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Comments

ON INFORMED CONSENT

The tradition of medical practice is based on the assumption that the patients come to the doctor for professional advice and service. Having done so, they have the right to reject the advice or refuse the service, and to go elsewhere. There are a few exceptions to this general rule. Children do not come to doctors, they are brought to them. In that case, the rights pertain to the parents. Persons who are so seriously injured or ill that they cannot exercise their judgement, will be brought for treatment, and it is then assumed that the doctors will use their professional judgement and do their best, considering the circumstances, for them. This applied also to those patients who were mentally disturbed in such a way that they could not make proper decisions.

At least, this was accepted until recently. Nowadays there is a loud chorus of disagreement and criticism, and increasing social pressure to constrain the doctors from giving the treatment which they consider advisable or necessary. At the moment this applies only to the psychiatrists, but it is probably only a matter of time before the other doctors will be included. It is proposed that when a patient is incapable of giving a valid consent to treatment then, before anything is done, another doctor should be called in to confirm the opinion of the first. It is doubtful if this will satisfy the critics. Soon it will be said that 'the doctors all stick to together' and that a tribunal should be brought in, preferably one which includes lawyers.

What has produced this change in opinion, in at least part of the public? Is it that the psychiatrists have become less competent or less trustworthy? There seems to be no evidence for that. Since the introduction of the National Health Service, the proportion of psychiatrists to patients has increased steadily. Their standards of training have risen and the efficacy of their work has obviously improved, as shown e.g. by the decreasing number of new long-stay patients.

It is an odd fact that just at a time when the treatments available to all branches of medicine have become so much more powerful and effective, the public's criticism and suspicion of medicine has become much stronger and more vocal. One reason is that trust in the medical profession has been permanently diminished by the revelations of what was done by the Nazi doctors in the German concentration camps, and has been unaffected by the adoption of the Nuremberg Code concerning consent. Another arises from the increasing effectiveness of treatment; the old traditional treatments did not help much, e.g. Mistura Expectorans, but they did not hurt much either. This is not true of modern treatments, both medical and surgical. They can do much good, but they can also do much harm. Public awareness of the risks has been heightened by the disasters that have been associated with the introduction of some new drugs. As awareness of the risks of treatment has become more widespread, patients have increasingly demanded that they should know about them before accepting treatment, and quite rightly.

Another important reason is the increasing disillusionment with science and technology, as instanced by the spread of superstition and the proliferation of pseudo-religious cults. The anti-psychiatry movement is part of the anti-science and anti-medicine movement.

One product of this movement is the notion of 'informed consent'. But what is 'informed consent'? There is no such thing. I believe that it is a lawyers' myth and I am not alone in this opinion (Fellner and Marshall, 1970). The idea is that patients must not be given treatment unless they have agreed to it after they have been fully informed about their illness and the treatment offered, its benefits and risks, *and have understood it.* It is in the last phrase where the nonsense enters. How does one explain to patients the nature of their illness when, according to the opinion polls, half of them do not even know where their stomach is? Without an adequate background of information, it is impossible to understand explanations about disease and treatment.

Attempts to make 'informed consent' conform to lawyers' requirements can best be described as pathetic. Aside from the actual content of 'consent' forms which are incomprehensible to the majority of patients (Grunder, 1980), their presentation at the clinical interview leads to much misunderstanding. Cassileth *et al* (1980) found that more than three quarters of patients believed that such documents were designed to protect the physician's rights and two out of seven thought that when they were given consent forms, they had to sign them. Although 85 per cent of patients thought they understood all or most of the information

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provided in the explanation, 13 per cent said that they understood little or nothing. Not surprisingly, the situation is worse with patients admitted to mental hospitals. Appelbaum *et al* (1981) investigated the competency of patients to sign voluntary admission forms and found that the majority would not be regarded as competent by legal standards. The literature on this subject is now astonishingly large.

Anybody who finds all this difficult to believe can test this quite simply for himself. Give your patient as good an explanation as you can, and then ask him to repeat what you have just said. What you will hear will sometimes make your hair stand on end. If you wait a week the result will be even worse. Soon after I was qualified (a long time ago) I came to the conclusion, based on what my patients said their previous doctors had told them, that my fellow-doctors were idiots. I learned better when one of my colleagues asked me if I had really told one of my former patients so-and-so and such-and-such. I could not believe my ears. Memories which are understood fade surely and inevitably. Memories which not understood fade even more quickly and, what is worse, become garbled. Patients frequently complain after they have left hospital 'Nobody ever told me anything'. Even when trials have been made to explain as much as possible, three months after discharge the type and frequency of such complaints remain the same.

