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CLINICAL
FREEDOM

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INTRODUCTION

In seeking to identify the origin of the term 'clinical freedom' it seemed sensible to return to the debates that preceded the establishment of our health service. Lord Dawson of Penn, who regarded the prospect with limited enthusiasm, said in the House of Lords debate in June 1943 'It was not to be expected that a learned profession was going to give up its freedom to think and do what it thought best. Freedom for initiative and individual responsibility were the life blood of the medical profession' (1). Exploiting an argument that would not be unfamiliar to those who still find it necessary to defend our rights, he went on to say: 'If anything were done to damage that, the patients would be the first to suffer'. Dawson was not without support. Ernest Brown, Minister for Health, said later in the year, 'the true liberty of the professional man was freedom to exercise his knowledge and skill according to his conscience and his ability, without fear or favour' (2).

By the end of 1946 the advent of the Health Service was no longer in doubt. The profession accepted its inevitability and concentrated now on establishing the boundaries of its autonomy (3). In November 1946 the BMA Negotiating Committee declared: 'The medical profession should remain free to exercise the art and science of medicine according to its traditions, standards and knowledge, the individual doctor retaining full responsibility for the care of the patient, freedom of judgment, action, speech and publication, without interference in his professional work' (4).

This concept of medical freedom was disputed by Sir Theodore Fox in his Croonian Lectures for 1951. 'Complete freedom is right outside human experience', he said, '... membership of a profession necessarily involves some additional loss of personal liberty' (5).

Fox considered a state of complete freedom in medicine: 'A boy or man wishes to be a doctor. Having learnt as much or as little as he pleases, he can see whatever patients consult him, when it suits him; he can give what advice he pleases, however

unorthodox, and provide whatever treatment he pleases, however expensive or lethal; he can behave towards his patients however he pleases and extract from them whatever they will pay'.

He pointed out that this was 'precisely the freedom enjoyed by the unqualified practitioner of medicine, the amateur Membership of a profession implies that the member, in exchange for the professional status he wanted, has fulfilled certain conditions and accepted a code of conduct or set of rules that limits his freedom to do as he likes'.

Doctors, of course, have always been subject to codes of practice. As early as 2200BC Hammurabi, King of Babylon, introduced a set of laws that limited their fees and stipulated punishments if their treatment resulted in injury or death. Similar laws were enacted by the Persians, Jews, and Hindus. In Europe in 1224 Frederick II specified the type of instruction a physician should receive, the need for examination and licensing of physicians and for limitation of fees. His statutes were accepted by the German and Italian states in the 14th century. Thereafter, Colleges and Guilds gradually assumed the role of regulating the profession to safeguard it against erosion by quackery, charlatanism, or other forms of knavery.

The evolution of systems for constraining the liberty of doctors was predicated by the recognition that patients were vulnerable and needed protection against malpractice; there was a need to safeguard their interests. An initial and fundamental requirement was the assurance that those who practised medicine were properly educated and qualified to do so. The granting of licenses was developed as a device to distinguish them from non-professionals, which could readily be verified by the public. In Europe such licenses to practise medicine were dependent on the attainment of university degrees. In England, for instance, in 1421, almost 100 years before the Royal College of Physicians of London was founded, physicians petitioned King Henry V to restrict the practice of physic to those who 'have long tyme y used the Scoles of Fisyk withynne som Universitee, and be graduated in the same; that is to say, but he be Bachelor or Doctour of

Fisyk'. Their motives were impeccable. They argued that the 'unconnyng an unapproved' in the science of physick caused 'grete harm and slaughtre of many men: Where if no man practised thern but al only connyng men and approved sufficently y lerned in art, filosofye, and fisyk . . . there shulde many men that dyeth, for default of help, lyve, and no man perysh by unconnyng' (6). The interest of patients was seen to be paramount.

The formation of the Royal College of Physicians in London in 1518 provided the first instance of licensing of doctors by a purely professional body. This introduced the idea of self-regulation by the profession, and heralded a shift of emphasis from the intellectual or academic skills inherent in the attainment of a university degree to the demonstration of practical skills. Again, the motive was concern to protect the patient—'to curb the audacity of those wicked men who shall profess medicine more for the sake of their avarice than from the assurance of any good conscience, whereby very many inconveniences may ensue to the rude and credulous populace' (7).

Fox observed how remarkable it was that the limitations imposed on medical practice were 'ethical rather than technical' and 'enforced by custom and convenience rather than by outside sanctions'. The basis of these considerations has been enshrined in early texts such as *Percival's Code of Institutes and Precepts* (1803) (8), or the Codes of Practice of the American Medical Association (1848) which defined the duties of physicians to their patients, duties of physicians to each other and to the profession at large, and—interestingly—obligations of patients to their physicians. Ethical codes of behaviour were based on considerations of 'good manners'; thus, the Medical Society of the State of New York in 1883 declared 'that the only ethical offences for which they claim and promise to exercise the right of discipline, are those comprehended under the commission of acts unworthy a physician or a gentleman' (9). Those who deplore our current loss of clinical freedom should reflect on Percival's Precept XIX which states: 'In consultations on medical cases, the junior physician should deliver his opinion first and others in

the progressive order of their seniority . . . a majority should be decisive', or Precept XXIII, 'no important operation should be determined upon, without a consultation of the physicians and surgeons, and the acquiescence of a majority of them'.

The nature of the relationship between doctors and government and between doctors and the public has necessarily changed over the years. The introduction of a State medical service in Britain brought with it a profound alteration in the status of medical practitioners. Most doctors have become 'wholtime salaried servants of State or local authorities', a circumstance viewed as wholly unacceptable by the BMA in 1945 (10). As a result, they have largely forfeited their freedom to choose their place of work and, even, their preferred discipline or speciality. Changing public attitudes to medicine and its practitioners have forced new appraisals of the status of doctors in Society. Governmental control of the medical purse-strings has curtailed the freedom of doctors to prescribe, to operate, even to offer optimal treatment to all their patients. The advent of the NHS seems to have brought about those conditions of restricted clinical and personal freedom that the BMA so vociferously warned about more than forty years ago. In this lecture I shall examine some of the constraining factors and the extent to which they have affected our freedom to practise. I shall look particularly at the constraints exercised through financial controls, through legal, ethical, and moral considerations.

Because the system of health-care in the US is so fundamentally different from our own, I shall try to assess the consequences of some of these constraining influences as they have appeared on both sides of the Atlantic. As our different systems have evolved over the past few decades doctors in both the US and the UK have felt 'the winds of change'. I suspect that, on balance, despite our recruitment to a State-run service, we have retained a substantial degree of clinical autonomy, perhaps—one might venture—somewhat more than our colleagues in America who are less overtly subject to governmental control.

FREEDOM OF CHOICE OF PRACTICE

Inherent in the system through which the NHS was established was an understanding that doctors would no longer have the freedom to practise where they wished or in the specialty they preferred. This inhibition had been anticipated and resisted by the BMA—'Doctors should, like other workers, be free to choose the form, place, and type of work they prefer without Governmental or other direction' (11). Nevertheless, it had been appreciated that one of the main objectives of a nationalised health service was to distribute doctors more-or-less equitably throughout the country and to distribute specialised services in a way that would facilitate access for those living in remote areas. No longer would it be necessary for complex cases to be referred to the better-endowed teaching hospitals of London or other large cities. The introduction of panel-lists for general practitioners and the regulation of the size of these lists ensured evenness of primary care: this limited the freedom of GPs to work where they wanted, and the requirement to hold an appointment at a hospital in order to have access to its beds reduced the mobility of consultants. The only escape from this geographical strait-jacket was provided through whole-time private practice; but, for practical purposes, outside of a few affluent suburbs of London, whole-time private practice was unlikely to yield a reasonable living.

These constraints upon movement did not apply only to doctors who had reached the ultimate stage of their careers, i.e. who were ready to seek appointment as consultants or principals in general practice. The development of sophisticated and specialised services at major provincial teaching hospitals and, also, at many non-teaching district general hospitals demanded the support of junior medical staff. Inevitably, the range of experience offered in these posts came to be appreciated both by those in training and the Joint Committees responsible for assessing their suitability for training. Large numbers of posts throughout the country were approved and filled by aspirant consultants. This resulted in the imbalance with which we are now faced, through which

many more young doctors are currently being trained than can possibly be accommodated in career-posts as consultants or principals in general practice. The recommendations of the Joint Planning Advisory Committee (JPAC) to deal with the problem of senior registrars and of 'Achieving a Balance' designed to regulate registrar posts are currently being implemented. Through the former, planned redistribution of senior registrar posts is taking place which will intensify their centrifugal movement to peripheral hospitals and further limit the opportunities of those young doctors who for one reason or another wish to remain in London or other large centres. 'Achieving a Balance' introduces a new dimension of control. Recognising the disparity between the number of junior doctors required to run the NHS and those required to fill potential career-posts in hospitals, it has recommended the creation of a new Intermediate Service Grade. Into this perhaps 5 per cent of all British medical graduates will be diverted, thereby not only restricting their freedom to select a place of work, but effectively removing their opportunities to train for or occupy a consultant post.

Such steps are an inevitable consequence of a system in which health services are tightly controlled and job opportunities regulated. Other countries with less formalised national health services are beginning to experience similar problems in their attempts to tailor entry into training grades to their projected requirements. In America, where one's freedom of choice of place and style of practice is regarded as sacrosanct, questions are now being asked about the number and distribution of training posts in medicine (12,13,14). In Canada in 1983 the province of British Columbia was met by legal opposition when it set out to restrict the number of doctors and to achieve a better distribution of medical services by rationing the billing numbers which give physicians the right to claim payment for their medical services (15). Protests by the profession led to a Supreme Court ruling that such rationing was a violation of the Canadian *Charter of Rights and Freedoms* but a new Bill was passed by the British Columbian Government to enable it to introduce control of billing numbers, and their Supreme Court has recently ruled that no

government is obliged to hire workers beyond 'its requirements for such workers'. Events in British Columbia are being watched with great interest by other Canadian provinces as it is likely that governmental success there will be followed by similar actions throughout the country to control the number and distribution of doctors. Arguments reminiscent of our pre-NHS debates are being adduced in the debate—references to 'the thin edge of the wedge' (of government control), to 'a two-tier system, with some doctors inside and others outside medicare', to a loss of patients' rights, and removal of competition.

In such debates it is worth reflecting on the freedom of other non-medical professionals to work how and where they choose. Engineers, lawyers, school teachers, are all subject to some limitations, their freedom on the whole being dictated by their willingness to respond to opportunities provided by free market-forces; university academics are even more restricted. In any equitable system of health-care acceptable standards of practice must be made available to all. The price we have to pay for this is loss of our professional mobility and, even, our freedom to select the branch of medicine in which we would like to practise. In Britain this limitation of choice is no longer an issue; generations of young doctors have emerged from medical school in full awareness of its inevitability. It remains to be seen how they will react to the tightening of the screw now being applied to training posts and hence to their final career prospects.

RESOURCE CONSTRAINTS AND CLINICAL FREEDOM

In a White Paper issued in February 1944, Sir John Hawton wrote: 'The government have announced that they intend to establish a comprehensive Health Service for everybody in this country. They want to ensure that in future every man and woman and child can rely on getting all the advice and treatment and care which they may need in matters of personal health; that what they get will be the best medicine and other facilities available; that their getting them shall not depend on whether they can pay for them, or on any other factor irrelevant to the real need—the real need being to bring the country's full resources to bear upon reducing ill-health and promoting good health in all its citizens'. An admirably simple expression of an admirably conceived plan. The fact that it has not quite worked out is not a reflection on the concept; it is largely a matter of resources. I do not intend to discuss the reasons for the increasing costs of medicine; this has been done often and by others more expert than I am (16,17,18,19,20,21,22). Among the factors that have been blamed for increasing costs are: specialisation and the extravagant use of expensive medical techniques; the wasteful and rather mindless routine use of cheaper and less exotic techniques; in the US in particular, the adoption of 'defensive medicine' to safeguard against the threat of litigation. Common to all sophisticated systems of health-care is the high cost of salaried staff, usually estimated as 70–80 per cent of the overall costs. The NHS is now said to be the world's largest employer with a total staff number exceeding one million: the impact of even small salary increases for all grades of medical or ancillary staff within it is readily appreciated.

Doctors generate the bulk of these costs including the need for substantial supporting staff and, until recently, have not been called on to account for them. The imposition of cash limits within the NHS less than a decade ago has forced a

more thorough appraisal of how costs are derived, with a view, of course, to their effective reduction. This appraisal has exposed the failure of most doctors to show a proper sense of responsibility towards the medical role in the generation of costs and the allocation of resources. Not only is greater medical participation now being encouraged in the overall management of the resources of the NHS, but individual doctors are now expected to be more accountable for the financial consequences of their own clinical decisions. Inevitably, the need to take this factor into account is leading to changes in the style of medical practice. To what extent might this be seen as curtailment of clinical freedom?

No system that hopes to be comprehensive and progressive can be immune to the problem of rising costs. In Britain over 95 per cent of health expenditure is paid for through the Health Service, i.e. through tax-revenues. In the US roughly 40 per cent comes from government, 30 per cent from private insurance schemes and 30 per cent is paid privately by the individual. In Britain we spend 6 per cent of our GNP on health-services, about £360 per individual per year; in the US the figure is 11–12 per cent or about \$1700 (£1100) per head. Even within a single country striking disparities exist. Wennberg *et al* (23) have recently shown that New Haven spent \$451 per head of population on inpatient care in 1982, whereas the demographically similar area of Boston spent \$889. In that year Boston spent about £300m more in hospital expenditure. The authors ask 'Are hospital services rationed in New Haven or over-utilised in Boston?'

Such variations in the funding and expenditure of health-care systems immediately introduce questions about outcome, about the health status—the morbidity and mortality rates—of the recipient populations. Do the people of those nations that spend less on their health-services enjoy a lesser degree of health? Conversely, if a country spends more on its health-services, is it able to 'buy' immunity from disease or a longer life for its inhabitants? The picture is complicated by the fact that other important modifiers of health are a function of the relative wealth of a country, such as availability of food, a clean and abundant water supply, adequate housing, and

general standards of hygiene; and the fact that affluence encourages expenditure on tobacco, alcohol, and dietary excesses that militate against an improvement in national health. There is also an apparent direct correlation between the wealth of a country and the percentage of GNP spent by it on its health services: the poorer the country, the lower the percentage, and vice versa. Disparities in health-care and in the health of populations are thus amplified by indirect indices of available wealth.

The substantial and striking difference between the total and per capita costs of the US and UK systems of health-care has led many health-watchers to examine them in detail. Of particular interest is the different response of our two systems to the pressure of technological advance. Rosemary Stevens (24) has attempted to explain this in terms of their historical evolution, our system having a long tradition of primary care and state responsibility for providing services; theirs a more vigorous and adaptable approach and a stronger commitment to technological excellence. Aaron and Schwartz (21) in *The Painful Prescription* have critically compared the use of resources in the two countries and tried to assess health-outcomes. More recently, Hiatt has examined the use and availability of services in the UK, US, Canada and, by way of contrast, China (20).

Aaron and Schwartz showed that, despite a far lower expenditure on health-care in the UK, there was no significant difference from the US for such crude indices of health-outcome as average life expectancy or infant mortality rate.

They also showed that for most matters of life and death we are not parsimonious: the same number of haemophiliacs get the clotting factors they need; megavoltage therapy for cancer is available as freely as it is in the States; so is bone-marrow transplantation, renal transplantation, and chemotherapy for potentially curable tumours. We do lag behind, sometimes badly, in the provision of renal dialysis (especially for the elderly), CT scanning, coronary artery bypass surgery, total parenteral nutrition, and chemotherapy for less responsive tumours. With the exception of renal dialysis, the clinical consequence of these deficiencies is at least open to debate.

Aaron and Schwartz's analysis went beyond the acute hospital sector and concluded that the UK system provided inadequate services for the elderly, the mentally ill, and the chronic disabled. This is undoubtedly true and I would not wish to ignore the problem, but in the context of 'clinical freedom', which is the topic of my lecture, this aspect of their analysis may not be entirely germane.

In the UK the combination of rising costs of services and rising demands for care has led to a system of rationing and queuing. Willingness to queue, no doubt, reflects a traditional national propensity; what is readily accepted at bus-stops is equally well accepted for hip operations. While queuing is a function of the recipient of health services, rationing is a function of the donor, in most cases the doctor. Does acceptance of this function compromise our clinical freedom? It is not easy to identify or isolate the part played by awareness of costs when individual doctors, GPs or consultants, decide whether or not to investigate or treat a patient. The open and direct opinion, 'This would cost too much', is rarely expressed and, I suspect, not often consciously entertained as a discretionary factor. Even if it were, it would be regarded simply as one of the factors that needed to be taken into account in order to establish a course of action. It would not often be seen as detracting from the doctor's clinical freedom. Whether he was influenced or not by consideration of costs would be entirely up to him; his autonomy would be unimpaired. A more important question from the point of view of clinical freedom is whether and to what extent doctors are prevented from doing something they wish to do for their patients by an authoritarian embargo based on resource considerations which is in conflict with their professional judgement.

The introduction of the limited drug list was seen by many doctors as a gross infringement of their freedom to prescribe. On 8 November 1984 the Secretary of State for Social Services announced that certain groups of medicines would no longer be available for prescription on the NHS. The primary purpose of this restriction was to achieve projected savings of £100m per year; a secondary purpose was to reduce the level of prescribing for the relief of minor and self-limiting ailments

for which medical intervention was thought to be inappropriate and, more specifically, to constrain the excessive prescribing of benzodiazepine sedatives and tranquillizers. A provisional list of 'prescribable' drugs in various categories was issued for comment. The reaction from most of the profession was immediate, intense, and critical. They expressed concern that patients might be obliged either to accept medicines that were unpalatable to them or to pay for non-listed drugs that were more to their liking; this would create a two-tier system in which those who paid would receive the drugs of their choice (or their doctors' choice), while those who did not would be limited to less acceptable and, it was implied, less efficacious remedies. 'In thousands of cases patients will no longer be able to obtain, under the NHS, those drugs which may be best for them. GPs and hospital doctors will be forced to write private prescriptions and patients will have to pay the full cost of their drugs.' (25). The thrust of this argument was that patients would suffer.

There was a more fundamental objection which saw this new mandate as an encroachment on clinical freedom . . . 'doctors should always be allowed to prescribe whatever particular preparation they deem most appropriate in the case of any given patient' (26).

The principles underlying the Department's scheme for limiting the list of prescribable drugs should not have given offence within the profession—reducing unnecessary costs of the NHS and simultaneously reducing the consumption of unnecessary medicines by the public could hardly have been objected to. Collier and Foster subsequently reported (27) that at least 150 hospitals or hospital groups were already successfully operating some kind of restriction on the availability of drugs. Application of a local restricted pharmacopoeia had resulted, for instance, in an approximate saving of £500,000 in Wandsworth hospitals for the year 1984–85; the authors felt that prescribing habits had been improved by operation of the scheme. Harding *et al* (28) reported a similar experience using a restricted list of 245 drugs in a large inner London group practice; they did, however, urge flexibility and regular revision of the proposed limited list.

