Chapter 7

ETHICS AND PATIENT RIGHTS

This chapter deals with ethical issues as they applied to this Inquiry, and to circumstances and events which were raised during the hearings and which require comment.

Historical background

A patient who enters hospital for examination or treatment will usually be nervous and feel out of her depth. She may be surprised by how little information is offered about her diagnosis and management. Frequently she will ask very few questions of the nursing or medical staff. Occasionally, she will be outraged when she learns that treatment or procedures have been undertaken without her knowledge or consent. Overwhelmingly, however, she will trust the medical, nursing and administrative staff to have one overriding goal: her health and welfare.

The ancient oath of Hippocrates contained this concept as its first principle. In the Declaration of Geneva 1948, that principle was reaffirmed as "the health of my patient will be my first consideration". It is instructive therefore to review whether medical and health care professionals have seen the patient's health and welfare as their prime objective over the past 30 years, and whether practices at National Women's Hospital have reflected that approach.

Although there are many similarities in the ethical considerations that apply to treatment of patients and to research involving patients, there are some historical distinctions which should be placed in perspective. According to Dr Campbell, Visiting Professor in Biomedical Ethics at the Otago Medical School, until the end of the Second World War the ethics of medical practice appears to have been a relatively undeveloped subject which was discussed (if at all) only within a strictly professional enclave.

There had long been an emphasis that members of the medical profession behave towards each other with the utmost courtesy. Similarly, it has been expected that they will not unnecessarily interfere in each other's work. As Professor Campbell said, "Historically, the medical profession had been 'really confusing ethics with etiquette'." From the early 19th century when Percival's Code was published, the profession has maintained a strong commitment to loyalty to colleagues, summarised in the 1948 Declaration of Geneva as "my colleagues will be my brothers". However, Professor Campbell emphasised that this has never been a principle which should override the primary duty to the patient:

> *"It is clear from Percival onwards, that although one should not officiously interfere in the conduct of a colleague,...where one has evidence to think that actions are not appropriate medically, one should."*

CLINICAL FREEDOM

For at least 100 years the notion of clinical freedom has existed in medical practice. Although the Hippocratic Oath "makes the doctor the **sole** decision maker as regards 'his' patient" (Campbell), there have in fact been significant developments, particularly during the period with which this Inquiry is concerned. Professor Campbell said:

> *"The main effect of this* [development] *was to alter quite dramatically the traditional image of the clinical doctor as a wholly autonomous and authoritative*

judge of 'what is in the patient's best interests'. In its place there has come the recognition that patients themselves are usually the best judges of this, provided they are properly informed of the options available."

It has not always been easy to recognise the responsibilities attached to clinical freedom. Dr Jordan spoke of the

"Reluctance of colleagues to impinge on clinical freedom. Clinical freedom is something which doctors, and consultants in particular feel is very important to them. But we have all seen examples where clinical freedom, which means the consultant doing what he thinks is right, is not necessarily in keeping with current opinion and it becomes very difficult under these circumstances to say, 'Well, is he doing something which is really bad?' It may be a difference of opinion and I would defend anyone's right to say, 'Well, you would treat that patient that way. I would treat that patient this way.' It is different, but the end result could be exactly the same."

The Auckland Hospital Board has also been reluctant to become involved in clinical matters. As Dr Moody, a former Medical Superintendent-in-Chief, said:

"The Board upheld the widely accepted principle of professional freedom, by permitting members of its medical staff, including members of the University of Auckland medical staff who became honorary members of the Auckland Hospital Board medical staff upon taking up their University appointment, to practise medicine the way they wished to, according to their professional beliefs, training and experience and to currently accepted methods and standards.

"At the same time, the Board expected its clinicians and its honorary medical staff to act always in the best interests of the individual patient."

Furthermore, Dr Moody considered that had a Superintendent-in-Chief become involved in a clinical dispute, the specialist staff would have interpreted that as administrative interference in a clinical issue. When asked, "Are there any circumstances in which what you see as 'administrative interference in a clinical issue' would take place?" Dr Moody replied:

"Yes. If something was in my opinion illegal. And there were several occasions while I was Superintendent-in-Chief where I intervened and gave instructions that things were to stop. My job is not only protector of the patients but also the protector of the public. If the public interest was involved, yes I would intervene, and I did. Always with the support of the Chief Executive because he speaks for the Board, not me, the Chairman of the Board and almost in all cases a Committee or the Board itself. Yes there were occasions.... If something was going on which in my opinion was unlawful I would stop it."

Counsel: *So are you saying that the limits of professional clinical freedom are illegality or unlawful? Are there no other limits on professional clinical freedom?*

Dr Moody: *I cannot honestly give you an extemporaneous yes or no. I can't.*

Dr Moody placed the individual doctor's conscience as the primary element of clinical freedom:

"...Surely to goodness...you must give doctors the benefit of being, the great majority, people of standing, of integrity, who are loyal to themselves and to their own consciences, basically to their own consciences,...honorably and according to the cloth. When you take up medicine, you have it in your heart that you will do the best for the individual patients. Surely that's enough isn't it?"

Dr Leslie Honeyman, the present Medical Superintendent-in-Chief, considered that the concept of clinical freedom requires free, frank and open discussions among those with specialised knowledge. He acknowledged the difficulties for those, including administrators, who wish to obtain information but who do not have specialised knowledge. In particular, he spoke of the difficulties for those who wished to challenge that knowledge. 'Outsiders' meet real barriers to free informed discussion and cannot successfully attack the freedom of the specialist to give whatever treatment he or she thinks best.

Dr Jordan, having known Dr Green and his work, summed up the difficulties encountered with clinical freedom as they applied to Dr Green's 1966 clinical trial:

> *"There were times over a period of years when attempts were made to get Professor Green to change his mind about the work he was doing, and that was ignored.... The reluctance of colleagues to impinge on clinical freedom is something which we all feel.... I feel...that the people he was working with did not feel sufficiently strongly about what he was doing to make sure that he stopped it. Otherwise they would have done."*

In essence, clinical freedom in relation to the 1966 trial meant that a gynaecologist was able to instigate and continue a trial without effective intervention from his colleagues or, if they were unwilling or unable to intervene, from the administration. Clinical freedom can no longer be permitted to imply the right to treat patients as one wishes without intervention from administrators or colleagues.

At least one writer believes that the era of clinical freedom is over when it applies to unsupported opinion. Professor Hampton, Professor of Cardiology at University Hospital, Nottingham, wrote in 'The End of Clinical Freedom'[1]:

> "Clinical freedom is dead, and no one need regret its passing. Clinical freedom was the right – some seemed to believe the divine right – of doctors to do whatever in their opinion was best for their patients. In the days when investigation was non-existent and treatment as harmless as it was ineffective, the doctor's opinion was all that there was, but now opinion is not good enough. If we do not have the resources to do all that is technically possible then medical care must be limited to what is of proved value, and the medical profession will have to set opinion aside....
>
> "Clinical freedom died accidently, crushed between the rising costs of new forms of investigation and treatment and the financial limits inevitable in an economy that cannot expand indefinitely. Clinical freedom was a myth that prevented true advance. We must welcome its demise, and seize the opportunities now laid out before us."

However, clinical freedom will always be relevant where it requires that the doctor with his or her specialist knowledge, determines the best course of management for the patient.

Now the patient must be involved in decisions concerning her management and medical colleagues must intervene if there is risk to the patient for any reason. The doctor is no longer wholly autonomous. As a concept, clinical freedom has been proved worthless at National Women's Hospital when patients' safety or the rigorous testing of a new treatment protocol were at stake.

PEER REVIEW

Peer review demands from the doctor first an ability to analyse his or her own work and learn from past professional experiences. There is a second requirement: the ability to know when consultation is necessary or desirable and the will to do this. Dr Campbell said:

> *"It has also been recognised that in* ***all*** *situations of uncertainty, the clinician is under an obligation to seek full advice from medical colleagues and from others who can offer a different perspective on the patient's situation."*

Therefore, there has long been an ethical obligation known as peer review that a doctor seek and accept criticism and advice from professional colleagues. There is also a strong obligation to maintain realistic self-scrutiny. It is not a concept peculiar to the medical profession. Many disciplines require full exchange and discussion of ideas as a form of supervision or quality control of the service offered or product manufactured. No one person can hold the complete knowledge and wisdom needed to treat a patient who has a difficult medical condition; or whose social circumstances require a re-thinking of orthodox treatment. It is also of interest that Professor Campbell does not restrict peer review in the medical profession only to those who are medically qualified.

