New Zealand medical community. I was also struck by the compassion that so many showed for the women whose files they were considering or for other patients who were directly involved with this Inquiry.

Although in some minor areas their opinions on the appropriate treatment of CIS or invasive cervical cancer differed, nonetheless there were broad areas of agreement in major matters. Their evidence was derived from an examination of medical literature, a review of research projects and personal experience in practice at various periods from the early 1950s. This evidence enabled me to come to the following broad conclusions.

1. From the early 1960s carcinoma in situ has been regarded as a condition which will progress if untreated to invasive cancer in a substantial proportion of cases.
2. The appropriate treatment for CIS, if invasive cancer is to be avoided, is to remove the lesion. The patient must then be monitored so that further treatment can be offered if there is persisting disease or a recurrence, as evidenced by positive cytology. As those patients diagnosed with CIS have a higher risk of recurrence than other women, they must be monitored for life by cervical or vaginal vault smears.
3. With certain exceptions, such as during pregnancy or when a patient refuses treatment, the lesion should be removed as soon as practicable after diagnosis. The least amount of tissue consistent with excising the lesion should be removed.
4. From the 1950s to the present time, methods of removing the lesion have differed. Originally hysterectomy was undertaken whenever CIS was diagnosed. Today hysterectomy is used far less frequently, but it is still a viable option for treating women who may suffer from CIS as well as other disorders, such as menorrhagia.
5. From the time that Dr Green began publishing, there has been a move both in New Zealand and in other countries towards more localised methods of treatment. They have the advantage of being more precise, have less effect on the reproductive function in young women and, on occasions, can be performed without a general anaesthetic.

METHODS OF DIAGNOSIS AND TREATMENT

The emphasis in diagnosis has gradually changed from the mandatory cone biopsy to establish a histological diagnosis, to a combined colposcopic-histological assessment which may result in the need for a less radical biopsy to establish the diagnosis. Because different methods of treatment are required, it is critical to distinguish in diagnosis between a cancer precursor and a preclinical (hidden) invasive cancer.

From the 1960s, cone biopsy was the preferred method of treatment for CIS both at National Women's Hospital and in many other parts of the world. Hysterectomy following a diagnostic cone biopsy was no longer the norm except in parts of the United States of America. With the development of colposcopy as a visual aid to the clinician in observing the lesion, localised destructive techniques have developed in most parts of the world.

When certain conditions are met, diathermy, cryotherapy and more recently laser therapy are now accepted as adequate techniques by most gynaecologists. Colposcopic examination is essential if localised destructive techniques are to be used so that the site, nature and distribution of the lesion can be fully identified.

Until 1966, with the exception of those cases managed by Dr Green where patients were monitored with persisting positive cytology, treatment offered at National Women's Hospital was in accordance with generally accepted world standards. Its aim appeared to be the eradication of carcinoma in situ. Patients were monitored following primary treatment to ensure that further treatment was not required because of continuing positive cytology or a recurrence of the disease. There had also been a move from more radical treatment by hysterectomy to cone biopsy in the majority of appropriate cases.

The aim of treatment

All overseas authorities were agreed that since the mid-1950s the aim in treating a patient with a diagnosed cancer precursor, including CIS, has been to eradicate the disease. The method of treatment has always depended on the available skills and equipment, but the aim remains unchanged.

Methods of treatment must evolve as new data and techniques emerge. If the new treatment demonstrates more benefits or fewer risks, it will become standard treatment. If fewer benefits and more risks emerge, then patients so treated should be recalled and offered generally accepted treatment. Where new treatment methods emerge, they must still meet the fundamental aim of treatment.

Other aspects of adequate diagnosis and management

If a condition is to be managed adequately, then the clinician responsible for treatment should where possible be confident of his or her diagnosis. In the case of CIS, diagnosis depends not only on the clinician's skills, but also on those of the cytopathologist, the colposcopist and the histologist. Collaboration between these team members has been discussed in the chapter, 'The 1966 Proposal'. The detection and management of the disease relies on a partnership among these four specialists. All of them have a critical part to play in the detection, monitoring and management of the disease. If one does not recognise the others' skills and abilities, then the partnership will not operate efficiently and the patient's care will suffer. As Professor Richart said:

"It is absolutely unacceptable to have different members of the team working at cross-purposes as it compromises patient care which must be the ultimate goal of the medical programme.

"...The importance of the role of the pathologist and the cytologist in the management of patients with abnormal smears must not be underestimated. Cytology is the key to detecting the patient with suspected neoplasia, but is also important in identifying those patients who are at high risk of having invasion.

"If a skilled cytologist indicates that invasion is present based on an examination of the Pap smear, then it is mandatory that the clinician rule out invasive cancer before managing the patient as having a cancer precursor. Histology is universally recognised as the sole appropriate end-point in establishing the patient's diagnosis. If the histologist determines that invasion is present, the clinician is required to treat the patient as invasive carcinoma or to have the diagnosis revised.