Yet, the profession did object to the government's proposals, because they saw in these new regulations incipient signs that their conduct might increasingly be subject to governmental control. In the event the Limited List was introduced, after modification of its original content and the creation of a review body to monitor its appropriateness. In March 1987 the Minister for Health announced that savings of £75m had been achieved in the scheme's first year of operation, and a survey conducted by the Drug and Therapeutics Bulletin suggested that the majority of GPs were not dissatisfied or disadvantaged by these constraints in their prescribing powers.

The profession in this instance chose a weak issue on which to defend its rights; that they did so is an indication that the tenet of 'clinical freedom'—in this case, to prescribe freely—is still firmly entrenched in the professional mind and its sanctity is to be safeguarded.

Petrie and Scott (29) have recently emphasised the educational, as well as cost-containing, benefits of hospital formularies, and deplore the tardiness with which they are being introduced and the reluctance of hospital consultants to accept them. 'Defenders of clinical freedom', they say, 'argue vigorously against hospital formularies, but individual clinical freedom carries with it the responsibility to define a personal formulary and to relate it to the agreed recommendations of fellow prescribers.'

The flavour of the different approaches of the UK and US to the need for conserving funds may be discerned from the example of cardiac transplantation. The operation was first carried out at the end of 1967 at Groote Schuur Hospital in Cape Town; the recipient, Louis Washkansky, died within a short time. A second operation was carried out almost immediately on Dr Philip Blaiberg who was to survive with his new heart for about 18 months. In the ensuing euphoria, two operations were soon undertaken in Britain. Concerned by the cost-implications but, more important, by adverse publicity and increasing doubts about the ethics of the operation, the Chief Medical Officer convened a group of experts who advised that the operation was still largely

experimental and recommended that no special resources should be made available for it. This recommendation was communicated to Regional Health Boards in 1973. At the same time progress in the field was closely followed by a special Advisory Panel established by the DHSS and composed of wide medical representation. In 1977 the Panel agreed that the improved worldwide results of cardiac transplantation now justified its introduction into clinical practice and criteria were outlined for the designation of a few centres to carry out a closely-supervised programme. In 1979 heart transplants were performed at Papworth Hospital, in 1980 at Harefield. There was still considerable public and professional opposition, based on moral grounds as well as the feeling that the expense of the operation was not justified by the results. Initial funding for these two centres came from charitable sources. The Department commissioned an evaluation of the costs and benefits of the procedure and, having received relatively reassuring advice, eventually referred the matter to the Supra-Regional Services Advisory Group which accepted its inclusion as a specifically-funded supra-regional service in 1985.

Throughout this long saga the Department showed itself unwilling to impose its own decisions about treatment on the profession. In his original letter of 1973, the CMO stated the principle underlying the intrusion of the Department: 'Clinical decisions about the treatment of individual patients are, of course, for the consultants concerned, but the diversion of resources from other hospital work is a matter which involves the Board'—a clear acknowledgement that professional clinical freedom would be respected *so long as* it did not act against the wider interests of society. It is also apparent that the control exercised by the Department was financial and not through the application of law. Indeed, the health notice setting up the arrangements for supra-regional designation (HN(83)36) states: 'It has been agreed with the medical profession that units other than those designated *should not be encouraged . . .*', a choice of words that indicates the form of partnership that exists in the UK between the DHSS and the profession, as well as the restrained manner in which the former directs the conduct of the latter.

How has the same problem been tackled in the US? In 1980 the trustees of the Massachusetts General Hospital (MGH), after months of deliberation, announced they had decided against allowing the hospital's cardiac surgical service to begin a limited programme of heart transplantation. The request had come from the Chief of the General Surgical Services with support from almost all of his colleagues from other services; there was no question of the excellence of the hospital's cardiac surgery department or its scientific and experimental competence. The Trustees of the MGH—a private and non-profit-making hospital for which they held fiscal and legal responsibility—took this decision largely because of the effect the procedure would have on the allocation of costly and limited resources. A precedent was created by this decision: 'that physicians may not make independent final decisions regarding what professional services they provide, and that . . . there is a clear responsibility to evaluate new procedures in terms of the greatest good for the greatest number' (30). Later in my lecture I shall consider the ethical problem underlying the second part of this statement; at present I am concerned with 'clinical freedom', the right of doctors to make their own clinical decisions. Before the ruling by the MGH trustees it had been accepted—not always with equanimity—that new therapies could be introduced at will by each clinical service, depending on its own evaluation of the procedure. This freedom to amend existing procedures or introduce entirely new ones has always been seen as an inherent part of the clinical autonomy of doctors, especially surgeons, whose innovations have, for some reason, not been subject to the same scrutiny as the introduction of new drugs. The MGH decision stimulated intense debate which eventually sucked in the Department of Health, Education, and Welfare. A contract was awarded to the National Heart Transplantation Study to collect data and make estimates about the need for and costs of the procedure (31). Public interest and demands, in the meantime, led to a rapid proliferation of heart transplant centres—from 11 in 1983 to more than 80 in 1985—whose expenses were covered by Blue Cross-Blue Shield and other commercial insurers. Finally, yielding ultimately to public as

well as professional pressures, the Department of Health and Human Services announced in 1986 that Medicare would now cover heart transplantations (32). As a final rider to the evolution of external controls over medical practice, Medicare stipulated that they would only reimburse centres that performed 24 heart transplants over two years *with 65 percent two-year survival*. The factor of quality of medical care was now introduced into the system of appraisal and allocation of resources. In addition Medicare stipulated criteria for patient selection including the exclusion of recipients older than about 55 years.

I have dwelt at length on the issue of heart transplantation because this is one of the clearest and most cogent examples of authoritarian encroachment on clinical freedom. Both in the UK and the US pressures were exerted, first, to limit the right of doctors to act autonomously; second, to permit their activities *subject* to their meeting satisfactory standards of performance.

It is abundantly clear that no system can offer the best possible medical services to all of its people at all times. Some form of rationing is inevitable. In Britain we already seem to have accepted this, through some curious, unstated and ill-defined understanding between doctors and, even, between doctors and patients. Partly—and to a large extent unconsciously—this is achieved by a widespread acceptance by the public as well as the profession that resources are not unlimited and that the doctor has a responsibility to Society—through a thoughtful allocation of scarce resources—as well as to the individual patient.

There is an important difference in medical philosophy on the two sides of the Atlantic. In the US there is a tendency to continue treating the patient until there is no longer any chance of success or benefit (33); in the UK treatment will not be offered or will be withdrawn when benefits are thought to be marginal or improbable, especially if the gravity of side-effects is thought to be unacceptable. This difference is only to a limited degree explained by the ever-present threat of litigation in the US. There is a more fundamental difference in approach. American doctors do not readily accept defeat;

the patient is given every benefit of every doubt. In Britain we give up more readily, when we perceive that there is little likelihood of substantial or prolonged benefit to the patient. This does not imply that British doctors care less about their patients. Rudolf Klein (34) has said, 'a humane, clinical conservatism in Britain both sustains and is, in turn, reinforced by constraints in resources'; Americans tend to adopt a more 'heroic and aggressive style of medicine' than we do.

To some extent this difference of approach is 'patient-driven'. In the US, with its greater freedom for patients to 'purchase' additional medical care, doctors are persuaded to provide it, perhaps even against their better judgement of the value of the outcome. In the UK it is accepted that limitations of choice and, indeed, of the range of treatment are part of the price we pay for providing open and free access to our health-service. The alternative route of private medicine, through which additional and preferential treatment might be bought, is currently open only to about 10 per cent of our population and it fails generally to provide sufficient facilities for acute emergencies or chronic care; it is most advantageous for non-urgent elective surgery. It might be argued that the intrinsic rationing of services implicit in the British system is balanced to some extent by the rationing that obtains in the US through the admittedly freely-exercised choice of an estimated 37 per cent of the population to carry no or inadequate medical insurance. A National Access Survey in the States has actually shown deterioration in access to medical care among the poor, minority groups, and uninsured citizens between 1982 and 1986 (35.).

Although we might differ in our interpretation of the best way of providing health-care, perhaps even in our judgement about the extent to which it should be freely accessible, the profession and the public in the UK and the US probably have not dissimilar concepts about what constitutes good medicine. Is the clinical freedom of a doctor more constrained in our nationalised and bureaucratic health system than in the US where professional 'free-trade' and self-determination prevail?

The recent history of American medicine warrants brief consideration (18,19). Developments there suggest that how

ever free American doctors may now feel themselves to be, changes in the systems for providing health-care are increasingly likely to encroach on their clinical freedom in the future. In the mid-1960s Congress introduced the Medicare-Medicaid programmes. Hospitals that had survived on philanthropy now received more than 90 per cent of their funding through third-party payments; as the cash-flow increased, benevolent and indulgent Boards of Trustees were replaced by hard-headed financial advisers and administrators. At the same time private hospital chains began to spread and flourish; from 1976 to 1984 the number of acute care beds owned by such chains doubled from 55,000 to 110,000 and they managed another 41,000 (18).

As the entrepreneurial spirit began to permeate hospital care costs began to escalate. The Medicare-Medicaid programmes were particularly vulnerable because their system of retrospective claims for payments to hospitals permitted no control over expenditure. 'Cost reimbursement was just an invitation to steal' (36). To contend with this Congress enacted laws to establish PROs (Peer Review Organisations) with the following aims: to shift care from inpatient to outpatient settings which are less costly; to reduce the use of invasive procedures; to reduce re-admission of patients (37). While some of these aims might be seen as contributing to improved medical care, their real objective was cost-containment. Their success could not have been substantial, for in 1983 Congress established a new system based on a classification of 467 diagnosis-related groups (DRGs), through which payment was made prospectively to a hospital in respect of a patient's illness, the amount being specified according to the classifiability of the illness (38,39). The impact on hospital practice might have been predicted. Encouragement was given to increasing the number of patients admitted (since each brought in a fixed DRG fee) and to accelerating their turnover. Within the first year hospital costs rose 8.4 per cent against an expected rise of 3.4 per cent. To keep costs within the prescribed limit, a closer look was taken at doctors' use of expensive—and also non-expensive—techniques. As Ginzberg remarked, 'the earlier untrammelled freedom of the profession to determine

how, where and for how long patients would be treated was being circumscribed by new rules, regulations and protocols' (18).

Doctors had become accountable.

In 1986 a bill entitled the *Medicare Quality Protection Act* was introduced into the US Senate. Speaking to it, a Republican Senator, H. John Heinz III of Pennsylvania, said that his investigating committee had found that DRGs were driving patients out of hospital 'sicker and quicker'; that hospitals were 'pressuring doctors to violate their own medical judgement in treating patients'. 'A number of hospitals', he said, 'publicly rank the performance of their doctors, with good marks and even financial bonuses going to those with shorter stay, money-saving patients, and black marks for those with the sicker, older "DRG losers".' (40).

The implications of this account signify a serious encroachment on clinical freedom. But in the US further control may yet come to pass: In 1986 Tessa Richards published a searching and critical analysis of health maintenance organisations (HMOs) (41). Once called 'medical soviets' by the American Medical Association, these organisations have a long history—the first was started in 1929 to provide medical care for the employees of the Los Angeles Department of Water and Power. The concept was adopted almost 50 years ago by the Kaiser Permanente Health Plan which, with almost 5m members, is now the largest HMO in the US. The Health Maintenance Organisation Act of 1973 stated that all employers with more than 25 workers on one site had to offer their employees the choice of an HMO as well as conventional medical insurance. By June 1985 there were almost 400 HMOs enrolling 19m people. By the year 2000 it was estimated by Tarlov that this figure would rise to 120m [quoted by Schroeder (12)]. If Tarlov's estimate is correct, HMOs will become a formidable component of the American health-care system. It is therefore worth considering them in greater detail. For a full and proper discussion I refer to Dr Richards's excellent series of articles; I shall confine myself to considering those factors that appear to impinge on clinical practice—and autonomy.

I should first make it clear that the standards of operation of HMOs are inevitably variable. The prototype Kaiser Permanente was recognised to provide good patient care and to encourage a high degree of proficiency among its medical practitioners including the facilitation of research and other academic pursuits. (It even published its own educational bulletin in the early years.) The growing commercialisation of HMOs has focussed attention on profitability, sometimes to the detriment of high standards of practice. HMOs provide total medical care, including dental and ophthalmological services, under one roof. They offer impressive facilities with on site radiology, laboratory services, and a variety of paramedical support staff. They provide long hours of access, after-hours advice, an appointment system. They are staffed by general internists and paediatricians, who provide primary care because family doctors, as we know them, are a scarce commodity in the US, and by specialists who may be full-time or part-time. For this total health care patients pay a set fee—about \$250 a month for a family, \$100 a month for a single person. All of this sounds very much like our own NHS, except for the method of enrolment and payment. As Dr Richards points out, complaints about the system also sound depressingly familiar—obstructive discourteous staff, inability to see one's own personal doctor, long waiting times for appointments, lack of continuity of care and, it is believed, reluctance on the part of HMO doctors to refer patients to specialists who work outside the plan. 'A limited choice of both doctors and hospitals is an inevitable sequel of belonging to an HMO'. So much for patient freedom. How do doctors fare in HMOs?

Doctors are salaried employees in HMOs but they benefit from the provision of full malpractice cover, conference leave, paid holidays, financial advice and, even, a retirement income. In return, they are subject to peer review which influences their chances of promotion within the scheme. This review embraces the number of patients they see each day—a criterion of dubious acceptability; the 'processing' of a large number of patients is no guarantee of good medical care. The review also enquires about the quality of doctors' relationships

with patients (information often supplied by patients) and information about teaching and research activities. Doctors score points in each category, are placed in ranking order and salary increments are awarded, or withheld, on this basis.

In HMOs the use of resources is closely monitored. Each internist, for instance, might receive a regular report about his use of investigative facilities, his 'drug-bill', or the rate at which he refers patients to a specialist; since this is more costly, such referrals may be discouraged. HMOs set standards about criteria for admission to hospital and in-patient management. It is not uncommon for nurses to be asked to monitor medical practice that might be interpreted as 'excess utilisation'. Many doctors enjoy working in HMOs that offer an opportunity for efficient and high-quality care. Some complain about the rigidity of rules that govern their decisions about admissions to hospital, the length of stay of their patients, the frequency of outpatient visits, choice of drugs and investigations, indications for referral to a specialist. Dr Richards concludes that 'a decline in clinical freedom may grudgingly be accepted as inevitable—it is evident in all spheres of medical practice in America now—but the lack of flexibility within HMOs is widely criticised'.

I have devoted so much attention to the American medical scene because I believe a 'decline in clinical freedom' has taken place, and is still taking place, to a greater extent in their commercialised and competitive system than in our nationalised, bureaucratic, and more tightly-controlled NHS. A recent comment by a distinguished American physician, Dr George Silver (42) suggests that my opinion is not simply an expression of chauvinism. He writes: 'The British doctor, discontented as he or she may be with the inadequacy of the financial rewards of practice in the UK, or dissatisfied with the shabby and inadequate facilities in many places in which medical work is performed, is still largely free and untrammelled in the practice of medicine; . . . (whereas) American physicians . . . are pinioned by regulations and controls far beyond . . . colleagues in most other countries.' American physicians have been obliged to adapt their styles of practice to cope with these regulations and controls. Most now find that

they must join or contract to some type of organisation in order to survive; many find the transition painful. Motivated only partly by the threats to their income, physicians are beginning to rebel against their loss of control over patient care and against organisational approaches that they see as obsessed by the need to reduce costs and insensitive to clinical perspectives and the patient's needs (43). It remains to be seen whether they can influence these organisations towards a more acceptable clinical approach *within* the constraints of economic considerations. It remains to be seen whether we in the UK can retain our greater degree of clinical freedom in the face of increasing economic pressure and demands for greater accountability. Hampton (44) maintains that clinical freedom is already dead in the UK—and welcomes its demise. No longer have doctors the right 'to do whatever in their opinion was best for their patients' . . . 'we must know which investigations and which treatments are valuable and which are not' . . . 'medical care must be limited to what is of proved value'. I would agree with these comments, but not that clinical freedom is dead. Ailing it might be, but it will recover if doctors apply their freedom wisely. This will require a more judicious use of our limited resources and a concession that we have no 'right' to expend resources on what is not 'of proved value'.

THE PHYSICIAN'S DILEMMA

A few years ago the West Midlands Health Authority tried to impose a limit on the number of patients admitted to a renal dialysis programme because 'the budget . . . was overspent'. In a letter to the *Lancet* the two renal physicians who were subject to this constraint said 'patients with renal failure who were judged to be medically suitable for treatment and would die without it should be treated and that to withhold a successful treatment for a lethal condition for purely financial reasons was unethical'. In the ensuing debate Professor Cameron asked 'Should a doctor ever allow a patient to die of a treatable disorder because he is ordered to do so by a representative of the State?' (45).

In my previous section I have implied that this sort of choice is inevitable—‘no system can offer the best possible medical services to all of its people at all times’. A responsible Government has a duty to limit public spending. Within this limit it has freedom to choose how it allocates its resources, a freedom that can be removed from it at the ballot-box if its choice fails to please the voters. Our present Government has set out its cash spending plans to the end of this decade: expenditure on health and personal social services is scheduled to rise from an estimated outturn of £16.7b in 1986–87 to £19.1b in 1988–89. A future government might choose to augment this allocation, perhaps by reducing the almost exactly equivalent expenditure on defence. If it does so, it will alleviate the pressure on our health services for a time. Sooner or later, the pressure will build up again and the same awkward choices will face us. In the USA, with a more lavish budget estimated to be of the order of £510b in 1987, costs of health services were estimated in 1985 to be increasing by 15 per cent per year (46). The annual increase has diminished since then, but is still much higher than the rise in overall inflation or the increase in the gross national product (47).

The problem does not stop there. Within the overall budget, distribution must be made between the main care groups—acute hospital services; maternity services; services for children, for the elderly, the mentally ill, the mentally or physically handicapped, the terminally ill; primary and community health care; preventive medicine and health promotion. If a greater allocation is made to one sector, and the overall budget remains the same, it stands to reason that another sector must be deprived. ‘The NHS forces explicit choices’ about these relative priorities (34).

Sound and persuasive arguments may be adduced in favour of all of these priorities, but it is in the field of acute hospital medicine that the conflict becomes most starkly real. For here decisions are no longer being taken in the abstract—they apply to real patients whose fate—whose life or death—is in the balance. It is one thing for the responsible doctor to understand that ‘obtaining scarce resources for an individual patient clearly reduces their availability to others’ (48); it is

quite another to expect him to explain to his patient that treatment which might be life-saving cannot be made available because of costs. Douglas Black has said (49) that 'medicine is primarily for the individual patient and it is our duty as doctors to set the interests of our patients above our own self interest'.