The concept itself is common sense; but the gravest difficulty has always been in implementing peer review. To some clinicians peer review means discussing topics during coffee breaks. Those informal sessions certainly have their value but cannot replace the formal setting where cases are systematically reviewed. National Women's Hospital established a group called the Tumour Panel where difficult cases were discussed. But peer review should extend beyond the unusual or difficult case and into the area of everyday clinical practice, particularly as the Tumour Panel (which has essentially had a teaching task) proved to be ineffective as a forum for dealing with the consequences of the 1966 trial.

Dr Duncan, President of the Royal New Zealand College of Obstetricians and Gynaecologists, told me that the College had believed that peer review had been operating at National Women's Hospital and that the Auckland Hospital Board was effectively managing any problems arising out of the 1966 trial. However, it was his view that the patients' rights of privacy together with clinical freedom could effectively mask any problem that might arise. He favoured a system where "you and your colleagues discuss...your problems in such a way that you were better informed, perhaps both of their activities and your own", to a formal review of one individual's work.

The real difficulty in such a procedure, for all its worth, is that mistakes, incompetence, or rigid adherence to outmoded treatment protocols might not be discussed. Every human being finds it difficult to accept the possibility of criticism with equanimity. Nevertheless, the effort must be made.

In 'The Critical Attitude in Medicine: The Need for a New Ethics' by MacIntyre and Popper,[2] the authors say:

> "Doctors are expected to profit from their experiences, and from their earliest days medical students are exhorted to learn from their mistakes. To learn only from one's own mistakes would be a slow and painful process and unnecessarily costly to one's patients. Experiences must be pooled so that doctors may also learn from the errors of others. This requires a willingness to admit that one has erred and to discuss the factors that may have been responsible. It calls for a critical attitude to one's own work and to that of others."

There are other difficulties identified by MacIntyre and Popper. The first lies in the nature of the doctors' work.

> "Doctors rarely observe the work of their colleagues at firsthand; they rely on their own approach and on their own ability, so their work tends to be self-validating and self-confirming.... These factors encourage personal rather than collective responsibility."

Secondly,

> "Many doctors believe that audit and peer review would threaten the doctor-

> patient relationship. This relationship is founded on the acknowledged skill of the doctor, but also on his patient's fears. His authority may crumble should patients hear of mistakes."

These problems are not insurmountable and are minor when compared with the damage that can occur when peer review is neglected.

Peer review is possible, given the right spirit and environment and the encouragement and support of administrators. But it should be established in a formal setting. The profession can no longer rely on informal discussions which may or may not include all relevant staff members and where there is no systematic review of procedures. There is the example of peer review in practice, established by a hospital in Birmingham, which was reported in the Journal of the Royal College of Physicians of London, July 1980.

The report commented on the beneficial results of holding a regular medical audit among five consultant physicians and their junior staff, including final year students. Benefits have included the improved documentation of patients' cases so that doctors who do not know the patient may, with confidence, rely on the notes. One result has been an increased awareness that investigations or treatment might need to be justified at a later stage, and this has led to more critical thought being given to the problems while the patient is in the ward. Also, greater emphasis is being placed on proper communication with the patient and relatives as an integral part of the management. Systematic and organised peer review as illustrated in this example could, however, be improved by the inclusion of other health professionals (particularly nursing staff and social workers) in the group.

In 'Institutional Ethics' (The Lancet, October 1987), Silver says:

> "Those academic institutions who claim leadership in medicine should now be hard at work devising a system whereby practitioners can maintain the skills and excellence that are fostered in medical schools.
>
> "Secondly, practitioners should be encouraged to look critically at what they themselves are doing, in terms of the need of people for care and cure. The self scrutiny that began with the clinical pathological conferences and infant and maternal mortality conferences, needs to be extended to the daily practice of medicine."

When it came to evaluating or reviewing the 1966 trial, Dr Green's peers failed him. Twenty-one years after the first oral and written challenges to the Proposal, an article in a non-medical magazine achieved in a few days what his colleagues could not. Drs McIndoe and McLean, then Dr Warren and latterly Dr Jones, had all expressed their disquiet in a variety of ways. They attempted intelligent peer review through private discussions and consultation with the Medical Superintendent-in-Chief, called on the advice of a world authority in gynaecological oncology, and raised the question of the safety of the trial and consequential treatment of patients at meetings of the Hospital Medical Committee. In the long run all this counted for nothing. The publication of the 1984 and 1986 scientific papers hardly seemed to cause a ripple among the staff at National Women's Hospital; they were read by colleagues and yet no special effort was made to locate and treat women who needed review. Of even graver concern is the fact that the Auckland Hospital Board took no steps to ensure that patients' welfare was not at risk even though it had known of the risks, through its Medical Superintendent, since 1975.

The response to the magazine article, published in June 1987, was instant and spectacular compared to these years of neglect. In contrast with what had been published before, "An 'Unfortunate Experiment' at National Women's" was written by lay people. It initiated the first real action to review the 1966 trial and its consequences for patients. The magazine went on sale at the end of May 1987. By 10 June 1987 the Terms of Reference for this Inquiry had been settled and I had been appointed pursuant to the Commissions of Inquiry Act 1908 to prepare a report for the Minister of Health.

An Inquiry into medical practice is one form of peer review, albeit enforced. It is also the most disastrous for the profession, for patients and for the public purse. I believe that unless the profession can establish adequate peer review and adequate systems to cope with the inevitable mistakes or problems caused by incompetence, then there will be a continuing succession of inquiries of this nature.

INFORMED CONSENT

The obligation to obtain a person's consent to participation in non-therapeutic research was stipulated unequivocally in the 1947 Nuremberg Code which stated:

> "The voluntary consent of the human subject is absolutely essential.
>
> "This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.
>
> "This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.
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> "The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity."

This first principle encapsulates the modern doctrine of 'informed consent'. Although the principle was limited to non-therapeutic research only, by 1964 the World Medical Association had published a code of ethics known as the 1964 Helsinki Declaration which stated:

> "It is the mission of the doctor to safeguard the health of the people. His knowledge and conscience are dedicated to the fulfilment of this mission.
>
> The Declaration of Geneva of the World Medical Association binds the doctor with the words, 'The health of my patient will be my first consideration'; and the International Code of Medical Ethics which declares that 'Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest.'
>
> Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to each doctor in clinical research. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.
>
> In the field of clinical research a fundamental distinction must be recognised between clinical research in which the aim is essentially therapeutic for a patient, and clinical research the essential object of which is purely scientific and without therapeutic value to the person subjected to the research.

I. Basic Principles

1. Clinical research must conform to the moral and scientific principles that justify medical research and should be based on animal experiments or other scientifically established facts.

2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.

3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.

5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

II. Clinical Research Combined with Professional Care

1. In the treatment of the sick person the doctor must be free to use a new therapeutic measure if in his judgment it offers hope of saving life, re-establishing health, or alleviating suffering. If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation. In case of legal incapacity consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.

2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

III. Non-Therapeutic Clinical Research

1. In the purely scientific application of clinical research carried out on a human being it is the duty of the doctor to remain the protector of the life and health of that person on whom the clinical research is being carried out.

2. The nature, the purpose, and the risk of clinical research must be explained to the subject by the doctor.

3a. Clinical research on a human being cannot be undertaken without his free consent, after he has been fully informed; if he is legally incompetent the consent of the legal guardian should be procured.

3b. The subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice.

3c. Consent should, as a rule, be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject, even after consent is obtained.

4a. The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.

4b. At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued. The investigator or the investigating team should discontinue the research if in his or their judgment it may, if continued, be harmful to the individual."

This was revised by the World Medical Association and republished in 1983 (see Appendix 9). Throughout the period from the late 1950s, therefore, there has always been a clear evolving duty to provide adequate information and to seek the patient's consent to inclusion in a clinical trial. In 1966, as I have already noted, the 1964 Helsinki Declaration required:

> "If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation.
>
> In cases of legal incapacity, consent should also be procured from the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.
>
> 2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient."