"In order to achieve good patient care, the cytologist, pathologist and clinician must be concordant in their views and in the individual patient, the diagnoses of all three should be in agreement. If there is a discrepancy and particularly if there is a continuing series of discrepancies, then it is mandated that the reason for the discrepancy be discovered and that remedial action be taken.

"If for example, the pathologist consistently diagnoses invasion which the clinician fails to confirm, the criteria which are used by both must be re-examined and if agreement cannot be reached it is mandatory that outside consultation be obtained if necessary and the issue discussed until agreement can consistently be achieved. To do otherwise puts the patient in jeopardy and precludes the team's ability to successfully manage the patient.

"If it is found that one or the other's skills are inadequate then the substitution of someone with adequate skills on the team is required or remedial training is called for."

Cytology

As far back as 1970, Dr McIndoe reiterated the recognised principle of specialist collaboration in a lecture titled 'Cervix Biopsy':

"The closest of collaborative efforts between the cytologist, clinician and pathologist are necessary for the proper assessment of the type and extent of the cervical lesion."

Mr Michael Churchouse, Charge Technologist of the Cytology Laboratory at National Women's Hospital, spoke of devices Dr McIndoe employed to ensure that cytology reports would be noticed and acted upon. For example he said that Dr McIndoe had coloured stickers printed with brief cytology reports such as "Positive for malignancy" to "make them take more attention of it". When a sticker was removed on one occasion, he ordered new non-removable batches which were to be franked with a special stamp. Such efforts to have reports heeded must be almost without parallel in a professional environment. Furthermore, Mr Churchouse was aware of

"the disregard which Professor Green had for cytology. The feedback from medical registrars who were training at National Women's Hospital was negative where cytology was concerned. This was expressed on more than one occasion as, 'What are you screening for? Herb Green's just told us it is a waste of time.'"

Dr Green's public statements also reflected his attitude that cytology was of little use in screening for cancer precursors. For example, in an article in the Auckland Star, June 21 1972:

"Professor Green asserted that a woman with a positive cervical smear showing what is called 'cancer in situ' is no more likely to develop invasive or malignant cancer of the cervix than any other woman of the same age. In other words, in situ cancer is not a forerunner of invasive cancer, and the smear test is over-rated."

From reading Dr McIndoe's papers, it is obvious that he found these disparaging remarks disturbing and potentially dangerous and he went so far as to co-author a letter with Dr SE Williams entitled 'The Value of Cytology' which was published in the New Zealand Medical Journal in August 1972.

Even this step was unlikely to counteract the impression the Registrars and other hospital staff gained that screening for cancer precursors was useless. More importantly, a gynaecologist who doubts the value of cytology as an early warning sign, will place little significance on reports of abnormal cytology. Many of the patients' notes reflect this fact.

Pathology

When CIS was diagnosed following biopsy or reported after a small biopsy with the warning 'invasion elsewhere', from time to time Dr Green ignored the diagnosis or questioned it. Dr McLean, the Pathologist in Charge at National Women's Hospital since 1962, was also concerned about the dangers of inadequate biopsy which put patients at risk by delaying definitive diagnosis and treatment.

Dr Green, to his credit, took a great interest in histology. However, he was not a trained pathologist and it was inappropriate for him to disregard or alter pathology findings. This disregard at times led him to overlook early or hidden stages of invasive cancer such as microinvasion or occult invasion. Women who harboured this disease were therefore erroneously included in the 1966 trial.

The evidence suggests that he did not work effectively as a member of a team dedicated to the accurate diagnosis and appropriate treatment and management of the disease. For example, Dr McIndoe and Dr McLean were anxious to collaborate. Their efforts to achieve excellence in cytology and histology reporting were at times downgraded or disregarded by Dr Green. Dr McLean told me of several occasions when Dr Green crossed out his diagnosis on the pathology report form and replaced it with his own diagnosis without consultation or agreement with Dr McLean as the specialist Pathologist. One example will serve to illustrate Dr Green's disregard for an histology report.

In 1970 CIS was reported following a biopsy of a patient's cervix (Patient code 8L). The carcinoma in situ was also present in the curettings. Seven months later the pathology report stated:

"Endocervical curettings.

Sections show fragments of keratinising tissue that look(s) malignant.

Endocervical tissue fragments – probably malignant.

"I think the origin and nature of this malignant looking tissue should be investigated further."

(Dr McLean)

Eight months later, following a colposcopic examination, the patient was readmitted and the pathology report on a ring biopsy of the cervix confirmed carcinoma in situ of the cervix which extended to the endocervical excision margin. Just over two months later, the clinician examining this patient wrote:

"Findings discussed with Professor Green. To return to clinic in six months."

A positive smear was reported.

Six months later she was examined by Professor Green who noted,

"no complaints. Cervix looks completely normal with small external os about 2-3mm in diameter. No bleeding on probing endocervical canal. See in one year."

A grade 2R smear was reported.