This is a notion I have no difficulty in supporting. But does a doctor's duty to his patient override his obligation to society or to the State when it comes to allocation of resources? The *Handbook of Medical Ethics* issued by the British Medical Association states: 'As the resources within the NHS are limited, the doctor has a general duty to advise on their equitable allocation and efficient utilisation This duty is subordinate to his professional duty to the individual who seeks his clinical advice.'

How can one reconcile these two major interests—that of the State to keep a controlling hand on public expenditure, even when it concerns matters of health; that of the doctor to safeguard the interests of his individual patients? Faced with the stark West Midlands problem of deciding which patients should be given life (by dialysis) or suffer death (from renal failure), few physicians would simply accept a situation where, one's allocation of patients having been reached, all further patients with renal failure would be refused dialysis treatment regardless of the medical indications or prospects of success.

Schwartz and Aaron (50) discuss how physicians in the UK have found 'ways to reconcile the economic limitations with their personal and professional values'. As part of the process, they suggest, doctors may be less than explicit in their discussions with patients: whereas in the US 30 per cent of dialysis recipients are over the age of 65 years, if the patient is thought to be above a somewhat arbitrarily-defined optimal age for renal dialysis the British doctor might simply advise that nothing of medical benefit can be done, or might emphasise the unpleasant or burdensome aspects of dialysis. They suggest that some doctors might even persuade themselves that some treatable patients would not benefit, for instance from coronary by-pass surgery. They point out that many doctors are conscious 'that they are acting as Society's

agents in the rationing process' and find ways of rationalising their behaviour by this emphasis on the negative components of treatment.

How does this conform to principles of clinical freedom? 'Under the rubric of clinical freedom', they say, 'physicians can sometimes divert scarce resources to patients in whom they are interested, or . . . other doctors may intervene when they recognise that such a situation exists . . . (there are) trade-offs born of the recognition that the participants must spend all or most of their professional lives in each other's company'. They suggest, too, that the system can cope with 'the abuse of clinical freedom' because physicians have no direct financial interest in the allocation of the hospital's resources. Patient compliance is an essential feature of this rationing process—'the readiness of the British patient to defer to the doctor's authority largely explains a willingness to forgo the various kinds of care that are in short supply'.

Accepting as valid their proposition that British doctors do engage in a rationing process, how is this achieved in practice?

In a much-quoted study Challah *et al* (51) sent a questionnaire comprising 16 case-histories of a variety of patients with established end-stage renal failure to a large number of general practitioners, consultant physicians, and specialist nephrologists, who were asked whether treatment by dialysis or transplantation or both would be appropriate. Perhaps not surprisingly the number of cases rejected by both general practitioners and consultant physicians was significantly higher than by consultant nephrologists. This result would conform to Schwartz and Aaron's view of the 'gatekeeping' role of British physicians through which they 'spare the nephrologist from having to say no, spare the patient and family a painful rejection, and avoid having to face the patient and relatives after rejection'.

Eisenberg (52) considers the implications for American medicine of a system such as ours in which patients must turn first to their personal physicians (general practitioners in the UK, often general physicians (internists) in the US), who act as 'gatekeepers' by controlling referrals to more specialised services. He acknowledges the cost-containment benefits of

such a system but views its introduction in the States with suspicion and caution. In particular, Eisenberg expresses concern about potential underuse of the medical system through doctors failing to recommend care that is necessary, loss of free choice of specialist by the patient, and removal of the competitive element in American medicine.

In their analysis of the acceptance of this 'abuse of clinical freedom', Schwartz and Aaron make a number of rather critical judgments about the ways in which British doctors cope. At times our doctors are made to appear less than honest (by withholding or distorting information given to the patient), or self-deluding (by persuading themselves that the treatment might not be beneficial), or Machiavellian (by diverting resources when they desire), or artful (by considering 'trade-offs'), or perhaps simply compliant (because they have no primary financial interest). What they do not suggest in their article is that British doctors might actually be more discerning—genuinely, and perhaps correctly—more critical of the potential benefits of some treatments, e.g. coronary bypass surgery or total parenteral nutrition, more aware of the problems associated with long-term renal dialysis, less inclined to squeeze the last drop of potential benefit from any form of treatment.

This element of critical discernment might explain, for instance, why chemotherapy for potentially curable tumours is administered at approximately the same rate in the two countries, whereas tumours that are not highly responsive are treated far less often in the UK.

My awareness of this difference in approach was heightened during a recent visit to America where I attended a meeting to discuss the ethics of withholding treatment from a young infant with a rare form of congenital leukaemia. The infant had been given a course of treatment no different from those that had already been reported to be unsuccessful in similar cases. The side-effects had been severe—vomiting, diarrhoea, anaemia, and bleeding from platelet inhibition; a very short and incomplete haematological remission had been achieved. The question was whether a second course of chemotherapy was justified. After discussion with the parents and a debate by

doctors, nurses, social workers, psychologists, a professor of medical ethics and, of course, the hospital lawyer, the decision was taken not to go ahead. In Britain, I suspect, the approach would have been different. The first course of chemotherapy would not have been given, and this decision would have been taken by the doctors, the parents being informed that the only known treatment was both ineffective and likely to cause undesirably severe side-effects. I have no doubt that our own approach would have been more humane.

The paper of Challah *et al* dealing with the treatment of end-stage renal failure contains a suggestion that there may be more than one interpretation of the motives behind some clinical decisions: Whereas UK nephrologists rejected for treatment a mean of 4.7 of the total of 16 cases, the figure for US nephrologists assessing the same cases was only 0.3, i.e. almost all of the 16 cases would have been accepted. Is the discrimination wholly negative? Are British doctors acting against the interests of their patients by rejecting such a high percentage? Is the almost total acceptance of all 16 patients by US doctors based entirely on their appraisal of benefit to the patients and thus motivated solely by proper professional altruistic concern?

In the first Jan Brod Memorial Lecture given in Oxford on 24 April 1987 Dr Arnold Relman, Editor of the *New England Journal of Medicine*, discussed this question in greater detail. He pointed out that in the US 80–85 individuals per million of the population were accepted for treatment of endstage renal failure (ESRF) each year; in the UK the figure is less than half, about 30 per million. Until 1973 in the US haemodialysis was only available through an act of charity on the part of teaching hospitals or through private payment. In that year Congress agreed that Social Security would pay for all treatment of ESRF through its Medicare programme and physicians were invited simply to render their estimate of charges for each patient. Entrepreneurs, quickly recognising the potential profits to be made through treating ESRF, established business-enterprises to provide such treatment, and claimed all costs from Medicare; at present 40–45 per cent of all dialysis programmes in the US are provided through private for-profit

organisations. Some teaching and research hospitals, which had previously refrained because of the high costs of treatment, joined the bandwagon. The number of patients undergoing treatment in the US rose from 20 per million of the population in 1972 to about 450 per million in 1985; by comparison, in the UK, the figure rose from a similar starting-point in 1972 to about 230 per million in 1985: in an international survey Relman showed that, in general, those countries with a socialised medical programme in which physicians were paid salaries regardless of the number or type of patients they saw (such as the UK, Denmark, Sweden, and New Zealand) had a far lower prevalence of patients being treated for ESRF; countries like the US and Japan, in which a fee-for-items-of-service system operated, had the highest prevalence; those with mixed systems, such as Australia, France, and Germany were intermediate.

Relman further pointed out that treatment by dialysis was more profitable to an institution in the US than the alternative of renal transplantation; and treatment by dialysis in a hospital unit was more profitable to it than home-dialysis. In the US 80 per cent of all patients being treated for ESRF received dialysis (i.e. only 20 per cent were transplanted) and 80 per cent of these were treated within an institution; in the UK roughly half of all patients received a transplant and 70 per cent of dialysis patients were treated by home dialysis. In other words, in the US, a far higher proportion of patients were given more profitable forms of treatment, particularly unit-dialysis. Breaking this down further Relman showed that non-profit-making teaching hospitals had an average of 24 per cent of patients on less lucrative home dialysis, profit-making units had only 11 per cent. Relman deduced that the choice of treatment offered patients with ESRF in the US might be dictated more by its potential profitability than by purely medical considerations. The outcome of treatment is clearly important. In terms of mortality: in the US only 44 per cent of dialysis patients are alive at the end of 5 years; in the UK the average figure is 56 per cent. The difference might simply reflect the selection criteria used by both countries, the UK, for instance, tending not to treat groups at higher risk, older patients, or those with

concomitant diseases. Proper assessment of the quality of life of patients on dialysis is more difficult but the high rate of withdrawal by competent patients (reported by Neu and Kjellstrand (53), see later) suggests that life on dialysis is not always well-tolerated.

In America the rising rate of deliveries by Caesarean section has recently come under scrutiny (54,55). The rate trebled during the 1970s and is still increasing. Haynes de Regt *et al* (54) demonstrated a significantly higher rate among private patients than non-private patients even when differences in case-mix were eliminated. They conclude this is accounted for predominantly by the private obstetricians' concern about professional liability if there is an adverse outcome. It is quite likely—and others have suggested it—that financial considerations play a part.

If considerations of cost are now to be more formally incorporated into clinical decision-making, doctors will have to adapt to the prospect, not of doing all good to all people, but most good to most people. 'Instead of stopping treatments when all benefits have ceased to exist, physicians must stop treatments when marginal benefits are equal to marginal costs' (33). To assist them in this adaptation they will need to look more closely at cost-benefit analyses of various procedures. There is no shortage of publications on this topic. Roberts and his colleagues (56), for instance, ask 'How much can the NHS afford to spend to save a life or avoid a severe disability?' Their estimates (in 1981-82 terms) of costs to the NHS range from £900,000 for a pre-operative chest X ray, £300,000 for screening for cervical cancer, £80,000 for screening for breast cancer to £9,000 for open heart surgery, £7,000 for renal transplantation, £200 for a haemoglobin estimation, and £100 for blood pressure screening. Casscells (31) applied the same approach but used different analytical techniques to deduce that heart transplantation would cost about \$34,000 for each added year of life, coronary artery bypass grafting about \$10,000, haemodialysis for endstage renal failure about \$32,000 and screening and treatment of mild hypertension about \$30,000; for comparison, he adds, treatment of a single case of acquired immunodeficiency syndrome would cost

about \$140,000 (the cost per added year of life is unknown; this figure was calculated before the advent of azidothymidine). It is possible to take this accounting process even further. Doubilet *et al* (57) cite an analysis by Eddy to show that screening for cervical cancer carried out annually would achieve an increase in life expectancy of 67 days at a cost of \$315 per diagnosed patient; if carried out at 3-year intervals, the increase would be 62 days at a cost of \$95.

I would not care to defend the details of these calculations or the assumptions that underpin them but their general point is that it is possible to attach figures to the costs of various procedures and to their benefits in easily-established indices such as added life-expectancy.

Arguing that much of medical practice lacks a firm, quantified scientific base, Fuchs (58) pleads for 'a major effort to identify the benefits that patients receive from the various components (of) health care'. Various attempts have been made to quantify the quality of these benefits in terms other than extension of life. Williams (59,60), Rosser and others (61) have taken into account factors such as capacity for physical activity, mobility, disability, and distress. Using a graded scale of scores to indicate degrees of disability and plotting these against degrees of distress, it is possible to construct a grid from which a 'quality of life' index can be derived. This has then been applied to outcome assessed in added years of life to derive 'quality-adjusted life years' (QALYS) which provides a scale of comparison against which the costs of various procedures may be compared. Using such a scale it becomes possible to calculate the cost per QALY of coronary artery bypass grafting for angina pectoris associated with two- or three-vessel disease (£1,000—£2,500), for kidney transplantation (£3,000) against hospital dialysis (£14,000), for heart transplantation (£5,000) against hip replacement (£750).

Assuming that such calculations are valid, are clinicians more likely to accept rationing in the belief that the best use is being made of existing resources? Would such knowledge assist them in their explicit problem of determining which treatments should be offered to which patients? Who goes

into the last available ITU bed? Who gets the last available place in the dialysis programme? Whether to refer a patient with recent myocardial infarction for coronary angiography with a view to bypass grafting or simply to treat him with β -blockers? Most physicians, I suspect, would not find that the application of a pre-determined numerical index makes it any easier to decide which of several competing patients receives the only available treatment. As Alwyn Smith (62) has pointed out, they might find QALYS helpful in deciding between alternative treatments.

Fuchs, looking at the American scene, argued that 'health-plan managers, hospital administrators, insurance company executives and government officials' must use cost-benefit analyses as a basis for allocating scarce resources (58). It is notable that clinicians were not specifically included in his management structure. Recently, in the UK more emphasis has been given to the participation of doctors in the process.

In October 1983 Roy Griffiths reported to the Secretary of State the outcome of the NHS Management Inquiry through which it was hoped to achieve more effective use of 'manpower and related resources'. The report observed that the NHS 'still lacks any real continuous evaluation of its performance Rarely are precise management objectives set; there is little measurement of health output; clinical evaluation of particular practices is by no means common and economic evaluation of those practices extremely rare'. Griffiths recommended a system of management that emanated from a small, strong, central professional group through Regional and District Authorities to the Units (particularly the major hospitals) 'where most of the hospital patients are seen, most of the money is spent and most of the staff are employed'. The report recognised that doctors largely dictated the use of all resources and recommended their greater involvement in management—'the nearer that the management process gets to the patient, the more important it becomes for the doctors to be looked upon as the natural managers': 'management responsibility . . . goes with clinical freedom'. This view was endorsed by the Government's

response (DHSS Circular HC(84)13 issued in June 1984) . . . 'clinicians should be both encouraged and enabled to play a more active role in management and especially unit management'. In 1976 the Minister of State, Dr David Owen, said 'Clinical freedom is very precious and the medical profession is right to cherish it. If politicians or administrators start to make economic choices without involving doctors, doctors will face an inevitable curtailment of clinical freedom' (63). Douglas Black in his Harveian Oration of 1977 (49) had warned of the 'very real dangers to the future of medicine if health service economics is left to politicians, administrators and economists lacking an adequate medical input'. The Government's response recognised this and recommended that full account should be taken of 'the priorities of patient care and the advice of clinicians'. The encouragement to doctors to participate more fully in management has, not entirely surprisingly, met with limited success. At the time of writing, one of 14 Regional Managers is medical, 15 of 191 District Managers, and 103 of 612 Unit Managers. In an attempt to attract more doctors into this role the NHS Training Authority has recently issued a Discussion Document ('Developing the Role of Doctors in the Management of the NHS', October 1986) and several new initiatives (notably that of the King Edward VII Hospital Fund) have set out to offer training courses for them.

The emphasis of the NHSTA document is on money . . . 'giving doctors the economic skills to be able to explore the costs and benefits of particular therapies, the budgeting skills to enable doctors to husband their resources efficiently' (64). Important this may be, but obsessional concern with a more efficient use of resources measured solely by financial criteria fails to take into account the quality of personal care given to individual patients.

Sensible doctors now accept that more effective management is essential if the NHS is to survive in an acceptable form. If they fail to co-operate by providing the necessary clinical information and advice and, indeed, by participating fully in the management process, they will find that they have lost a substantial part of their clinical freedom. If they do co-

operate and participate, they might help to ensure that the resources and facilities of the NHS are put to the best possible use in the interests of their patients.

Doctors are best placed to shift the emphasis of managerial enquiry from its pre-occupation with resources and costs to health outcome and patient satisfaction. For this reason alone medical participation in management is imperative. By ensuring that resources are devoted optimally to serve the interests of patients, doctors will find that their own clinical freedom is maximised.

ETHICAL CONSTRAINTS

Professional autonomy and patient autonomy

The doctor's need to determine his own priorities in clinical practice against a background of resource-limitation introduces a profound ethical dilemma. The evolution of modern medicine has introduced many others, most concerned with matters of life and death. At one end of the scale we have in vitro fertilisation, embryo research, abortion, and our ability to salvage infants weighing as little as 0.5 kg; at the other end, our ability to keep patients alive through life-support systems, the need occasionally to turn them off, euthanasia, and 'living wills'. Doctors in clinical practice cannot avoid being exposed to these dilemmas—obstetricians and gynaecologists or intensive care specialists, perhaps, more than most—and quickly learn that their freedom of action is, quite properly, constrained by the need to comply with certain ethical guidelines laid down by society. Increasingly, through the normal process of consultation they find it necessary to reconcile their clinical judgements with the explicit and sometimes conflicting views of the relatives or the patient himself. I shall select one or two areas in which medical action might seem to be constrained in this way.

KEEPING PEOPLE ALIVE AND BRAIN DEATH

When I first qualified in medicine I 'inherited' responsibility for the hospital 'iron lung'. It was used exclusively for patients with respiratory problems associated with potentially reversible neurological disease—poliomyelitis or infective polyneuritis of the Guillain-Barré type. There seemed to be no ethical problem about its use (although in my hospital it was available only for white patients), and there was no apparent problem about the decision to terminate treatment. Patients were almost always young, their disorders were potentially rever-

sible, one made every possible effort to keep them alive. Treatment was stopped when death supervened; this moment was recognised by cessation of the heart-beat. As instrumentation improved, the provision of intensive care and life-support systems became cheaper and more readily available; special wards were created for their use, and more patients were admitted to them. Some had reversible pathology; some had not. A new ethical problem had been created: even when the outcome was judged to be hopeless, could a decision be made to switch off a ventilator, to remove life-support, thus allowing a patient to die? If so, who made the decision and in what circumstances? The problem was compounded by the realisation that some patients who had suffered profound brain damage usually as a result of temporary cardiac arrest could be kept for months or even for years in a vegetative state from which recovery would not take place. The implications in terms of the distress suffered by the family and, particularly in America, consideration of the costs of maintaining life-support demanded a new set of criteria, both medical and ethical, for withdrawing treatment. The medical prerogative to make the decision was now challenged. Many people wished to express their preference for or against such treatment in advance of an event that might limit their competence to decide, and relatives began to exercise what they saw as a moral duty to intervene in the interests of the incompetent or unresponsive patient. In patients whose hearts and lungs could be kept functioning by artificial means, it became necessary to reconsider our notions of death. This process had already begun when the advent of heart-transplantation gave it new cogency through the unexpected requirement to remove a heart that was still beating.

This marked my own introduction to the dilemma at the end of 1967 when, as physician-on-call, I was asked to pronounce whether the heart of a young man admitted under my care with a subarachnoid haemorrhage could be removed; the second of Barnard's patients, Dr Blaiberg, was waiting to receive it. I shall not describe the anguish of this decision but I was aware of an expectant surgical team, a throng of journalists from all over the world gathered at the door of

Groote Schuur Hospital—and my feeling of total inadequacy to make a sensible scientific judgement. There were no accepted criteria that allowed one to pronounce as dead a patient whose heart was still beating, although media and public response to the excitement of the world's first transplant a few weeks earlier suggested that the procedure of removing a beating heart was not itself entirely unacceptable. After a sleepless night and three visits to the bedside to satisfy myself that there were no signs of life (other than a beating heart), I acceded to the request.

