

HEART DISEASE, GUIDELINES, REGULATIONS, AND THE LAW

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The practice of cardiology is increasingly constrained by guidelines, regulations, and legal considerations. Cardiologists, like any other group of doctors, have a primary duty of care to individual patients, but also have wider responsibilities to society in general, to their institution, and to their colleagues. In the UK these duties and responsibilities have been defined by the General Medical Council and have been described in a series of publications which have been sent to every doctor; these contain the answers to questions about good medical practice, the role of doctors in the management of health care, confidentiality and other issues.

THE DEMISE OF CLINICAL FREEDOM

Clinical freedom died around 1983.¹ A number of factors sounded the death knell. Among the more important were, first, the incontrovertible results of randomised controlled trials. Many of these were in the cardiovascular field—for example, coronary artery bypass grafting for patients with angina and severe disease, thrombolysis and β blockade for myocardial infarction, and aspirin for the acute coronary syndromes. These, together with earlier trials demonstrating the efficacy of antihypertensive treatment, and subsequent trials showing the benefits of statins and angiotensin converting enzyme inhibitors, have fundamentally altered the practice of medicine. Physicians have to have good reasons for denying patients the potential benefits of these treatments.

Financial constraints were a second factor that killed off clinical freedom. These became apparent in the British National Health Service (NHS) somewhat before other countries and have led to the universal recognition that third party payers of health care should not be expected to fund treatments simply on the assertions of a doctor, however distinguished. Evidence of benefit is mandatory.

A third factor has been the gradual realisation by the public that doctors are not always to be trusted. Some have fallen off their pedestals rather publicly, so that nowadays doctors not only have to keep up to date but must also be able to demonstrate their continuing competency. Although continuing medical education (CME) is deemed compulsory, methods of enforcement have yet to be agreed for specialists in the UK. In other countries this obligation is ensured by linking CME to remuneration. A similar development here seems inevitable.

Managers and doctors nowadays share the responsibility for providing a clinical service. The term “clinical governance” describes an institution’s method of assuring that individual doctors and groups of doctors provide a competent clinical service.

SAFE PRACTICE OF CARDIOLOGY

In the NHS ultimate responsibility for the safe practice of cardiology rests with the hospital trust board. Accountable managers are required to ensure that doctors maintain their skills through continuing professional development, audit, and appraisal. While demonstration of continuing competence is primarily a prerequisite for a doctor’s employing authority, cardiology, like any other specialty, has to be subject to national scrutiny. The British Cardiac Society’s peer review scheme, the annual publication of interventional cardiological practice and similar databases, and the production of national guidelines are all designed to enable institutions and their doctors to compare their practice with others and to ensure uniformity of standards within the NHS.

In the UK every doctor has to comply with the provisions of the Medical Act 1983 and appear on the medical register. A specialist register was established under the European Specialist Medical Qualifications Order 1995. This includes cardiovascular disease among the specialties. Cardiologists who held substantive posts in NHS hospitals on 31 December 1996 were automatically entered into the specialist register. Only those whose names appear on the register can legally practise the specialty in the UK and be employed as a consultant cardiologist in an NHS hospital. Entry to the register is either through completion of the six year training programme and award of the appropriate certificate, or via direct entry. The latter demands that the training and experience be at least equivalent to that required by the specialist advisory committee in cardiology; it is very rarely granted.

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Physicians who wish to practise cardiology and who have been denied entry onto the specialist register have had the right of appeal to the statutory training authority. They were entitled to a hearing which was held before a barrister. This right was exercised by specialists, many of whom had been employed in subconsultant grades before 1996; the right to this method of entry expired in 2001. But others, notably those who qualified overseas, may be allowed entry onto the register, if they can demonstrate that their training and experience is equivalent or superior. The appointment of a senior academic cardiologist from another country would be an example. The register does allow those physicians who have a CCST in general internal medicine to practise some cardiology, but to what extent is ill-defined. At the moment general medicine is largely acute medicine, hence coronary care is certainly within the remit of the generalist. In future, however, the dissemination of data showing that patients cared for by cardiologists have better outcomes will add to the pressure from patients and their relatives who want all those suspected of suffering from heart disease to be seen by a cardiologist.

Cardiologists also belong to a wider international community. The major European and US meetings and journals are a rich source of CME. Management protocols for specific cardiac problems have unsurprising similarities, regardless of their country of origin. There is free movement of labour throughout the European Community, in theory at least. Every member of a national cardiac society in Europe is automatically a member of the European Society of Cardiology (ESC). Increasingly, therefore, cardiologists will have to heed developments in other countries. Two are of current interest in Europe.