Positive or equivocal smears were reported throughout the next seven years, when a smear report noted:

"appearances consistent with severe dysplasia or small cell carcinoma in situ, but are suspicious of more advanced lesion."

Invasive carcinoma was diagnosed five months later, eight years almost to the day since Dr McLean had asked for further investigation.

The dangers of lack of collaboration

One case vividly illustrates the dangers of the gynaecologist placing too much emphasis on his or her own clinical skills without establishing a histological diagnosis.

Patient Code 9G was first examined at out-patients clinic and all the classical features of invasive cancer were noted. Arrangements were made for "admission within ten days for a cone biopsy". Details from her history on the day before a total hysterectomy was performed record an

"abnormal cervical smear. For cone biopsy. Post coital bleeding. P.V. discharge.... Cervix wide erosion, irregular and hard – ...contact bleeding.... Ca cervix ? grade".

No cytology reports appear on the file at this time but in the letter to her general practitioner following this initial admission, the Registrar said:

"This patient was admitted...having had a cervical smear reported as showing cells strongly suggestive of malignancy. The reports being from both Dr Sullivan and our own Laboratory.

"There was a history of post-coital bleeding for five weeks and a vaginal discharge for three months. Ordinary examination showed no abnormality and abdominal hysterectomy was carried out...following consideration of her case by Professor Green.... No report has yet been received on the histology of the uterus removed at operation but since the patient will be reviewed at the Gynaecological Follow-up Clinic in a week or two, an opportunity to consider this will present itself at that time."

I could find no comment in the notes about the change of procedure from cone biopsy to hysterectomy and no indication of the reasons for this decision. Dr Green told me, however, that at that time he and the Hospital pathologist believed that cytology with the aid of a clinical examination could predict the presence or absence of invasive disease. A biopsy before proceeding to hysterectomy would not therefore be so critical. The symptoms recorded on admission are not consistent with a precancerous condition; they are indications of invasive disease. Dr Green told me

"...if it was clinical suspicion of invasive cancer, then the correct procedure for that would be biopsy and not hysterectomy.... If there was clinical suspicion of invasive cancer, and if there had been in this case, I certainly would not have proceeded to an abdominal hysterectomy.... I would have done a biopsy because if it is invasive cancer, it is necessary, or it is best to have the uterus as a vehicle for the radium."

Question: *Why did you proceed to excise the uterus if there was then no clinical suspicion of invasive cancer?*

Answer: *Because that was the correct treatment, or a correct treatment at the time for carcinoma in situ, which is what Dr S and I decided on cytology and clinical examination, that it was."*

After the hysterectomy performed on this patient, no pathology report was available for approximately four months. In the meantime, the patient had returned for her follow-up appointment. Dr Green had taken her uterus to an overseas hospital while he was on study leave and it was from there he reported back to National Women's Hospital:

"Normal looking uterus and cervix. External os a regular slit 2cm long. Visible non-suspicious erosion for 1cm all round. Nothing suspicious noted on blocking cervix for section; canal looked normal. From the squamocolumnar junction outwards and from 11 o'clock to 5 o'clock a **moderately well differentiated invasive carcinoma (squamous)** of cervix. Extends in stroma up cervix for 2cm between 11 and 1 o'clock and for 1cm between 1 and 5 o'clock ie direction of spread seems to be up the anterior lip. From 5 to 11 o'clock is extensive carcinoma in situ. Carcinoma in situ seen in canal for half centimetre up from squamocolumnar junction on posterior aspect of canal. No ulceration of canal. This is a very localised STAGE IA tumour clear of excision margins of uterus and cervix by 1cm at least in all directions. No vascular or lymphatic emboli. I would think that at the least she should have vault radium if not DXR [deep x-ray therapy] to pelvis even though excision margins appear clear. I would say that there is no possible doubt about invasion and Saul G...agrees."

There were in fact two lesions detected; the one arising in the canal was 1A while the more serious lesion was located more superficially on the surface of the cervix. Almost seven months after the original hysterectomy this patient was re-admitted to National Women's Hospital for an examination under anaesthetic and insertion of radium. In notes headed 'Radiation Response' the following comments appear:

"Uterus had been taken to New York by Dr Green, thought previously to have been Ca-In-Situ.

Stage IIAB.

Prognosis based on clinical appraisal: Fair (40-60%) Factors adversely influencing prognosis:

Previous hysterectomy.

Delay in definitive treatment.

Age."

By this time the cancer had spread to both the upper vagina and pelvic tissues. After many more admissions to hospital and attempts at treatment, this patient died just over two years after the original hysterectomy. Although the initial symptoms were consistent with invasive cancer (post-coital bleeding and smear tests reported as "strongly suggestive of malignancy") no attempt was made to establish a histologic diagnosis before hysterectomy was performed.

The specialists treating her after the hysterectomy faced real difficulties in effectively applying radiation. In addition, the Hospital apparently had no system which ensured that a pathology report was obtained as promptly as possible after the operation so that definitive treatment could, if necessary, be started without delay.