In 1976 the Conference of Medical Royal Colleges and their Faculties in the UK, conscious of the difficulty of the decision to withdraw life-maintaining treatment, published a report setting out criteria for the diagnosis of brain-stem death—an opinion that was intended to guide medical decisions, and which would have been a great help to me some 8 or 9 years earlier. In a second report issued in 1979 they equated brain-stem death with death. This was an important notion as it recognised that death was a process in which not all organs or tissues died simultaneously. It became necessary, therefore, to define a 'moment of death', a point at which the patient was no longer sentient and death of the rest of the body was inevitable; this moment was taken to be the time of death of the brain stem since this implied irreversible loss of the capacity for consciousness and for spontaneous respiration. (For a full discussion of these points see Pallis (65). In practice, experience of the proper application of these criteria has strengthened their validity and almost all doctors now apply them when they consider terminating cardiopulmonary support. Not all doctors—nor, indeed, all of the public—accept that these criteria, or any other, are sufficient to allow the removal of organs for transplantation purposes. To them no criteria could be taken to signify that life was over, so long as the heart was still beating spontaneously.

We are now aware that the demand for heart-transplantation as a life-saving measure greatly exceeds the potential supply of organs and that this shortage of organs applies also to livers, kidneys, and corneas. Various measures have been proposed to improve the supply of organs. Most require the

co-operation of the donor (in advance) or of the relatives. Some would implicate the clinician. Foremost among these is the so-called 'required request', through which it is proposed that doctors should always be required to request permission to remove organs from suitable brain-dead patients, or to notify a transplant co-ordinator who would arrange a request. Under this scheme doctors, even those who have conscientious objections to the process, would have no choice. The request would have to proceed. By their very nature ethical problems do not have clear-cut right or wrong answers; it, therefore, seems proper to me that no coercion or inducement should be applied to those who find it difficult to accept or assist in the removal of any organs. This, I believe, would be a morally-unacceptable encroachment on their freedom as individuals or doctors. The Working Party recently set up by the Conference at the request of the DHSS to consider ways of improving the supply of organs for transplantation, has rejected the practice of 'required requests', but has recommended other measures to achieve this objective.

Early in 1987 a heart transplant operation was carried out on a young infant using an organ taken from a newborn anencephalic. The ethical issue here was not the appropriateness of the accepted brain-stem criteria; since brain-stem death is equated with brain death, evidence of the former could hardly be required when the infant had no forebrain. Nor was it necessary to establish the inevitability of death; this form of anencephaly is incompatible with more than a few hours of independent life, although heart and lung function might be maintained by mechanical means for a limited but so-far undetermined time. The question was whether a newborn anencephalic infant could justifiably be kept alive expressly for the purpose of providing its organs for transplantation. Baldly stated, this proposition might seem unacceptable. Yet, in the case of adult donors, once death has been established by accepted criteria, a parallel situation obtains. Mechanical measures are then being used not for the direct benefit of the patient but simply to maintain organ perfusion and function until a matched recipient is identified and the transplant operation can take place. The obligation of a doctor to

safeguard the interests of his patient now becomes secondary to concern about the interests of another, the potential recipient. The dilemma surrounding the use of anencephalic infants as potential organ donors is comprehensively and thoughtfully reviewed by Caplan (66). He concludes that anencephalics *should* be used as organ or tissue donors for the purposes of transplantation or research and suggests that existing law and public policy in every nation should be modified to allow organ procurement. He dismisses the idea that doctors who remove organs from anencephalics might be guilty of murder.

Hypothetically, the problem might be compounded. Anencephaly can be diagnosed with certainty during pregnancy by assay of alphafetoprotein in the maternal serum or amniotic fluid and confirmation by ultrasonography. The diagnosis is usually considered an absolute indication for termination of pregnancy. How should a doctor respond to a parental request for the pregnancy to proceed so that the organs of the doomed infant might be used to save the life of another child? Is the response made easier if parents make a similar request once the anencephalic infant has been delivered at term? The delicate ethical issue of multiple conflicting interests has not been resolved: that of the parents who might wish to donate their baby's organs; of the parents of a potential recipient whose life might depend on the availability of an organ for transplantation; of the attendant doctors who might find the process of maintaining life for this express purpose unpalatable; of the surgeon who wishes to proceed in the hope of effecting a life-giving operation; and, not least, those responsible members of the public who wish to see the preservation of the highest possible moral code in such medical decisions. The legal position is clear: Diana Brahams (67) has emphasised that a handicapped non-viable fetus may be legally aborted, but once it has been born alive it has full legal status. 'Although parents and doctors may regard handicapped fetuses as potentially destructible . . . they must take good care that this attitude does not affect their behaviour once such a baby is born alive.'

It seems reasonable to fall back to the presumption that a doctor's first duty is to his patient. In the case of the doctor

attending the mother pregnant with an anencephalic baby, his first duty would lie with her. It would normally be expected that he would explain the situation to the parents and advise termination of the pregnancy. In most cases this advice would be accepted. What if it is not—if the parents wish pregnancy to continue so that the organs of the foetus may be used to give life to an otherwise-doomed child? Can the wishes of the parents override those of the doctor? Can he be obliged to maintain his care of the pregnant mother for this express purpose even if he finds the process morally repugnant? To what extent are the actions of the doctors subordinate to the wishes of their patients?

This raises the wider question of the 'autonomy' of the individual to make decisions about his or her medical management. The use of the term 'autonomy' is seen by Dunstan (68) to embrace two notions. The first is the expression of a wish *not* to be treated or operated on without consent; in general, granted competence of the individual, this notion is granted. The second is 'of freedom to order one's life as one will; to assume unfettered capacity for choice and to claim paramount, if not always absolute, value for that choice'; within this notion is the presumption that someone (a doctor) can be obliged to act as an agent for the individual whatever his own conscience or professional code of ethics might dictate. This second notion is clearly less readily accepted.

Decisions about clinical management were once quite easily determined; they were made by a doctor and usually accepted without reservation by the patient and family. Today, it is part of good medical practice to provide as much medical information to those concerned as might be needed for their informed participation in decision-making. The extent of this information and of their participation is almost certainly greater in the US where patient-rights are a more powerful issue. What are the boundaries of a physician's responsibility to respect the wishes of his patients, and to what extent might his freedom of decision and action be constrained by their wishes? The problem emerges perhaps most clearly in decisions about life and death, from which one could take a single example—the decision 'not to resuscitate' selected

hospitalised patients who suffer cardiopulmonary arrest. Traditionally in the UK this decision has been taken by the responsible consultant often in discussion with his junior staff and one or more of the senior nurses. Doctors may convey and discuss the decision with the relatives but it is not customary for them to seek the prior agreement of the patient. In assuming this responsibility doctors have, in general, been guided by humanitarian principles, recognising the extreme difficulty that both the patient and the relatives might experience because of their emotional involvement in such distressing circumstances. In the US, in particular, there has been increasing pressure for patients to be directly and dominantly involved in decisions affecting their own care, although the guidelines issued by the American College of Physicians emphatically state: 'A decision not to attempt resuscitation is the ultimate responsibility of the physician. Such responsibility cannot be taken over, morally or legally, by institutional committees on ethics or any other person or group of persons who may be available for advice' (69). On this issue, as on most issues covered in their admirable statement, we would not seem to differ.

In the US mentally competent patients frequently formulate advance directives or 'living wills' through which instructions are given or proxies are appointed to make decisions for them should they become incompetent. These directives carry moral authority and are usually considered helpful to doctors faced with difficult life-or-death decisions. In many American states such directives are legally enforceable. The choice made by the patient is regarded as the pre-eminent factor in medical decision-making; the physician's role is to provide information, perhaps to share his judgement or preferences with the patient, but not to make the final decision unless he is, himself, serving as appointed surrogate for an incompetent patient. The degree to which management decisions may be formalised in the States is illustrated by Uhlmann *et al* (70) who describe the application of a local policy created by an ad hoc committee to deal with nursing home patients. The detailed formulation of a code of practice such as this is designed to assist doctors to make difficult

ethical decisions but might also be seen to offer enhanced legal protection to the doctors and the institutions they work in.

Bedell and Delbano (71) have recently analysed information received from the attending physicians and 104 patients who had been resuscitated after cardiopulmonary arrest. Of 151 physicians who professed to believe in discussing resuscitation with patients, only 15 (10 per cent) had actually done so before the arrest; only 32 (21 per cent) had discussed it with the family. Overall, only 30 (19 per cent) of the patients had been given the opportunity to discuss resuscitation with a doctor before the event. The authors conclude that physicians frequently form opinions about patient's attitudes to resuscitation which are seldom based on proper discussion with them or their families. They conclude, further, that 'many patients may know what they want' and would like 'to make their own contribution to this difficult debate', including 'competent, emotionally stable patients who decide against cardiopulmonary resuscitation'. Most discussions of the topic of acute resuscitation include instances like this in which patients express a negative wish—not to be treated, not to be resuscitated, not to be kept alive by heroic means. This conforms to the first notion embraced in the concept of 'autonomy' as discussed by Dunstan and, provided it does not clearly conflict with an expectation of successful medical intervention, such a wish is generally honoured by the attending doctors. Whatever moral feelings a doctor might have about withholding potentially beneficial treatment from a patient who has expressed a wish not to have it, the legal position seems clear. Any attempt to impose treatment on a competent patient against his will would constitute an assault. In law, the capacity of a competent person to choose not to be treated in full knowledge of the consequences is respected. A contrary view has been taken by some American Courts that have forced pregnant women to submit to caesarean section or other intervention on the advice of doctors who considered the fetus to be at risk (72). As Annas has pointed out, this reflects an unusual eagerness on the part of physicians to involve judges actively in decisions about medical treatment (73).

What of the obverse of the coin—Dunstan's second notion within the concept of 'autonomy'? Do patients ever have positive rights to medical care, to demand a specific treatment of their own choosing or more general intervention such as resuscitation in the event of cardiac arrest? In the radical American movement of the late 1960s some feminist groups demanded the right to have abortions regardless of medical opinion and went so far as to learn how to perform the procedure themselves, even to set up an underground service for abortions. This demand was part of a political movement that 'advocated the rights of women, children, prisoners, students, tenants, gays, Chicanos, native Americans' (19)—and to medical care. Dealing with more specific requests for intervention by individual patients, Brett and McCullough (74) present some illustrative but less dramatic cases that demonstrate a conflict with reasonable medical advice. These include a demand for penicillin for an acute viral infection of the upper respiratory tract for which it was deemed inappropriate; a demand for diazepam by an anxious and insomniac woman; a demand for a CT scan to rule out a tumour as a cause of headache—requests that are not themselves of momentous importance. Even for these relatively simple requests the authors correctly conclude that physicians are not under any obligation to offer treatment or carry out investigations that they consider unnecessary or harmful. One hopes that most conflicts of this type would be resolved by proper discussion of the options of treatment, and the doctor's reasons for choosing one—or none—of the options.

Somewhat more complex are situations in which a patient wishes to have treatment which is refused or not offered, not because it is considered unnecessary or harmful by the doctor but because of financial constraints. I have already discussed the ethical aspects of such judgements and the way in which 'solutions' are found in the UK in relation to the acceptance of patients with renal failure for dialysis. The legal position of a doctor who denies such lifesaving treatment to a basically-treatable patient is discussed by Diana Brahams (75) 'If he tells the patient that he or she is unsuitable for dialysis (knowing

that dialysis could be helpful, but the doctor simply has no facilities to offer it) and he leaves the patient with the impression conveyed, either directly or indirectly, that there is no hope for him or her because the condition is beyond treatment, then it is very highly arguable that the doctor has failed in his duty of care. He may even be on the way to committing a crime . . .'. Fortunately, to my knowledge, no action of this sort has yet been brought to court.

Before leaving this topic of the rights of patients to demand or to reject treatment, I shall refer to two further studies. The first (76) is a study by questionnaire of 118 homosexual male patients with AIDS who were asked specific questions about life-sustaining treatment; they were young, well-educated and severely ill, and they expressed a strong preference for heroic treatment. In the event of their contracting *P. carinii* pneumonia 95 per cent wanted hospitalisation and antibiotic treatment, 55 per cent wanted admission to the intensive care unit, and 46 per cent wanted cardiopulmonary resuscitation. What was striking was their extremely optimistic assessment of the outcome of treatment—they estimated that a majority would survive to discharge after intubation in the treatment of this infection, whereas medical reports indicate that only 14 per cent actually do so. The extent to which this misconstruction had affected their wish to be treated energetically is not clear but the study illustrates the unreliability of seeking simple answers to complex questions. If the wishes of patients are to be taken into account, it is imperative that they have a proper and informed understanding of the relevant facts. Is this easily achieved?

A second study (53) examined the causes of the 704 (39.9 per cent) deaths that had occurred in a series of 1766 patients on long-term haemodialysis. In 155 (8.8 per cent of all patients and 22 per cent of all patients who died) death took place because dialysis was stopped, i.e. not because of any medical complication but because a decision was taken to withdraw treatment. This experience is apparently not unique. Participation of patients in the decision to withdraw from a life-saving programme such as dialysis is of particular interest because they were not being asked to consider a

hypothetical step such as whether they wished to be resuscitated or not in the event of cardiac arrest, or to weigh up the pros and cons of a treatment that was on offer; they were already being treated when they decided to stop. The decision was real, not hypothetical; the outcome final.

Sixty-six patients, half of the 132 whose notes were available for analysis, were considered competent to make the decision to stop treatment; of these almost all (77) did so independently; *they* decided they did not wish to go on with treatment and their medical attendants complied. For non-competent patients the decision to withdraw treatment was initiated by the doctor and/or the relatives. The authors discuss the roles and rights of patients and their relatives in such circumstances. They agree that competent patients have the right to reject treatment—but court action has been needed in the US to entrench this right. Discontinuation of treatment for the incompetent patient raises far more problems and shifts the issues towards the courts of law.

A current and cogent question is whether a doctor has the right to refuse to treat a patient because of the perceived risks to himself. Dr Raanan Gillon discusses this in the context of refusal to treat AIDS and HIV positive patients (78) citing the published statement of a surgeon who 'reserve(d) the right to decline to operate on those in whom recent or continuing infection with HIV is likely other than in life-threatening circumstances'. Gillon says 'a plausible case can be made for the claim that in a free society people in general should not be forced to do what they perceive to be dangerous to themselves to benefit others'. Does the same apply, he asks, to members of the medical and other health care professions? He concludes that doctors have a duty to treat HIV infected patients whatever their perception of the risk but concedes there is no legal obligation to do so. As a corollary to this, Gillon considers whether doctors may withdraw on moral grounds because they disapprove of the mode through which AIDS is most commonly contracted (homosexuality or mainline drug abuse). A report of the General Medical Council (GMC) says it is unethical for a doctor to withhold treatment for any patient merely on the grounds that (he) disapproves of the

patient's lifestyle. 'It is unethical for a registered medical practitioner to refuse treatment, or investigation for which there are appropriate facilities, on the ground that the patient suffers, or may suffer, from a condition which could expose the doctor to personal risk. It is equally unethical for a doctor to withhold treatment from any patient on the basis of a moral judgement that the patient's activities or lifestyle might have contributed to the condition for which treatment was being sought. Unethical behaviour of this kind may raise a question of serious professional misconduct' (79). The Third BMA Statement on AIDS (1987) says: 'There are no circumstances in which a person should be refused necessary medical or dental treatment because they carry HIV infection'. Gillon suggests that a patient might have a legitimate *prima facie* case for complaint to the GMC if a doctor failed to 'provide or arrange' treatment solely on the grounds that he was HIV positive or had AIDS, and the doctor would be likely to be found guilty by the GMC of 'serious professional misconduct'. If Gillon is right in his view that there is a legal as well as a moral obligation to treat these patients, this might be construed as a serious infraction of clinical freedom. I have no doubt where my personal sympathies lie—the refusal of doctors to treat patients on the basis of perceived risk is indeed inconsistent with the traditions of the medical profession. (One reflects back to the role of the RAMC dealing with wartime injuries, or to other professionals—firemen, policemen, ambulancemen—who accept an element of risk as part of their routine duties.). Whether doctors should be *disciplined* for failing to take perceived risks or for refusing to treat certain patients on moral grounds is more problematic. The Abortion Act of 1967 contained a conscience clause that was intended to safeguard those who had moral or religious scruples about termination of pregnancy. In this circumstance it was accepted that doctors should not, and could not, be coerced into acting against their own personal codes of ethics. The case for the same principle to be applied to those who find it morally repugnant to treat patients with AIDS is far weaker. An analogy may be drawn with the legal profession whose members not infrequently find it necessary to defend individu-

als against charges of a morally unacceptable variety and whom they believe to be guilty. Their failure to assume this obligation may lead to disciplinary action. The GMC statement on AIDS shows some inconsistency. Despite its warning about 'serious professional misconduct' it accepts that it is 'entirely proper for a doctor, who has a conscientious objection to undertaking a particular course of treatment . . . to refer that patient to a professional colleague'. This 'let-out' clause might help to preserve the integrity of the doctor's clinical freedom, but it leaves me with a distinct feeling of unease. On a related topic I feel similar unease over the motion that emerged from the recent annual BMA Conference. The Conference accepted that doctors could, on the grounds of risk to themselves or their families, carry out tests for HIV infection on patients suspected of exposure to the virus *without their knowledge or consent*. Leaving aside the somewhat irrational reaction to what is an insignificant risk, their stance introduces another moral dilemma. If the test proves positive, there are powerful practical reasons for wishing to transmit the result to the patient. In view of the grave prognosis and the serious effect this intelligence is likely to have on the patient's domestic, business, and other relationships, is it proper to carry out the test without prior counselling of the patient? Adler and Jefferies (80) concede that testing without consent might be acceptable in extreme circumstances to aid differential diagnosis. It has also been argued that it might be justifiable in the prosecution of epidemiological studies. Its application simply to provide enhanced protection for doctors is far less acceptable.

ETHICAL CONSTRAINTS

Freedom to perform research

In previous sections in the content of limited resources I have discussed the tension that exists between a doctor's obligation to his individual patients and to society at large. Tension of a similar sort exists in the field of research. Here, the medical profession's (lesser) obligation to seek new information that might benefit patients in general is at times in conflict with the need to expose individual subjects to a small but distinct risk through experimentation that is required to gain the information. In recognition of this tension a variety of measures have been introduced in developed countries to control experimentation on human beings, aimed—insofar as possible—to protect subjects from potential harm without, at the same time, unduly restricting or inhibiting the acquisition of new and important information.

