

3. A treatment protocol requires a certain discipline on the part of those who offer treatment to the patient.
It implies, of necessity, an up-to-date knowledge of the nature of the disease and the management available, given the constraints of the particular institution.
4. The patients could be informed of the treatment protocol and use that information as the basis for understanding procedures as they are offered to them throughout the period of their hospital care. A treatment protocol could provide the basis for printed information to be given to patients.
5. The treatment protocol can be used as the basis for peer review and discussion.

The development of a treatment protocol however, must not take the place of formal peer review. The main danger in having developed a protocol is that it will not be regularly reviewed. It should be the responsibility of the Hospital Medical Committee to ensure that treatment protocols are developed and that a timetable for reviewing those protocols at regular intervals is agreed upon.

PATIENTS' RIGHTS – What did they know?

Among the patients I met and interviewed, 44 were part of (or related to one of) the group accumulated as the result of the 1966 Proposal and monitored with continuing positive smears. These women have been called Group 2 patients, following the analysis of their management in the 1984 paper 'The Invasive Potential of Carcinoma in Situ of the Cervix' by McIndoe, McLean, Jones and Mullins.

There was a total of 131 patients in the group written up by McIndoe et al. As at June 1983, this group showed a 22 per cent incidence of invasive carcinoma of the cervix or vaginal vault. The other group totalling 817 patients whose monitoring showed normal cytology, developed invasive carcinoma in 1.5 per cent of cases. Only one woman (Patient Code 2Z1) knew that she had been included in a research project. Many, including 'Ruth', believed they had been used as guinea pigs; but equally, some when they spoke to me were still of the view that they had been offered generally accepted treatment. For example, one Group 2 patient (Code 5R1) told me:

"I never felt that I was being deliberately kept in the dark about anything...in a situation where you are a hospital patient, you are completely trusting. I am reasonably sure that in my case I was not experimented on because the Metro article quite categorically said 'that Dr Green actually ruled out any definite or invasive cancers'. That at least is my understanding of what the Metro article said.

"The article, however, has raised a feeling of disquiet in me but I have a feeling that [if I had] positive smears, Dr Green would have done normal treatment on me. If a doctor discussed it with me now, I would be perfectly happy to be used as an experimental subject, but in 1969 I think I might have been very hesitant because my family was still very young and it would have given me a completely different outlook if I had been asked."

This woman had initially been admitted for investigation of menorrhagia (excessive bleeding) and persistent positive cervical smears, both of which are possible symptoms of invasive cancer. Histology reported carcinoma in situ of the cervix and from then until March 1973, the smear report on eight occasions was 'cells strongly suggestive of malignancy'. At that point a ring biopsy was performed. From 1973 to 1977 when she was readmitted for a second cone biopsy, she had eight further smears, all of which indicated the possibility of malignancy. A clinical examination in March 1977 caused the doctor concerned to report 'suspicion of malignancy' and to take two smears to be certain that the Grade 4 report was accurate.

After the second cone biopsy in 1977, the smear reports returned to normal and have continued so. Her treatment from admission in 1969 until the cone biopsy undertaken in 1977 is entirely consistent with that of a patient whose condition is being monitored with continuing positive smears and no definitive treatment. Yet she felt secure in her treatment and in the knowledge that she was being well cared for. She was aware that she had positive smear reports and said:

"I was never in any doubt that I was being treated for a cancerous condition which was in an early stage but that it was not at a dangerous stage. I felt they thought they could get rid of it by curette or by biopsy. I thought they knew what they were doing and I am in perfect health now and am still intact. I am really glad that I didn't have a hysterectomy when it was first thought that I would have to have one."

The outcome has been entirely satisfactory for this woman but she was not informed that her continuing positive smears were a sign of a potentially dangerous condition.

Another woman, Patient Code 8K, advised to have no further children, entered National Women's Hospital to have a tubal ligation. She said:

"When I came out of the anaesthetic, I discovered that I had a lot of packing which I inquired about and was told that it was normal."

After several return visits to the Hospital, she heard Dr Green say, "Oh this is the lady with the positive smear." She told me:

"I recall those words very clearly because they gave me a tremendous shock at the time."

She then read her notes and found for the first time that a cone biopsy had been performed while she was under anaesthetic for a tubal ligation. Until she read the magazine article 'An "Unfortunate Experiment" at National Women's Hospital', she had never heard the term 'carcinoma in situ'. She had never been told that she was being monitored for this condition, and her permission for the cone biopsy had not been sought. She said:

"I loathed and detested being a patient and going through the clinic. I can't explain the shock that I felt when I found out by accident that I had a cone biopsy. I am the guardian of my own body and I believe it is an invasion of my rights to have something done without being told about it. I also recall the guilt you feel when you are flicking over the pages of your own file and hope the doctor will not come walking in and catch you. I don't believe you should have to do that."

One woman, Patient Code 7V, had been attending the consultation clinic at National Women's Hospital since 1963. In 1983 for the first time, she learnt something of the nature of the condition for which she was being monitored. She asked the doctor examining her, "Why am I still coming here when I feel good?" The doctor replied, "Because you had cancer."

"I said, 'You are joking. No-one has ever told me that.' The doctor then told me that I had to keep coming to visit at the clinic until I had clear smears for 10 years, then I could go to my own GP. I couldn't believe that I had had cancer."

This woman had never been told that she had had a series of positive smears and a diagnosis of CIS before treatment was undertaken in November 1974. Her husband had made unusual efforts to find out what was wrong with his wife. He had made an appointment at National Women's Hospital to discuss his wife's condition. He said,

"I made an appointment to see Dr Bonham to clarify the reason for Mum's [his wife] visits because both Mum and I did not know what was going on. Dr Bonham was no help and referred me to Professor Green, who as I understood to be the head of A-team and also the doctor who Mum saw when she visited the clinic. I asked Professor Green what was wrong with Mum and why she

needed to attend the clinic. He answered that Mum was required to undergo tests. I asked what the test were for and his reply was beyond my comprehension.

"I left the interview as ignorant of Mum's condition as I was when I first went in. I could not explain to Professor Green that I did not understand him and felt that I just had to lump it anyway, even though I did not understand. I got no satisfaction at all.... When Mum was discharged from further clinic visits, she was told then and told me later of her having cancer of the cervix.

"It scared the hell out of me and I felt at the time that had any of those doctors been present, I would have punched their bloody heads in. I felt angry then and still do, knowing what I know now, and my anger is at the arrogance of those who profess to know more than a woman about her body and what she feels and reacts to. Carcinoma in situ are words I have just learnt. I did not understand its meaning or what it relates to. I understand... what cervical cancer relates to. I feel that people have a right to know of any condition that may develop internally or externally be it terminal or otherwise and whether they should be told or not should not be the doctor's decision, but that of the family."

After meeting this woman and her husband I could see no reason for not telling them the nature of the condition from which she was suffering.

The daughter of another patient (Code 1H) also made appointments to try and clarify her elderly mother's condition with her mother's knowledge and consent. She said:

"My mother relied on me to some extent to be informed about her condition."

After two unsatisfactory interviews, the woman told me:

"At the time, within the family, we knew that my mother had cancer of the vaginal wall. We thought it was fairly minor and couldn't understand why my mother's condition couldn't be treated. My mother eventually died on.... Between 1974 and 1980 my mother was in hospital several times and she would always explain to the family that she was going in for an examination under anaesthetic. I now understand that she was first diagnosed in 1974.

"She had carcinoma in situ of the vulva as well as the cancer of the vaginal wall. In... she had a vulvectomy for microinvasive cancer of the vulva. I certainly never knew of this and my strong impression is that my mother never knew that she had cancer in more than one site. My mother went into hospital at various stages and my strong impression was that she never really knew why she was being hospitalised. She would explain it to us that they just wanted to have a better look under anaesthetic but I now understand that she had several operations after the initial radium treatment."