Legal comment on informed consent

Although from 1966 on, there have always been clear ethical standards applying to non-therapeutic and to therapeutic trials, there has been little developed case law in New Zealand which deals with the concept of informed consent. The subject has come before Courts in other jurisdictions. Useful statements can be gleaned from various decisions.

In Canada, as early as 1965, the Saskatchewan Court of Appeal in **Halushka v the University of Saskatchewan** [1965] 53 DLR (2d) 436, concluded that the subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent. The plaintiff was entitled to rely upon the special skill, knowledge and experience of the medical staff who were, in the Court's opinion, entrusted with this responsibility.

The test enunciated in **Smith v Auckland Hospital Board**,[3] relates to medical treatment (and in particular surgery). The two judgements share common elements which require the provision of information which is peculiarly within the doctor's knowledge. While the reliance that a patient must have on his or her doctor was acknowledged, the decision in **Smith** limited the obligation to provide information to that which the patient sought.

It is not difficult to imagine a situation where a patient has too little medical knowledge to ask the right questions. The level of knowledge of the condition and treatment of most patients I interviewed vividly illustrates this. It is my view that today the reasonable patient would expect full information and that a Court's rulings would be likely to reflect that development.

There is a obvious overlapping between the patient's right to know and to consent to inclusion in a research project and the patient's rights with respect to treatment. In my view, the test should centre on the patient. It should not be a test which is dependent on deciding whether or not treatment was offered in the course of a research project, be it therapeutic or non-therapeutic, or simply part of a treatment programme available to that and other patients in the hospital.

The patient has certain basic rights and, in some cases, limited obligations. If the research project is non-therapeutic, then the investigator should have an absolute duty to inform the patient that she has been included in the trial and to outline the risks before seeking the patient's freely given consent. In her evidence, Mrs Vennell referred to an article by Brazier – '**Patient Autonomy and Consent to Treatment: The Role of Law?**'[4] In that article, Brazier states the basic proposition:

> "A patient who is sufficiently mature and intellectually competent to under-

> stand what is entailed in treatment is entitled to make up his or her own mind as to whether to accept or reject proposed medical treatment. This right is part and parcel of his or her autonomy, of sovereignty over one's own body."

Mrs Vennell's opinion, which I accept, is that the controversy about informed consent arises not because self-autonomy is not accepted by the medical profession, but

> *"rather how far should the doctors go once the patient has made an initial decision to seek treatment. Having made the initial decision, should the doctor give any further information?"*

The patient has a right to information, not only at the outset when treatment is first offered and accepted but as treatment progresses and knowledge of the patient's condition improves and options for treatment emerge. Where there are options the picture is less confused.

> *"One thing is clear, that if there are alternative available courses of treatment, both must be explained so that the patient can decide which they will decide to follow. This is freedom of choice."* (Vennell)

The real difficulty facing the doctor offering treatment, or the investigator seeking the patient's consent to inclusion in a clinical research project, is the amount of information that must be provided to the patient. In New Zealand, the enacting of the Accident Compensation legislation has almost certainly resulted in a failure to develop law in this field. If a patient can be compensated by means other than action against her doctor, then she is more likely to take that simpler, cheaper option.

Compensation is only one factor, however. Most patients would like to know the possible risks and benefits of a medical procedure before deciding whether to take part in a medical research trial or to accept treatment. Other jurisdictions have grappled with this question. In the United States, a Court has held (**Canterbury v Spence**[5]) that the doctor has a duty to supply the patient with all the information that she might reasonably consider necessary to assist her in coming to a decision. Furthermore the Court said:

> "Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians, rather than one which physicians may or may not impose on themselves."

The **Canterbury** judgement does not require the patient to have a complete understanding of the signficance and all the implications of the treatment. That would impose a heavy and on occasions, impossible burden on the doctor. The Court, however, agreed with the proposition that a risk would be material,

> "...when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy."

In the United Kingdom, in **Sidaway and the Bethelehem Royal Hospital**,[6] a less than 1 per cent risk of damage, which in fact occurred, was not disclosed to the patient. The House of Lords found that the doctrine of informed consent had no place in English law and rejected the **Canterbury** test.

> *"In other words, the Court held that what should be disclosed by the doctor, was governed by what was accepted at the time as proper, by a responsible body of medical opinion (the paternalistic approach)."* (Vennell)

The very low risk of the particular damage occurring unquestionably influenced the Court's view in the Sidaway judgement. However, it is interesting to note that Lord Scarman in the minority judgement, would have adopted the 'reasonable patient' test. It is also of interest to note that in Australia, where a body of case law is developing in South Australia, the Court has leaned towards requiring the consent of the patient to treatment after she has been given adequate information to assist her in making a decision.

Nevertheless, in one instance (**F v R**[7]) it was held that the doctor concerned owed no duty to the patient to inform her of the 'extremely remote risk' that the operation would fail and was therefore not negligent. The statistical failure rate was between 0.5 per cent and 1 per cent, but according to the evidence of the three specialists called, the odds on the basis of their experience, were very much lower. It was found that it might have been otherwise if either the patient had asked specifically about the risk of failure, or if there had been an alternative procedure available with an even lower chance of failure.

In its discussion paper, 'Informed Consent to Medical Treatment',[9] the Law Reform Commission of Victoria, in conjunction with the Australian Law Reform Commission and the New South Wales Law Reform Commission says:

> "It is a matter of speculation whether the High Court of Australia would follow Sidaway rather than the South Australian cases described above. Those cases now not only constitute a distinctive body of legal doctrine for that jurisdiction but also have significant persuasive influence in the rest of Australia. What is clear is, that in relation to a number of important common law issues considered by the High Court since 1963, that Court has chosen not to follow decisions of the House of Lords, even though they were unanimous."

The position in New Zealand is somewhat different. The **Sidaway** judgement would be far more influential. However, I consider, that the New Zealand Courts, if they had been freed from the constraints imposed by the Accident Compensation Act 1972 and its amendments, would be more likely to follow the Australian example. As a consequence of that legislation, the law in New Zealand relating to informed consent may need to be spelt out specifically. If the **Sidaway** judgement were to apply only to those cases like **F v R**, where the doctor was obliged to disclose all but the most unlikely or insignificant of risks to the patient, then there would be less room for concern.

Nevertheless, I have come to consider that the patient is entitled to all relevant information concerning her treatment, the options for treatment, and all information concerning her possible inclusion in a research trial. The focus should be centred on the patient, and not on the doctor. It is a principle designed to protect and preserve the patient's rights, not to protect the doctor from liability. Margaret Brazier's view is that the patient should be informed, simply because the informed patient is better equipped to participate in treatment. That view reflects my finding in individual patient cases.

Informed consent and the 1966 trial

Throughout the period when the 1966 Proposal was being put into effect, had patients been informed of their inclusion in the trial, informed of the types of treatment available to them, informed of the risks of procedures which were not conventional, definitive treatment for carcinoma in situ, and given the opportunity freely to decide whether or not to be part of the trial, then the trial could not be so severely criticised.

The consent of the patient even so, would not discharge the investigator or doctor from all responsibility. The 1966 Proposal was flawed in design. Even if the patient had given her consent freely to inclusion in the trial, that fundamental fault is not corrected. The risks, had they been properly evaluated, outweighed the benefits. In that situation, the investigator cannot shift the responsibility to the patient simply because she consents to inclusion in a research project.

Furthermore, if patients had been informed of their obligations: to return regularly for treatment or advice; to ensure that, even after discharge from National Women's Hospital, they continued to have smear tests at regular intervals; and to be constantly vigilant for any symptoms which might herald invasive cancer, then it is my firm view that fewer patients' carcinoma in situ would have progressed to invasion.

The investigator should have sought the patient's consent. In doing so, not only does he

or she demonstrate respect for the patient's autonomy but also provides her with information which is valuable for the preservation of her own health. These are principles which have clearly been enunciated throughout the period that the 1966 trial has been in operation, but which were breached from the outset.