Early experiments in which there were no ethical constraints often resulted in major advances with profound beneficial consequences for mankind. Edward Jenner, following John Hunter's famous advice: 'Don't think, try!', tested his hypothesis that infection with cowpox might confer immunity against smallpox by inserting into the arm of 'a lad of the name of Phipps . . . a little vaccine virus . . . , taken from the hand of a young woman who had been accidentally infected by a cow'. He went on to say 'I could scarcely persuade myself the patient was secure from the Small Pox'; despite this doubt, he proceeded to inoculate the lad with smallpox a few months later and 'proved that he was secure' (81). This simple experiment that led to the widespread adoption of vaccination against smallpox is usually regarded as the forerunner of the immunisation programmes that have so successfully eliminated or reduced the incidence of many disabling or fatal infectious diseases. It is unlikely that Jenner's plan to carry out the experiment would have been approved had it been submitted to any present-day ethical committee—even if the

ultimate vast benefit to society had been recognised. How did ethical constraints gradually come to be adopted by developing countries?

A first requirement was the emergence of professional conscience. In the first half of the nineteenth century William Wallace, a Dublin physician, felt no qualms about the deliberate inoculation of syphilitic material into five healthy volunteers aged 19–35 years (82). By contrast Neisser, who in 1879 had discovered the organism responsible for gonorrhoea, realised that ultimate proof of its pathogenic role required evidence of its transmission in man, as no animal was known to be susceptible to the infection. Neisser, to his credit, declined to carry out the necessary experiments but the world did not have to wait long. Within a few years medical colleagues in Germany had inoculated human subjects and successfully demonstrated that gonorrhoea was transmitted by Neisser's organism. This somewhat cavalier disregard for human rights offended both the public and the government of the day. On 29 December 1900 the Prussian Minister of Religious, Educational, and Medical Affairs informed the directors of clinics, polyclinics, and similar establishments 'that medical interventions for purposes other than diagnosis, therapy, and immunisation are absolutely prohibited . . . if the person in question is a minor or is not fully competent, . . . has not declared unequivocally that he consents to the intervention, . . . (and) the declaration has not been made on the basis of a proper explanation of the adverse consequences that may result' (83). The basis of this statement would read well in any modern declaration of the rights of research subjects.

A combination of professional conscience and legal constraint probably contributed to the increasing practice of self-experimentation. In this country the Haldanes, father (JS) and son (JBS), exemplified the practice. JS disliked experimenting on animals and 'preferred to work on himself or other human beings who were sufficiently interested in the work to ignore pain or fear. His attitude was much more like that of a good soldier, who will risk his life' (in order to save the lives of others) (82). The most famous modern exemplar of self-experimentation is probably Werner Forssmann who passed a

catheter into the right side of his own heart and then walked to the radiology department to check its position. The technique of cardiac catheterisation has saved many thousands of lives. Would a modern ethics committee have approved a request for its experimental use in man without Forssmann's prior demonstration of its safety?

The latest revision of the Declaration of Helsinki (35th World Medical Assembly, Venice, Oct. 1983) states: 'Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject'. On this basis—the importance of the objectives being great and the risks to the subject small—Forssmann's experiment, and Jenner's, might have been allowed. Experiments carried out in concentration camps by Nazi doctors encompassed objectives of great importance—the prevention of malaria and typhus or of deaths at high altitude or from exposure to cold—but the civilised world was appalled by their disregard for the suffering, indeed, the lives of the victims. No matter how important the potential benefits of research undertaken on human subjects such callous acts of inhumanity could not be tolerated. The revulsion felt by the medical profession and the public was expressed in the Nuremberg Code of 1947 and by the World Medical Association in Geneva in September 1948: 'Even under threat I will not use my knowledge contrary to the laws of humanity'.

Gradually over the past 25 years guidelines and laws governing the prosecution of research on humans have evolved. It is interesting that the UK approach to human experimentation has been non-statutory, relying on voluntary codes of practice rather than legislation. By contrast, research on animals has been legally restricted since the passage of the law relating to Cruelty to Animals in 1876.

In 1962–3 the Medical Research Council (MRC) in the UK laid down guidelines for research on humans carried out under their sponsorship. This preceded the World Medical Association Declaration of Helsinki (1964) which set out the basic ethical principles of clinical research and considered the problem of combining such research with professional care.

Effectively, for the past 25 years, medical freedom to conduct research on human subjects has been limited by voluntary codes of this sort, with additional legal restrictions in some countries.

Neither the Declaration of Helsinki nor the MRC statements provided guidance about the setting up or monitoring of systems to protect the subjects of research. In 1967 the Royal College of Physicians of London (RCP) recommended that all clinical research investigations should be subject to ethical review and proposed that committees should be formed in each district of the country specifically to carry out this function. The proposal has effectively been implemented. The majority of local ethics committees (LECs) are based within hospitals, especially teaching hospitals in which most research is carried out. Most have assumed responsibility for monitoring all research carried out in their districts and receive applications from general practitioners, pharmaceutical companies and others who wish to carry out research in the community as well as from hospital-based research workers. In some cases a LEC established within a single hospital will confine its interests to research carried out within that hospital. In such cases the control of research in the community may be less than adequate. In 1984 a second report from the RCP considered in greater detail the composition of LECs and their *modus operandi*.

Increasingly, the importance of lay (non-medical, even non-scientific) representation on LECs has been recognised, but the RCP report stresses that they need not be drawn from experts in moral philosophy, but should rather be 'people of goodwill with a high regard for the human personality, for truthfulness and for the continued advance of medical science'. In practice, most LECs now have roughly equal numbers of medical and non-medical members. In view of the sensitivity of the subject and in the light of some justly adverse publicity about unregulated research on humans, this oversight by lay people of medical-scientific practice is accepted by the profession as proper and desirable. Clinical freedom—in medical research—is no longer regarded as sacrosanct.

One of the important recommendations of the RCP report

concerns the obtaining of consent from the subject. This need was recognised in the 1900 directive from the Prussian Minister referred to above; it was incorporated into the Nuremberg Code, the MRC guidelines of 1962-3, and the Declaration of Helsinki in 1964. The last was quite explicit: for new experimental therapeutic measures that might offer 'hope of saving life, re-establishing health, or alleviating suffering . . . the doctor should obtain the patients' freely given consent after . . . a full explanation'; for non-therapeutic clinical research 'the nature, the purpose and the risk of clinical research must be explained to the subject by the doctor' and, again, 'research on a human being cannot be undertaken without his free consent after he has been fully informed'. The RCP report of 1984 recognises that different modes of consent may be appropriate for different types of research procedure, and even considers the possibility that some forms of research might be carried out without consent, giving such examples as minor or trivial procedures; or major procedures for which an attempt to obtain 'informed consent' might be 'impossible or devastating'; or the use of patient records provided confidentiality is preserved. The intention here is not simply to make life easier for the investigating doctors by removing the requirement to obtain proper consent, but to avoid those circumstances in which the subject (or relatives, in the case of incompetent subjects) might suffer mental anxiety or anguish as a result of the request.

The Belmont Report (84) (*Ethical Principles and Guidelines for the Protection of Human Subjects of Research*) explores the need to identify basic ethical principles for research on human subjects. Within the Report is a discussion of the 'nature and possibility of an informed consent' which embraces three elements: information, comprehension, and voluntariness. Some of the problems inherent in these three elements are recognised and provision is allowed for exceptions to their rigid enforcement. The Code of Federal Regulations 45 CFR 46 (*Protection of Human Subjects*) (85) is far less permissive and states in precise terms the need for 'legally effective informed consent' and how it should be sought. Full details of each

consent procedure are listed. A limited number of exclusions from this legal requirement are specified.

The dilemma surrounding the question of informed consent is well illustrated in the conduct of randomised clinical trials which are essentially experiments using human subjects. In such trials treatment of individual patients is selected randomly and not assigned by individual clinicians, i.e. the clinician has conceded his freedom to treat in favour of the rules of the investigation. In North America physicians are obliged by law to obtain written consent from their patients in clinical trials, the consent form being a legal document which confirms that patients have been told of their disease, the risks of treatment and possible side-effects, and that they have agreed to be randomly assigned to one of the trial's treatment options (86); these may include the use of placebo or dummy treatment. In the UK there is no legal obligation for clinicians to inform patients that they are entering trials of alternative treatments (87). It has, indeed, been argued that such explanations may introduce anxieties and doubts in the minds of patients once they discern that there is no single and approved treatment for their disease. Taylor and Kelner (86) conducted a questionnaire-based survey of 170 oncologists dealing with breast cancer in eight countries; 95 per cent of them stated that the requirement to obtain informed consent was an intrusion into and had a negative effect on the doctor-patient relationship. Ninety-one per cent felt it would lead to a loss of patient confidence in the 'care-giver'; only 6 per cent felt that 'telling a patient you do not know which treatment is best, results in a better informed patient'. A majority of physicians felt uncomfortable using a document that delineates a shift from individualised care to randomly assigned therapy. (Note they did not appear to feel uncomfortable about the actual shift, rather the fact that this was communicated to the patient.) Taylor and Kelner sum up their findings by suggesting that 'the introduction of informed consent for randomised clinical trials has effectively removed much of the basis for the authority of the physician:

(i) physicians are forced to be explicit about their own uncertainties;

(ii) the moral authority of the physician is undermined by the infringement of a "sacred covenant" between doctor and patient that assumes that the former would always try to act in the best interests of the latter;

(iii) the symbolic authority of the physician is reduced, raising doubts about the power of medicine to cure the patient's disease'.

I have no sympathy for those of my colleagues who refuse to participate in clinical trials on the grounds that their authority might thus be undermined. Doctors have a responsibility to ensure that the therapies they advocate have been properly evaluated, and should be prepared to contribute to the process. This point has been well-argued by Hampton (44). 'Clinical trials and research in general', he says, 'have become more rather than less important, and when resources are scarce a greater proportion of them must be channelled into evaluation.'

Baum (118) argues against the need for informed consent from a different vantage-point. He points out that a surgeon might practise mastectomy for early breast cancer for ten years, then suddenly—on the basis of an altered belief in their relative efficacies—switch to 'lumpectomy' and radiotherapy. Such a change of *practice* is instituted without the patient's knowledge or consent, yet is regarded as perfectly reasonable and ethical. On the other hand, an attempt to compare the two treatments by *research* using a prospective randomised study without informing the patients would be regarded as unethical. Baum suggests that the legal requirement for informed consent in the US was introduced chiefly to protect the doctor, whereas our concern in the UK might be more to protect the interests of the patient. This should not be taken in any way to suggest a less humane approach to the problem in the US, but there is a suspicion that the insistence on protection of patients' rights by law might be 'driven' by the threat of litigation if things go wrong. The rather rigid and legalistic Federal code dealing with 'The Protection of Human Subjects' referred to earlier (45 CFR 46) (85) lends some force to this suspicion. The policy outlined in the federal

document applies to 'all research involving human subjects conducted by the Department of Health and Human Services or funded in whole or in part by a Department grant, contract, cooperative agreement or fellowship'; it applies equally to research conducted or funded by the Department outside the US. Each institution engaged in research is required to provide certain written assurances about the ethical principles it applies and to establish a board (Institutional Review Board or IRB) to review all medical and behavioural research involving human subjects. Full details of the membership of each IRB must be provided, as well as written statements about its procedure. The constitution of IRB membership is, indeed, regulated within certain broad limits, and its authority, responsibility, and function are spelled out in detail. The force of these regulations is stated clearly: 'Federal funds administered by the Department may not be expended for research involving human subjects unless the requirement of these regulations . . . have been satisfied'. Sub-parts of the Report deal with research involving fetuses, pregnant women and in vitro fertilisation, and the use of prisoners and children.

Compared to these comprehensive regulations governing research involving humans, the UK guidelines appear rather lax and informal. Whereas Federal control applies in the US, here we rely on the individual and independent function of our LECs. How well do these function, and how are they monitored? From hearsay evidence it seems that most LECs deal properly and responsibly with applications that reach them; some, it is rumoured, take their responsibilities less seriously and are inclined to 'rubber-stamp' proposals; a few, it is alleged, do not meet at all. A survey carried out by the Institute of Medical Ethics (IME) emphasises the diverse ways in which LECs function—in their composition, the extent of their authority, their procedures, and their performance (88). There is no mechanism in the UK at present for monitoring the performance of LECs or even for ensuring that they exist and/or meet in all districts. There is, I would suggest, a need for such a mechanism to be established—perhaps nationally, perhaps at regional level. Although the existence or satisfactory functioning of LECs is not legally enforceable in the UK,

the Government has strongly encouraged their creation by circulating the original RCP report widely and giving advice (in 1975) that was largely based on it. Nor is there a legal requirement in the UK for all research projects to be submitted to and approved by LECs. Three powerful general prohibitions exist, however, that are influenced by the deliberations of LECs:

(1) Through grant-giving bodies: The MRC and other responsible research-funding organisations will not even consider the scientific value of a project until its ethics have been approved by a LEC. The MRC would not override the decision of a LEC to reject a proposal on ethical grounds but it reserves to itself the right to refuse to make an award on ethical grounds alone even if LEC approval has already been obtained.

(2) Through institutions in which research is carried out, mostly hospitals or universities, which may exert their rights as employers not to allow non-approved research to be carried out on their premises. (Their liability to provide compensation if things go wrong would strengthen their resolve.)

(3) Through medical and scientific journals, which may refuse to publish research papers that do not expressly state that ethical approval has been obtained. Most reserve the right to reject manuscripts on ethical grounds alone even if LEC approval has previously been obtained. The majority of journals dealing with clinical research publish a clear policy statement about the need for LEC approval.

The application of these three forms of control will persuade most research-workers in the UK to seek prior and proper approval from LECs, but there are loopholes for exploitation by less rigorous or scrupulous investigators, especially those who work outside of the University or NHS systems. In an attempt to block some of these loopholes the Association of British Pharmaceutical Industries (ABPI) has developed its own set of guidelines to cover pharmaceutical research, particularly if carried out on healthy volunteers; the Royal College of General Practitioners has established an independent ethics committee to deal with large-scale clinical

trials; and guidelines have been drawn up by the British Medical Association, the Faculty of Occupational Medicine, the British Paediatric Association (governing research in children), and other smaller and specialised bodies. Within this loose framework of guidelines and enunciated principles of ethical behaviour, most research involving humans is probably conducted responsibly in the UK. The system, however, is not watertight and some means must be found to close the gaps so that human subjects of research are fully protected. Possible ways of achieving this are discussed in the *IME Bulletin* (88). These include a less desirable legally based system and the interesting suggestion that medical protection organisations should refuse to provide cover for research that has not been approved by an ethics committee. Whatever system of reinforcement is applied, the need for monitoring LECs cannot be evaded.

I have tended to compare the UK system primarily with the American, largely because they seem in so many ways to represent opposite ends of a spectrum. In April 1987 I was privileged to attend an International Summit Conference on Bioethics which was concerned with research involving human beings. An outline of the policies adopted by the countries represented at the Conference was prepared by the World Health Organisation (WHO) in co-operation with the Council for International Organisations of Medical Sciences (CIOMS).

In *Canada* there appears to be no national or provincial legislation dealing with ethical aspects of human experimentation; the guidelines issued by the Canadian MRC are largely applied. In 1985 the Health Protection Branch of the Department of National Health and Welfare issued guidelines that are intended primarily for use of drug manufacturers in the conduct of clinical trials. In 1983 the Canadian Nurses Association provided guidelines for nursing research involving human subjects.

In *France* an order of 10 August 1976 established a protocol for the clinical testing of pharmaceuticals. There is considerable uncertainty about research on healthy volunteers; even their free and informed consent to participate is not regarded

as an adequate legal defence in the event of injury. A 1979 report entitled *Deontologie des Essais Therapeutiques* emphasises the need for strict scientific principles and fairness towards and respect for the patient. A further report in 1982 listed certain types of procedure that were not permissible. In 1983 a National Advisory Ethical Committee for the Life and Health Sciences was established 'to give its views on ethical problems raised by research in the fields of biology, medicine and health'. This Committee has pronounced on in vitro research on embryos (1986) and experimentation on patients in a chronic vegetative state (1986). In 1984 it published an important *Opinion* on ethical problems raised by trials of new therapeutic procedures in man.

In *Germany* an Interministerial Commission reported on in vitro fertilisation, genome analysis and gene transfer in 1985, and on the potentialities and risks of gene technology in 1987. In 1985 the Federal Chamber of Physicians adopted guidelines for research on early human embryos, and for the conduct of in vitro fertilisation and embryo transfer as methods for treating human sterility.

In *Italy* the principal provisions regulating ethical aspects of clinical trials are contained in a 1978 *Code of Medical Ethics*. A 1985 Circular of the Minister of Health prohibited the preservation of embryos for, inter alia, research purposes. There is legislation at subnational level that governs some aspects of human experimentation.

In *Japan* various Ordinances deal with the conduct of clinical trials, requiring appropriate scientific and ethical consideration to be given to the rights of research subjects. Ethical committees exist in most medical schools but are comprised almost exclusively of Faculty members without lay representation. In 1985 a report of a group of experts set standards for clinical trials of new drugs. In 1979 the Japanese Diet promulgated a Law on compensating those who suffered injury due to the adverse effects of experimentation.

From this brief survey it would seem that the US and the UK have been most active and comprehensive in their consideration of bioethical problems and in their attempts to provide laws or guidelines to deal with them. In both

countries much of the initiative has emanated from extra-governmental sources. In America one could mention particularly the Hastings Center and the Center for Bioethics at the Kennedy Institute. In the US draft regulations of policy formulations are exposed for public comment through their publication in the Federal Register. As indicated earlier, basic regulations for the protection of human subjects are entrenched in Federal law. In addition, individual States may legislate about specific ethical problems, so that, for example, almost 30 States have adopted legislation either prohibiting or restricting research on fetuses.

In the UK the Conference of Medical Royal Colleges and Faculties has played a special role which has facilitated the development of what might superficially appear to be a *laissez-faire* approach by Government. The MRC statement on Investigations on Human Subjects in 1962-3 stimulated the first report of the Royal College of Physicians in 1967 (89) which recommended the establishment of local ethics committees; a second report in 1984 (90) extended these guidelines which have been widely adopted. More recently, in response to a request from the Medicines Commission (a government body) the Royal College of Physicians has produced recommendations for the conduct of research on healthy volunteers (91) and, independently, a set of guidelines to cover the relationship between physicians and the pharmaceutical industry (92).

There are obviously non-clinical fields of research which demand close scrutiny and the application of strict ethical guidelines. The use of animals in research or of recombinant DNA technology cannot proceed without restriction. Since this lecture is concerned with clinical (rather than the wider 'professional') freedom, I have confined my attention to research in which human subjects participate.

The special relationship between the UK Department of Health and Social Services (DHSS) on the one hand and the Conference of Colleges and MRC on the other, is noteworthy as it has permitted the introduction of guidelines on ethical aspects of research that are accepted and, indeed, observed by the medical profession without recourse to law. Government

intervention in matters of bioethical importance is rare and never more than advisory to the profession. The flavour of this special relationship might have emerged from my earlier discussion of the role of the DHSS in constraining the development of heart transplantation in the UK but is, perhaps, best illustrated by the evolution of acceptable guidelines for in vitro fertilisation (IVF) and embryo research.