After radium treatment the patient developed a protruding lump in her left groin area. This worried her according to her daughter, and "she had all sorts of explanations for it ... from conversations I had with my mother, I feel that she never got an adequate explanation about this lump and it troubled her greatly."

Another patient (Code 3L) said:

"The things that upset me were that I was actually never told I had carcinoma in situ. I was told the first time... in June of this year. The fact that my GP was never told that I had a Grade 3 smear... After I had been to the clinic in March they had said, 'Oh well, you ring up for the results.' So I rang up and got the results myself and my doctor was never notified of this."

One patient (Code 1W1) admitted for treatment of carcinoma in situ in 1982 told me:

"After I had the cone biopsy I was told that they had got it all. I have since learnt that this was not the case. I was told that the chance of getting any form of cancer again were the same as any other woman."

In fact the Pathology report stated that the excision margins were not clear. She ultimately underwent a punch biopsy and then a second cone biopsy. The statement that she had the same chance as any other woman of getting any form of cancer was incorrect. Women who have had a diagnosis of carcinoma in situ are at higher risk of a recurrence than other women.

This woman was asked if she agreed with the proposition 'that if women with a cancerous or precancerous condition are told the full details of what they had and the risks that that might involve, they will worry unduly'. She said:

"I have often thought about this particular matter myself because I am a person who does worry. As I have said there, I worried for a year. On the other hand I feel that it is my body and that I really do have the right to be told about anything that affects me and that whether I worry or not is then up to me."

Another patient (Code 6Q) who had developed invasive cancer and was a Group 2 patient said:

"However I have damage from the radiation treatment. I had a slight bowel problem and for a time I used to get fluey sort of symptoms which I admit are getting less and less now. I can no longer have intercourse with my husband because my vagina has been affected with the radiation treatment. Although this is difficult to cope with, we manage and I feel that if you know what the problem is you can cope with anything."

Other women told me of incorrect information they had received and described their feelings of anxiety and uncertainty when they found information difficult to elicit. Several stressed the need to have adequate information in order to co-operate with a treatment plan. For example, one patient (Code 6F) who has been treated for invasive carcinoma told me:

"If I had understood in 1977 that I had a potentially life-threatening condition, I may have been less casual about having smears after 1977. I feel that if I had been in the picture and treated as a human being and not as an animated cadaver, I might not have gone into the dangerous position I did. I might have stopped smoking, looked at my health more seriously. For instance, if I had known that my biopsy in 1975 showed that I had microinvasion, I would never have ceased to go to follow-up clinics. But I should have been informed. By what right do these men play Russian roulette with our lives. I have this sword of Damocles over my head now, for the rest of my life."

I agree with Dr Collison's view that some patients will simply not absorb the information they are being given. However, I do not accept that most patients will completely misunderstand the nature of their condition, treatment or management plan and prognosis if it is explained to them in lay terms. Many people will forget the details but remember the main thrust of the information. It will often need to be repeated on subsequent visits but if a patient fails to grasp information concerning her health care, then the problem is usually with the person trying to communicate the information.

I disagree with the suggestion of one witness that many patients lack the intelligence to grasp essential information. In general, the level of information received by the patients I met was poor. It is disturbing that on occasions patients felt confident they had had full and accurate information when in fact that had not been the case.

A substantial number of patients praised the Hospital and its staff and many took the opportunity of this Inquiry to make sure that I realised that Dr Green was a person who cared intensely about his patients. One patient (Code 3W1) said:

"Dr Green was always available whenever I visited Auckland to see my parents. Dr Green's total honesty has always impressed me and I am convinced

that he would treat each and every patient with the same respect. He volunteered information and never at any stage did I feel that he was keeping anything from me. He always remembered that medical terms are in many cases foreign to patients. Therefore he was anxious to ensure that such terms were translated so that lay persons could understand them."

Others told me that in general, information proffered by medical staff has improved over the years and that the level of information they have received in recent times has been vastly better than in earlier years. This of course reflects changing attitudes towards patients and improved communication techniques.

Dr Collison, who had read the majority of patient interviews before giving evidence, was obviously concerned at the level of information received by patients and immediately began making inquiries to improve the communication of information to them. She told me for example that the consultation clinic staff had previously been instructed not to release information on smear reports by telephone and said:

"I am told that they will release the information if it is a normal smear and if it is not they have been in the habit of getting a doctor to ring the patient. Now I have said that I don't think this is satisfactory. I think the patients must be given their results."

Professor Bonham suggested that

"the resources at our disposal simply prohibit us from providing the level of individual care and attention which we would like. It is a problem that is not unique in New Zealand health services at the moment, and the casualties of the inadequacies of the system will invariably be some patients who will not get the care and attention we would like. Thankfully such cases are rare and I would strongly suspect that most who do have grievances have expressed them to this Commission."

In fact, only a minority of women or relations of patients who spoke to me had grievances to express about their treatment, about National Women's Hospital or about any member of the medical staff. After reading their files and listening to their experiences I could only conclude that the vast majority of the people I talked to had so little knowledge of the nature of the condition for which they or their relatives were being monitored, that they had no basis from which to formulate a complaint. Moreover, communication of information to patients will not always be improved by the application of more money.

RIGHTS IN TREATMENT

Written consent

Any treatment or procedure, be it surgical, diagnostic or teaching, which takes place under anaesthetic must have the prior written consent of the woman concerned. It should be obvious from the consent form precisely what the patient has been told and to what she has consented. In light of the evidence I have heard, the Hospital should consider providing the patient with a written summary of possible risks. I consider it is insufficient to state, as one example does:

"We have discussed the nature, effects and possible risks of the chosen procedure/treatment. I agree that it is in my interests to have this procedure/treatment."

The consent form must also include the name of the doctor who will conduct the operation or procedure. Only in emergency situations should one doctor be substituted for another after the woman has been anaesthetised.

Some doctors may consider that telling a patient of the risks associated with any treat-

ment or procedure is not appropriate 'patient psychology'. In my view it is paternalistic and unnecessary to withhold this information.

If the woman is consenting to a surgical procedure then no other procedure ought to be substituted or added once she is anaesthetised. Obviously there will be times when exceptions to this rule are necessary. These ought to be specified and explained to the woman before she consents to them.

There are other occasions when a patient's consent in writing should be sought. Once treatment protocols are established, then the patient should give written consent to any significant departure from that protocol. The reasons for the change in treatment must be explained to her. I fully appreciate that it is difficult to explain every procedure in detail to the patient in a large hospital. However, if a broad description of generally accepted treatments or procedures is available, the time spent with each patient obtaining her consent might be reduced.

Written consent to treatment or procedures must be based on certain criteria. The person seeking the patient's consent must be satisfied that she can read and understand the form. If understanding is reliant on translation into another language, then appropriate arrangements must be made before the consent form is signed. It is inappropriate for relatives or members of the Hospital staff who are not in a confidential relationship with the patient to undertake this task. Staff should also keep in mind the significant degree of illiteracy in the community. It should never be assumed that the patient who appears to read and understand a form has in fact read and understood it.

It is also a fundamental criterion that the consent of any patient, be it written or verbal, should be sought with maximum privacy for the patient.

Too many of the consent forms for surgical or medical treatment which I have seen tend to offer protection to the doctor rather than information for the patient. This is an emphasis which must be redressed.

Verbal consent

There are a multitude of minor treatment options, procedures and diagnostic tests which are conducted as an ordinary part of routine patient care. It would be unnecessary to demand that each of these have the patient's written consent. Not only would the patients become irritable, but the work of the Hospital would grind to a halt.

If the patient knows in general terms the nature of her condition, and the treatment, procedure or diagnostic tests which she is likely to be offered, she needs less explanation as each procedure is undertaken. If she is conscious, then on most occasions the nurse or doctor conducting the procedure can, with a brief exchange, ensure that she understands why she is being offered that drug or injection, or why a particular examination is necessary, and obtain her verbal consent.