Modern concepts

The consent of a patient to treatment or research starts with the premise of the right of a person to his or her autonomy or **self determination**. While there may be occasions when the greater good or risks to other people override this central premise, these must of necessity be rare. There is, in New Zealand, no general legal or moral concept which would require an individual to risk his or her personal health for the good of the majority.

The patient's consent is **a pre-condition to all treatment or research**. The only true exception is emergency procedures required for the preservation of life where the patient's consent cannot be obtained and the patient's view (perhaps disclosed by relatives or earlier consultations with the patient) are not known. The doctor does not have the right to insist on life-saving procedures if he or she knows the patient does not consent. To this concept of consent as a prerequisite to treatment and research, I would add, patient examination, or teaching situations involving the patient.

Consent must be **freely given**. The patient cannot be in a dependent relationship to the doctor who seeks her consent. One witness who was asked during labour to be part of a research programme said:

> *"There was no way I felt I could say 'no'.... I know that other women feel the same way, you are in something completely different, your state of mind is separate from the kind of world of medical research...."*
>
> **Question:** *You didn't feel at that stage that you could refuse to participate?*
>
> **Answer:** *No, no way, because I think it was also in there at that time, a real eagerness and willingness to please, in the hope that the whole thing would go on smoothly.*

She must not feel obliged to be compliant because of a cultural, lingual or social gulf between her and the doctor. As a corollory, the doctor has an obligation to know her cultural perspective and to ensure, if necessary by seeking the assistance of a respected member of her community, that 'yes' means 'yes' and is not just a desire to please.

The patient cannot be left with the impression that unless she consents, other rights will be withdrawn; or if she consents, she will get other advantages. If the medical profession realises that, rightly or wrongly, the woman patient may feel vulnerable, inferior in status to the doctor and less able to articulate her opinions than she would in her own workplace or home, then greater care may be taken in ensuring her consent is genuine.

If the patient's consent to treatment, research, examination or teaching is a prerequisite, then she must have **adequate information** on which to base her decision. It is obvious from the evidence that I have heard that some doctors do not believe that it is really possible to provide this information, given the constraints of time and the level of the patient's understanding.

In my opinion the latter is more a fault of the doctor's ability to communicate and the perception of the extra time it takes. The former can be addressed by far greater commitment to providing patients with more written and visual information before the doctor discusses the procedure, treatment or research with her. In **Smith v the Auckland Hospital Board**[7] the test placed the onus on the patient to ask the question and on the doctor, the duty to use due care in answering. I do not accept that that judgement is applicable to research, or a standard that should be alluded to in practice. Evidence given at the Inquiry shows that the public requires full disclosure and indeed this is the modern trend both in New Zealand and overseas.

The Nuremberg Code requires that the person who is to be involved in research "should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision". Most writers acknowledge a difference in the degree of information to be provided, which depends on whether or not the procedure is therapeutic or non-therapeutic; but all are agreed that adequate information is an essential part of the process of obtaining consent.

What is adequate information? I believe that the information must not only be accurate but that the patient must also understand it. Without understanding, the patient cannot be said to have consented to a procedure. One patient (Code 10L) said:

> *"Apart from having smear tests when I went to the hospital, I would sometimes give Professor Green tissue. He would ask me to come to the Hospital for this, and I would go down to the theatre and have an anaesthetic and he would take just a very little piece of tissue from the mouth of the womb for comparison with other patients.*
>
> *"My condition was fixed by the hysterectomy and Professor Green said he could not do anything more for me, but he would ask me to come in and give him a piece of tissue from time to time because he said my body could be helpful by way of providing comparison with other patients' bodies who weren't so healthy."*

Not only did this woman not realise that the smear tests and biopsies were taken from the vagina not the mouth of the womb, but she obviously gained the impression that the biopsies were more for the benefit of other patients than for her. This information was clearly inaccurate, and even if the patient had misunderstood the information given to her, her misapprehensions ought to have been corrected.

The physician has a duty to ensure that the patient has an objective or subjective understanding of the information. A subjective understanding has been described as:

> "The most demanding and difficult criterion, but it alone fully maintains the concept that consent involves understanding."[8]

In the Canadian decision **Reibl v Hughes** (1980) 78 DCR (3rd) 35. 14C CLT1 (with respect to liability and battery), the Court held that:

> "A physician [has] a strict duty to explain to his patient in language which the patient can understand, the essential nature and quality of the treatment he is to undergo."

And in relation to liability for negligence, the doctor must

> "take sufficient care to convey to the plaintiff and assure that the patient understood the gravity, the nature and extent of risks, specifically attendant on the [procedure]."

Although the doctor has a choice between ensuring the actual subjective or objective understanding, Professor Sommerville[8] suggests that the less difficult objective standard, that is what the 'reasonable patient' would have understood, is acceptable.

In Australia the Courts will generally apply the test as being the information that a **reasonable doctor** (which implies a knowledge of current scientific, clinical and ethical standards, or 'accepted medical practice') might offer to a **reasonable patient** (described as 'a standard set by reference to hypothetical behaviour of adult competent people in the sorts of situation which are presented to the Courts and other tribunals for decisions')[9]. In the context of this Inquiry perhaps, the 'reasonable patient' could more aptly be defined as the woman in the National Women's Hospital consultation clinic waiting area.

What information should the doctor provide? Generally, enough to satisfy the standard of information needed by the reasonable patient in these circumstances, "with an addi-

tional subjective test that if the doctor knew, or ought to have known, that certain other information was considered relevant by a particular patient, then this as well must be disclosed" (Sommerville, 19).

This information, particularly when applied to treatment, will often include the **options** open to a patient. Assuming that treatment options are based on conventional contemporary treatment standards, those National Women's Hospital patients with continuing positive cytology whose cases I have reviewed, have rarely been offered a hysterectomy as an alternative to years of observation and diagnostic techniques together with occasional localised destructive procedures. Some women would have appreciated the choice. The amount of **detail in the information** will be determined by the degree of risk or the magnitude of possible harm.

> "There is a greater duty to provide information about the possibility of serious harm even if the chance of it occurring is slight. Similarly if the risk is great, but the potential harm is relatively slight, there may be a greater duty to give such information."[9]

It is axiomatic that the doctor must evaluate the risks from contemporary information and not base the amount of information given to the patient on his or her hypothesis that the risk is slight. Dr Green knew of the findings of the possible risks of progression to invasion (Petersen et al) but chose to proceed with his project on the assumption that the risk was nil or minimal. Presumably therefore, he did not inform his patients of a significant risk of progression.

In treatment (particularly innovative treatment), research and even teaching, there is an absolute requirement **to monitor risk** constantly, so that the trial can be suspended or treatment curtailed if detrimental results are noted in any patient undergoing the same treatment, in the same research project, or undergoing similar procedures. There is a corollory that when the research project reaches the stage where the **benefits** are conclusive, it ought to be stopped and the results published.

The patient has the right to waive the requirement to information about treatment, but in my view should never have that right in the case of non-therapeutic research. While there are many problems inherent in obtaining informed consent, this must always be the goal even if the goal is not always achieved.

RESEARCH PROTOCOLS

In order to examine how well research projects are assessed when put to the National Women's Hospital Ethical Committee for approval, it is necessary to review relevant criteria. From the evidence and information placed before this Inquiry, I have synthesised the following principles:

1. A project must be scientifically valid.
2. It must be ethically valid.
3. It must be assessed by people independent of the investigators.

If it is not well designed, a research proposal is unethical. Poor design and inadequate safeguards have implications for patient safety.

Scientific validity

The Ethical Committee is the only committee at National Women's Hospital which reviews research projects. While it appears to have responsibility for their scientific assessment, it has no established procedure for independent assessment; nor for obtaining the opinion of referees; nor for assessing the adequacy of the method and design; nor for reviewing the hypothesis to see if it can be tested. As a result, research protocols

from the Hospital may not be adequately assessed scientifically unless the investigator is seeking funds from the Medical Research Council of New Zealand or from other funding bodies. Therefore, in-house research projects need a more critical aeessment.

The procedure adopted by the Medical Research Council provides a useful example:

1. An assessor from the appropriate discipline is appointed.
2. Suitable referees are chosen.
3. The application is circulated sufficiently in advance of the meeting to enable proper consideration and further information to be sought.
4. Two committee members prepare written comment prior to the meeting.