The first child resulting from IVF was born in July 1978. The MRC set up an advisory group in that year to review policy on research related to IVF and pre-embryo transfer in humans. Guidelines were published in 1982 and revised in 1985. In 1982, responding to the MRC's initiative, the Government established a Committee of Inquiry into Human Fertilisation and Embryology which produced the 'Warnock Report' in 1984. One of its main recommendations was that a statutory licensing authority should be established to regulate research and certain types of infertility services. Recognising that it would probably take time for the necessary legislation to be enacted, the MRC with the Royal College of Obstetricians and Gynaecologists agreed to set up, as a temporary measure, a joint *Voluntary* Licensing Authority (VLA) which met for the first time in March 1985. Their guidelines were intended to set minimal acceptable standards *as a basis for local ethics committees to agree 'their own house-rules'*.

The nature of this process should be noted. The profession played the dominant role in publicising its concern about ethical aspects of IVF, in advocating the formation of a statutory authority and in initiating a joint VLA. It is the *voluntary* acquiescence of ethics committees and their research institutions that has effectively regulated the conduct of IVF and research involving human pre-embryos. The role of Government has been to advise and facilitate, not to impose, although it is now seeking views about the formation of a statutory licensing authority.

It is this interplay between Government and the profession (through the Royal Colleges and Faculties, the MRC and the BMA) that has allowed the evolution of a high standard of ethical practice in the UK without the compulsion of the law. In terms of the original NHS Act the Secretary of State has

powers to regulate professional behaviour in such matters; they have never been applied. By insisting on professional participation Government has ensured its co-operation; by reacting in a responsible way the profession has retained its independence and the individual physician as much freedom as is reasonable in such delicate circumstances. Through this mechanism the profession has shown itself to be concerned about the interests of the public and has managed to retain its respect. In doing so it has escaped the less desirable approach of the US system in which decision-making on ethical issues is driven or dominated by legal considerations; where, as Dunstan has said "Ethical" becomes that which will give a physician a successful defence to an action; "unethical" becomes that which will cost him or his insurers heavy damages' (68).

MEDICINE, LAW AND LITIGATION

There are two main ways in which clinical freedom may be curtailed or influenced by judicial proceedings. The first concerns those legal judgements that have attempted to clarify the rights or protect the interests of patients; these include the rights of mentally incompetent patients and children who need protection; the rights of unborn children or of surrogate mothers; rights of patient access to their medical records; and their rights to confidentiality. Although the medical profession may not always like or agree with decisions made in courts of law, it is generally helpful for doctors to know the legal boundaries within which they may act, and the need to safeguard the rights of patients is well-accepted.

The second influence has been anything but helpful. I refer to the serious growth in medical litigation and the effect it has already had on good and caring medical practice. In the US it has generated a new style of medical behaviour known as 'defensive medicine', a term which covers those actions a doctor takes or does not take primarily to lessen the chances of subsequent litigation. The outcome of this behaviour has not always been in the interests of the patient.

THE LEGAL BOUNDARIES OF MEDICAL PRACTICE: CONSENT

It is a fundamental precept of medical practice that no treatment should be given without the consent of the patient; exceptions may be made to this rule in the case of emergency. The notion of consent implies competence on the part of the patient to comprehend the medical issues and the outcome of any decision he makes. It is therefore surprising to learn that legally the principle of consent applies in the UK 'even when the patient is under age, and *whether or not* he or she is capable of appreciating the reason for, and the importance of, the

treatment' (93). Problems are encountered when competence is lacking (as in the case of a child whose comprehension of the issues might be limited). Traditionally, in such cases, the responsibility for making decisions has been vested in the next of kin, a near relative or appointed guardian.

Notwithstanding the above quotation from the Pearson Report, in the UK for ordinary purposes parents *can* give their consent to procedures involving their children *under the age of 18 years*; this applies whether the children are mentally competent or not. In the US therapeutic proceedings may be performed on children with the consent of the parents; there is no legal requirement to solicit the child's assent, and the parents may override its dissent (94). There is debate about the age at which assent of a minor becomes important.

It has been suggested that the degree of disclosure of the nature and risks of a proposed procedure should be greater when a parent is being advised about a child than when advice is being given directly to a patient (95). Whereas they can decide how little or how much information they might seek about their own illnesses, parents are under a legal duty to act in the interests of their children. They must therefore inform themselves as fully as possible about their treatments and the attendant risks. Doctors should ensure that they are so informed. There is, however, a recognised 'sliding scale' that depends on the seriousness of the procedure; the more serious it is, the more important it becomes to be sure that the child itself understands what is intended to its maximum capacity.

This contention was recently tested through the action brought by Mrs Gillick to restrain a health authority from providing advice and treatment to girls under the age of 16 when they sought medical guidance about contraception and pregnancy. In the light of a House of Lords decision the GMC advised doctors first to satisfy themselves of the child's maturity and ability to understand, then to seek to persuade her to involve a parent in the consultation. If this is refused, a decision should be made in the patient's best medical interests. Allowance is made for a doctor to disclose information about the case if he is not satisfied about the child's ability to understand. The House of Lords thus recognised that some

girls under the age of 16 years could properly comprehend the issues and the parents therefore did not need to be informed; doctors were permitted to exercise their discretion.

The same principles probably apply to the question of consent for research procedures in children (96). Guidelines have been drawn up by the British Paediatric Association (97), the Royal College of Physicians (91) and the Institute of Medical Ethics (88); all of these reflect difficulty in defining the age at which a child's assent or dissent becomes essential. Chronological age does not necessarily reflect a child's ability to understand the issues or to make a decision. Special considerations apply to non-therapeutic research in children:

(i) It should be limited to studies that can only be done in children; research that could equally well be done in adults should not be approved;

(ii) The research should be of potential benefit to other children;

(iii) Pharmacological studies should be avoided unless scientifically valid results can only be obtained by including children;

(iv) There should be no financial or other reward to the parent or guardian;

(v) A paediatrician or child expert should be present when research projects on children are considered.

There is no clear machinery by which anyone can give consent on behalf of subjects *over the age of 18*, even those who are mentally incompetent, except through the provisions of the Mental Health Act 1983. (This might explain the haste with which a recent judgement was made in the case of a 17-year old mentally-handicapped girl, who did not need protection under this Act, for whom sterilisation was being advocated.) Yet it was recently ruled by Mr Justice Reeve (*The Times*, 4 June 1987) that it would not be unlawful to carry out an operation for the termination of pregnancy by reason only of a patient's lack of capacity to give informed consent. In this case, termination was considered to be in the girl's best

interests and medical opinion suggested there was a substantial risk of fetal abnormality. The consideration of fetal risk introduced a complicating factor but Mr Justice Wood has recently authorised the performance of abortion and sterilisation procedures on a 19 year-old girl with a mental age less than three years who was deemed unable to consent for herself. Mr Justice Wood accepted that no-one, not even the courts, had power to consent for her and in such an exceptional case 'a medical adviser is justified in taking such steps as good medical practice demands'. For mentally incompetent subjects over the age of 18 years it is customary to seek consent for a medical procedure from near-relatives or a guardian. If conflicts arise, as well they might do in such cases, the doctor's decision should again, as far as possible, be guided by the interests of the subject. Several judgements in American courts have demonstrated the insecure status of those who provide care for incompetent patients. Perhaps the most famous of all was the case of Karen Quinlan, a young girl in a vegetative state who was being kept alive by artificial mechanical means at great expense and without any hope of recovery. Her parents, devout Catholics, after extensive discussion and thought asked the doctors to remove the ventilator. This they refused to do, partly for moral reasons, partly for legal concern that they might be found guilty of ending the life of a patient who was not brain-dead. Eventually, the New Jersey Supreme court acknowledged that the girl's father, her doctors and the ethics committee of the hospital could decide whether to withdraw treatment or not. (This was done, Karen was fed and hydrated by tube and she survived, still in coma, for several years.) This eminently sensible decision to permit the withdrawal (or change) of treatment was rejected by the Massachusetts Court (the Saikewicz case) which asserted that all decisions about the application of life-prolonging measures to terminally-ill incompetent patients was a matter for judicial resolution—'. . . such questions of life and death seem to us to require the detached but passionate investigation and decision (of the) judicial branch of government' (cited by Relman (98)). In terms of this decision physicians would no longer be

allowed to exercise their professional judgement. The implications of this interpretation were profound and unlikely always to operate in the interests of patients; in fact, since even urgent decisions had to be deferred for court approval, thus leading to undesirable delays, the ruling could be said to be very much *against* their interests. In his criticism of the judgement Relman hoped for 'the exercise of judicial self-restraint lest there be any further sallies by the court into an area traditionally handled by private discussion between doctors and families'.

In the case of Claire Conroy (an 84 year-old institutionalised demented patient) the New Jersey Supreme Court ruled that tube-feeding or other life-sustaining treatment could be withheld if they were against the patient's wishes or best interests (99). The Court rejected the traditional view that such decisions are best made by physicians and the involved families, but required review by the State Ombudsman before withdrawal was implemented. Objections to this ruling were based on the introduction of State authority, not the law, as an arbiter in life or death decisions.

A related judgement was made in the Baby Doe case. This baby with Down's syndrome also had congenital oesophageal atresia; the question was whether to operate or not. In the US almost all infants with any chance of survival are treated aggressively, at least until sufficient reliable data have been amassed to justify withdrawing treatment on the grounds that a reasonable outcome would be highly improbable. In the case of Baby Doe neither the surgeon nor the parents wished to proceed to surgery. The authority of their decision not to act was challenged, and the Department of Health and Human Services promptly issued regulations that required hospitals to post notices stating that Federal law prohibited the withholding of nourishment and medically beneficial treatment 'from handicapped infants solely on the basis of their present or anticipated mental or physical impairments' (100). The DHHS provided a 'hot-line' manned 24 hours a day that could receive and react promptly to any reports of transgression from this ruling. The medical attendants were no longer free to make a clinical judgement, even with the concurrence of the parents.

It was predictable that physicians would lean over backwards to comply with the judgement in order to escape possible litigious consequences, and this is precisely what happened. As an example, a short while later newborn conjoined twins, not amenable to separation, were transferred to a tertiary care facility and given full intensive care including antibiotics despite uncontested agreement that the outcome would be fatal. This could not have been in their interests—or anyone else's. Treatment was given solely as a defensive measure against the possibility of prosecution.

In her admirable commentary on the Baby Doe case, Dr Marcia Angell (100) pointed to the anomaly through which in the US competent adults would have the right, 'buttressed by a growing body of case-law', to refuse treatment; many, in fact, do so because they find the quality of life intolerable (see earlier reference to withdrawal from dialysis).

Case-law in the US has even recognised that the interests of incompetent older patients may best be served by a decision to withhold treatment, a decision which may take into account limited prospects for a life of reasonable quality. This would allow treatment to be withheld from patients with Alzheimer's disease or after a stroke. Yet, this right of relief from suffering would be denied specifically to newborn infants if the Baby Doe judgement were to prevail.

In the event a Presidential Commission recognised the existence of this anomaly and made recommendations that allowed the exercise of discretion by doctors and by parents when the benefits of treatment were thought to be unclear. In 1984 the Bioethics Committee of the American Academy of Pediatrics produced guidelines for local ethics committees to *review* (not make) decisions in difficult cases. These committees now exist in a large number of neonatal paediatric centres in the US and are comprised of nurses, social workers, lay members, clergy, doctors, and lawyers. Their size (some have as many as thirty members) and the complexity of their membership usually render them too cumbersome for prospective decision-making. The flavour of their approach and authority may be gauged by three different decisions made recently by the committee that operates jointly between the

Albert Einstein and Montefiore Hospitals in New York (101). In the first case the parents refused to consent to an operation advocated by a surgeon; the committee called in an outside agency which over-ruled the parents. In the second, the parents and the surgeon agreed that treatment should not be given, but the committee persuaded them to go ahead against their own judgements. In the third case the parents wished to proceed, the surgeon did not; the infant died but the committee ruled retrospectively that the wishes of the parents would have imposed undue suffering on the infant and upheld the view of the surgeon that treatment would have been inappropriate. These examples illustrate how such ethics committees are designed to protect the interests of newborn infants; in doing so they lend proper weight to the views of the parents but they have effectively removed decision-making from the attending doctor.

In Britain the issue remains unresolved. In certain circumstances it is accepted that a handicapped fetus may be legally aborted; once it has been born alive, it acquires full legal status. Several conflicting judgements have left matters uncertain. 'To allow a body to die, though it is handicapped and rejected by its parents and the doctors involved are all agreed, may still be a crime. The judge may turn a blind eye and a jury may be reluctant to convict, but this is an uneasy truce-like situation which would erupt again in the future' (67).

In general, the law as it stands is too crude an instrument to resolve such complex problems of life and death. In his book *The Body as Property* Russell Scott says 'special legal provisions have to be created . . . to deal justly with the intractable problems of coma, of the helpless aged who are dying, of the hopelessly defective new-born, and of other human beings, whose existence may be an intolerable burden to themselves, their families, and the community' (102).

I would contest the view that legal provisions are the best way of dealing with such problems. General guidelines may be drawn up by well-informed, responsible and caring members of society, as for instance in the Warnock Committee on Human Fertilisation. In individual cases I would prefer decisions to be taken by well-informed, responsible and caring

doctors acting, of course, through appropriate consultation with relatives and other interested parties. In the UK such ethical decisions have always been regarded as an intrinsic part of medical practice; in the US the function has largely been usurped by ethicist-philosophers and lawyers. Not only do they enunciate general ethical principles but they now intrude into specific clinical decisions about specific patients. 'MDs can no longer exclude non-MDs from participation in moral discussions *and* clinical decisions . . . (103). Many hospitals in the US employ 'clinical ethicists' to provide an 'ethics consultation service'. Few of them are medically qualified and conflict easily and frequently arises when their views differ from those of the attending doctor (104). I readily concede that MDs (doctors) have no monopoly or absolute right over moral decisions in medicine; they do have a special and unique type of experience, but so do others—nurses, social workers, philosophers, theologians, and lawyers. General moral decisions should be made by people with balance, wisdom, and experience who care about the outcome; clinical decisions about individual patients should not be removed from the province of the doctor.

Several judgements have recently attempted to define the extent to which doctors have a duty to inform patients. In English law a person who is given medical treatment without his consent may sue for assault and battery. Kloss (105) considers the possibility that failure to obtain consent might be construed as negligence, and points out that negligence in medical treatment may arise in several ways:

(i) Where treatment is negligently performed; here, consent is obviously irrelevant.

(ii) Where the decision about the choice of treatment is negligent; here, the consent of the patient would only be material if the doctor had explained that he was seeking consent to carry out treatment that was not established practice and would be considered negligent by a majority of colleagues.

(iii) Where the treatment is proper but the patient was not

given sufficient information on which to make a decision whether to agree or not.

Diana Brahams discusses this question in the context of the Sidaway case (106). Mrs Sidaway sued for damages after an unsuccessful operation on her cervical spine on the grounds that the surgeon had failed to warn her of a 1 per cent risk of damage to the spinal cord. The surgeon was found not guilty of negligence since he had acted in accordance with the Bolam test, i.e. 'in accordance with a practice accepted as proper by a responsible body of medical men skilled in that art' [quoted by Clare Dyer (107)]. The House of Lords did *not* accept that doctors were allowed to set their own standards without any over-riding control from the courts. 'Even when no medical expert disagreed with non-disclosure, the judge might in certain circumstances come to the conclusion that disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it' (106). The question whether the duty of disclosure differed when the patient expressly asked questions was left unresolved by the Sidaway judgement. In the later Blyth case, Lord Justice Kerr accepted the applicability of the Bolam test and did not distinguish between information given voluntarily and that given in response to specific enquiries (107).

The doctor's duty was defined by Lord Scarman as 'one which requires him not only to advise as to medical treatment but also to provide his patient with the information needed 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' (106). Lord Scarman added that 'the doctor will not be liable if upon a reasonable assessment of his patient's condition he takes the view that a warning would be detrimental to his patient's health'.

In the UK it seems that the law still recognises and respects the medical role in decisions of a moral or ethical nature. While defining the boundaries beyond which it may not go, it has allowed considerable latitude to professional judgement.

Although hemmed in to a greater extent by legal constraints and by pressure from non-medical quarters, there is a hint that doctors in the US are beginning to regain some of their clinical autonomy in these areas.

My concern to preserve the central role of the doctor in clinical decisions, moral or otherwise, is not a reflexion of professional self-interest or a wish to perpetuate professional sovereignty. It is based on my belief that such decisions must rest on a proper knowledge of all the medical consequences of each option, physical and psychological, qualitative as well as quantitative; that they must be made with critical and professional detachment; and that they should be conveyed to and discussed with the patient and the family with compassion and sensitivity. This combination of qualities, I believe, is best embodied in the well-trained doctor, and the interests of patients will best be served by their proper application. In the words of Franz Ingelfinger (108), 'If you agree that the physician's primary function is to make the patient feel better, a certain amount of authoritarianism, paternalism, and domination are the essence of the physician's effectiveness'.

LITIGATION AND DEFENSIVE MEDICINE

In order to guard against possible liability for damages most doctors in the UK belong to one of three medical defence organisations, indeed it is compulsory for hospital doctors in the NHS to do so. In August 1986 two of the three, the Medical Protection Society (MPS) and Medical Defence Union (MDU), announced they were raising their annual fee by 70 per cent to a new height of £576*. They gave as their reason the increasing number of claims now being made and the increasing size of the awards that were being claimed and allocated. The average cost of settlement had increased by 400 per cent in a single decade. The MPS (109) recognised a number of contributory factors:

* These two organisations have recently raised their annual fee to £1080 from 1st January 1988.

(i) An increasingly critical examination of the quality of medical care through consumer-oriented groups such as Community Health Councils, Citizen's Advice Bureaux, and enhanced coverage by the media;

(ii) A legal expansion of the concept of 'heads of damage' to include such items as 'nervous shock', loss of estimated future income and pension rights and medical costs, e.g. of the upkeep of a child born after a sterilisation procedure. Advances in medical science now enabled more severely-damaged patients to survive for years with resultant increases in the cost of their medical care.

(iii) A change in social climate embracing diminished feelings of gratitude and loyalty to medical attendants.

The fact that individual doctors, even those who work within NHS hospitals, are faced with this substantially higher bill for medical protection arises historically from their own initial reluctance to accept that their employer (the NHS) should be responsible for acts of negligence; in 1948, in joining the NHS, they preferred to accept their own negligence liabilities, membership of a protection society having then been made an obligatory condition of their employment.