This method has a number of merits. It ensures dialogue between the patient and nurse or doctor, and it is an opportunity for the patient to seek further information or to decline a certain part of her treatment. It also allows the patient to give her family or whanau a fuller explanation and to seek their help in making decisions about health care. This is important for many patients.

Some of the patients I met during the course of this Inquiry have become deeply suspicious of the medical care they have been offered at National Women's Hospital. Good communication between doctor and patient will remove much of that mistrust and give the patient greater confidence in the care she is being offered. Although decisions about treatment can never be transferred totally to the patient, the responsibility is shared if the doctor knows that the patient understands the nature of her condition and the treat-

ment available and is a willing participant. I have talked about consent to treatment, procedures or diagnostic tests. Decisions not to treat a patient, or to monitor a patient's condition without any definitive treatment should naturally be included.

Code of Rights

The Auckland Hospital Board has a written statement, 'Code of Rights and Obligations of Patients and Staff'. The Code is available in Maori and a variety of Pacific Island languages. If it is followed by staff it would redress many of the concerns I have about adequate information, patients' rights in treatment or when included in trials, and their right to privacy, confidentiality and dignity.

Its distribution, however, is a matter of concern. I was informed by Dr Collison that this Code of Rights could be handed to each patient as she was admitted to hospital. I believe it ought to be freely available to out-patients as well. At present, the Code of Rights is supposed to be found in the patient's wardrobe. This is clearly inadequate, particularly when a patient is not mobile or has not been told that that is where she can find the Code.

It is of passing interest that on a private visit to a patient in an obstetrical ward at National Women's Hospital in February 1988, I found no copy of the patient's rights document in a four-bed room. The patient herself had never heard of the Code. It may well be that the staff place little emphasis or importance on the provision of this document.

Interpreters

National Women's Hospital serves a large community containing a variety of cultures and languages. There are significant groups who do not speak or read English, with ease. Many Maori women, although proficient in English would prefer to discuss their personal health problems in their own language. All groups are entitled to have their cultural values and language respected. This is particularly so when the patient is nervous, feels ill, or is embarrassed by the procedures she is offered.

The Auckland Hospital Board should urgently consider employing and training interpreters who would be bound by the rules of patient confidentiality. They would be available to help explain treatment or procedures and ensure that the woman's consent is freely given. The Board will need to evaluate which languages most need interpreting services. These services should be publicised throughout the Hospital and a woman should have easy access to an interpreter's help.

Health professionals proficient in the patient's language may often be the most appropriate person to manage that case. Other hospital workers, relatives and friends should not be relied on as interpreters.

TREATING THE PATIENT WITH DIGNITY

Although many of the following comments will strike health professionals as obvious, after listening to the evidence given by patients I feel it is necessary to reiterate some basic rules. These are rules which should be observed in any hospital but particularly so at National Women's where, of necessity, most patients will need a genital examination on almost every visit.

Privacy and modesty

The patient is entitled to meet her consultant while she is fully dressed and to change in privacy for an examination. While some consultants may see this as a waste of time, the patient's dignity must be the first consideration. The gowns provided ought to offer adequate coverage for all sizes of women.

Consultations should take place in circumstances which ensure privacy. It is unforgivable if a patient's personal information can be heard in the next cubicle or in the next bed. All physical examinations should be carried out in total privacy.

All health professionals must be aware of the taboos which society generally places on the public display of genital areas. This is particularly so in the Maori community. A patient must be treated with the utmost courtesy and respect. Examination for gynaecological malignancy is very different from examining a fractured limb in an orthopaedic ward, for example. No matter how used the doctors are to examining the genital area, they must remember that the patients themselves often find the experience embarrassing, and sometimes humiliating and threatening.

If students not involved in her immediate care are to take part in the examination, her permission must be sought before they enter her cubicle or room. No pressure should be put on her to permit the presence of students or other health professionals.

Colposcopy

The colposcopic examination, which is essential if positive smears or suspected invasive cancer are to be carefully evaluated and diagnosed, can be no less disturbing to the patient.

The chair in which the patient reclines has been designed to allow the gynaecologist to view the cervix through an instrument not dissimilar to a microscope. This means that the woman will often be lying in an elevated and what to her must seem a most undignified position. Nursing staff and gynaecologists who have discussed this procedure with me are all, to their credit, conscious of the difficulties that colposcopic examination presents. Administrators must be prepared to allocate resources to ensure:

1. The room in which colposcopy is undertaken is completely private.
2. A female staff member is always present or immediately available for the patient's reassurance.
3. The examination room is pleasantly decorated and furnished.
4. Where possible, she is examined at the same level at which the gynaecologist is sitting.
5. If possible an extra eyepiece should be available for her to watch the examination taking place. This has the additional benefit of allowing the gynaecologist to explain and demonstrate what he or she is observing.
6. The room should be large enough for the woman to have a friend or relation present if she wishes.

Out-patient clinics

A system must be devised to reduce waiting periods for patients at out-patient clinics. The principle should be that hospital care is for the patient, and not for the convenience of the doctors and other staff. There are very few patients who have sufficient time at their disposal to spend hours waiting for an examination or for treatment.

Women who have young children to care for, who work outside the home, who travel long distances to get to NWH and who have transport timetables to observe are all placed under great strain if they are kept waiting for inordinate periods. Added to this is the stress caused by concern about their health. Consideration should be given to decentralising out-patient clinics, so that doctors and support staff take their clinics to the people, rather than always requiring the people to come to the clinics. While it may not be possible to staff a clinic in the far North on a regular basis, serious thought should be given to staffing out-patients clinics in South Auckland and other distant suburbs.

Not all women are as assertive as the patient who had her pay docked each time she went to the Hospital over a period of many years. On one occasion she simply got up and left the clinic after being kept waiting for an inordinately long time. A more recent experience was recorded in a letter from another woman. She had an appointment at 2pm on a day in late December 1987. She wrote:

"And at 4.30pm, after about five people who had arrived after me had been before me, a nurse came up to myself and another lady waiting with me. They had lost our files and had to call a doctor back to see us. Everybody had packed up and the cleaners were cleaning. Both my husband and myself were nervous, not having had an experience like this before. So anyway, they called us in and told us to get changed into a nightshirt and wait for the doctor.

"When he came in, he was a horrid old man, obviously disgruntled at having to see us, he didn't look at my file, quickly asked what the problem was, then gave me an examination. The nurse was very nice, after the examination I was in tears as he was rough and the examination was painful. He then told me that my periods can't be like what I had told him and started lecturing me. He said it was all in my mind and that I was obviously emotionally disturbed and he would write to my doctor and tell her that."

After this patient had left the clinic the nurse followed her out to the car, apologised and gave her the name of a specialist whom she recommended. The nurse suggested that the woman go and see him.

This type of experience has been described on several occasions during patient interviews. I was concerned, however, that even while the Inquiry was still sitting, patients were being treated in this manner.

Case history forms

National Women's Hospital had a form, 'Special Cervix Case History', for women admitted to Ward 9, the ward in which invasive cancers are treated. The form contained two questions:

C. (age):.....

No. P:.....

The information sought was the age at which intercourse first took place and the number of sexual partners a woman had had. Although Dr Green said there were strict instructions that the questions were to be asked by him or by the experienced and respected ward sister, that was not 'Ruth's' experience. 'Ruth' was in fact interviewed by a house surgeon. After her admission to National Women's Hospital in 1985 for tests prior to caesium treatment, 'Ruth' was

"...asked general questions about my health and medical history. He also asked: a) at what age I had first had sexual intercourse, and b) how many sexual partners I had had in my lifetime.

"I was given no reason as to why these questions were asked. After my Wertheim's hysterectomy, the elderly lady in the room next door to mine in Ward 9 raised the matter in discussion. She had been asked the same question so we assumed that all patients who had been diagnosed as having cervical cancer were asked these questions. We did not understand their relevance. Such questions appear to me to be a total invasion of privacy. The questions were not justified by the doctor in that he gave no explanation or reasons as to why they were asked."