There will be occasions when the membership of an ethical committee does not allow adequate scientific assessment of a proposed project. It is possible to overcome this difficulty by arranging for off-site assessment or co-opting appropriately qualified personnel to undertake a particular task.

Ethical validity

For many years National Women's Hospital has recognised the need to provide ethical assessment for research projects. Until the Ethical Committee was established at the Hospital in 1977, assessment had been carried out informally by the Hospital Medical Committee and at least on one occasion, by the full staff of the Hospital.

Some of the research projects conducted during this period were discussed in the course of the Inquiry. I have already commented on the deficiencies in the ethical assessment of the 1966 trial. There were two other trials which were supplementary.

1. Vaginal swabs of neonates

In October 1963, the full staff of the National Women's Hospital approved a trial which involved vaginal swabs from newborn infants. The research proposal stated:

> "Up to about the 7th month of pregnancy, the respective sizes of the uterus and cervix of the female infant are approximately in the same proportion to each other as they are in the post pubertal female. Towards term, the cervix and upper vagina undergo a great hypertrophy, so that at term the cervix is about 3 times the size of the uterine body. The endocervical and vaginal epithelium are thickened and adult in form whilst the endometrium remains flat and atrophic. Following birth, the infant's cervix and vagina undergo regression and do not grow at the same rate as the uterine body, so that at puberty the adult proportions are attained.
>
> "It is considered by many authorities that carcinoma-in-situ originates in the basal cells of the endocervical epithelium. In the prenatal and neonatal cervix, the columnar epithelium extends out from the canal onto the ectocervix and vaginal vault in many cases. Probably this is due to the common origin of the upper vaginal and endocervical epithelium from the urogenital sinus epithelium (Fluhman 1960 Obst. & Gynec. 15. 62).
>
> "The possibility exists that some of these 'congenital erosions' may be the forerunner of carcinoma-in-situ of the ectocervical epithelium or vaginal vault in later life; where there is marked growth of any particular type of cell, there are likely to be cellular abnormalities. To investigate this point it is proposed to take swabs from the vaginal vault from as many newborn female infants as possible.
>
> "A preliminary trial study has shown that it is possible to take vaginal vault

> smears of good quality from female infants using a thin stick-type of applicator. A by-product of the investigation will be the revealing of a few genital abnormalities.
>
> "The co-operation of the staff is requested for this investigation. Dr Darby has already agreed that his department can handle the increased number of smears and it is proposed to continue the investigation until some 2-3000 smears have been taken."

In his evidence Dr Green told me that he had lost interest in this trial after 200 babies had had smears taken. Unfortunately his decision not to continue the trial was not communicated to the nursing staff and the trial continued until smears had been taken from 2244 new-born babies. There was no system in place that ensured that the trial stopped. Professor Bonham, as Head of the Department of Obstetrics and Gynaecology, although acknowledging overall responsibility for research made the point that he could not be expected to know the practical details of every trial. While this may be so, an effective system for monitoring research and ensuring that unnecessary procedures are not conducted, should have been in place. If this had been so, then more than 2000 babies would not have been subjected to a useless and possibly damaging procedure.

Moreover, there was no provision made to comply with the fundamental requirement that children are not included in research without the consent of their guardians. Contrary to Professor Mantell's public assertion, this was clearly a trial and not part of the day-to-day care of the babies concerned. It was non-therapeutic, clinical research.

2. The morphology and histology of the fetal cervix

During his evidence, Professor Bonham said that Dr Green had collected the cervices of stillborn and neonatal infants to do "research work on the morphology and histology of the fetal cervix". This study had formed part of a report of the Postgraduate School of Obstetrics and Gynaecology to the University of Auckland for the year ended 1966 and was being undertaken in collaboration with Dr E C Pixley from Western Australia. Dr Green gave me further information about this study which he had referred to in a paper published in the New Zealand Medical Journal in 1979.

I am satisfied that no ethical assessment or approval was undertaken for this study, although it clearly had the tacit support of the Head of the Department of Obstetrics and Gynaecology, and personnel from the Pathology Laboratory at National Women's Hospital co-operated and assisted Dr Green in the study.

Further attention was drawn to the study by the discovery in November 1987, of a box containing specimens of baby uteri described as 'sections of whole baby uteri set in wax'. The box was located in a clerical office at NWH and was acknowledged by Dr Green to be part of his study into fetal cervices. Both aborted female fetuses and uteri from stillborn babies were examined as part of this trial. In the case of the former, no permission for their use in research is legally necessary. These would have been sent to Dr Green at his request from the paediatric pathologist.

The sections of baby uteri located at the Hospital appeared on examination to have come from infants examined at postmortem but there is no way now of finally verifying this. Once again no permission was sought from any parent and the Hospital personnel co-operated in providing the specimens. If the uteri came from stillborn babies, it appears that the provisions of the Human Tissue Act 1964 were not complied with. That Act provides for the use of human tissue from a dead body (with relevant consent) for research, education or 'therapeutic' purposes. However, the Act specifically excludes a stillborn child from the definition of 'body'.

The study was abandoned by Dr Green and was not published as it did not "add anything

worthwhile to what others such as Dr Pixley had found". Although the study was recorded and apparently had the approval of the Head of Department of the Postgraduate School, neither he nor the Hospital Medical Committee exercised any control over it. The ethical and probably scientific safeguards were quite inadequate.

Summary of criteria for research projects

Some of the principles and criteria which I consider require further discussion and implementation are:

1. Paramount consideration must be given to the welfare of the patient to be included in a trial.
2. The patient's informed, free consent must be obtained. The information she is to receive and the form of consent must be approved by the ethical committee before the trial starts.
3. There must be an identifiable hypothesis, an evaluation of risks and benefits, subject inclusion and exclusion criteria and comment on the end point of the study.
4. There should be a review of literature for the benefit of the committee where relevant, and a system for monitoring the project established with the investigator.
5. The findings should be published, at least to the ethical committee, on completion or abandonment of the trial.
6. Where there is significant material which would assist any patient included in the trial in her future health care, she and/or her general practitioner must be informed of the trial results.

THE ROLE OF THE ETHICAL COMMITTEE

By the early 1970s it appears that the need to establish ethical committees in hospitals was recognised. In 1974 the Medical Superintendent-in-Chief set out guidelines for the introduction of ethical committees to Auckland Hospital Board institutions.

"INTRODUCTION.

1. This item is submitted to the Board because Clinical Research is now conducted in the Board's hospitals and has become accepted practice in them.
2. The Medical Advisory Committee has recommended that there should be Ethical Committees in all the Board's hospitals rather than one Central Body.
3. The Committee is advisory to and responsible to the Medical Superintendent for two purposes.
   1) To advise on all proposed clinical research investigations.
   2) To advise on any matter of ethics relating to the practice of medicine in the hospital.
4. There must also be occasions when such committees are nothing less than guardians of public health and safety.
5. It must be re-emphasised that in the practice of modern clinical medicine it is not always easy to define either the relationship of, or in some cases the difference between service and research aspects of patient management.

"GUIDING PRINCIPLES.

1. The principle upon which the individual Ethical Committees base their decisions vary from hospital to hospital but basically they are modelled on a large number of codes and statements which have been drawn up for the control of human experimentation.

