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Is the policy of informed consent in the interest of the surgeons or the patients?*

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> ". . . Sir, I have found you an argument: but I am not obliged to find you an understanding." (Boswell's *Life of Johnson*)

Dr Samuel Johnson would no doubt have heartily approved of the "argument" chosen for this 1986 Kay-Kilner Essay: but the competitor who must find an "understanding" cannot escape quite as easily from his self-imposed task as the learned Doctor.

I have no great affection for the keywords that grace so many of our medical and surgical journals but in the title of this Essay two words, "informed consent", fit the bill beautifully. They provide not only an excellent argument but also the key to its understanding. The qualifying adjective "informed" bristles with profound clinical, ethical, philosophical and social implications for the surgeon, the patient and society. So, too, does the noun "consent", for the range of surgical operations or investigative procedures for which we should perhaps now deliberately seek consent is far wider than in our medical student days. The tiny conjunction "or", tucked away in the question, by suggesting that the policy of informed consent could provide a conflict of interest between surgeon and patient, challenges our conception of what the doctor-patient relationship should be: compassionate and caring, fiduciary or purely financial? Finally, although the question has been aimed at surgeons, let us not forget that we are first of all doctors: one of Lord Moynihan's *obiter dicta* was ". . . I am a physician doomed to the practice of surgery." Though some surgeons may still regard themselves as a race apart, we cannot afford to distance ourselves from the work that is done in other clinical disciplines and research departments or to ignore the responsibilities we owe to our colleagues, our patients and the society in which we live.

In the days when few infants could be expected to reach adolescence without repeated exposure to life-threatening illnesses and adults fared little better, it was hardly surprising that doctors came to be invested with almost divine status and, whether they liked it or not, assumed a God-like role in the eyes of those who sought their help. After all, did not the author of Ecclesiasticus provide scriptural authority for this view? "Honour a physician with the honour due unto him for the use you may have of him. For the Lord hath created him, for of the most high cometh healing . . ." It is easy to forget that even as recently as the late 1930s there were very few effective remedies available to the physician. The sulphonamide group of drugs were not discovered until just before World War II, radiotherapy was in its infancy and cytotoxic drugs unknown. As for surgery, its more dramatic successes were accompanied by an unacceptably high morbidity and mortality with post-operative chest complications due perhaps far more to the quality of the anaesthesia than the age or physical condition of the patient. Small wonder that "Mother Nature", admittedly with the help of some excellent nursing, was often the real architect of survival—though rarely given the credit—and various interpretations of God's will were invoked to ease the pain and distress caused by death.

In a fascinating article entitled "God and the Doctor" (*New England Journal of Medicine*, 1980, **302**, 555) Dr Humphrey Osmond, from the Department of Psychiatry in the University of Alabama School of Medicine, has discussed the interaction of what he has termed the "sick role" (a part assumed by the patient with inbuilt rights and duties) and the medical or "Aesculapian" authority wielded by the physician in the forging of a satisfactory, if only temporary, doctor-patient relationship. He pointed out that this "Aesculapian" authority, relying on its sapiential, moral and charismatic components, was ". . . recognised the world over, for when people are sick they revere it.

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However, once they recover, they are quick to forget the pain, humiliation and helplessness that attend so much medical treatment. To some, the doctor then becomes an awkward reminder of bad times, others are not fully satisfied with the results of treatment, while still others may find the expense of medicine too great when seen from the vantage point of health restored . . ." John Owen, the 17th Century Welsh epigrammatist expressed this change of mood beautifully,

> God and the doctor, we alike adore,
> But only when in danger, not before.
> The danger o'er, both are alike requited,
> God is forgotten and the doctor slighted.

However, post-war developments in medical and scientific research, the introduction of newer techniques of investigation and treatment, some of them classified generically as "invasive", the issues raised by organ transplantation, in vitro fertilisation and the definition of brain death, to name only a few, have profoundly disturbed many aspects of the doctor-patient relationship that were regarded as stable enough only a few years ago. As for surgery, the pace of progress, even in our own specialty of plastic surgery, has been so rapid in the last decade that if we were to take as our scale of measurement the extremely unwise claim made by Lord Moynihan in the late 1930s that ". . . Surgery as a craft has reached its peak . . .", we are now well on our way into outer space!