Several other patients told me of their concern at the implication that they had been involved in multiple sexual relationships. A number of them were made to feel somehow

to blame for the disease they had contracted. One woman put it colourfully when she wrote:

"...and I wonder how many women like me are walking around thinking their sex life must be rather outrageous."

At the age of 19 she had been told she had atypical cervical cells by a doctor outside Auckland. She wrote:

"...but in the next breath told they were absolutely nothing to worry about. Once I was even told that they could have been caused by having overly energetic sex!"

Professor Skegg's evidence satisfied me that the information sought in these forms about sexual behaviour will frequently be unreliable unless the questions are asked in a carefully controlled interview. Nor could the information obtained be interpreted accurately without measuring it against a comparative group. Towards the end of the Inquiry it was conceded that these questions should no longer be asked. First, because the questions could not add to knowledge about the disease, and secondly because of the likelihood that women would feel embarrassed.

There is also an unanswered question about the use to which these case history forms were put. I consider that any patient who is asked to provide information which is not directly relevant to her treatment or the management of her condition, has a right to know for what purpose the information is being used. If it is for properly conducted research, she is entitled to know that. The person asking the questions also has a responsibility to ensure that the information is put to some use, and that ultimately the results will be disseminated for the information of the medical profession and therefore the public.

The patient with invasive cancer

When a woman is told she has cancer of the genital tract, she will experience many emotions. Fear, need for reassurance and shock would not be uncommon. Generally the nursing staff have been highly praised for their caring attitude to the women they nurse. Doctors have not always received such praise. Some have been described as uncommunicative, others as lacking in compassion.

One woman (Patient Code 6F) said:

"About my treatment, I must say that I didn't find much compassion at all. Certainly not among the majority of the doctors. On the other hand the nurses were all very nice. They were just like angels in Ward Nine. I feel that when you have cancer, the whole person should be treated. For instance nobody has ever asked me if I was happily married or talked to me about diet or asked me whether I was in debt or was I taking drugs. I believe that diet as a feature of health is of vital importance. When I go back to the Hospital I tell them that I have put myself on a diet and I have the feeling that they don't attribute my success to my diet at all."

She also said that on one occasion two doctors had shown her great kindness.

Another young woman (Patient Code 1E) who had symptoms of abdominal pain and bleeding after intercourse was referred in 1984 to a gynaecologist with no connection to National Women's Hospital. She was examined both under anaesthetic and while she was conscious. She was tested for various conditions such as chlamydia and for a number of months she was told repeatedly by this gynaecologist that she did not have cancer. Her smear tests were relied on to confirm this view. When she was finally referred to National Women's Hospital she was told by a gynaecologist there:

"Mrs A, you have invasive cancer of the cervix. That was just looking at me without even having anything, and I just felt that the whole world was crashing around me. I couldn't believe it after all those months of it being denied

and being looked at that he could say that to me. I don't remember that day even getting home. He just – I just felt that he was daring me to show any kind of emotion and he just said he wanted me in National Women's Hospital, I think, the following Wednesday.

"Anyway I was pretty shocked by all of this and I suppose that shocked state lasted for some weeks. I just sort of felt that I was going through emotions really. But I didn't seem to be able to have anybody to explain anything to me and I, really thinking back, I did try. I did try."

Question: You tried to get explanations?

Answer: Yes, but nothing, you know what I mean. I know that particular day when he delivered that news to me I was probably shocked and I remember asking him to tell it to me again so I got it right. So I had to put up with that for a few days and then I had to go into National Women's Hospital, then I was told. I went in on a Wednesday. I was told that it would be by no means certain that I had invasive cervical cancer until they looked at me under an anaesthetic.

God, I had just been under an anaesthetic. And then truly I began to cling to hope that I didn't have it at all, you know, that it was just a big mistake.... There were three of us went through that system together and I thought surely I will be the one that doesn't. I know it is probably pretty normal denial kind of thing.

Later:

"We were prepared for caesium rod treatment before going to theatre, very very briefly prepared. It was made to sound as if it was just a piece of cake but of course the possibility was explained to us that after caesium implants, six weeks later would follow hysterectomy.... Waking up after that to discover nothing had been done to me after anaesthetic to be told it was too far advanced and that I would need another treatment, that it would not be a hysterectomy then.

"...I had to wait several weeks.... They were having a problem at Auckland Hospital with their machine...and I was told at that time [my chances] were probably sort of 50/50, and...that the radiation treatment that I would receive would be nothing to worry about. I certainly wouldn't have any side effects.... Most women just carry on a normal life and it doesn't affect them in any particular way.

"That wasn't the case for me. It affected my bowel dreadfully. It just seemed to me all the way through that it was a lack of information given to me. When I was discharged from NWH I had – my back was completely out, my bowel was in a shocking state. This was even prior to having any radiation at all.... I saw my GP who, when she examined me rectally, she was shocked too.

"At no point did anybody think to tell me that I had been examined rectally under anaesthetic and that things were not wonderful.... The tumour obviously was pushing into the bowel which was making it difficult for me to have a bowel motion.... They hadn't bothered to tell me that....

"When I was admitted back into NWH to have the caesium after-loaders...we...were given a brief explanation as to what it would be like and it was described to me as being just slightly uncomfortable, nothing to worry about, no problems.

"The other time that I had been in NWH and I had been prepared for the caesium after-loaders, it was described in the same way.... There was a lady there

who was being treated with the after-loaders and she was in a very upset state and we were told not to speak to her because she would give us the wrong impression of what it was really like.... Another lady was produced who had a better attitude to her disease and everything and she was chosen as being a more suitable sort of person for three newcomers to the ward to speak to.

"So we were told to keep away from this other lady who was in her bed crying and upset, you know, not a good example. Well unfortunately I wasn't a good example either. We were prepared for theatre and everything. I woke up from that anaesthetic screaming, absolutely screaming. I was out of control because I was in so much pain. It was like waking up to torture and...I must have been in the recovery room. I don't remember where I was.... In the end I think they gave me some Pethidine or something like that and I was told that I was not doing myself any service, that I was just making things worse for myself if I didn't stop. But the pain was so awful.

"It wasn't until I read my notes at the Inquiry, my own records, that there was reference to the fact that one of the rods had pierced the cervical canal wall, so possibly that did add greatly to my discomfort. Nobody told me that at the time and during the three days that followed.... [They] were the worst I think I have ever spent in my life. I felt like a leper. I was just so uncomfortable, I couldn't do things for myself.

"I felt sorry for the nursing staff because obviously with the radiation present they weren't able to spend time. I needed people. I think we all do but the situation there was just dreadful because, I would wish that there was a way they could re-organise things that you could actually have contact with people without fear. I just felt...upset, angry, in pain the whole time and I was made to feel that everybody else was coping.

"...At no point did they say to me that actually, yes, we do understand or give me a little bit of sympathy. It wasn't until I read that...they had made that mistake and it had been righted in the end.... But the fact that it had perforated that area surely must have added to my discomfort. So I was pretty distressed and they asked me if I would like to speak to somebody which I did. So they called in a lady from Cornwall House and I spoke to her and she thought I was quite sane afterwards...and once the rods were removed I felt hugely better.

"Now the only advice given to me when I was discharged the next day was 'resume your sex life as quickly as possible'. I could not believe that. And that was the only form any of the advice ever took. Resume your sex life. When your body has just been mucked about, that was the last thing, the absolute last thing that I would want to be advised to do. There was no other help available, just that, resume your sex life."

During her period of follow-up, this woman suffered various side-effects. She still considered that her feelings and symptoms were not being taken seriously.