MICROINVASION

Although my Terms of Reference do not require me to consider the adequacy of treatment of any condition other than carcinoma in situ, there has been such confusion about the management of microinvasion at National Women's Hospital that it seems appropriate to comment on this topic.

There has been no consistent definition of microinvasive squamous cell carcinoma of the cervix in medical literature. Dr Linda Holloway, Senior Lecturer in Pathology, Wellington Clinical School of Medicine, told me that diagnosis of this condition "implies rigorous examination to exclude more extensive invasion; this usually means careful examination of a cone biopsy specimen". This diagnosis is distinguishable from CIS in that it involves invasion of the stroma (the surface lining epithelium of the cervix). The allowable depth of invasion varies from 1mm to 5mm.

Microinvasion is, therefore, a more serious disease than CIS which is a preinvasive condition. However, Dr Green did not believe this to be the case. He was asked about a particular patient (Code 105) who, in 1964, had a diagnosis following cone biopsy of "carcinoma in situ with minimal microinvasion and lymphatic permeation". He was asked:

"So you are saying that...microinvasion is really no more than carcinoma in situ?"

Answer: *I am following some world authorities in that.*

Question: *And you feel quite comfortable now with a letter informing the practitioner that this condition is not of any serious import?*

Answer: *No more than carcinoma in situ.*

Dr Green had written to the woman's general practitioner,

"You will remember this patient had an A5 smear suggestive of invasive carcinoma and the letter from our registrar which told you that it was carcinoma-in-situ with minimal microinvasion.

"As the result of smears of many of these so called 'microinvasive' cases, I am convinced that this diagnosis, certainly as it is made in this hospital, is not of any serious import. So far I have followed about 30 of these cases and not one of them has recurred or gone on to be anything more major."

Sixteen months later after an anxious query from the general practitioner, he wrote again, "No, I don't think your A4 smear may be due to a mix-up at your end. I say this

because our findings were not quite normal as indicated by the registrar's discharge letter to you. The smear taken on admission here was actually A5. Despite this the colposcopic findings were essentially normal and a punch biopsy taken on what Dr McIndoe describes as 'equivocal colposcopic findings' showed nothing. The practical outcome is that although there is cytological suspicion about this case, there are no clinical or colposcopic suspicions and that **there is no need for concern**, even if she continues to have positive smears. If she keeps doing this for another year and the cervix looks normal please let me know again. Don't think you will do her any good by doing a hysterectomy to cut the Gordian knot, for like as not she will turn up with positive smears in the vaginal vault at a later date. I say this from experience of scores of similar cases and only clinical suspicion makes me get worried about these cases.

"To help keep your morale up about this particular case, I enclose a couple of reprints. I know it sounds like heresy but the American Journal have recently accepted a very extensive paper on the subject of the doubtful value of cytology in such cases."

A few months later he wrote again to the general practitioner,

"I saw this patient again today and am even less inclined to worry about her positive smears after viewing her cervix. This cervix is 100% normal. If there had ever been any possibility of anything developing from the original diagnosis, it would have developed by now. I have asked to see her again in six months.

"In the meantime, for the sake of your peace of mind, I would suggest that you did not take any further smears."

Although eventually the outcome for this woman was satisfactory, her microinvasion had been treated lightly and that message clearly given to her general practitioner.

Despite the fact that Dr Green persisted in equating CIS with microinvasion, his views received no support from those authorities who gave evidence at the Inquiry. Dr Pixley, Dr Jordan, Dr Noda and Professor Kolstad all agreed that it should be classed as Stage 1A on the FIGO (Federation of International Gynaecologists and Obstetricians) classification. Dr Jordan and Dr Pixley confirmed that although methods of management might be controversial, the controversy was limited to how radical the treatment should be. It was their view that excision of the entire microinvasive lesion by cone biopsy was mandatory.

However, Dr Noda said that this disease was handled differently in his unit in Japan. "We consider it sufficient merely to follow-up the patient without further treatment until such time as we observe microinvasive carcinoma. At that stage, a hysterectomy is performed."

When Drs Jamieson and McIntosh were asked about their definition and treatment of CIS with microinvasion, they both said that they would make a distinction between CIS and carcinoma in situ with microinvasion for clinical purposes and for their records. Dr Jamieson agreed that cone biopsy would be the minimum acceptable procedure. He also believed it was quite safe to excise a microinvasive lesion locally and watch the patient very closely, although he thought that most clinicians today would prefer to remove the uterus. Both Drs Jamieson and McIntosh considered that their follow-up of microinvasive cases would be different from that of cases of CIS. They took the view that there was definite potential for invasion and that the disease was "highly likely invasive". Dr Green's views therefore, are out of step with most of local and overseas authorities.

A number of cases managed at National Women's Hospital, however, still illustrate a tendency to manage microinvasion as if it was CIS. In my reports to the Minister in

compliance with Term of Reference 3, I have isolated several cases where microinvasive carcinoma has not been treated with even the least radical procedure: a cone biopsy which has completely excised the lesion.