It was inevitable that some of these rapid developments in therapeutic and investigative techniques would introduce a greater risk of mistakes leading to legal actions on the grounds of negligence, professional incompetence or sheer carelessness. Furthermore, in the course of experimental trials of new drugs in human volunteers and in clinical trials in patients, many compounds were found to be unsafe. Appalling congenital defects and deformities had been produced in the unborn child, resulting in various degrees of physical and mental handicap in those who survived. In adults, the discovery that certain drugs used alone, or in combination with others, could produce serious adverse reactions forced drug companies to withdraw many new drugs from circulation, at least in this country. These incidents and accidents were widely reported in our medical journals and gained much publicity in the press and on our TV screens where, in some remarkably frank interviews, many of the ethical problems of drug trials and therapeutic "complications" were sensibly discussed.

When it came to light that on several occasions, experimental and clinical trials had taken place without the human volunteers or the patients being made aware of the possible attendant risks of the trials, for which no form of written consent had been sought or obtained, there was immediate and sustained protest from the general public, patients and very many doctors and health workers. Even greater anger was expressed when it was discovered that some clinicians (including surgeons) and research workers were continuing with their work, paying scant, if any, attention to the guide-lines drawn up by major Research Institutes, some of our medical and surgical specialist Associations and in particular the various Declarations made by the World Medical Association. The titles of some of these World Medical Association Declarations are worth noting:

- The Helsinki Declaration on biomedical research involving human subjects (1964: revised in 1975)
- The Oslo Declaration on therapeutic abortion (1970)
- The Sydney Declaration on the determination of the time of death (1968)
- The Tokyo Declaration condemning the use of torture or other forms of cruel, inhuman or degrading treatment (1975)

The realisation that a great deal of experimental and clinical research work was being pursued on patients and human volunteers with little explanation being given of its nature, purpose and the risks involved compelled many doctors, health workers and researchers to take a closer look at the ethical implications of the work they were doing. The physical risks were obvious enough: one of my former colleagues, the late Alexander Brown, Professor of Medicine in the University of Ibadan, Nigeria, would often remark ". . . I always say you have to be fighting fit to go into a Teaching hospital!" But as newer techniques were widely brought into general clinical use, many doctors could find themselves closely associated, whether they liked it or not, with therapeutic programmes in which decisions were becoming now the responsibility not necessarily of one individual but of a team. Not least of their anxieties was the need to provide far more information about the patients they were treating to the relatives and, in some cases, to the general public in view of the national and international interest in the work that was being done. One has only to recall the excitement

following Dr Christian Barnard's first heart transplant, the first babies born after in-vitro fertilisation or the first heart-lung and liver transplants. The desperate need for sufficient kidneys to be made available for transplantation raised a host of medical and surgical dilemmas. How could viable kidneys be obtained quickly enough, in good condition, from potential donors to provide the best possible chance of a successful transplant? How could the time of death be determined in those from whom consent had already been obtained in life? If life-support machines had to be switched off, in other circumstances, how could consent for organ donation be obtained from the relatives and who would decide when to switch off the ventilator? In the case of new-born infants presenting with gross neural tube defects, who should make the crucial decision immediately after birth as to whether or not an attempt should be made to close the defect: the parents, the surgeon or a medical "committee"?

These dilemmas were a clear warning to doctors that they had to "inform" themselves far more fully than they had been hitherto accustomed before they were in any position to justify or explain to others the reasoning on which their clinical advice was based and the actions that they would recommend should be taken in the course of investigating and treating their patients. Above all, the rights of the patient, or parents, to give or refuse consent for such investigations and/or treatment should be respected. The fundamental ethical principles that we are enjoined, but by no means compelled, to observe have been widely debated and discussed in many journals, books and conferences: but they are so important that they cannot be repeated too often. They are—

- To respect the autonomy of the individual: in other words the right of a patient or parent to take a decision and determine his or her own actions.
- To do good and not to do harm: the principle of beneficence being the duty to do good, that of non-maleficence being the positive principle not to do harm.
- To tell the truth: the patient may specifically insist that he does not wish to know the truth: the surgeon may not wish to cause his patient distress by telling him the whole truth, but to practise deliberate deception is unforgivable.
- To preserve not only the sanctity of life but to respect its quality. It is only fair to point out that the traditional (Western and Eastern) doctrines of the sanctity of life are no longer tenable and several modern philosophers have proposed a new understanding based on the very important distinction between "being alive" and "having a life". A clear exposition of this approach is given by Professor James Rachels in his book *The End of Life: Euthanasia and Morality* (Oxford University Press, 1986).
- To maintain the confidentiality of the doctor-patient relationship.
- To accept the principle of justice. This is often called the principle of distributive justice under which those in greatest need have their needs met first. It is the basis on which a society with limited means may attempt to justify its efforts to allocate or ration resources.