2. In the long run no law or code however detailed, can be a substitute for basically what is a trust between the medical profession and society, between the patient and the doctor.
   It must be frankly recognised that, for practical purposes, an inescapable moral responsibility rests with the doctor concerned for determining what investigations are, or are not, proposed to a particular patient or volunteer.
3. Copies of the following statements can be made available if required:
   1. The Declaration of Helsinki 1964.
   2. 'Responsibility in investigations on Human Subjects'. Statement by the General Medical Council (UK) BMJ 18 July 1964.
   3. 'Ethics of Experimentation'. Statement issued by the Medical Research Council of New Zealand August 1971.
   4. Royal College of Physicians of London. 'Committee on the Supervision of the Ethics of Clinical Research Investigations in Institutions', published 30 November 1973.
   5. 'New Horizons in Medical Ethics'. An article from BMJ 28 April 1973.
   4. Health Department Circular Letters. [Reference to five circulars dated from 1967 to 1974]

"GENERAL STATEMENT OF POLICY

1. The object of the Ethical Committee is to safeguard
   1) patients and healthy volunteers
   2) the reputation of the medical profession
   3) the individual hospital and the Auckland Hospital Board in matters of clinical research investigation. The Board has a duty to see that unethical practices do not occur and the public has a right to be satisfied likewise. The medical profession also must be vigilant in guarding its reputation from the harm that could come to it if unethical conduct went unchecked.
2. All proposed clinical research investigations are considered by the Committee where the investigation
   1) Involves the active participation of human subjects.
   2) Compares an established procedure, whether therapeutic, non-therapeutic or diagnostic, with that which is not recognised as established either by virtue of its recent development, discovery or use in a new or unfamiliar way.
3. All drug trials are automatically included as are trials involving the use of radioactive isotopes.
4. Whilst the assessment by the Committee will be principally directed towards the ethical standard of the proposed research, it is recognised that details of techniques may affect that judgement.
5. The Committee particularly concerns itself with the form of consent to be obtained from participants in each research investigation. In most cases, this involves the principal investigator declaring in writing that the subjects or their responsible and authorised relatives, will give informed consent to the proposed procedure.
6. The basic elements of informed consent are:
   1) A fair explanation of the procedures to be followed, including an identification of those which are experimental.
   2) A description of the attendant discomfort and risks, if any.
   3) A description of the benefits to be expected.
   4) An offer to answer any inquiries concerning the procedure.
   5) An instruction that the subject is free to withdraw his consent and to discontinue participation in the project or activities at any time.

7. As a guideline it is recommended that wherever the research investigation is not expected or is not intended to benefit the individual, a full explanation of the proposed procedure should be given and the subject must feel completely free to decline to participate or to withdraw at any stage.
   Except for trivial procedures, eg venepuncture, an explanation should be given by a responsible person and the agreement of the subject or patient should be recorded with the signatures of the person who gave the explanation and a witness.
8. Where the research is intended to benefit the patient, although consent should ordinarily be sought, there are sometimes circumstances in which it would be inappropriate or even inhumane to explain the details and to seek consent. The Committee will examine such cases with particular care.
9. Clinical research investigation of children or mentally handicapped adults which is not of direct benefit to the patient, may be permissible provided that the procedures only entail negligible risk or discomfort. The parent or guardian should be consulted and his permission recorded even though legally no-one has the right to give consent for experiments to be carried out on another person. In the case of research procedures which may be of direct benefit to the patient, the ordinary criteria for other patients would apply.
10. Freedom to withdraw or to refuse to participate, is particularly important where the subjects are in a dependent relationship to the investigator, eg students or lab technicians.

"LAY REPRESENTATION ON HOSPITAL ETHICAL COMMITTEES

1. At the present time, none of the Board's Hospital Ethical Committees has a lay representative.
2. The report of the Royal College of Physicians of London published in November 1973 says this:
   'The medical members should be experienced clinicians with a knowledge of clinical research investigation **and in addition there should be a lay member.** By layman we mean an individual who is not associated with the profession in any paramedical activity ie a biochemist or a psychologist would not be considered as a layman for this purpose. It is envisaged that the Committee will sometimes have to seek expert help from specialist outside sources, for instance to ensure that a complex technique is being used ethically.'
3. The Medical Superintendent, Auckland Hospital has asked for Board approval in principle to lay representation on the Auckland Hospital Ethical Committee.
4. This request has my support in principle."

National Women's Hospital Ethical Committee

It appears that the Auckland Hospital Board resolved to adopt the above recommendations at a meeting on 26 August 1974 and eventually the National Women's Hospital Ethical Committee began its deliberations in 1977. I can find no record of these recommended guide-lines being formally adopted by the NWH Ethical Committee, but I have inferred that it observes them informally. Although the Auckland Hospital Ethical Committee and other similar hospital ethical committees in New Zealand have formal guide-lines which are reviewed from time to time, the NWH Ethical Committee has never done this. It therefore has no written principles for clinical research to assist investigators in developing protocols, nor has it produced an application form which might serve the dual purpose. However, Dr Collison told me that the Ethical Committee has developed criteria which must be met by each research proposal put before it. These are:

- Scientific worth
- Patient safety and acceptibility
- Patient understanding and consent
- Impact on resources and cost
- Publication of results

Without the discipline of a proper form, it is difficult to assess a scientific protocol. More should have been required of the National Women's Hospital Ethical Committee in this regard. My review of the Minutes of Ethical Committee meetings over approximately 10 years has left me with some serious reservations. During this period the Committee met 17 times, considered 52 new research proposals, deferred a small number for further consideration and turned down only one project. There is little indication recorded of the extent of the discussion but, as meetings were on the whole short and a number of proposals were approved, it seems likely this discussion was brief.

There is no indication of discussion of referees' comments and seldom any suggestion of independent scientific assessment except where funding bodies had put a project to the Committee for ethical assessment and approval.

1. Information and consent forms

Only on rare occasions is the form for obtaining the patient's consent provided by the investigator for the Ethical Committee's consideration. Although the term 'informed consent' is used freely, particularly in latter years, there is little to suggest that much care has been given to ensuring that the patient whose consent to inclusion in a clinical trial is sought, does so freely and with full knowledge of the trial. In most cases where studies involved an intervention (as opposed to simple observation of a patient), no consent form was forwarded with the application. When this occurred, the Ethical Committee did not require a consent form to be presented before approving the trial.

2. Impartiality

Professor Bonham chaired all 17 meetings; at least 13 meetings considered one or more proposals put forward by members of the Postgraduate School of Obstetrics and Gynaecology. On one occasion, a proposal put forward by Professor Bonham himself as a co-investigator was considered. There is no record of any occasion when he vacated the Chair or absented himself during discussion of this or any other proposal from the Postgraduate School.

It is too difficult for an Ethical Committee to operate in an environment where the Chairman of the Committee does not appear to be independent of the investigator seeking approval for a project.

3. Review of existing research projects

In her evidence, Margaret Vennell considered that from 1976, an ethical committee should have established a system for reviewing long-standing research programmes. In her view, the Committee has a watchdog role. The Chairman of the Committee reported in the Minutes of 22 April 1982, that he was reviewing previously approved projects to "try and find out what had happened to them". I could find no record of the results of that or any other review. The Auckland Hospital Ethical Committee uses a system of annual reports from clinical investigators. Professor Richmond, Chairman of that Committee, said:

> *"This has the effect of ensuring that the Committee is aware of any problems arising during the course of the clinical investigation and of any decision to terminate a project and of the need for any subjects to be followed up longterm."*

4. Lay membership

For at least 10 years the need for a lay member has been acknowledged by the Auckland

Hospital Board. Throughout that period there has been one lay member on the NWH Ethical Committee (a pharmacist), increased I am informed in recent months to a membership of two or possibly three. The modern trend towards increased lay participation in ethical assessment was described by Professor Campbell in his guest editorial 'The Hospital Ethics Committee'[11].

> "Membership.
>
> In order to make adequate assessments of research proposals, a committee must be both competent and impartial. Without the competence to judge both the validity of the research design and the potential usefulness of the outcome, committees are in no way equipped to make informed judgements. On the other hand, if all the members are themselves engaged in medical research, they may lack the ability to raise the critical questions which are often required to ensure the adequate protection of research subjects.
>
> "The requirements for both competence and impartiality can be met only by ensuring a diverse but balanced membership in every committee. In large research centres, committees should be set up for all major specialties and should contain individuals competent to assess the scientific aspects of the research proposals.
>
> "This specialist membership must be balanced by researchers from other fields, by members from other professions (in particular nursing) and by 'lay' members, capable of mediating the research subjects' point of view.
>
> "It can be an advantage to select the lay membership from those with a specific professional qualification (eg in law, philosophy or theology), since this also gives input to the discussion from another discipline.
>
> "Members should not see themselves as merely representatives of a particular group (researchers, nurses, the lay public) but rather as contributors to the discussion from a particular perspective. The aim is to provide a balanced judgement, not to provoke interprofessional rivalry and debate. The emphasis on a diversity of membership should ensure the protection of the research subject from the narrowness of one professional perspective."