Professor Kolstad referred to the international rule which anticipates that microinvasive carcinoma will be reported separately from CIS. At National Women's Hospital this requirement has not always been observed. Before 1977 all cases with a histological diagnosis of CIS with microinvasion were recorded as Stage O in the site and cancer registers (NWH records). This information appears to have been sent to the National Cancer Register (New Zealand-wide records). The classification required by FIGO should have been Stage IA. These inaccurate data from National Women's Hospital will have distorted the information regarding treatment and prognosis of both conditions.

Although the cancer registers at National Women's Hospital after 1977 show a classification in some cases of O/1A, it has continued to be recorded as Stage O in the hospital site registers. This confusion requires immediate clarification and much more accurate reporting in future. If there is a lingering view at National Women's Hospital that the two can be equated, then patients may not be treated adequately for microinvasive disease. The following case history is just one example which illustrates the reason for my concern.

Case history

After a series of positive smears, Patient Code 10G (see also Appendix 10) had a ring biopsy in November 1973 which established a diagnosis of CIS. From March 1974 to March 1979 she attended National Women's Hospital on 11 occasions with 10 reports of Grade 2R, Grade 3 or Grade 4 smears. In May 1976 she had a second ring biopsy (with incomplete excision) which confirmed the diagnosis of CIS. In May 1979 a cone biopsy (again with incomplete excision) was performed. This time the diagnosis was carcinoma in situ with microinvasion.

From August 1979 to December 1986 the patient visited National Women's Hospital on 12 further occasions receiving a series of Grade 1 smear reports, two Grade 2R and two Grade 3 smears. Late in 1986 this patient was placed on the waiting list for admission for a hysterectomy in February 1987. There was no further record of her attending the Hospital. I am informed that, as a consequence of an interim report to the Minister, she was located and treated.

After her hysterectomy the pathology report confirmed the presence of microinvasive disease – "residual carcinoma in situ with microinvasion. Inactive hypoplastic endometrial polyp."

Her notes show that this woman had become anxious about her continuing disease. In June 1976 the notes say, "Apart from be[ing] frightened to be examined, she does not have any complaints." Again in March 1979, "She is very panicky but not too difficult to reassure", and "terrified she is going to die of cancer...looks extremely well." By 1986 her notes say, "Mrs...is well and has no complaints apart from some fear from coming here." And six months later, "Mrs...is quite happy to have a hysterectomy although she worries about the anaesthetic and she is very unhappy about vaginal examination."

There is also reason to infer that her diagnosis was not taken seriously by Dr Green. Following the diagnosis of carcinoma in situ with microinvasion, adenocarcinoma in situ and 'pill' cervix, the patient returned to the clinic three months later when her notes say, "The histology report will be treated just as a carcinoma in situ. Discussed with Professor Green. Review in six months."

In summary, this woman's condition was monitored after an initial histological diagnosis of carcinoma in situ in November 1973 until May 1979 when the diagnosis became carcinoma in situ with microinvasion. She continued to be monitored solely by cytology in

spite of the fact that the excision was incomplete and that she had positive or equivocal follow-up cytology following the cone biopsy in May 1979.

The pathologist's report of carcinoma in situ with microinvasion was "treated just as a carcinoma in situ". But not even the CIS was treated. No definitive action was taken until the end of 1986 when a hysterectomy was recommended. Even then the notes disclose no sense of urgency about performing the operation when the patient did not contact the hospital in February 1987.

This woman was last seen by Dr Green in October 1981 and had been seen by various other clinicians before that date. I am concerned that in spite of being seen on seven subsequent occasions, by a variety of clinicians, no sense of urgency was attached to the report of carcinoma in situ with microinvasion, the continuing evidence of disease demonstrated by Grade 2R and Grade 3 smears, as well as the fact that the pathology report from the last cone biopsy commented on incomplete excision.

The management of this patient does not comply with generally accepted standards of treatment for microinvasive carcinoma, or where there is continuing positive cytology after an incomplete excision. There is no apparent reason in the file why the pathology report of carcinoma in situ with microinvasive carcinoma was treated only as CIS. There is no histological confirmation for this re-diagnosis. There is no suggestion in the file that the patient was adamantly opposed to a particular form of treatment and no obvious explanation for the way her disease was managed. In fact there is evidence that she was concerned and anxious about her continuing disease and its possible implications.

The significance of confusing microinvasion with a preinvasive disease is obvious. Professor Richart said that if a patient has microinvasion it would be expected to progress continuously, increase in size and depth of penetration and at the point at which it exceeded 3mm in depth, could be expected to metastasize. In his view, provided the patient was treated before invasion had exceeded 3mm, then the cure rate should be almost 100 per cent.