But it was not only the doctors and health workers who took the issue of informed consent seriously. Patients who had personally experienced or been involved with some of the controversial features of modern medicine and its technological advances were joined by many others who were deeply concerned with human rights, racial discrimination and particularly the need to respect the autonomy of the individual and the confidentiality of all information contained in medical records. Not unexpectedly, many of the most energetic, effective and best informed "agitators" were women. Certainly they produced some of the best polemical, if emotionally charged, writing to support their campaign—an excellent example being Carolyn Faulders's recently published paperback *Whose body is it? The troubling issue of informed consent* (Virago Press, 1985). They had good reason for their concern. Had not some of them given birth to babies with congenital abnormalities, some of them treatable, others not? They were well aware of the issues raised by the unwanted pregnancy, abortion law, the advantages and hazards of the pill in its various combinations and the dangers of many of the intra-uterine devices used in contraceptive control. Had not some of them found themselves involved in clinical trials of several kinds for the management of cancer of the breast, some of them in controlled randomised trials, the significance of which was never properly explained to them, if at all, and in certain cases not even disclosed to their family doctors. When it came to the question of infertility and its investigation and treatment, to

whom could they turn for informed advice on the possibilities of AIH, AID, in-vitro fertilisation or even surrogacy? Could they be certain that their identity would not be divulged, the confidentiality of information preserved and their personal dignity respected? They were well aware of many of these difficulties, long before the Warnock Committee began its deliberations. No wonder that their views should be so passionately expressed. Let Carolyn Faulder herself explain:

> ". . . Informed consent is a matter of ethical principle not a legal formula, or a courtesy which the doctor may or may not extend to his patients as he thinks fit and only to those he deems capable of acting upon it. It is about the right to control our own destinies and to determine our own ends as far as is humanly possible: the right to make choices and the right to refuse treatment . . ."

So far, in this Essay, we have said little about consent. It is defined in the OED as a ". . . voluntary agreement to, our acquiescence in what another proposes or desires: compliance, concurrence, permission". In essence, it means agreeing with or saying YES to a proposition: but, as our legal colleagues gently remind us, the proposition must be properly "put". In medical and surgical practice any examination, investigation or operation involving touching the body without consent constitutes an assault which, in law, is both a crime and a civil wrong. Consent may be:

Implied: The very act of going to a doctor's surgery or attending a hospital out-patient clinic indicates a willingness or intention to seek medical help or guidance.

Expressed: this is usually obtained by the doctor or nurse and is illustrated, for example, by the patient's response to such propositions as "Let's listen to your chest" or "I'll just check your blood pressure" or "We'll have an X-ray of your chest". Consent to this type of proposition is usually verbal, but may be visual—a nod or shake of the head. When faced with other propositions such as "Let's take a sample of blood", the patient may wish to know why it is required and may well refuse consent if there are serious medico-legal implications, as in the determination of blood alcohol levels.

Written: this is the type of consent with which patients and doctors are most familiar, because it requires deliberate action on their part, unlike implied or expressed consent that is usually taken for granted or not even thought about at all.

For most hospital doctors and surgeons the only forms of consent that immediately spring to their minds are those required for an operation, or a post-mortem in those instances when the Coroner or the Procurator Fiscal are not involved. The purpose of a written form of consent for an operation and the administration of such form of anaesthesia as may be necessary is to protect the surgeon against an action for assault. It does not, in this country at least, protect him against action for negligence, as our medical defence organisations repeatedly advise us. Its wording, nevertheless, is important as an operation consent form, properly completed, legibly signed and correctly dated provides a permanent record of the proposition that was "put" to the patient or parent. The name of the operation is given: the name of the doctor who explained the nature and purpose of the operation is given and he/she has to countersign the form confirming that this explanation was given personally, in the patient's presence. The form also contains a clause to the effect that ". . . No assurance has been given to me that the operation will be performed by any particular surgeon". Finally, in bold capitals, most consent forms contain a caution: *If you do not understand this—please ask.*