Both Professor Campbell and Dr Hodge provided me with details of the recommended composition of institutional ethics committees adopted by the Australian equivalent of the New Zealand Medical Research Council. The recommendations adopted were:

> "Institutional ethics committees shall be composed of men and women reflecting different age groups and include at least five people as follows:
>
> A lay woman not associated with the institution.
> A lay man not associated with the institution.
> A minister of religion.
> A lawyer.
> A medical graduate with research experience.
>
> "A lay person in this context is one who is not closely involved in medical, scientific or legal work."

These categories, although too restrictive for a community the size of New Zealand, give a good indication of the cross-section of lay representation that an ethical committee could strive to co-opt.

5. Consultation

I have already indicated that independent assessment seldom appears to be sought by the NWH Ethical Committee. On one occasion, the Minutes noted that a trial on the management of prolonged pregnancy would require the full co-operation of obstetricians

at the Hospital. For that reason, quite properly, the protocol was referred to the Hospital Medical Committee for approval. At the next meeting of the Ethical Committee on 1 November 1979, the Minutes record that the Hospital Medical Committee had accepted the project in principle but that some doubts had been expressed. Members had therefore been invited to submit comments to the Chairman of the Ethical Committee for the Committee's consideration.

A very detailed submission was received from an obstetrician on behalf of B-team. It was in two parts. The first part read:

"Comments on proposed research project re prolonged pregnancy

"Resolving the problem of how best to manage postmaturity is an important subject for research because this condition is a cause of perinatal death, but the main difficulty is how to diagnose postmaturity in the individual case.

"The risks of the condition have to be balanced against the risks of induction of labour, which we have outlined in the accompanying teaching notes.

"We should feel obliged to offer our patients for inclusion in the clinical trial only if we are convinced that they face minimal risks and that there is a reasonable chance that useful results will emerge from this research.

"In the past there have been numerous attempts to resolve this dilemma, none of them conclusive. We therefore see induction for postmaturity practised commonly in Britain but rarely in the USA.

"The concept of postmaturity is based on several assumptions, any of which may be incorrect; that ovulation, and therefore conception, occurred on day-14 of the LMP cycle. That the duration of pregnancy is 272 days and that the range is ± 14. This depends on Naegele's rule which must be about 150 years old and may be inaccurate.

"The concept of inexorable ageing of the placenta is entrenched but this does not explain extremes of duration of pregnancy, as in cases of anencephaly or well-documented 12-13 month pregnancies.

"Protocol:
Method of assessment of maturity is not detailed. It should be based on: booking before 12 weeks; initial assessment of uterine size by an experienced member of the staff; date of quickening; echography; x-ray; exclusion of unmarried patients, Polynesians, those recently taking hormones, and teenagers. Amniocentesis late in pregnancy may be dangerous. Amnioscopy? Perinatal mortality increases from 40 to 42 weeks, but does not increase exponentially thereafter – why?

"Nearly all studies have been retrospective (cf. Melbourne), therefore of limited value to quote. Dunn reported two series of 3000 and 1432 patients in prospective studies managed without induction (references available, if desired).

"Method of study – second sentence: there is no question of including any patients except those with uncomplicated pregnancies.... Informed consent – how fully informed can a patient be about this type of clinical dilemma?

"Non-induction group: "spontaneous labour will be awaited" – for how long? Will they be allowed to go several weeks "overdue".

"No mention of how many cases and for how many years the trial will go on. These facts must be stated; some trials go on automatically indefinitely, long after the instigator has left. 300 cases was a figure mentioned in conversation.

> These would produce only 5-6 fetal deaths; it would be impossible to draw conclusions from such a small sample. A more realistic figure is needed, but would a large number be feasible?
>
> "Why would OCT not be employed?
>
> "Management in labour: the list of variables to be considered is well set out. But how can so many possibly be coped with to draw a simple conclusion about a single factor (postmaturity) or a single management (induction)?
>
> "Anticipated outcome: this is an ideal aim, but is over-optimistic.
> The scheme as outlined is unconvincing and we would not be happy to commit the patients we are responsible for to it as we see it at present."

The second part was headed 'Hazards and Disadvantages of Surgical Induction'. It itemised eight hazards and disadvantages including failed induction, inefficient labour, prolapsed cord and psychological stress for the patient. The conclusions gave several criteria which B-team regarded as "inadequate indications for surgical induction".

The Minutes record that the Chairman of the Ethical Committee said:

> "As it appeared that the B-team consultants were not prepared to include their patients in this project, this raised the question of whether or not to continue with the project."

The principal investigator responded that he had always intended to approach each consultant about each case and to discuss the patient's inclusion in the project. As some consultants did not wish their cases included, then it would only mean that it would take a bit longer to gather the required number of patients.

The Ethical Committee then approved the project on that basis – on the understanding that the patients to be included would be those whose consultants were prepared to allow them to participate. There was no comment made about obtaining the consent of the patient herself and the project was approved notwithstanding carefully expressed concerns about its design and the patients to be included in it.

Obligations to the public

The NWH Ethical Committee was established at the direction of the Auckland Hospital Board. The Committee has certain duties to the public as a consequence. The guide-lines recommended in 1974 by the Medical Superintendent-in-Chief for the introduction of ethical committees to Auckland Hospital Board institutions set out certain objectives which recognised this duty:

1. The Ethical Committee was to safeguard patients and healthy volunteers.
2. The Board had a duty to see that unethical practices did not occur and the public had a right to be satisfied that they did not.

The NWH Ethical Committee has not always achieved the second stated objective. The Minutes of the NWH Ethical Committee for example, record that approval was sought for the next stage in a trial which involved the harvesting of fetal islets from fetuses older than 12 weeks. One of the investigators had commented:

> "Dr B has established a good working relationship with Mr T and the samples to date have been collected with a minimum of fuss and a maximum of discretion."

The Ethical Committee Minutes note that the Committee discouraged late terminations of pregnancy which "were to be avoided where possible" and "the only remaining concern of the Ethical Committee was controlling the publicity and the applicants were to be advised to use their discretion in publication, particularly to the media."

The clear inference (in the absence of any provision in the Minutes for obtaining the

mother's consent to the use of this tissue) is that it was thought prudent to avoid any public disclosure of this particular trial. With only one lay member on the Ethical Committee, it is unlikely that ethical dilemmas on which the community may wish to comment will be discussed. Therefore, there is a possibility that important ethical issues on which the public **should** comment, will be debated only within a very narrow medical/scientific forum.

When the authors of the magazine article 'An "Unfortunate Experiment" at National Women's' read the 1984 paper by McIndoe, McLean, Jones and Mullins, they began some research of their own. Preparatory work involved interviews with, and letters to a wide range of experts in the field of gynaecological malignancy, screening for cervical cancer and ethics of medical research, and teachers of obstetrics and gynaecology. Usually their enquiries were greeted with helpful and professional responses; but I was concerned when I read the correspondence from Professor Bonham, writing as the Chairperson of the Ethical Committee of National Women's Hospital in response to certain queries. A letter had been written to each member of the National Women's Hospital Ethical Committee,

> "Can the Ethics Committee of National Women's Hospital please tell me:
>
> 1) If the untreated women chose not to have their cancer treated?
> 2) What information these women who chose nontreatment were given?
> 3) How their consent to nontreatment was recorded."

After consulting the Committee's members, Professor Bonham replied:

> "I apologise for the delay in replying to your enquiry dated 11th September, but as it subsequently transpired that you had written to other members of our present Ethical Committee, I thought it appropriate that the Ethical Committee should have an opportunity to consider your letter and our reply.
>
> "As you will realise from detailed reading of the McIndoe paper that you referred to, the overall incidence of invasive cancer after the treatment of cervical intra-epithelial neoplasia (what used to be called carcinoma in situ) is only 4.3% while in patients who remain with negative smears after the treatment of the carcinoma in situ however mildly it is treated, the incidence of invasive cancer is only 1.4%.
>
> "In 1966 the treatment of an abnormal smear tended to be under American influence, a total hysterectomy even in quite young patients, and at that time some centres were carrying out cone biopsies as an alternative to hysterectomy. The mortality and morbidity of hysterectomy or even cone biopsy for such relatively benign conditions such as abnormal smears in the absence of invasive cancer was of considerable concern to our Hospital Medical Committee which at that time (1966) constituted the only medical ethical committee in New Zealand. It was decided therefore that a trial would be carried out of not carrying out radical treatment by hysterectomy or full cone biopsy for a proportion of the patients with abnormal smears. In all cases biopsies were carried out and often colposcopy and in the trial that was approved in 1966 colposcopy and biopsy was to be the standard method of management without further treatment so long as smears remained negative and again at all times in the absence of invasive cancer on biopsy.
>
> "The trial was successful and in fact shows that only 4.3% of the patients so managed would ever develop invasive cancer. It also showed that follow-up cytology was a particularly effective way in managing the cases in that it would give adequate warning of a deteriorating cellular condition. As is our normal practice, patients were made aware of the situation.