"I just felt that there was a patronising kind of attitude and they would look at me and say, 'Oh yes, well this is to be expected' or 'Yes that is to be expected.... Any complaint I made was never looked at. It was heard but nothing was ever done.they felt that my attitude to sex was not a good one. I think they felt perhaps I wasn't making any effort. They could not appreciate that it was physically uncomfortable for me and that was the part that I resented the most. Everything seemed to come back to that. That we are all sexual animals and once you start doing those things, you know...you will be better.

"But it has never improved for me. I still have problems with that area and that sort of saddens me. I wish things were differently.... Okay, I was listened to

but never was anything done, and when I was examined it was always a smear test, always a very very brief, quick pelvic examination.... Everything I said, I sort of read on things, were dismissed. Anything I had read in the press or in books was always... 'Oh that's old hat' and 'Things are out of date'. Nothing I said was given any sort of credence really."

She was not happy with the check-ups she was receiving and asked for a scan which was refused. She said:

"I would get the feeling that...they were just dreading my check-ups because I always found something to moan about or ask about, and it occurred to me at the time, my God there must be a lot of women who sit there and say nothing.... I thought that perhaps I should just become passive and sit there and say nothing because... I am not getting anywhere, my being vocal or asking. I am getting nods and sympathetic looks and nothing else, nothing else. Anything I complained about or was worried about, there was always a sort of explanation: 'Oh probably scarring'; 'Oh probably radiation'; 'Oh probably this'; 'probably that'. Never anything. I didn't ever feel that it was dealt with, you know."

The side pain that she had suffered prior to the initial diagnosis began to return. She was worried about it and mentioned it "again and again" at the Hospital.

"They told me that that pain I was experiencing had nothing at all to do with my cancer, but it just did not let up and it went from strength to strength. I was given Panadeine by the nursing staff on Ward Nine but it was just not acknowledged in any shape or form.... Halfway through the radiation treatment in Hamilton, the pain began to lessen and it stopped. So I was pain-free from that time until Christmas that has just passed."

"When I returned from my radiation treatment in Hamilton, I did mention the fact that I had had relief from pain and they said to me then that quite possibly it was connected, but they refused to acknowledge that there was any such connection at the time."

In March of 1987, this woman was referred by her general practitioner to a bowel specialist. While his tests were being conducted she was due to return to National Women's Hospital for a six monthly check. She said:

"I had at that stage seen Mr N [the bowel specialist]."

I think by that point he had given me a barium enema and he was further investigating the pain. When I had described the pain to Mr Jamieson at my appointment in March [at NWH] and said that I was being seen by Mr N, he said, 'Oh, it's probably a bit of colic.' He said, 'Quite common after radiation, you get a bit of colic.' And I said, 'What does colic feel like?'; and he described it to me as being 'sort of wind pain'.

"I said, 'No it's not like that.' With that he seemed to be perfectly happy with the rest of me. I got an extremely briefer than brief pelvic examination that day and a smear and he said, 'I don't think we need to see you for a year', and that was that.... Of course it was only a matter of two weeks later that the CAT scan revealed my recurrence."

"So Mr N felt that he had to then refer me back to NWH with this discovery. Obviously I was pretty upset by it all, so he asked me who I wanted to see there. So I said I felt that I had had more to do with Mr Jamieson and would prefer to see him. I took my sister with me and he was very nice to begin with until my sister asked him what would have happened had I not come back to NWH for a year."

"He ignored her and said to me, 'And what did take you to Mr N anyway?' He seemed to sort of be quite miffed about the whole thing and obviously indicated to me that he felt that it was sort of, the kind of symptoms I was having didn't warrant any further treatment anyway.

"Then he went on to say that two years ago they had suspected lymph node involvement. They had suspected it; and I opened my mouth to sort of protest and he said, 'And I suppose now you are going to ask me why you couldn't have had a scan?' I said, 'Yes, you got it in one' and he again said what Mr W said, that there is just no way that they could possibly scan anybody. If they scan one, they have to scan the lot and we can't offer that facility here because we haven't got the facilities – as simple as that.

"So the whole thing... I... couldn't believe that that was the attitude.... I felt surely there must be certain cases... where these things might be looked at in a little more depth.... He was obviously annoyed that somebody else had discovered the recurrence and NWH hadn't. Quite frankly, the kinds of examination that I was given at NWH anyway, wouldn't have discovered anything.... I would hardly call them thorough."

This woman then started on a course of chemotherapy at Auckland Hospital. She found the contrast in attitude very helpful.

"I have monthly visits to the doctors there and I find them terrific actually. They are very caring people and they don't clockwatch.... They seem to recognise a need to talk about things and I have found them absolutely helpful and the attitude is so different, so different.... All I know now is that I did not respond to the chemotherapy, that the disease in fact progressed during that three months, and there is nothing, absolutely nothing available for me.... It was explained to me when the chemotherapy treatment was started that... they could not cure the cancer but they hoped for a remission by chemotherapy....

"I was perfectly happy with that. I was hopeful.... But then to be told three months later that it was in fact progressing, that was a bit of a blow.... I sort of think back now [to] all those months and the diagnosis.... No-one is treated as an individual; like there is a method, 'Oh yes, for Grade 3B's we do this.'

"The friend I was talking about before, who had also had the pain, the year after her radiation she had a secondary discovered on the bone. She, at the moment, is still alive. She won't be for much longer. The other one died, so I am left now. Of the three of us, I am still here. I hope I'll be here for a wee while yet, but I don't know....

"In my checkups after the treatment, never was I looked at once above the waist [at NWH]. I was never examined rectally at my checkups at NWH ever. Never looked at above the waist although in the clinic the nurses used to say, 'Put on a gown, you will get a breast examination today.' But I never did. I used to say, 'Well I think I am supposed to be having a breast examination.' 'Oh no, I think you can do that for yourself' and then there would be a piece of paper thrown at me with a little diagram of how to do it. No, it was never above the waist."

This woman considers she has had supportive treatment from the bowel specialist, the nursing staff at National Women's Hospital, the specialist staff at Auckland Hospital and also at Waikato Hospital. She also said:

"My GP has been very supportive and she has given me authority to say on her behalf how she feels that I got a bad deal... with the attitudes to pain....

She did all she could for me but unfortunately she was not kept in touch. They didn't report to her after each visit of mine.... She said to me that unfortunately it was a problem always, the communication between the hospital and the GP. The GP is kept in the dark about things. All through this thing I learned the results a lot sooner than my GP.... I was always telling her."

I have quoted from this woman's interview (with her permission) in some detail. Many of the matters she touched on were mentioned by other patients and her experience is not exceptional. It is possible that her illness would still have developed to this serious degree. However, I have been left with a number of questions after hearing of her experience and from many others who have had similar experiences.

1. If there had been an effective screening programme for cervical cancer precursors, this woman's disease may have been diagnosed before it reached the invasive stage.
2. If her report of pain had been taken more seriously, perhaps other treatment could have been offered or a scan done sooner than it was.
3. If her first gynaecologist had understood that her symptoms were consistent with invasive cancer, and not relied just on smear test results, perhaps this woman's disease could have been averted.
4. Above all, if she had been treated in a caring sensitive manner and given the information she needed, perhaps her distress, anger and resentment would have been a great deal less. To be made to feel a nagger, a nuisance and a person with a poor attitude is extraordinarily insensitive. If the staff at National Women's Hospital cannot cope with women who are seriously ill, then other health professionals such as social workers must be introduced to the system urgently, to assist with communication, reassurance and support, both for the patient and for her family.

I am acutely conscious that those who treat women with serious disease at National Women's Hospital can themselves be distressed by the fact that women in their care are seriously ill. It needs a special person to manage these patients; one who can combine the skills of the gynaecologist with the qualities of humanity. Some advice and training from a discipline skilled in working with the seriously ill and their relations could well be of great benefit.

CONSENT TO INCLUSION IN CLINICAL TRIALS

There are two fundamental rules (already discussed earlier in this chapter) which must be observed if patients are to be included in clinical trials.