More and better teaching of human biology at school will not solve the problem. 'Informed consent' also implies a rational judgement, i.e. the ability to give proper weight to all those factors which may influence a decision. But patients are suffering, they may be in pain, and they are afraid. Their fears prevent them from understanding and interfere with their judgement. The evidence for this is that sick doctors, who at least have the necessary background of information, can behave just as stupidly as lay patients. When the emotions are involved, judgement is almost impossible. That is why the profession has had the long tradition that doctors should not treat their relatives, their friends, and even themselves. There is an old saying among the legal profession that 'the man who acts as his own lawyer has a fool for a client'. It is equally true for the medical profession.

Does this mean that there is no way out of the difficulty? Not at all. It is very rare to find a person who does not want to know as much as possible concerning his person when he is ill, and the good doctor does what he can to satisfy his patient, though well aware of the limitations to what he is doing. This is an essential part of the doctor-patient relationship. I have always tried to explain everything to my patients, though more often than not, I am interrupted by the patient saying 'All right doctor, it's as you say'. With this statement, the patient informs me that he has given me his trust and that implies that I must carry out my duties in a way that deserves it and retains it.

If a patient refuses treatment that is because the doctor is not being trusted. Except in acute emergencies, and these are very rare, the doctor's aim should be not to force the patient to accept the treatment but to win that trust. There is never any need to hurry. The subject can be discussed another day. Even more important, discussions can be held with the relatives and friends. There is no need to go into details of how to cope with all the difficulties which arise in the clinical situation. The doctor who does an honest job, which means applying his expertise with sympathy and understanding, will not require detailed instructions.

It is a pathetic fallacy that professional behaviour can be improved by legislation. If doctors are forced to give explanations they will do so. 'I am going to give you these tablets for your rheumatism. Each one will make your stomach bleed and it has been known for some people to lose one or two pints of blood that way'. Who would accept aspirin after that explanation? 'I am just going to put a tube into your arm and push it up so that I can measure the pressure in your heart'. That is an accurate description of cardiac catheterization. These statements would fulfil the requirements of the law, but they are not what I call an honest job.

'Informed consent' has been regarded as particularly relevant in clinical trials. If it is meaningless in the ordinary clinical situation, it is equally so in a clinical trial. The responsibility is upon the person conducting the trial, and no 'informed consent' or signed document can shift it away. A clinical trial presupposes that the possible benefits of a new treatment are likely to outweigh its disadvantages, as compared with other treatments or even none at all. If the 'trialist' is not reasonably convinced of this, he should not be carrying out the trial. A useful criterion is for the trialist to ask himself whether he would be willing to enter such a trial as a patient, or to allow his nearest and dearest to do so. In the end it is a matter of self-respect and standards of clinical practice.

The authors of a clinical trial report should recognize that they stake their reputations on the way it was conducted. The profession should come down firmly on any research which may impair the trust of the sick and suffering in their doctors. Those who abuse their trust should be discredited and praise should be given to those who expose such abuses. In this respect, the medical profession has been somewhat laggard in recognizing its responsibilities in a situation where the rate of development of new treatments, both medical and surgical, is increasing steadily.

It is necessary to explain to the lay public that proper clinical trials are an unavoidable necessity. The

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alternative to properly controlled trials is uncontrolled trials and they open the door wide for quackery of the worst type. I have heard old-fashioned opponents of controlled trials complain that there have been plenty of good treatments introduced without all 'that fancy stuff'. That is true, but they ignore the myriad of useless and even dangerous treatments which have been foisted on unfortunate patients on this basis.

Every prospective patient should understand that the benefits he obtains from treatment puts him into debt to those previous patients who were involved in clinical trials. There is only one way to pay that debt. It is argued, not unreasonably, that is is only poor patients who have to pay it, not the rich. Of course, the rich have their troubles too. Nobody seems to mind when they are fleeced for fancy useless treatments in fashionable clinics. It must be admitted that poor patients are more likely to be included in clinical trials than rich ones. The fact that it has always been so does not mitigate its unfairness. But that is part of the society in which we live. It is unfair that the rich can stay in the best hotels, travel first class, eat the nicest foods and wear the best clothes. As citizens, doctors have the responsibility of doing what they can, like other citizens, to mitigate and abolish the unfairness of our society. As doctors they must be honest and do the best for their patients. That depends on professional self-respect and not on laws, compulsions and penalties.

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