> "So far as your specific questions are concerned:
> Under 1. This question does not mean anything as none of the patients had cancer. They had abnormal cytology but not cancer.
>
> "On questions 2 & 3. A full explanation of the problem was given to those patients, though it is not normal to record full details of the explanation given to patients.
>
> "We appreciate your concern but this concern appears to result from a belief that invasive cancer was not being treated. Such has never been the case and never will be the case unless the patients specifically request their invasive cancer be not treated. This is a very rare event indeed but over the years we have had an occasional case. In such cases a record is made in the notes that the patient refuses to avail herself of the therapy offered."

(The McIndoe paper distinguished between two groups of women treated for carcinoma in situ at National Women's Hospital. It found that 1.5 per cent of those women who had normal cytology follow-up developed invasive cancer and that 22 per cent of those whose abnormalities were untreated, ultimately developed invasive cancer of the cervix or vaginal vault.)

1. "The Trial Was Successful"

As there has never been a formal review of that trial, unless the McIndoe paper can be described as such, I do not know from what source Professor Bonham was able to make this judgement. If by "successful" he means that patients' health was improved by the protocol set out in the 1966 trial, the outcome for the Group 2 patients shows the contrary to be true.

2. "Follow-up Cytology was a particularly effective way in managing the cases"

Follow-up cytology certainly did give "adequate warning of a deteriorating cellular condition". Professor Bonham failed to tell the authors that the warning was not heeded in many cases; some patients were not treated by generally accepted standards and some not treated at all.

3. "Patients were made aware of the situation"

Only one of the women who were part of the McIndoe paper's Group 2 and whom I interviewed, knew that she was part of a trial. 'Ruth' did not know that she was part of a trial. Not one woman I met was aware when her treatment differed from generally accepted standards.

Despite Professor Bonham's statement, "A full explanation of the problem was given to those patients, though it is not normal to record full details of the explanation given to patients", I do not accept that any of the women had adequate information about the nature of their condition, the proposed form of management and the fact that they were to be included in a trial.

4. "None of the patients had cancer"

In answer to the author's first question, "If the untreated women chose not to have their cancer treated?" Professor Bonham replied, "This question does not mean anything as none of the patients had cancer. They had abnormal cytology but not cancer."

That may be a purist approach to the condition carcinoma in situ, but most gynaecologists

throughout the world with expertise in this field, described the condition as precancerous or as a cancer precursor, even in 1966. Gynaecologists at National Women's Hospital including Professor Bonham, took the disease seriously and treated it with cone biopsy and on occasions, with hysterectomy.

It is understandable that members of a profession may resent or misunderstand attempts by lay people to find out more about their work. What is not acceptable is for the response to be couched in misleading terms and for misinterpretations to be placed on factual matters.

Professor Bonham went so far as to check on the letter writer's credentials with the Registrar of Victoria University. This is in marked contrast to the responses received from eminent overseas experts such as Leopold Koss, Professor and Chairman of the Montefiore Medical Center, and Dr D A Boyes, the Director of the Cancer Control Agency of British Columbia, who responded in a professional manner.

More importantly, the Chairman of the Ethical Committee was prepared to suggest that the 1966 Proposal was ethically sound and was successful as put into practice. Yet during the course of his evidence, Professor Bonham repeatedly declined to acknowledge that the 1966 Proposal was in any sense a research proposal, notwithstanding his use of the word 'trial' in the letter.

Summary and conclusions: The Ethical Committee at National Women's Hospital suffers from some grave disadvantages. It has no clear concept of its role, and has not discussed and settled its own guide-lines for its work or for proposals put to it for approval.

It has demonstrated no sense of responsibility to the public in providing accurate information when it is sought, and on at least one occasion suppressed information in case of public reaction. It lacked independence and impartiality during the period covered by the Minutes I have seen.

Lay representation has been inadequate. Furthermore, there is little indication that the Auckland Hospital Board has taken an interest in the work or composition of the NWH Ethical Committee except to require lay representation.

I have come to the conclusion that National Women's Hospital is too small an institution and too closely associated with the Postgraduate School to be entrusted with the critical task of evaluating the scientific and ethical content of in-house research proposals. The Ethical Committee lacks the broad scientific and ethical base needed to contemplate major issues confronting modern society. I have real concerns when I consider the quality of assessment given to some of the projects which not only have scientific implications but ethical and legal ramifications as well.

In my view, the Auckland Hospital Board must establish an ethical committee which is able to be more detached, which will cover a broader range of scientific and ethical disciplines, and which will have a clearer view of its own role and structure.

PROCEDURES FOR APPROVING TREATMENT AND ITS SURVEILLANCE

There is ample evidence in the Minutes of the Hospital Medical Committee (HMC) to show that before the 1966 trial was approved, senior gynaecologists had met relatively frequently to discuss the nature of carcinoma in situ, learn of new developments in its detection and treatment, and reach a consensus on how they would manage and treat it. The subject was carefully debated particularly during the 10 years before 1966.

After the 1966 trial was approved, there is a period of about 10 years where the Minutes of the HMC contain little evidence that these discussions continued. It was not until the

1975 Working Party reported, that small groups were established to discuss the treatment and management of two or three gynaecological diseases and to bring back recommendations to the specialist staff.

I am conscious of the fact some witnesses in this Inquiry have been confused about the difference between 'research' and 'treatment'. In fact, on occasions the line between the two is blurred. In my view there should be no artificial classification in ethics between research or treatment procedures. Attention must be focused on the outcome for patients and on their protection. Ethical standards must be applied rigorously to research and treatment protocols on behalf of the patients.

No doubt it was for these reasons that the Superintendent-in-Chief, in his submission to the Hospital Services Committee and to the Auckland Hospital Board, advocated that ethical committees should

> "advise on all proposed clinical research investigations and...on any matter of ethics relating to the practice of medicine in the hospital".

Dr Collison said:

> *"Other matters which may be placed before the Ethical Committee are new treatment proposals. These would then go to the Hospital Medical Committee for approval and adoption."*

However, the NWH Ethical Committee has not effectively discharged its duty. There is little evidence of a systematic review of new treatment proposals.

The case for treatment protocols

In essence, a treatment protocol will reflect generally accepted standards of management or treatment in a hospital at a particular time, given the knowledge of a condition and the available skills and resources for treating that condition in that hospital. In order to develop a treatment protocol, senior staff must be prepared to debate and reach a consensus which will be generally acceptable to them all.

This protocol then forms the basis for treating that condition at that hospital. As Professor Kolstad said:

> *"We have a treatment protocol that we follow. These treatment protocols will of course, time by time, be changed, according to new experience. But we have a treatment protocol, so it is very easy for us to decide upon and we always discuss management or the treatment with the patient. They are always informed about what we are doing."*

Counsel for the Ministry of Women's Affairs said:

> *"The obvious advantages of the treatment protocols are: they facilitate peer review and clinical audit; they provide a basis for adequately informing patients of the treatment they may reasonably expect."*

I believe that the development of treatment protocols for precancerous and cancerous conditions of the genital tract would have certain advantages for National Women's Hospital.

1. The development of a treatment protocol requires the joint approach of all specialists who are charged with assisting in the diagnosis or treatment of a particular condition.
2. A treatment protocol for a disease such as carcinoma in situ will enable the nursing and other health professional staff to understand more clearly the procedures that the specialist staff propose to follow. Social workers will also have information that will be valuable in developing procedures which take account of patients' emotional and family circumstances. That can only result in a more efficient level of care being offered to the patient.