While there is cause to be concerned about the increase in insurance rates in the UK—largely because it is seen to portend the shape of things to come—the position in the US has become critical (110,111). The problem is not new. In 1871 an eminent American doctor [quoted by Rosemary Stevens (24)] declared: 'A certain class of patients make it a business to extort money in this way (by malpractice claims), by the aid of a certain class of lawyers who go halves in the speculation'. Two reports from the American Medical Association (AMA) in 1984, (112) refer to annual premiums in 1983 of \$20,000, \$30,000, even as much as \$70,000; these figures are now substantially higher; a premium of \$140,000 for an obstetrician was recently cited (113). It was estimated in the AMA report that the national average of claims made annually against doctors stood at 20 per 100, i.e. an average of one in five physicians could expect to face a claim or suit each year. In

mid-1984 the American College of Obstetricians and Gynaecologists reported that 60 per cent of all their specialists had been sued, 20 per cent of them three or more times; a Florida survey indicated that 25 per cent of obstetricians/gynaecologists no longer delivered babies and a further 30 per cent were considering stopping, because of their vulnerability to litigation. Mid-point verdicts for damages had risen from \$48,580 in 1975 to \$200,000 in 1983/84, and to \$1.5 million for injuries to the newborn. More than four \$1m awards were made each week. Dr Richard Smith (114) cites an award of over £50m to a woman after treatment for food-poisoning had gone wrong. In Britain we have just seen our first £1m award.

The size of the problem in the US may be gauged by the extent of involvement of the legal profession in medical litigation. In New York recently I was introduced to a young lawyer who worked in a firm of 160 lawyers, all of whom practised entirely in this field. I was informed that this firm limited its activities to metropolitan New York, an area it shared with several other similarly-specialised firms. Another young lawyer told me she had recently been recruited to a firm to deal specifically with the backlog of over 50 cases of medical litigation.

The consequences of this litigious activity have been profound. Almost all doctors in America have been affected by the issue of professional liability. Economically, they are required to pay exorbitant premiums (recovered, by those in private practice, by simply incorporating them into increased charges to their patients); emotionally, they suffer the ignominy and trauma of a malpractice suit; professionally, many have found it advisable to abandon certain procedures or to modify their practice styles. Thus, many doctors have given up obstetrics, working in exposed areas such as emergency or accident units, or offering their services to charitable institutions which might not carry adequate insurance cover. Many now seek the protection of group practices, preferring to function as 9 am to 5 pm employees. Early retirement is an easy and popular route of escape. Quam *et al* (115) have pointed out that the behaviour of doctors is too complex to be

attributed solely to litigation; other social and economic factors unquestionably play a part.

There is no evidence that the threat of malpractice action has improved the quality of patient-care, i.e. it does not seem to have had a corrective or deterrent effect on those members of the profession whose standards of practice might have been less than satisfactory. On the contrary, the adversarial approach has had a deleterious effect leading to an erosion of the relationship between doctors and patients. 'The fact that every patient that walks in the door is a potential enemy and a potential litigant . . . is . . . detrimental to the quality of medical care' (116)

Iglehart has written (117): 'I don't think there is any issue that is more important to the medical profession today than that of professional liability, because physicians see it as not only an attack directly on their professionalism but an attack on their ability to provide the type of care that needs to be provided'.

In the face of such threats it is not surprising that doctors in the US have adopted a policy of defensive medicine. This form of practice may be characterised as positive or negative: positive defensive medicine may be defined as the use of unnecessary or redundant diagnostic or therapeutic measures primarily to protect the physician from being found liable if things go wrong; negative defensive medicine includes the withholding of diagnostic or therapeutic measures of potential benefit to the patient because of the fear that an adverse outcome might lead to a malpractice suit (118).

The full extent of defensive medicine is hard to determine. A survey carried out by the American Medical Association (AMA) found that 40 per cent of physicians admitted that they had unnecessarily ordered additional tests and 27 per cent had carried out additional procedures simply because of the threat of litigation. The AMA report calculated that its annual cost was between \$15b and \$40b and added 5 per cent to total US health care expenditure, but it is difficult to isolate the defensive factor from other motives for using costly and often unnecessary procedures. Not all of defensive medicine entails expensive technology. Relatively cheap routine pre-operative

ECGs or post-traumatic skull X-rays have been shown to offer very little benefit to patients; their summated cost is considerable. To what extent is their use predicated by a defensive attitude?

In Britain the threat of litigation still lags well behind the US. As yet, the spectre of defensive medicine has not cast too great a shadow over medical practice. There are signs, nevertheless, that we might be moving in the US direction. It is, therefore, reasonable to consider why litigation has had so profound an impact in the US compared to this country.

First, we are protected to some extent by the nature of our health-care system. In this country, particularly in non-urban areas, the GP is known personally by his patients who, more likely than not, feel well-disposed towards and loyal to him, and are disinclined to initiate legal action against him. The GP, in turn, takes an almost paternal interest in his patients, acts as a filter between them and hospital services and is able to detect and head off possible friction before too much resentment has built up. In the US a primary care system such as ours does not exist, patients have direct access to doctors of their choice—general physicians, paediatricians, or specialists. They commonly accumulate a number of doctors, each to deal with a specific area of complaint; when they are dissatisfied with one, they may simply try another. The same sense of loyalty of patients to a single doctor, and the almost parental sense of responsibility felt by British GPs towards their patients, would rarely exist. The very structure of the doctor-patient relationship in the US renders it more vulnerable to litigation than the cosy ‘family’ feeling, the sense of ‘belonging’, that so often exists in the UK.

There is a threat that this relationship might be changing in the UK. Group practices, the increasing use of emergency and out-of-hours services in general practice and the impersonal nature of hospital services are beginning to change public attitudes. But other elements of our system help to preserve the traditional relationships; important among these are the panel-lists of GPs and the insistence on referrals to consultants being made through GPs, who thus retain primary responsibility for patient-care.

Of importance, too, is the financial relationship. In the UK GPs and hospital doctors are known to be salaried and, hence, in general to have no direct pecuniary interest in the treatment of their patients. In the US increasingly they are seen as no different from others who supply essential services in return for payment; if the goods they deliver are unsatisfactory, compensation would seem to be justified, even to the extent of taking legal action to secure it. In addition, patients who pay directly and quite heavily for medical care are likely to feel more aggrieved and more ready to litigate if something goes wrong.

A further development in the US is fragmentation of the medical profession. Doctors are now more willing than ever before to testify, even publicly, against their medical colleagues. The 'fraternal' loyalty that once characterised the profession has yielded to other pressures, often financial. In the UK, perhaps because of its smaller size and therefore more intimate relationships between doctors, as well as the recognised need for doctors to work in close partnership with one another in NHS establishments, there is still reluctance to give evidence against one's colleagues. It is usually easier to get medical experts to provide opinions for the defence in litigation cases than for the plaintiffs. There is a suggestion that this professional unity is beginning to break down.

Quam *et al* (119) have highlighted differences between the legal systems that operate in the US and UK. They draw attention to the relatively conservative approach of British judges, and differences in access of claimants to the courts, in their ability to assemble a good case and in the response they are likely to encounter. An important factor is the absence of contingency arrangements for legal costs in the UK. This system clearly constitutes a considerable incentive to some lawyers in the US to pursue every possible legal avenue and to some patients to grasp all opportunities to seek legal and financial redress in what is for them a non-losing situation, even when the claims have little merit. In the UK, in the absence of contingency arrangements, potential complainants are bound to consider the possibility of failure and the costs they might then have to face.

If the shadow of medical litigation is now beginning to reach our shores, what steps should we take to contain it before our own style of medical practice is affected? There are three possible ways of tackling the problem: (i) by improving standards of medical care so as to reduce the incidence of negligence or malpractice that might lead to claims for damages; (ii) by limiting the amounts awarded to plaintiffs by the courts; (iii) by introducing a different system of compensating the victims of medical injury, e.g. 'no-fault' compensation.

(i) Improving medical care

We should recognise the extent to which deterioration in doctor-patient relationships fuels this confrontation and do all we can to prevent this from happening. It is clear that most instances of resentment by patients or their relatives about treatment, or the lack of it, stem from a failure of communication. This point is made so well and so frequently that I shall not dwell on it. At all levels the interests of the patients must be held paramount and, in the public eye, they must be seen to be so. While one has sympathy with the plight of many underpaid and overstressed workers within the NHS, it must be seen to be fulfilling its primary and proper role of caring for patients so that, in the words of Sir John Hawton, 'every man and woman and child can rely on getting all the advice and treatment and care which they may need in matters of personal health'. If public faith in doctors and in the Health Service can be maintained and/or restored, there is less likelihood of the contagious spread of pernicious litigation.

The retention of public faith and confidence in the profession demands action on our part:

(a) We need to scrutinise, and accept that others might scrutinise, our professional performance and our general clinical competence, a topic I shall return to later. This should include an analysis of all cases in which an unexpected adverse medical outcome has been identified.

(b) We need to improve the quality of our communication with patients and their relatives. Time must be allowed for

adequate discussion and explanation, for questions to be asked and answered, and anxieties to be allayed.

(c) We need to reassure the public that the medical attention they receive is of the highest possible standard, that it is provided by consultants or by junior staff only after full and proper training or under supervision.

(d) We need to develop improved procedures for dealing with complaints from patients about or professional standards or behaviour.

In the UK the General Medical Council is authorised to deal with complaints of a more serious nature and is empowered to take punitive action, such as removal of a doctor's name from the Medical Register, for 'serious professional misconduct'. Within the profession a system has been established to deal with 'the sick doctor'—one whose clinical performance or general behaviour has deteriorated because of alcohol or drug abuse or mental incompetence. We lack a clearly-defined mechanism for dealing with doctors who are rude to patients, who persistently come late to their clinics or do not attend at all (leaving their patients to the care of unsupervised junior staff), who infringe our professional standards in other ways, e.g. by overcharging, or who are recognisably incompetent. Complaints relating to the clinical judgement of hospital doctors that are deemed less serious and not likely to proceed to litigation, may be dealt with through a defined procedure that culminates for complaints of a substantial nature in referral to senior doctors nominated through the Colleges or Faculties; this process would be acceptable if it could be speeded up—far too often one or even two years elapse before the complainant is finally given the opportunity to discuss the matter with independent consultants. By this time—understandably—impatience and resentment have reduced the prospect of successful intervention. A new improved and accelerated mechanism must be found through which complaints about what Mr Nigel Spearing, a Labour MP, calls 'unacceptable' professional conduct are rapidly heard and discussed. A sympathetic audience at an early stage would do much to reduce the anger, resentment, and suffering of an

aggrieved patient or relative. If it were known that such an audience was readily available, recourse to the law might also be discouraged.

(ii) *Limiting the size of awards*

It is important to ensure that the policy of contingency payment is not introduced in this country. In the US pressure to do away with the contingency-fee system has been unsuccessful (110) on the grounds that this would be discriminatory. Legal action, it is argued, is expensive and cannot be undertaken by everyone; without such a device, those with genuine and compensatable complaints might be deterred from initiating a legal action that could be complex, prolonged, expensive—and possibly unsuccessful. In the UK we must ensure that these deterrents are minimised, that such complaints are dealt with promptly and efficiently with access to the courts where appropriate, and that the factor of contingency payment is not introduced as a mechanism for ensuring satisfaction. It is too vulnerable to abuse. It is desirable to place some limit on liability. I referred earlier to the drastic rise in the mid-point verdicts for damages in the US, where they are assessed and awarded by a jury which takes into account the high proportion of the award paid in legal contingency fees as well as the cost of providing medical care for the injured party, usually through the expensive private system. In the UK a jury might make a decision about liability but the amount of damages is determined by a judge; the award is likely to be smaller because the costs of medical care are recognised to be lower due to its availability through our health-service. As a result of intense lobbying and threats of strike action by doctors, almost every State in the US has passed a statute limiting plaintiff's rights and many have tried to place a limit on premium rates (115). Despite our more temperate approach, the escalation of awards in Britain gives cause for alarm. In 1970 a brain-damaged child might have received £20–40,000 in compensation; by 1981 agreed damages for a severely brain-damaged child reached £100,000; today awards between £300,000 and £650,000 are common.

Such large settlements may well produce a US-like response in this country: insurance premiums could rise, doctors could begin to practise defensive medicine or react in other ways that are not in the interests of patients; a greater incentive could be given to lawyers and the public to seek compensation when things are thought to have gone wrong. To head off such a development a mechanism needs to be found through which fair but not inordinate compensation is awarded.

(iii) *Introducing a new system of compensation*

There is a problem in reconciling the interests of the victims of medical accidents with the interests of the medical profession—hence, indirectly, of their patients—from the damaging consequences of overpowering litigation. Within the tort system in the UK a patient must prove that on the balance of probabilities the defendant doctor was negligent. This requires proof that ‘there is a usual and normal practice; secondly . . . that the defender has not adopted that practice; and thirdly (and this is of crucial importance) . . . that the course the doctor adopted is one which no professional man of ordinary skill would have taken if he had been acting with ordinary care’ [Lord Clyde, quoted on p. 281 of the Pearson Report (93)].

The Pearson Report draws attention to the insignificant number of claims made in the UK. At the time of its publication 6 million in-patients were being treated annually in NHS hospitals and some 19 million people attended outpatient departments. Yet, in a whole year no more than 1,000 claims were made. Action for the Victims of Medical Accidents (AVMA) has no evidence to suggest that many medically-injured people go uncompensated. Dr Richard Smith (114) cites a Californian study that showed that over three million hospital admissions in 1974 led to 140,000 injuries, of which 24,000 were the result of negligence. ‘Yet, even in that most litigious of communities only 4,000 claims were filed, half of which were successful.’

The unfairness, the futility, the damaging consequences of the present system of compensating those injured through medical accidents has led to increasing demands for the

adoption of a 'no-fault' system of compensation. This is defined as 'compensation which is obtainable without proving fault and is provided outside the tort system. No-fault compensation is a system of obtaining payment from a fund instead of proceeding against the person responsible for the injury' (Pearson Report, para. 34). 'No-fault' compensation has been introduced in New Zealand where a comprehensive scheme embraces every type of accidental injury—medical or non-medical. Because the claimant only has to show that he suffered an injury, not that it was due to a medical error, medical litigation has all but disappeared. There is concern about the financing of such a comprehensive scheme but the cost in New Zealand is not exorbitant and the system is generally regarded as successful. In Sweden, and more recently in Finland, a similar scheme has been operated but compensation is limited to those injured in a medical accident. Problems of distinction between accidents and unavoidable complications of a disease or its treatment are inherent in this and the New Zealand scheme.

Opposition to a 'no-fault' compensation system has come from AVMA and from the Pearson report which recommends the retention of the tort system: 'Liability was one of the means whereby doctors could show their sense of responsibility and therefore justly claim professional freedom. If tortious liability were abolished there could be some attempt to control doctors' clinical practice to prevent mistakes for which compensation would have to be paid by some central agency' (Pearson Report, p. 286-7). I find it ironical that the present system of tortious liability is seen, on the one hand, as protective of the professional freedom of doctors; on the other, as conducive to the practice of defensive medicine which is so often an erosion of this freedom. The reference to controlling clinical practice implies that clinical guidelines might need to be introduced to provide a generally acceptable standard of practice which would act as a yardstick for determining medical liability. Most doctors would see this as a serious encroachment of their clinical freedom (77). Harvey and Roberts (77) quote excerpts from the Pearson Commission ('Some penalty helped to preserve the patient's opportu-

nity to express disapproval and obtain redress') and the Medical Defence Union (that 'their investigation . . . brought home to the doctor the part he had played and encouraged a sense of personal responsibility'), and comment that 'the current system of individual tortious liability is alleged to fulfil a quasi-disciplinary function, regulating standards of medical practice via the threat of exposure in the courts'.

In this interpretation our fault-based system might be seen to serve partly as a means of administering a cautionary smack on the bottom to erring doctors, not hard enough to cause excessive pain (as our medical defence societies would bear the cost of any award) but sufficient 'pour encourager les autres'. This is not a convincing argument in favour of retaining the present system or for rejecting one that offers prompt and proper compensation to victims of medical accidents without recourse to law. The Pearson Commission seems to have been sufficiently impressed by the defects of a no-fault system to have discouraged its introduction in the UK. They suggest, instead, that its application in New Zealand and Sweden should be further observed.

Although it had originally expressed reservations about no-fault compensation schemes in general, a recent report from the BMA recommends adoption of a scheme along the lines of the Swedish model. Within this model compensation is provided but limits are established for indemnity, basic support for injured parties being available through a comprehensive and effective system of health-care. Access to courts of appeal is open to those who remain dissatisfied by an award. The present system of compensation is clearly unsatisfactory. The initiative of the BMA in advocating adoption of the Swedish system, albeit with some modifications, needs our support.

Where does this leave the medical profession in the UK? Do we need to rely on the threat of judicial admonition as a mechanism for ensuring a satisfactory standard of practice? Is liability really a means whereby doctors can 'justly claim professional freedom'? Would our professional freedom not be better preserved if we relied less on the courts and more on our own efforts to monitor and improve our standards?

If we are to be accountable—and I most firmly believe we should be—would it not be preferable for us to account to ourselves?

Iglehart (120) quotes Representative Wyden's contribution to the debate: 'There is no quick fix for the malpractice problem. Doctors are in the best position to do something about malpractice—because they see it happening around them'.

ACCOUNTABILITY OF DOCTORS

In his Pulitzer Prize-winning book, *The Social Transformation of American Medicine* (19), Paul Starr traced the rise of medical authority in the States (referred to by him as 'professional sovereignty') and its more recent decline as it was transformed into 'a vast industry'. In America at least, he suggested, the public image of medicine and its practitioners has become tarnished. To some extent this is a reflexion of changing attitudes to authority, an anti-establishment expression of the political radicalism that flourished in the 1960s. It reflects a rejection of professional paternalism and an insistence that individuals should have more say in decisions, medical or otherwise, that affect their own destinies. 'The issue was basically professional dominance, and (the) aim was to increase the power of consumers'. The public image of medicine has also changed because the nature of medicine itself has changed. Escalating costs have turned health-care into a political and public issue. The spotlight has focussed on high technology and specialisation, and increasingly it has become clear that individual doctors and the health-care system as a whole have to become more accountable. No factor has tarnished the public perception of the profession more than its flagrant commercialisation. In a society in which doctors are seen as 'providers' of marketable health-care products to 'consumers' or 'clients', their standing in the community is assumed to warrant no more recognition or respect than that of other purveyors of essential goods.

If doctors wish to redeem themselves in the eyes of a disillusioned public they must offer a recognisably high standard of ethical behaviour; if they wish to restore a sound and proper relationship with their individual patients they must demonstrate their possession of clinical competence, technical skill, and good judgement; above all, they must evince personal qualities of caring, devotion, and compassion.

R. K. Merton discussing the 'composite of social values that

makes up the concept of a profession' lists 'first, the value placed upon systematic knowledge and the intellect: knowing. Second, the value placed upon technical skill and trained capacity: doing. And third, the value placed upon putting this conjoint knowledge and skill to work in the service of others: helping. It is these three values as fused in the concept of a profession that enlists the respect of men' (121).

