costs amounted to $578 per employee but by 1984 they had tripled to $1700. Cost-sharing and co-insurance rapidly became widespread, the employee often having to make a substantial contribution to the family health care bill. In addition, the economic recession added significant stresses. Since health insurance at discount rates can only be obtained by major companies, redundancy often results in immediate loss of health cover.

The 1981 legislation also encouraged real competition to enter the arena for the first time. Hospitals formed into chains or became 'for profit' institutions. Those that have retained charitable or 'not for profit' status have had increasing difficulty obtaining capital from the financial markets, that is, from banks and investors, even though recent evidence suggests that 'for profit' health plans have 10% higher costs than 'not for profit' plans.[4]

Most important has been the growth in managed care, which involves continuing responsibility for care rather than *ad hoc* arrangements where patients go to any doctor they choose. Physicians linked together as 'independent physician associations' and centres joined to offer packages to insurers and employers as 'preferred provider organizations' or as larger 'health maintenance organizations'.

All of these new trends have cost containment as the priority and evaluation of care has taken a back seat. The first effects are now becoming apparent. Health maintenance organizations seem to have reduced inpatient stays by up to 40%[5] and costs by 25%, probably by being less technical and shifting more care to the outpatient ('ambulatory care') side of the equation. However most health maintenance organizations care for a very skewed population — those who can afford the insurance premiums or those with an employers' contribution. Thus the clientele are usually young, fit and in employment. Few are elderly or chronically sick and only a small proportion (about 5%) of the 20 million patients currently enrolled are covered by Medicare or Medicaid. In this way health maintenance organizations are able to maximize ('cream off') their profits. Whether there has been an overall cost saving remains unclear; analysis of data to 1981[6] suggests that health maintenance organizations at most make a once-and-for-all reduction in costs.

It is estimated that about 15% of the population in the USA have no formalized health cover — the 'medically indigent'. Not all are poor. Many are in low paid jobs, have inadequate insurance or are only insured for part of the year. In a 'for profit' system one might expect these people to fare badly and Lurie[7] found (perhaps not unexpectedly) that termination of insurance benefits reduces health status by dissuading people from treatment for chronic problems such as hypertension.

In addition, Lohr[8] and her colleagues have shown some effects of cost-sharing. Payment for services does not deter the well-off from seeking care for a range of problems from the major to the self-limiting. Cost-sharing does, however, dissuade the poor from seeking appropriate help and it dramatically reduces the access to health care of poor sick children — in the Rand study by more than 40%.[8]

Despite this worrying picture there may yet be scope for improvement. The scenario runs thus — health maintenance organizations and 'for profit' hospitals have successfully 'creamed-off' the profits and success has led to expansion and increased capacity in the health service. Unused capacity does not make a profit therefore there must be a constant search for new clients. However, most of the healthy are already provided for so that patients must be attracted who are supported by other funds — mainly Medicaid and Medicare.

When the professional standards review organization programme was dismantled it was replaced by the 'utilization and peer review organization' programme. Written into the legislation is a requirement that those providers who accept Federal funds must also accept quality assurance programmes. Competition and cost containment have thus driven the argument full circle in the search for clients and the measurement of quality is on the agenda once more.

This complex interplay between legislation, efforts to contain costs and the search for value for money has much in common with current concerns in the NHS. The evidence from this short review suggests that cost containment measures in a 'for profit' environment may achieve savings but do so at the expense of the disadvantaged sick. Enthusiasm for radical and uncontrolled experimentation with the financing of the NHS should be tempered by that knowledge.

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Informed consent

FOR generations of doctors the Hippocratic maxim *Primum non nocere* conveyed the message that above all else one's treatment should do no harm. This precept known to medical philosophers as that of non-maleficence is a negative attribute clearly of lesser medical value than the positive one of beneficence, in which at least some improvement in the patient's health may be expected. This ideal of doing good and having good done is the image of medicine which has appealed to most doctors and their patients since the time of the Greeks. And so modern medical historians looked again at the old maxim and decided that the message in the *Corpus Hippocraticum* should really be interpreted as 'help, or at least do no harm'. Beneficence was given classical priority over non-maleficence. Children could safely be taught that 'Doctor knows what is best for you', while doctors could decide not only which treatment was most appropriate, but which information should be withheld if it were considered harmful. As often as not, information was withheld simply because it was thought that it might worry the patient, or perhaps more significantly because if he learned the risks of an operation this might dissuade him from consenting to an intervention considered to be in his best interests by his surgeon.

This paternalism could extend to what Richard C. Cabot (1868–1939), a young physician at the turn of the century, described in his own practice as 'benevolent lying', before he decided to follow a path of immutable honesty with his patients for the rest of his career.[1]

The problem of full and honest information given to the patient

in terms that he can understand also complicates his consent to clinical trials. Here serious attempts have been made to formulate criteria for an investigator to follow. The Nuremberg Code for example states that 'The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be resolved by the experiment.' But who decides on the humanitarian importance of the problem? The doctor has a primary role in this dialogue with the patient, but in the end adequate consent should have no more or less to do with the liability of professionals as the agents of disclosure, than with the autonomous choice of patients to consent or refuse. The inefficacy of purely legal requirements in safeguarding the patient from doctors is ironically demonstrated by the fact that in Germany in 1931 the Reich Health Department had enacted guidelines for the control of human experiments and the use of innovative therapies in medicine which remained operative throughout the existence of the Third Reich. These regulations were at least as adequate as the Nuremberg Code. The subsequent Declaration of Helsinki in 1964 expressed the World Medical Association's view that a code should distinguish ethical from unethical research. Yet the randomized trial is not easy to reconcile with the traditional belief that the physician's primary interest should be the personal care of an individual patient.