1. The patient must be given information which allows her to understand what is involved in the trial, including its potential risks and benefits. She must know that refusing to enter a trial or leaving it at any time is her choice and will not compromise future care.
2. She must give her consent freely. She must not be in a dependent relationship to the person seeking the consent, must not feel vulnerable or under any obligation and must have a good grasp of English or have satisfactory interpreting services. She must be given time to decide and to consult whānau, family or friends.

These rules have seldom been observed in clinical trials at National Women's Hospital. However, they are standards which can and must be attained.

I have found it useful to compare the way in which the Auckland Hospital Ethical Committee performs its duties. The Auckland Hospital is one of the institutions, like National Women's Hospital, which comes under the control of the Auckland Hospital Board. It

established its Ethical Committee just a few years before National Women's Hospital. It, too, has a close relationship with the University of Auckland School of Medicine. However, it has developed quite different and detailed procedures for the approval of research and the dissemination of information to patients who are to be included in trials. For example, Professor Probert, Associate Professor of Oncology at the University of Auckland and Head of the Department of Clinical Oncology at Auckland Hospital, produced an informed consent form which:

- a) provides for the nature and extent of the patient's disease to be set out clearly;
- b) explains that the patient is being invited to be included in the trial of "an experimental drug which has been extensively tested in the laboratory and in animals but not yet in patients";
- c) explains that the drug is not generally accepted treatment, how it will be administered and under what conditions the patient will be removed from the trial;
- d) confirms that the patient has the right to enter or leave the trial without jeopardy to his or her usual care and treatment; and
- e) explains the side effects that might occur and that compensation would not be available.

It is frank and clear information which sets out the risks of the trial. It is the type of information to which any patient entering a trial is entitled.

I was also given a copy of a booklet produced by the United States Department of Health and Human Services in December 1984, 'What are Clinical Trials all about? A Booklet for Patients with Cancer'. It also explains procedures, defines terms (and tells how to pronounce them), and raises and discusses scientific and ethical issues in an exemplary manner. Both these leaflets address the patient's fears and potential questions with apparently accurate and straight-forward information. No attempt has been made to gloss over problems or to patronise.

Inclusion in more than one trial

During the course of this Inquiry, I became aware of an additional matter which caused me concern. On more than one occasion, when hearing the evidence of a patient or reading her notes, I found that she had been included in two or more clinical trials obviously without her knowledge and therefore without her consent.

One of these women (Patient Code 9Z), was included in the punch biopsy series and is one of the patients who were referred to as 'Group 2' in the McIndoe et al 1984 paper.

She was first examined at the consultation clinic of National Women's Hospital in 1967 with symptoms of intermenstrual and post-coital bleeding, both possible indications of invasive cancer. Carcinoma in situ of the cervix was diagnosed following a wedge biopsy. Almost eight years later, after repeated examinations, colposcopic examinations, and punch and wedge biopsies, she was admitted for a cone biopsy of the cervix which disclosed invasive mature squamous carcinoma of the cervix. The notes say:

"She is suitable for surgery and is therefore included in the R-series. The indicated treatment is radium plus external x-ray."

I have met this patient. She had no knowledge of the trial and her consent was not sought, either formally or informally. She did discuss the type of treatment with Dr Green but her understanding of some procedures included some extraordinary misconceptions. The information was quite inadequate as a precondition to giving her consent to inclusion in the R-series trial. When she was asked what treatment she received for her invasive cancer, she said:

"Radiation, but I remember discussing that with Professor Green because at

that stage I was a barmaid and I used to get, I used to feel terrible for some of the women that used to come in and they used to brag about having a hysterectomy. And they were quite loose women and I used to think, 'Gosh, what's a hysterectomy?' You know, I didn't know and I thought if it makes women go like that... I wouldn't have a hysterectomy.

"I remember telling Professor Green that.... I didn't really know much about radiation but I didn't want a hysterectomy because I didn't want to go like other women.... I know I wouldn't have radiation again either.... It was dreadful and I had a lot of pain while the rods were inside me and I remember telling Professor Green and he said, 'It's nothing,' and I said to him, 'I'm not one to complain about nothing.'

"It was real pain in my groin, you know. I just couldn't stand it. Then I knew something was wrong because the other women who had radiation the same time as me, they went home for weekends and they were okay...."

This woman still returns to the Hospital for treatment and monitoring. About two years ago the following comment appeared in her consultation clinic notes:

"Mrs .. is having irregular two-monthly withdrawal bleed on oestrogen replacement. Her discharge is not a problem at present. Vaginal and pelvic exam normal, she has agreed to participate in the trans-dermal oestrogen trial. Review in one year's time."

Over the course of 19 years this woman has been involved in three clinical trials. She has apparently consented to inclusion in the most recent, but I could find no indication that she had signed a formal consent form, or any indication that she received a full explanation of the risks and benefits of taking part in the oestrogen trial.

The R-series trial was approved by the Hospital Medical Committee on 18 May 1972. Dr Green's memorandum to the Medical Superintendent said:

"Despite the large number of radical hysterectomies done in this Hospital for carcinoma of the cervix, the place of radical surgery in the treatment of this disease in comparison with that of radiation alone is still uncertain. This is so because, as elsewhere, factors used to select patients for surgery are just those factors that might be favourable for treatment with radiation alone.

"To answer the question once and for all, it was decided at a meeting of D-team in February that an attempt would be made to solve the problem in a way that has never been attempted before in medical literature for this problem — that of a randomised prospective trial. This will be achieved as follows:

- a) Patients will be selected with factors favourable to surgery as they have been selected in the past. These factors are — comparative youth; extent of disease (not more than early stage IIB); absence of general medical and surgical disease including obesity; and presence of any factors making the patient a suitable candidate for radical surgery.
- b) This group of patients is then randomised into two subgroups: 1) this group will be treated by radium and radical surgery as in the past; 2) this group will be treated by radium and external radiation.

"It is estimated that there will be enough information available from this trial in six years time to decide whether surgery contributes anything or not to the therapy of cervix cancer.

"Approval and comments of the staff are sought."

The Hospital Medical Committee's only comment on approving the proposal was:

"The Committee would like to see the final programme for this trial when this has been prepared."

There was no further comment to be found in the HMC Minutes in response to this request, although at Senior Medical Staff meetings the method of randomising the patients into the two groups was discussed and tossing a coin was apparently accepted as the method.

Dr Pasupati, the Radiotherapist who worked in co-operation with Dr Green to grade the level of invasive disease, told me that the method of treatment was decided while the patient was still unconscious. Dr Wright summarised the procedure:

"...diagnosis was made or confirmed, the appropriate investigations performed, the patient then taken to theatre and examined under anaesthesia, when the final staging [grading] of the disease was made.... Now that examination was conducted by the gynaecologists concerned (Professor Green and myself usually but sometimes only one of us) and the Radiotherapist... The three of us then agreed as to whether or not the patient and the extent of the disease were such that surgical treatment was feasible.

"Having reached that agreement, she was then allocated randomly to one or other of the two arms of the trial. The question of informing the patient about the trial as a routine was considered and discussed and we agreed not to do so. Dr Green and myself and others discussed this question of informing women in the trial about it when it was initiated in 1972. We decided in the end not to tell patients about the trial. We told them they would be examined under anaesthetic when the most appropriate mode of treatment would be decided and then that we would proceed accordingly.

"If any patient were unhappy with this procedure, we would not start treatment until there had been a further opportunity to discuss it with the patient. I appreciate that the topic of informed consent is important and agree now that in 1987 I cannot defend the decision not to inform patients about the R-series trial...."

However, Dr Hodge said:

"I wish to clarify one point on the procedure for seeking consent from patients in randomised controlled studies of different treatments. This is to emphasise that it is not permissible to offer a choice between the two procedures for subjects participating in such research. The consent sought after full explanation must be that of consent to participate in the study as a whole, and to be randomised into one or another procedure – this requirement must be fulfilled before the process of randomisation."