Patients can tell us much about the personal qualities of doctors—their warmth, their kindness and sympathy, their willingness to listen, and ability to communicate. We should pay more attention when they complain of a lack of them. They are however in a less favourable position to judge clinical and technical competence. This is something we, as professionals, should be doing. Dorothy Emmet (122) has written: 'A profession thus carries with it the notion of a standard of performance; . . . (it has) a fiduciary trust to maintain certain standards. These are partly standards of competence, or technical ability . . . But not only so, professional competence has to be joined with professional integrity.' There is a manifest need for us to examine more closely the standards of competence that obtain within the medical profession.

Assessment of the quality of care provided by individual doctors is not easy. Drife (123) has pointed out the fallacy of indicators such as the amount of time a doctor spends with NHS patients, the number of patients he deals with, the number of operations he performs, or the amount of drugs he prescribes. Considerable deviations from the average tend to be regarded as representing substandard care, whereas they might equally well reflect the opposite. It is unlikely that any satisfactory quantifiable assessment of quality of care will ever be evolved. Yet, within the profession we all recognise good medical practice. General practitioners tend to refer their patients to consultants whom they recognise to provide high quality care; consultants know which of their colleagues to call in when help is needed. All doctors exercise discrimination when they or their families need medical attention.

If we agree that standards of clinical competence should be appraised; that patients themselves are not favourably placed

to make such judgements; that attempts by administrators to assess quality of care are likely to be based on unacceptable and often irrelevant quantifiable criteria; and that only doctors themselves have the appropriate insights into the competence of their colleagues; then the need for doctors to establish their own systems of monitoring seems to be ineluctable.

MEDICAL AUDIT

Dr Archie Cochrane (124) entitled his Rock Carling Lecture of 1971 *Effectiveness and Efficiency: Random reflections on health services*. He chose the former term to embrace the measurement of the effects of particular medical actions in altering the natural history of particular diseases for the better, a process perhaps best achieved through well-designed randomised clinical trials. He applied the term 'efficiency' to the problem of determining the optimal use of personnel and materials (resources) within the NHS. He did not consider the assessment of performance of individual doctors but recognised the considerable clinical freedom enjoyed by doctors in the NHS and predicted its curtailment. In a memorable passage he said:

Indications for prescriptions, diagnostic tests, admission, length of stay in hospital, etc., will get more and more clearly defined and a sort of 'par for the course' associated with each group of signs and symptoms will be established, and those doctors with too many 'strokes' above or below 'par' will be asked to justify themselves before their peers . . . Some will undoubtedly object to this, but if the evidence on which the 'par' is based is made clear and the objective of being fair to all patients served by the NHS is explained I doubt if many will emigrate.

In 1976 the Nuffield Provincial Hospitals Trust published *A Question of Quality? Roads to Assurance in Medical Care* (125). Professor Archie Duncan, invited to follow up this series, wrote a review of 'Quality Assurance' (126) in which he debated the best name for the activities that embraced this practice. After considering 'quality-control', 'patient care

evaluation' and 'peer review' he selected 'medical audit' as the term most likely to survive (despite 'its connotation of accountancy and accountability'). In deference to him—and because it is still so widely used and understood—I shall use the term myself.

The Royal Commission on Medical Education (cited by Duncan) stated that 'the esteem in which the doctor is held by the community in general will be determined more by his demonstrated competence than by the mystique of his calling'. Duncan advocated 'scrutiny of that part of medical care which is amenable to audit' by the profession, lest measures should be imposed from without. He quoted a threatening message from *The Times* of 8 September 1978: 'Whether doctors move fast enough to satisfy public and parliamentary pressure or whether Parliament will decide it cannot wait long enough for doctors to put their house in order . . . are questions still to be answered'. Despite a plethora of persuasive articles on the subject there is no sign that medical audit has penetrated deeply or widely into clinical practice. Although the threat of parliamentary action might temporarily have receded, I would contend that some activity is needed now to reassure the public that the profession is concerned to safeguard their interests. If we hope to continue to enjoy our clinical freedom we must pre-empt and ward off any public or parliamentary action that might tend to constrain it by imposing external scrutiny rather than our own.

Already we have evidence of governmental interest in the process of audit. Indeed the implementation of new management structures demands it, as managers will be judged by the degree to which they have achieved pre-specified targets. As a means of evaluating the medical contribution towards their success, Performance Indicators have been introduced. Classically, audit procedures are concerned with three issues: Structure, such as the number of beds or operating theatres, the number of staff employed, the material or personal resources that are available or required in the future; Process, or the way in which these resources are being used; and Outcome, the result of intervention. It is with the second of these aspects that Performance Indicators are mainly con-

cerned and the most commonly applied criteria evaluate bed-occupancy, duration of patient stay in hospital, the number of patients seen at outpatient clinics or operated on during a week. In an evaluation of the third criterion, Outcome, governments tend to look most closely at costs. Successful intervention is all too readily equated with cost saving; the quantity of interventions per fixed cost is used to determine 'value for money'.

The medical profession has, quite reasonably, objected to such criteria on the grounds that a more efficient 'processing' of patients cannot be equated with quality of medical care, in fact, as Drife suggested, it often bears an inverse relationship to it.

What is needed, I would suggest, is less emphasis on the audit of structural or procedural aspects of medical care or on the costs of items of service, more evaluation of personal clinical aspects; less concern with institutions and authorities, more with individual patients *and* individual doctors.

We do not live in a perfect world. There are doctors who are rude, inconsiderate, unsympathetic, even negligent or venal. Our complaints procedures should be strengthened to identify and suitably chastise them. There are also doctors who are ill-informed or ignorant of modern medicine, whose judgement is inadequate, whose use of costly medical techniques in the management of patients is too extravagant or too parsimonious, who make too many errors that lead to suffering, or, even, death—who are, simply, incompetent. Experience suggests that not many are seriously incompetent, but how do we know how many there are or who they are if we do not look? In the preface to *The Doctor's Dilemma*, Shaw said: 'As to the honour and conscience of doctors, they have as much as any other class of men, no more and no less'. We should not delude ourselves that our behaviour and competence are always beyond criticism.

In America, formal review of professional standards has largely been predicated through tighter fiscal controls and the not entirely unrelated, ever-present threat of litigation. By 1970 medical care organisations had begun to examine the ways in which Medicaid programmes were being utilised by

different institutions, identifying instances that deviated from statistical norms, e.g. in length of stay of hospitalised patients. PSROs (Professional Standard Review Organisations) threatened to limit the discretion of hospital doctors, who were now obliged to take into account their own deviations from conventional standards or take the risk that their hospitals would not be reimbursed for services that were regarded as inappropriate. The emphasis was entirely on review of the process of medical care; the incentive for the review was primarily cost-control. This system of review has been adopted and reinforced in the growing number of HMOs (see earlier).

It is much more difficult to audit *clinical* competence or to take action when it is found to be lacking. Peer Review organisations are now beginning to extend their interest from cost-control to competence, examining such aspects as unexplained hospital re-admissions soon after discharge, medical, or surgical mishaps, adverse drug reactions, faulty diagnoses, and unnecessary admissions. The performance of individual doctors as well as institutions is increasingly subject to surveillance. Certain doctors have been excluded from the Medicare programme because their care of patients was thought to be substandard. In the USA the Joint Commission on Accreditation of Hospitals, which is a Federal institution, visits all hospitals every three years (127); a similar organisation exists in Canada. One of the requirements in the US system of review is that there should be 'a process of analysis and evaluation of the performance and outcome of the professional clinical work of a unit, department or Service'; part of this process should be concerned with the *quality* of patient care. The College of Physicians and Surgeons of Ontario has established a 'Peer Assessment Program' which comments on the adequacy of care provided by physicians and surgeons who *agree* to take part. It is likely that among those who do not agree are the doctors most in need of peer assessment.

In the US the effectiveness of peer-review systems has been greatly undermined by the fear of retaliatory lawsuits brought by physicians who are the subjects of disciplinary action

(120,128,129). Initially, physicians who were denied staff-rights at hospitals to which they had been attached brought law-suits against the hospitals and their peer-review committees in order to seek re-instatement. Recently defamation actions and discrimination suits have been brought against the physicians who served on credentials and disciplinary committees. Far more seriously, violations of Federal anti-trust laws have been claimed in the past five years; these laws prohibit competitors (in this case, other physicians) from preventing entry by new competitors into a relevant market (the hospital) or from disciplining fellow-competitors by exclusion or restriction of their trading-rights. Peer review by hospital medical staff fits this proscribed model. In the Patrick case, fought out for nearly ten years in Astoria, Oregon, a verdict was returned in favour of the disciplined surgeon-plaintiff, Dr Patrick, with damages awarded to him of almost £2m. In a more recent decision of the Court of Appeals this verdict was reversed on the grounds that the defendant physicians were immune since State law required the type of peer-review they conducted. In 1986 a new law, The Health Care Quality Improvement Act, was passed to protect 'good physicians' who wished to prevent 'bad medicine' by ensuring immunity to reviewers subject to a number of general safeguards. This Bill has received support for three main reasons: first, improved peer review is thought likely to moderate the incidence of malpractice; second, the profession needs to convince the public that it is doing everything reasonable to police itself; third, it will allow the compilation of reliable data about medical malpractice. It is this third reason that has given rise to disquiet, for the new Act makes it compulsory for details of all malpractice suits in which payment has been made in settlement or satisfaction of a judgement, to be reported to a central clearing house. This information will include the names of practitioners involved, the amounts of payments, and descriptions of the acts or omissions that led to the claims (120). There are concerns about potential abuse of the information contained in such a central data file. Henry A. Waxman, Chairman of the Subcommittee on Health and the Environment of the US House of Representatives has said:

'This bill provides the medical community with an opportunity to demonstrate a new willingness to act decisively to weed out incompetents' (128).

In the UK we have dragged our feet. Professional resistance to the concept of clinical audit has been considerable. 'Too often, both peer review and audit have been seen as a threat to their clinical freedom rather than as an educational exercise that may identify means of improving the treatment of patients and possibly obtaining better value for money' (130). In its evidence to the Royal Commission on the National Health Service in 1977, the British Medical Association (BMA) stated 'Any supervision of the competence of an individual doctor to practise must be by the profession', but went on to say that, apart from the setting of proper standards of admittance and qualification and the need to ensure continuous training and study, the best guarantee of competence was "the individual doctor's conscientious assessment of the standards of his treatment against the standards of his colleagues . . . All very well, provided the doctor has a conscience, and the insight to apply it. (To its credit the BMA took a more positive and constructive attitude through its Annual Representative Meeting in 1979.)

There are many different forms of clinical audit, some formal and threatening (127), some informal, friendly but challenging. Shaw (131) suggests factors that should be common to all systems of audit:

purpose: should be educational and relevant to patient care;

control: should be by clinical peers with voluntary participation;

standards: should be set locally by participating clinicians;

method: should be non-threatening, interesting, objective and repeatable;

resources: should be cheap, simple and cause minimal disturbance;

records: should contain adequate clinical content and be easily retrieved.

In its review of hospital audit procedures the Professional

Standards Review Organisation (PSRO) requires each hospital to carry out at least four quality review studies annually; two of the topics are decided by the PSRO, two chosen by the hospital itself. This type of study of internal clinical practice is easily carried out, is not threatening and conforms to the criteria laid down by Shaw.

A different and common form of audit is that described by van't Hoff (132) in which all deaths that have occurred in the previous month are reviewed by all consultants in the hospital. This fulfils an admirable educational function but fails to expose to scrutiny many other important aspects of medical care that do not have a fatal outcome.

A more comprehensive scheme adopted by the Medical Unit at the Queen Elizabeth Birmingham, was described by Heath *et al* (133). This is now operating successfully in its 10th year. A one-hour lunchtime meeting is attended by the consultant physicians on the Unit, their junior staff and the senior medical students attached to the consultants at the time. The inpatient notes of randomly selected patients discharged within the previous month are reviewed by a consultant or a member of the junior staff on the basis of a detailed proforma. Questions relate to the quality of the notes, the use of investigations, the appropriateness of treatment, the (recorded) information given to the patient, relatives and on discharge to the general practitioner. After two years Heath tried to assess the effect of audit on performance (134). Most notable was an immediate improvement in all aspects of note-keeping, including the recording of information about the patient that had been passed to others. There was a reduction in the use of common investigations and in the number of drugs prescribed when the patient was discharged; whether these reductions were in the interests of the patients is, of course, open to question. No study of outcome was possible.

The main benefit of the weekly meeting was educational. The knowledge that their management of a patient might be discussed openly and in detail led both consultants and junior staff to think more critically about their decisions. At the audit meeting they could expect to be challenged and to have to provide reasonable explanations for their actions. The need to

justify one's actions led to a more thoughtful use of investigations and treatment. Whether a decision was correct or not was considered less important than the fact that it could be justified. Difficult issues were often not resolved by discussion—nor would one expect them to be in clinical practice which has little place for dogmatism. The important outcome of the process of audit was an acceptance of the need to be accountable.

In a more recent comment Heath (135) refers to his disappointment that other consultants in his hospital were not persuaded to join the audit scheme. Amongst the reasons given by them was the fact that audit had not been shown 'to save money'. This, alas, is true of most educational processes but hardly justifies their abandonment. Sadly, one has to conclude that many doctors still feel threatened by open discussion and criticism of their case-management and are reluctant to participate in audit reviews. Van't Hoff has pointed out (136) there are pockets throughout the country where 'physicians now think some form of audit is necessary and have done something about it'. There are far more pockets where they have done nothing.

Encouragement would be given to the adoption of audit procedures if the Colleges and Faculties were routinely to enquire about their practice when training posts were being assessed. This would heighten awareness of their importance and give emphasis to their educational merit. If the Colleges were to insist on the establishment of audit procedures as a criterion of approval of training posts, standards of clinical care would be enhanced, and public anxieties would be allayed. The Royal College of Physicians of London has already introduced this criterion.

An approach that has been tried in America with only limited success is the periodic evaluation of professional competence by examination, the so-called 're-certification programs'. In 1974 the American Board of Internal Medicine set its first Re-certification Examination; it did so again in 1977 and 1980. In May 1987 a new examination was introduced which consisted of questions in core internal medicine as well as in optimal specialty topics. There has been

a disappointing decline in the number of participants, presumably because of the voluntary nature of the process. As with audit procedures, it is likely that more competent and responsible physicians who kept abreast of advances in medicine see the need for and accept the challenge of re-examination, those whose skills and knowledge have declined fail to participate. A recent comment referred to the examination as 'The Last Gasp of Voluntarism', a hint, perhaps, that re-certification in the US might one day become mandatory (137).

Insistence on re-certification through examination introduces the problem of dealing with a practising doctor who fails. It is one thing to require a young doctor to spend an additional six or twelve months improving his clinical skills and adding to his medical knowledge before agreeing to his advancement to the next stage of training; it is quite another to require a senior physician or surgeon to withdraw from practice until he has achieved success in examination. In the US several doctors who practised in rural areas have had their right to reimbursement by Medicare withdrawn because they failed to be re-certified. As a result, several rural communities have been deprived of medical care. The protests from these communities and their praise for the humane and caring qualities of the dispossessed physicians raises doubts about the applicability of the standards of examination to all sectors of the medical profession.

In general, examinations test knowledge and clinical skills. They may be manipulated to test reasoning skills and, perhaps, even judgement. They cannot easily be applied to assessment of a doctor's wisdom, understanding and compassion, nor to his ability to communicate humanely with or console his patients, or their relatives. Tests based on knowledge that do not take these qualities into account will not properly distinguish good doctors from bad. This is one reason why I do not favour the formal re-examination of doctors. It is difficult to devise an appropriate test to take account of both general medical knowledge and the high degree of specialisation that many physicians attain. How can one properly assess the skills of a surgeon who practises only rectal or thyroid

surgery? Or the physician who deals exclusively with inflammatory bowel disease or endocrine aspects of infertility? Within the profession we recognise that such superspecialists have much to offer; indeed, we seek their opinions when we encounter particularly difficult clinical problems. It would be absurd to test them in their fields of excellence, equally absurd to fail them and perhaps, therefore, to prevent them from practising because they display limited knowledge of other fields, such as general cardiology or neurology. To me the essence of good practice is to be aware of one's own limitations, to be willing to seek expert advice when you sense you are getting out of your depth. This critical quality is not readily testable. Philosophically, I regard the application of formal examination as being more appropriate to the young. As people mature and gain experience through practice, they acquire qualities of merit that are less easily measurable or assessable. Most of us in the profession can recognise these qualities—or the lack of them—in our colleagues. Examinations will not expose them, nor will impersonal procedures of medical audit, although some impression will be gained from the sort of audit procedure advocated by Heath. What is more important, this approach provides opportunities for junior colleagues and students to appreciate the significance of the intangible qualities that make a good doctor.

Any profession that appropriates such a large fraction of the national public expenditure cannot hope to escape the attention of financial auditors. Our own profession has the additional authority to exert a profound influence on the lives of individuals, even to confer life or to end it. Some scrutiny of our competence to bear such great responsibility should not be construed as an encroachment on our authority. We should welcome it, indeed insist on it, for only by such scrutiny can we lay any claim to the preservation of the clinical freedom we so fortunately enjoy.

FINALE

As my lecture developed I became aware that I was indulging inordinately in a transatlantic comparison. This was not originally intended, nor was it introduced chauvinistically to demonstrate the superiority of the British system over the American. We have in common a proper appreciation of what constitutes good clinical practice and a shared respect for the application of high moral and ethical values in research and practice. It seemed pertinent, therefore, to ask to what extent the limitations to clinical freedom that we sense have appeared in the UK have also affected doctors in America. Three major differences between our countries may have had an influence: First, the fundamental difference between our two systems of health-care, ours being almost entirely State-run, theirs only partially (although I venture to suggest that the development of the HMO in the US looks suspiciously similar to our own NHS in miniature form); second, the rather more obtrusive part played by the law in the US and their far greater indulgence in litigation; third, is 'patient-power', the more insistent demand of American patients to be informed about and to be responsible for their own medical decision-making. These differences have, I believe, placed rather burdensome constraints on the clinical freedom of American doctors, a feature they themselves have recognised and against which they are beginning to rebel.

In discussing the prospects for health services in the United States, Friedson (138) has said:

Medical practitioners . . . have attempted to maintain their freedom to exercise their own economies, organizational and clinical judgment without the intervention of patients or third parties. While they have become weaker as a political force, they still have considerable influence and are likely to continue to have it so long as they are the sole or major experts on the diagnosis or treatment of

illness or discomfort, and so long as health care remains organized around their skill.

The retention of clinical skills is clearly central to the status of our profession. Not only must the public be satisfied that we have retained them but we ourselves need to ensure that they are practised to the highest possible standards. More than ever, it is now necessary for us to introduce a system for assessing professional competence. If we do not, we shall fail to satisfy the public and invite regulation from outside the profession that will seriously curtail our clinical freedom. As Davidson (139) has said: 'If we lose control of the way we practise our profession, both we and our patients will suffer. Much of the choice is ours.'

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