Historically, medical ethics have been concerned solely with the behaviour of the doctor and they have been written about at length by such medical thinkers as Thomas Percival (1740–1804).[2] In the past few decades of this century the emphasis has shifted to a consideration of the right of the patient to divest himself of his doctor's beneficence. Western society now concerns itself with human rights, whereas before it concerned itself with duties. There is felt to be a need for informed consent and therefore the patient must be given an understanding of the advantages, disadvantages and risks of any treatment or experiment, so that he may come to an autonomous decision. In the new morality, the physician is required to protect the patient's rights.

One of the common problems for a clinician giving practical advice is knowing whether or not the patient has understood. There are several reasons for a failure of understanding, ranging from inadequate or incomplete disclosure on the part of the doctor, through a numbing fear that prevents the intelligent patient from hearing what is being said, to a simple disability of mind. It is difficult to assess what constitutes full disclosure by the doctor or whether there has been full understanding by the patient and it is not surprising that many patients still regard informed consent as 'Letting the doctor do what he thinks best'. Hospital staff, anxious to make the patient better, still regard the most convincing evidence of willing compliance to be a signature on the consent form.

In practice, it is easier to learn if one has transgressed the law than a moral code; and the concept of informed consent involves much more than the fulfilment of a legal obligation, being more concerned with matters of ethics than of justice. The difficulty of resolving this ethical component now exercises the post-Hippocratic thinkers and inevitably involves the jurists. There have been attempts by many professional bodies to define informed consent, including a massive American contribution by the President's Commission for the Study of Ethical Problems and Biomedical and Behavioural Research (1980–83), which at one point described the process as active shared decision making. This is attractive in its simplicity but there is the possibility that an erroneous decision can be reached in this way. If the doctor makes a wrong diagnosis, from which the choice of treatment must follow, then the jurists may become involved in deciding the doctor's liability for negligence.

The legal area which is most likely to be concerned is known as the law of tort. A tort is a civil injury to one's person or property that is intentionally or negligently inflicted by another and it is measured in terms of, and compensated by, money damages. The legal duty of the doctor in relation to informed consent and negligence has begun to be argued in the law courts of the USA, Canada and the UK.

In English law negligence on the part of the doctor was already held to include his failure to act with that degree of competence practised by his medical peers. Specialists were thus presumed more skilful in their own specialties than other doctors. This was confirmed by the trial judge in Bolam v Friern Hospital Management Committee (1957, 2 ALL ER 118), when the doctor's duty to warn was tested by 'the standard of the ordinary skilled man exercising and professing to have that special skill'. Advice, as well as diagnosis and treatment, is part of the triad of medical practice.

The newly emerging issue is whether negligence can be attributed to a doctor because he has obtained consent for treatment from a patient who has been inadequately informed. This introduces the patient as an active party to the contract.

In informing the patient and considering his response there can be a divergence of opinion between the aims and interests of patients and their doctors. The doctor, for example, may believe that the disclosure of a risk would not be in the patient's best interest and withhold such information as a therapeutic privilege. However, if the patient asks, the doctor must tell.

In Sidaway v Bethlem Royal Hospital (1985, 1 ALL ER 643) the plaintiff had suffered serious disability following an injury to her spinal cord, resulting from an operation performed for the relief of pain. Being unable to sustain a claim based on a negligent performance of the operation, she contended that the surgeon had been in breach of his duty in having failed to warn her of all the possible risks inherent in the operation, and as a result she had not been in a position to give informed consent. At the trial, expert evidence was given that there was approximately 1% to 2% risk of damage to the nerve roots and less to the spinal cord. The trial judge dismissed the plaintiff's action and she was given leave to appeal. This was rejected in the Court of Appeal, where Lord Justice Dunn, commenting on the personal nature of medical practice, reflected that 'Doctors after all treat patients and not diseases'. He disliked the evocative reference made to 'medical paternalism', which he saw as 'the doctor–patient relationship as it has developed in this country' to the advantage of patients, who must often 'put themselves unreservedly in the hands of their doctors'. When the case was taken to the House of Lords, Lord Scarman defined the doctor's duty 'to be one which requires him not only to advise as to medical treatment but also to provide his patient with the information needed to enable the patient to consider and balance the medical advantages and risks alongside other relevant matters, such as, for example, his family, business, or social responsibilities of which the doctor may be only partially, if at all, informed'. For his opinion, Lord Scarman relied on the American case of Canterbury v Spence (1972, 464F. 2d 772). The American court had made a demanding interpretation of self determination and the right of the patient to autonomous authorization.

> 'True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible.'

Although the House of Lords was not unanimous in its view and Lord Scarman's opinion could be regarded as dissenting, all five law lords, including Scarman, agreed in dismissing Sidaway's appeal.

Despite the benign view taken by these judges of the integrity of the traditional medical viewpoint, most doctors probably now agree that the patient has a right to free choice. It would seem prudent for the general practitioner and his consultant colleagues to consider the doctrine of informed consent in all its historical, moral and legal aspects. They could not do better than begin by reading Faden and colleague's *A history and theory of informed consent.*[3]

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