That procedure was not followed at all. In fact Dr Green told me that the patient would be told, "We think that this other treatment is better", without of course telling her that the treatment decision had been reached randomly.

The names and details of those women included in the R-series cannot readily be established although I am informed the trial has now been concluded. I have not been able to obtain information which might assist me in deciding whether any of these women need further advice or treatment, or both.

Summary: Inclusion in a clinical trial does not necessarily imply that women have not been adequately treated. However, they were entitled to take part in this sort of decision which so obviously concerns their treatment. Clinical research is a critical part of the development of medical and scientific knowledge. If women feel that they have been used as 'guinea pigs', as so many told me, then their consent will not be readily forthcoming in the future. They need to be reassured that properly planned and well monitored trials may on occasion benefit them and may well benefit future patients.

HOW FAR SHOULD ETHICAL MATTERS AND PATIENTS' RIGHTS BE REGULATED?

There are a number of themes that run through the events examined during this Inquiry. Briefly, they are:

- a) a failure to offer generally accepted treatment to certain classes of patient
- b) a failure on the part of colleagues to ensure that generally accepted treatment was offered
- c) failure on the part of other health professionals to provide protection for the patients
- d) acquiescence in poorly evaluated and monitored research even when the dangers for patients became apparent
- e) inadequate scientific and ethical assessment of research projects
- f) failure to ensure that patients were informed of the nature of their condition and that the treatment offered was not generally accepted treatment
- g) Patients, neonates and fetuses were included in research trials with almost no attempt to seek appropriate consent
- h) Some teaching and clinical practices were outmoded, disrespectful to women patients or unmindful of their feelings or desire for privacy
- i) preventive health measures were discouraged by failing to give women or their general practitioners accurate information about their condition and by the active downgrading of the value of screening for cervical cancer
- k) the doctrine of clinical freedom was observed to a dangerous degree.

While some of these themes began to appear many years ago, the following factors have led me to believe that fundamental corrective work is needed:

- laissez-faire administration at Board level
- failure of peer review and the consequential dominance of clinical freedom
- what one submission described as the "collective abdication by National Women's Hospital medical staff [and members of the profession outside NWH who knew what was going on in the 1966 programme] of their ethical and professional responsibilities in respect of CIS patients".

Not all these problems have remained in the past. There are still signs that some (albeit few) patients are not being managed adequately by currently accepted standards. There is a basic lack of understanding of the ethical importance of providing information to patients, be it about the nature of her condition and its management, or inclusion in a clinical trial. Communication with patients can still be poor and occasionally attitudes are punitive.

I had fully expected that most doctors, and other health workers or administrators, who have been the focus of attention during this Inquiry would have demonstrated changed attitudes and updated their knowledge of the scientific and ethical issues that have been discussed. Some obviously have done this. But there has been a pervading atmosphere of defensiveness and even arrogance which, while understandable at a human level, does not bode well for the future care of patients at National Women's Hospital. The following points illustrate just some of the reasons for my concern.

1. With one exception, no administrator or gynaecologist (who was entitled to be present) listened to the evidence of a number of patients heard 'in camera' on the ninth and tenth days of the Inquiry. Dr Collison is apparently the only staff member who has read most of the patient interviews.
2. Professor Bonham, who is Head of the Postgraduate School of Obstetrics and

Gynaecology, and Chairman of the Ethical Committee and, until the last few years, responsible for the clinical work of members of his department, accepts overall responsibility for research at National Women's Hospital. However, he did not intervene to ensure that the 1966 trial was formally terminated and the patients involved were treated.

3. Nurses who most appropriately should be the advocates for the patient, feel sufficiently intimidated by the medical staff (who do not hire or fire them) that even today they fail or refuse to confront openly the issues arising from the 1966 trial.

4. Professor Mantell publicly and incorrectly stated that vaginal smears on neonates were a routine part of the care of the newborn. Dr Baird, a former Acting Superintendent of National Women's Hospital and Chairman of the New Zealand Medical Association, was reported publicly as saying that the vaginal smears had been taken to check for infection and that, at the most, 150 smear tests would have been taken. Dr Baird's statements were incorrect. Therefore, Professor Mantell and Dr Baird both gave incorrect information to the public outside of the Inquiry.

5. Dr Baird, Professor Bonham, the Auckland Hospital Board and Dr Collison at various times have all known that intra-uterine devices were being inserted in women for teaching purposes without their consent, and vaginal examinations on unconscious non-consenting women were being performed. However, there is evidence to suggest that these practices may have continued up until the time of the Inquiry.

Quite obviously old habits and attitudes provide a sense of security for many who have been buffeted by the cold winds of this Inquiry. Gynaecologists, administrators and health professionals need to listen to their patients, communicate with them, protect them, offer them the best health care within their resources, and bravely confront colleagues if standards slip. If this does not happen, then the kind of events disclosed during this Inquiry may well occur again.

With some regret I have concluded that I cannot leave the encouragement of new habits and practices to the medical profession alone. In Auckland, in many other parts of New Zealand and even overseas, the problems arising out of the 1966 trial were known but not confronted and resolved. Peer review failed and patients suffered. Moreover, some teaching practices revealed mediocre standards. Yet doctors, nurses and administrators would agree that their role is to protect the patient and offer the best and most ethical health services possible.

Past practices are not easily relinquished but there are ways of encouraging change by establishing new rules or stating existing ones in legislative form. New Zealanders have done this on many occasions in the past. The Human Rights Commission Act 1977, Status of Children Act 1969 and Race Relations Act 1971 are all examples. Although I do not believe that legislation will right all wrongs, it will codify principles and be a rule against which ethical and medical standards can be measured.

In the absence of a Bill of Rights, and in a jurisdiction where the financial accountability of the medical profession has been distorted by no-fault Accident Compensation legislation, there needs to be a procedure which patients or their relations can follow if they want more information about their health problems; if they need someone to negotiate or mediate on their behalf; or they want some form of sanction to be considered.

I believe that most patients would not want a return to the days when doctors could be sued for negligence. Not one patient told me she wanted financial redress. The vast majority want information, a chance to take part in a treatment decision, the opportunity to decline inclusion in a trial, and the right to ensure that a negligent, rude or incompetent doctor's reputation is known so that other patients can choose alternative health care.

There are several courses of action which I recommend.

In National Women's Hospital

1. The patient advocate

I accept that individual doctors, nurses as a group, and the medical superintendent all believe that they put the patient first. But I also have ample evidence that this is not always the case.

The Medical Superintendent, with all her administrative duties, cannot be an effective full-time patient advocate. Nurses have been conditioned to protect patients by stealth. They cannot therefore be effective advocates who will act bravely and independently. There is among all groups a feeling of institutionalisation. The patient, her needs, her pain, her views and her whanau or family responsibilities sometimes take second place.

Several witnesses and submissions addressed the notion of a patient advocate. I consider that the appointment of a patient advocate to National Women's Hospital would have several advantages.

- a) Attention would be focused on the patient and attitudes would, of necessity, change.
- b) Patients' needs for better information in their chosen language would be recognised and new systems developed.
- c) Patients would have one person to whom their immediate grievances could be addressed.
- d) The advocate would have a voice at ethical committee level and in the development and dissemination of information about treatment protocols.
- e) The advocate would heighten awareness of patients' emotional, cultural and social needs when teaching or patient examination techniques were implemented.

There are disadvantages. The first is that such a person should not be necessary. However, it is clear that there is a need to provide a human link between the medical and administrative services and the patient. The role of the patient advocate should be reviewed at regular intervals to ensure that her duties are still appropriate.

Secondly, the nature of the role demands that the advocate must be independent of the University of Auckland and the Auckland Hospital Board. At the same time she will remain bound by the principles of patient welfare upon which the Board builds all its activities, and will need to keep Board and University fully informed of her work and consult with them when appropriate.