During the course of the Inquiry I asked Dr Ron Jones to report on cases of carcinoma in situ with microinvasion treated at National Women's Hospital between 1955 and 1976 because these cases had been excluded from the McIndoe 1984 paper. Dr Jones is a part-time visiting specialist in obstetrics and gynaecology with a particular interest at National Women's Hospital in cervical pathology and colposcopy. From his evidence it is clear that at least 25 patients were followed with cytological abnormalities (positive smears) after the diagnosis of microinvasive carcinoma. There was evidence that the lesion had been incompletely excised. In Dr Green's 1969 paper, 'Invasive Potentiality of Cervical Carcinoma in Situ'⁴, he refers to 12 patients diagnosed as carcinoma in situ with microinvasion who were not treated by hysterectomy and had positive follow-up cytology. The 25 patients isolated by Dr Jones confirmed the information contained in Dr Green's paper. The outcome for these women has been very poor indeed. Of 23 cases with evidence of incomplete initial treatment for carcinoma in situ with microinvasion, 11 (or 48%) subsequently developed invasive cancer.

FURTHER DIMENSIONS OF PREINVASIVE DISEASE OF THE GENITAL TRACT

In his evidence, Professor Kolstad spoke of women who had been diagnosed with cervical invasive cancer. He said that his experience had

"...convinced me that even if we can cure the patients, they have a lot of problems after discharge from the hospital, both physical and psychological. There are many, many divorces among these patients."

Dr Jordan also commented:

"In addition to the physical morbidity, there is of course the psychological trauma involved in having premalignant disease diagnosed and treated. A recent study performed in London by Campion and Singer, has assessed the psychological problems following the diagnosis and treatment of premalignant diseases of the cervix. They have confirmed that there is a definite effect on the patient's psychosexual state and on her anxiety state. It would seem important therefore, that when a patient is known to have premalignant disease, she should be told the exact nature of the disease, the planned treatment to eradicate the disease, and that she should be reassured that the disease has gone following her treatment."

These opinions were confirmed by the evidence of Te Ohu Whakatupu, the Maori Women's Secretariat of the Ministry of Women's Affairs, and the evidence of 84 patients or relations of patients who gave evidence privately during the Inquiry. I also received many letters and less formal communications from and about patients who suffer from precancerous or cancerous conditions of the genital tract. In the end I was in no doubt that Professor Kolstad's and Dr Jordan's statements were true, both for those women who suffer from invasive disease, and for those whose condition has been monitored or who have been diagnosed with CIS.

Essentially there are two issues to be considered. The first is the sacredness of the area of the genital tract both to Maori and, to a lesser degree, to Pakeha women. The second is the feeling of anxiety, helplessness and extreme concern when any disease of the genital area is diagnosed with its consequential repeated examinations, usually by male doctors.

The sacredness of the genital tract

The genital area is private for the Maori and Pakeha woman. It is associated with the most personal relationships between male and female and with fertility.

a) Maori women

Te Ohu Whakatupu provided much valuable information on Maori attitudes to health issues. They told me:

"Our cultural mores of modesty are not understood by, or even recognised by most health professionals and especially doctors.... The cultural inhibitions on modesty and what is or isn't proper exposure is ingrained into most Maori girls at an early age. Exposure of the pubic area is forbidden and proper behaviour and practice during menstruation especially is taught at the onset of menses."

Against this background, the implications of repeated visits to hospital for examinations of the genital tract, sometimes with minimal privacy, are grave. It is mandatory that any woman who has or has had positive cytology must have her condition monitored for life, even if treatment for any precancerous condition appears to be successful. The known risk of recurrence is such that it is dangerous for such women not to have regular checks.

It has been impossible to ascertain a general pattern of behaviour amongst Maori women, but I strongly suspect that the thought of repeated vaginal examinations would make most women extremely reluctant to adhere to a health programme of this nature. Rua Barlow, a Plunket Nurse, District Nurse, Public Health Nurse, Industrial Nurse, Maori Welfare Officer and Mother, presented a paper to the Cervical Screening Working Party in May 1987. In that paper she said:

"I have talked with individual Maori women of varying age groups -- topic: 'Cervical Cancer Screening'. Sad to say that the climate around this type of intrusion into the sanctity of womanhood is rather cool.... I asked a Kaumatua

what he thought about the subject. His reply, 'Thua mai te tangata ite aroaro o tana whaea, kia tipu ai, ia ia, iroto ite honore mete kororia, otona whakatipu tanga.'"

In other words,

"That is a very sacred territory where you and I come from into this physical plane, and then be nurtured at her breast to thrive."

The implications of the sacredness of the genital area for Maori women cannot be underestimated. They will have repercussions not only for population-based cervical screening but also for the treatment and monitoring of CIS as well as invasive cancer. There seems to have been little cultural understanding of these mores on the part of the profession.

Any doctor conducting a vaginal examination, needs a sympathetic understanding that the genital tract is a sacred part of a woman's body which should be treated with respect, examined in total privacy, and under conditions which enable the woman to respond with trust and to communicate her views, symptoms and feelings as an equal. If her consent is sought to any procedure or treatment, it is critically important that the health professional is certain that that consent is freely given and that she has not acquiesced from natural courtesy or a wish to please someone who appears to be of greater status than herself.