It is, however, quite clear that this particular form of consent gives no guarantee whatever that the information provided to the patient or parent was necessarily accurate, complete, intelligible or properly understood. Indeed did the doctor who sought consent really understand the proposition properly himself? Was his explanation of the "nature" of the operation in accordance with what the surgeon had explained to the patient in the out-patient clinic or on the ward round? Can he appreciate why the patient may become extremely agitated when he/she learns that no assurance can be given that the operation will be performed by a particular surgeon? I have certainly met several patients who have quite deliberately refused to agree to this part of the consent form and have deleted it. Was anything said to the patient or parents about any specific complications or risks that might be associated with the particular operation or investigation that was proposed? This could become an extremely important issue should

full disclosure and explanation of all the possible risks involved become legally binding in this country. For if a surgeon had to do this to avoid the risk of crippling damages in an action for negligence brought on the grounds that he had failed to provide the patient with a "check-list" or inventory of every possible form of disaster, he would find himself forced to practise defensive medicine alongside his sometimes aggressive surgery. Not a happy combination!

However, the operation consent form is really a "red herring" in the debate on informed consent. It is the ethical basis of our surgical practice that is on the block. It is how we conduct ourselves and how we treat our patients before we pick up the scalpel that matters: if indeed we even need to pick it up at all. We should be thankful and grateful that there are so many members of society who are deeply concerned about human rights and who share the concern of an increasing number of doctors who are also troubled by the ethical issues and dilemmas that we encounter in providing health care. Their activities have probably had more effect than they imagine. The World Medical Association at its meeting in Lisbon in 1981 adopted a Declaration on the Rights of the Patient. In 1984 a resolution was tabled by the European Parliament instructing the European Commission to submit as soon as possible a European Declaration on the Rights of Patients and as recently as July 1986 the Association of Community Health Councils in England and Wales approved a Patients' Charter. They may be even more surprised to learn that as long ago as 1973, the American Hospital Association approved a Patients' Bill of Rights.

In the Plastic Surgery and Burns Centres in this country, because of the long-term follow-up required by so many of our patients (particularly those with congenital lesions, burns and malignant disease) we often find ourselves in much closer professional and personal relationships with our patients than colleagues in other disciplines. Indeed our understanding of the hopes, fears and anxieties of many of our patients comes very close to the empathy extended by a good family doctor. But in spite of all that has been said, do we always take these responsibilities seriously enough?

What comfort and guidance can we give to the parents who come along with a new-born baby with a surgically untreatable anomaly?

How can we describe in detail the management of an infant with a cleft lip and palate when the parents come along with booklets, pamphlets (even tapes) recommending a régime of treatment at complete odds with our own practice?

How do we care for and support the parents of a young child who is desperately ill and dying in our Burns Unit?

What do we tell a young married man or woman, with a family, who presents in our clinic with a very rapidly growing and almost certainly incurable malignancy?

Do we allow our patients to be included in clinical trials without their full knowledge and consent? Has the design and conduct of the trial been approved by a properly constituted and competent ethics committee or just passed "on the nod"? Were we even aware of the existence of the trial?

Is it justifiable to perform a large number of operations using the latest technique of reconstruction to build up an impressive personal series of cases to present at the next clinical meeting or International Congress, when safer and simpler methods are available and preferable?

If we delegate operations to our trainees and junior staff are we satisfied that they are competent and that they will carry out as far as possible the operation for which the patient gave informed consent and not embark upon a fanciful surgical peregrination of their own?

When we listen to enthusiastic advocates of tissue expansion (who can be as persuasive as the best of salesmen) do we ever ask ourselves what is being expanded: the patient's tissues or the operator's reputation?

To what extent do we respect the confidentiality of our patients' case notes and the clinical photographs that we are so fond of taking?

Do we ever devote enough time and effort to explain to our patients the unfavourable results that unfortunately may follow our surgery? Plastic surgeons are quite often wrongly regarded as "invisible menders" or "miracle workers". Those of our colleagues who are engaged largely, if not exclusively, in aesthetic surgery are well aware of the hazards of this theatrical role and know how to take sensible precautions: but do we?

Perhaps after asking everyone else so many awkward questions, the surgeon should put one to

himself: "Am I really the right person to do this operation?"

The answer to the question posed in the title of this Essay is quite simple. The policy of informed consent can only be in the best interests of both the surgeons and the patients. Informed consent can only help to build and maintain intact the trust and respect that the patient and surgeon owe each other. Just imagine the alternative: a policy of "uninformed consent"? What a turn-up for the lawyers!

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