The role will be a difficult one to fill and discharge. Some of the qualities that will be needed are:

- the independence and confidence to maintain status in the Hospital. She must have the power to work side-by-side with administrators, researchers, nurses and doctors;
- an awareness of the barriers to good health care for women and familiarity with the Maori culture and language;
- excellent communication skills.

2. Audit

Peer review and internal or external regulation of research and treatment has not always operated in the interests of patients. Although National Women's Hospital has now reviewed its management of patients diagnosed with CIS between 1955 and the end of 1986, this initiative did not occur until the magazine article provoked public comment and debate.

Formal audit must be independent, objective, but also supportive of treatment and management procedures at the Hospital. The New Zealand College of Community Medicine in consultation with the Royal NZ College of Obstetrics and Gynaecology, may well

be an appropriate body to consult in planning and implementing an audit that ensures generally accepted treatment is offered, that reviews teaching and research practices as they affect patients, and makes certain that an acceptable level of competence is maintained.

In 1986 the then President of the Royal College of Physicians, Sir Raymond Hoffenberg, wrote,

"Some scrutiny of our competence to bear such great responsibility should not be construed as an encroachment on our authority. We should welcome it, indeed insist on it, for only by such scrutiny can we lay claim to the preservation of the clinical freedom we so fortunately enjoy."¹¹

I see formal, external medical audit not so much as a means of preserving clinical freedom but as a means of ensuring that the patient knows that her treatment is up to the highest possible standard. Such reassurance is necessary at present, but will also demonstrate to the public that the Hospital can and does achieve excellence in many areas of its work.

Outside National Women's Hospital –

A system for grievances and information

Most of the patients I met lacked the most basic information about the nature of their condition and its management. Many feel aggrieved, and I predict the rise of a more assertive patient who will ask and expect to receive adequate information. However, there will always be occasions when the patient or her relatives still are not satisfied, or wish to have incompetence, insensitivity or rudeness addressed. There is a need for an independent body which will help negotiate and mediate disputes if the patient advocate cannot resolve them in the Hospital.

1. A Health Commissioner, attached to the Human Rights Commission, is an appropriate person to whom these grievances could be addressed.

During the last decade the implementation of the Human Rights Commission Act and the way in which successive Commissioners have seen their role has resulted in the significant development of procedures for negotiation, mediation and education. It is not appropriate to allow all grievances concerning the medical profession to be resolved in the Courts where the only real resolution available is measured in financial terms.

A Health Service Commissioner was created in the United Kingdom in 1973 and his or her powers and the limitations on them are set out in the National Health Service Act 1977. In her book, 'Medicine, Patients and the Law', Margaret Brazier analyses the role, its procedures, and the scope of the Commissioner's work. Among her comments, these stood out:

- "Successive Commissioners pride themselves on good relations with health service staff, rendering resort to powers of compulsion unnecessary" and
- "The most common remedy is an apology from the authority and the staff member involved. Increasingly [the Commissioner] recommends [that there be] changes in practice to avoid a recurrence of similar complaints" and
- "...in 1984-5 on the initiative of the Commissioner steps were taken to review procedures for writing to GPs on the patient's discharge, to improve communication with relatives, and to improve monitoring of complaints procedures" and
- "The reports of the Commissioner from 1974 onwards make interesting if somewhat depressing reading. Certain sorts of complaints recur. Waiting lists, lack of communication by medical staff, inadequate liaison with GPs, delay in attendance by doctors and unsatisfactory supervision of the elderly and vulnerable appear again and again.

"Maternity and geriatric care seem to generate a disproportionate number of complaints. Rudeness, lack of sympathy and even in extreme cases, allegations of assault by staff cause the Commissioner much concern."

These statements reflect some of the issues which have been raised as a consequence of the current Inquiry. Existing structures within the Hospital and the Auckland Hospital Board and the present system for disciplinary procedures have not responded adequately. The appointment of a Health Commissioner who could negotiate or mediate a solution to disputes is preferable to a return to the Court system.

2. Medical disciplinary procedures need urgent revision so that the public can confidently take action against an incompetent or negligent doctor. It is unacceptable that, in the past, successful disciplinary procedures have left some patients out of pocket. Consultation with community health groups and those representing different cultural views is vital. The following structure is one possible alternative to the present methods of resolving disputes. It is a system which would focus on the protection of patients and would be independent of National Women's Hospital.

- (i) **The patient** or her near relative 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
 - (b) a Committee of the elected representatives of the Auckland Hospital Board (or Area Health Board) and to the administration when she is concerned about a lack of information or has other concerns or grievances
 - (c) the Medical Superintendent as at present.
 - (d) the disciplinary procedures, currently under review, which are provided in the Medical Practitioners Act 1968
 - (e) a Health Commissioner of the Human Rights Commission office.
- (ii) **A patient advocate** responsible to the Director-General of Health should be employed at National Women's Hospital to ensure that patients who are involved in research, teaching or treatment are protected, to help develop material for the information or, where appropriate, the education of patients and 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. The patient advocate should report to the Director-General of Health and provide copies to the Health Commissioner and to the Auckland Hospital Board. She should have the power to use the complaint procedures pursuant to the Medical Practitioners Act 1968, and access to a Health Commissioner or to the Board on behalf of a particular patient or class of patients. Before research which involves patients is undertaken, she must be informed of those who are to be included and given the opportunity to comment. Where possible, she should be a member of the ethical committee.

- (iii) **The Board.** Elected representatives to the Auckland Hospital Board or Area Health Board should take greater responsibility for the patients' welfare, and should ensure that the administration and the academic unit make the patients' health their primary consideration. The administrative and elected branches 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.

A sub-committee of elected representatives should have the power to seek further information from the ethical committee where appropriate.

- (iv) **The Human Rights Commission Act** 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
- negotiation and mediation of complaints and grievances by patients;
 - heightening health professionals' understanding of patients' rights;
 - and taking up cases to put before the Equal Opportunities Tribunal on behalf of a patient or class of patient.
- The Commissioner should have the power to accept complaints from or refer complaints to the patient advocate, or to the Hospital Board. He or she should have access to the disciplinary procedures provided by 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 continue to give urgent consideration to the improvement of ethical standards at National Women's Hospital and should monitor progress and improvements. The Director-General should also ensure that the role of the patient advocate is reviewed and developed and that her independence from the administrative structures of the Hospital is maintained at all times. The Director-General should ensure that lay representation on the ethical committee responsible approximates one half of the membership, and should encourage the development of better procedures within that committee.
- (vi) **The University** should improve the teaching of ethical principles and communication skills at all levels of the medical degree and should take some responsibility for encouraging community debate on medico-ethical topics. It should ensure that academic staff members are encouraged to take part in ethical or scientific assessment committees, so that well-planned research can be carried out at National Women's Hospital.

In summary, I prefer to advocate a system which will encourage better communication between patient and doctor, allow for structured negotiation and mediation, and raise awareness of patients' medical, cultural and family needs. The focus of attention must shift from the doctor to the patient.

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2. British Medical Journal, 1983 Vol 287, 1919
3. Smith v Auckland Hospital Board, [1964] NZLR 241
4. 7 Legal Studies, 169 (1987)
5. Canterbury v Spence 464 F2d 772 (DC Circuit), 19. (United States Court of Appeals)
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7. F v R [33 S.A.S.R. 1983], 189 on Appeal
8. Professor Margaret Sommerville, Faculty of Law, McGill University in 'Consent to Medical Care', a study paper for the Law Reform Commission of Canada
9. 'Informed Consent to Medical Treatment', Discussion Paper No. 7, October 1987, Australian Law Reform Commission
10. 'Hospital Therapeutics' August 1987
11. Rock Carling Monograph 'Clinical Freedom', London: Nuffield Provincial Hospital Trust