If she is not offered these conditions, her management is not adequate. If a patient is unable to speak freely with her doctor out of embarrassment or a feeling of inferiority, then important symptoms might pass unnoticed. There is also a requirement to deal face to face with the Maori patient who is less likely to respond to correspondence or even telephone calls. This last point was confirmed during an interview with a patient who required monitoring after a hysterectomy in 1980. She said that on one occasion the Hospital had contacted her husband:

"They rang him to get in touch with me. They are supposed to send me an appointment card and they haven't...."

Question: *And did you go and see them?*

Answer: *They just wanted me to ring them to see how I was.... She said she would send me an appointment card but I haven't had one yet.*

As this woman had not received her appointment card, she had not returned to National Women's Hospital for examination or treatment since the date of her hysterectomy.

b) Pakeha women

I do not underestimate the reactions of Pakeha women to examination and disease of the genital tract. In many cases the patients who spoke to me had similar feelings to those attributed to Maori women. There was a strong thread running through the patients' evidence of constant disruption to their lives from repeated returns to the Hospital for monitoring and/or treatment, and of marital problems, family difficulties in arranging childcare or time off work, embarrassment and humiliation at the procedures employed, anxiety and downright anger. These feelings were common to both races.

c) Samoan women

A meeting with a group of Samoan women revealed that they too place great emphasis on modesty, privacy and the need for discussion with health professionals from their own culture. Their views of disease or examination of the genital tract fell somewhere between the Maori women's feelings of sacredness and the social embarrassment and desire for privacy felt by both Maori and Pakeha women. They regretted that the programme allowing Samoan-trained nurses to be retrained for registration in New Zealand had been curtailed. The result was a diminishing pool of Samoan nurses who might help Samoan patients cope with the special stresses of vaginal examination and genital tract disease.

The emotional and social impact of disease of the genital tract

I could provide many examples from various racial groups of the emotional and social effects of having a disease of the genital tract and of regular attendance at National Women's Hospital. The Hospital consultation clinic notes sometimes touch on these factors. For example:

On her thirteenth visit to the Hospital following a diagnosis of invasive cancer and treatment by radium plus radical hysterectomy, this patient's (Code 5Y) notes record:

"Patient complaining of dyspareunia, postcoital bleeding and also libido. She is also worrying about losing her husband...."

On the next visit:

"Patient has a lot of social problems, her [husband] spends only half the time with her and she is afraid of being deserted. Coitus causes dyspareunia. She feels not well enough to resume her work and is generally insecure and depressed...."

Another patient told me:

"Having to visit the hospital so frequently became a strain. I was very uptight and I felt diseased. My husband got rather sick of it too. We lived a long way from the Hospital and he was always left with the children to look after and at that time we had two businesses to run. At the beginning the visits to the Hospital weren't such a problem, but as it went on for so long it caused lots of trouble which contributed to our family problems."

"Eventually I used to visit the Hospital in a taxi because my husband didn't want to take me. I eventually got sick of going to the Hospital. I was worried that I had cancer but they didn't seem to be doing anything about it."

She was also concerned about lack of dignity and privacy.

"Every time I went there, there were several doctors who talked about me in my presence as if I was a piece of furniture. They talked amongst themselves about me instead of to me and I would be lying on a bed with my legs in stirrups and a sheet in front of me...."

"When you went there for an appointment, you were told to be there at 10 o'clock in the morning. You would just sit and sit in the waiting room full of women; and then you found out that everyone had been told to be there at 10 o'clock. Sometimes you would sit there for two and a half hours before anyone did anything to you."

"Then they put you in a little white gown with no strings on the back and sometimes you sat in a little cubicle for another three quarters of an hour. Even when the doctor came to see you, the beds and curtains were so close together you could hear exactly what was being said from one bed to the other. There was no privacy and it wasn't very nice."

Other patients received quite the wrong impression of the nature of their disease. One woman who was refusing to allow any form of monitoring, either at National Women's Hospital or through her general practitioner, told me:

"I have got to the stage now, what happens, I don't worry about. It is terrible. I am petrified of hospitals. I will tell you too, that I haven't had sex since then. They were coming up with a lot of theories that it could have been through a lot of sex, perhaps two people weren't suited to one another, where they thought that perhaps that could trigger it off, and also stress."

"They were definitely not sure of anything at that stage and trying to figure things out. But that put the wind up me and I thought I will not have sex any

more either.... I suppose it possibly could have had an effect on my husband, but he's accepted it. He knows now I will never let any man within a foot of me. I just couldn't stand it.... It was more that you could have sex with your partner and it would trigger off again and I thought, 'Oh, I am not going to risk that.'"

Returning to the consultation clinic at National Women's Hospital for repeated examinations and procedures over the years have their own special impact on some women. For instance:

"I first became a patient at NWH in 1963 when I was expecting my second baby. I have had five children altogether.... As well as attending at the Hospital for checkups before and after the births of my children, I became a regular patient at one of the Hospital clinics. I did not really understand why I had to visit the Hospital.

"I now understand from reading my notes that I had carcinoma in situ of the cervix and that they must have asked me to keep coming back so they could keep an eye on it. I can remember one occasion when I had photographs taken of the inside. I remember that very well because it was embarrassing. At the time I had no idea why the photographs were being taken and now looking at my notes I see that I had punch biopsies in June 1965 and April 1968. I have knowledge of them, but was not told the results. I just assumed it was more painful than the usual smear test.

"After the birth of my fourth [child]... I asked for something to be done so that I didn't get pregnant so quickly again. I had a loop inserted by Professor Green. Afterwards I was asked to return to the Hospital after the loop was inserted. I thought the reason was so they could keep a check on the loop. If I missed an appointment for any reason they would send me a letter. In the end they even sent me telegrams asking me to make another appointment. I wondered why.

"About four years after the loop was put in I began bleeding.... A doctor removed it. The bleeding stopped after the loop was removed. I had another child born in 1972 and after... I became very ill. I was in a lot of pain but tried to take no notice of it. I had marital problems and I had my children to look after. At one stage it got so bad that I was taken by my husband to Middlemore Hospital. I had terrible pain and fever....

"I have looked at my notes and they say that I was in NWH twice during that year before I had an operation in November, but my recollection is that I was actually admitted in hospital three times before the operation. Towards the end of... I saw Professor Green as a patient in Ward Nine. I begged him to do something for me. I asked for tubal ligation or hysterectomy or anything.... My bad health was having an effect on our family. My husband was having to take time off work to look after the children and he lost several jobs because of this. We had no money and at times no food for the children.

"In November 1974 I was admitted to NWH. I can remember after the operation being told that they had taken out one of the tubes because it was infected. I understood that I had gone in to have both tubes tied. I now know from looking at my hospital notes that I had a ring biopsy at the time and I do not remember being told about it.... Towards the end of 1985 I started having heavy fortnightly periods and I had a curette done at NWH. When that did not fix the bleeding problem I asked for a hysterectomy which I had in July 1986.

"Now that I look back on my medical history and file I feel that I should have

been told about the carcinoma in situ of the cervix. I feel that a woman has a right to know what she wants to know from a doctor. I used to have a lot of faith in doctors but I have lost it because of the things that have happened to me. I am sick of women being downtrodden and I think they should be told what is wrong with their bodies."
(Patient Code 7V)

This woman's husband felt equally strongly about the effects, particularly the lack of information and the consequences to their family. I cannot underestimate the difficulties faced by a woman with young children being obliged to return repeatedly to a clinic. The anxiety of coping with pain, the care of young children, marital difficulties, and the loss of the breadwinner's job because of attending hospital so frequently, becomes, cumulatively, an extremely serious matter. Had the gynaecologists, nursing staff or social workers elicited that information from this woman, the decision to do little more than monitor her condition, without definitive treatment and without listening to her need for reliable contraception, might have been different.

SUMMARY AND CONCLUSIONS

1. Adequate treatment of carcinoma in situ is that which is based on generally accepted treatment and evidence of disease eradication.
2. The aim is, and over the relevant period has always been, to achieve this or, if there is any recurrence of the disease, to repeat the treatment.
3. National Women's Hospital has had an efficient follow-up system for patients diagnosed with CIS. This system has been in place for many years and before it was generally accepted that these patients needed lifelong follow-up. However, a minority of patients have not received adequate treatment by generally accepted standards of the time.
4. Adequate treatment for women who have CIS now requires that they are treated with the aim of eradicating the disease. They also must have their condition monitored for life. Moreover, these women must be advised of the nature of their condition and of their responsibility, to ensure that they attend for regular smear tests and examination.
5. Any definition of adequate management for CIS of the genital tract implies adequacy from a broad viewpoint; one involving the cultural, emotional, family and social consequences of the disease. Specialist staff at National Women's Hospital must clarify their scientific objectives in diagnosing and managing the disease and, of equal importance, come to terms with the personal problems encountered by patients diagnosed with this disease.
6. Protocols for managing disease of the genital tract should be developed at National Women's Hospital and reviewed from time to time.
7. Adequate management of carcinoma in situ of the genital tract must include:
 - a) Acknowledgement of the dignity of the woman patient and her right to total privacy.
 - b) Knowledge and acceptance of her cultural needs.
 - c) The provision of accurate information concerning diagnosis, treatment and future management of the disease.
 - d) Provision of adequate information about the consequences of treatment and the impact that her treatment or management may have on her personally, on her family, working life and her mental health.

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- e) Counselling should always be freely available and women should be encouraged to take advantage of a service which is culturally appropriate, accessible and confidential.

If these criteria are not observed, the patient is less likely to co-operate in all aspects of management including screening and follow-up.

1. 'Invasive Potentiality of Cervical Carcinoma in Situ' International Journal of Gynaecology and Obstetrics, Vol 7 No 4: 161.