The first development is the "European cardiologist". This is a diploma that recognises clinical skills and is granted on completion of basic training in the specialty comprising two years of a common trunk of medicine, three years of cardiology, and one flexible year spent in a related discipline. Currently applicants are also acceptable if they can demonstrate that their training and experience are equivalent to that set out in the recommendations.² Most of the many hundreds of diplomas awarded so far have been to cardiologists in countries in southern and eastern Europe. The legal status of the diploma has yet to be tested but under European law a holder can apply for a post in any EU country and his/her application has to receive due consideration. Any country, however, has the right to impose higher standards as a condition of employment in their healthcare system, as would almost certainly be the case in the UK at present. The second European venture is the creation of a European Board for Accreditation in Cardiology (EBAC). This board, like that which grants the diploma—the European Board for the Specialty of Cardiology (EBSC)—is an offspring of two parent bodies, the ESC and the cardiology section of the European Union of Monospecialists (UEMS), which is the cardiologists' official channel of communication with Brussels. EBAC became operational in September 2001 and provides a European umbrella for the approval of postgraduate meetings and courses.

Guidelines, regulations, and legal considerations may be locally driven, or emanate from national authorities, and an increasing number will stem from Europe. All have to be given due consideration; only the law has to be obeyed.

GUIDELINES

Guidelines are what they say they are, no more and no less. They may be defined as "systematically developed statements

to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances".³ The concept of medical practice according to guidelines was recognised by Plato who considered it debasing because the emphasis is on the average patient not the particular, and because guidelines produced by others "are not rooted in the mental processes of clinicians".⁴ Plato foresaw the likelihood of governmental insistence on guidelines and the potential legal consequences. Nowadays we suffer from an excess of guidelines. They may be inconsistent⁵ and lack quality.⁶ So where does the practising cardiologist stand?

Randomised trials

Most current guidelines are based on the analysis of randomised controlled trials. Cardiologists should remind themselves that such trials recruit a minority of eligible patients. In the stroke prevention in atrial fibrillation trials only a small fraction of patients screened were finally randomised to receive warfarin or placebo. In the statin trials 20–30% of those screened were randomised. In the thrombolytic trials recruitment was better, as might be expected from the captive population, but the best—GISSI 2—only recruited 60% of those eligible. Many of the earlier trials do not state the size of the screening programme.

A further weakness of guidelines based on randomised trials is that the participants are usually a highly selected subgroup of patients. Those with other pathologies are excluded. There may be an upper age limit—for example, 70 years in most of the statin trials. Yet the patients encountered in clinical practice are often elderly and have other diseases. Anyone who agrees to participate in a trial is likely to comply with medical advice. Even those in the placebo limb of a trial fare better than those who are not recruited.

Traditionally the practice of medicine was based on experience, not "evidence". From the outset it was evident that coronary angioplasty and bypass surgery could reliably abolish angina. A trial was never undertaken. Our advice to symptomatic patients to have a heart valve replaced or a permanent pacemaker inserted is likewise based on experience. Guidelines for the management of many cardiovascular disorders are thus drawn up by panels of experts without the benefit of an "evidence base". These are termed "consensus statements". There is a danger that such groups of experts may contain enthusiasts whose influence may lead to recommendations that go beyond the evidence. The pacemaker prescription in the British Pacing and Electrophysiology guidelines, for example, strongly favours dual chamber devices which seems perfectly reasonable in view of their physiological performance. The advice would be more compelling, however, if supported by the results of randomised trials which are currently being undertaken.

In the UK, guidelines also now emanate from the National Institute for Clinical Excellence (NICE). The encouraging recommendations for the more widespread use of intracoronary stents, implantable cardioverter-defibrillators, and platelet glycoprotein IIb/IIIa receptor antagonists have been very welcome, but may again reflect the views of advocates for these forms of treatment. There is a nagging doubt in some minds that the strength of some of the recommendations is not entirely supported by the evidence, and not equal to the authority of other guidelines, on the use of statins, for example.

Problems of guidelines

Implementing guidelines produces three problems: cost, complications, and the fact that a majority of patients are going to

receive a treatment that they do not need. No nation can afford universal healthcare. Some form of rationing is therefore inevitable, and this is of course a major reason for the development of guidelines. In those states and countries where criteria for treatments have been drawn up—for example, Oregon in the USA, and New Zealand in the case of coronary artery bypass grafting—the experience has not been a happy one. In theory guidelines for expensive treatments ought to provide equitable access based on clinical need. This is what every government desires of the profession. In practice each patient presents a unique set of problems and many if not most do not conform to the agreed indications for the treatment, especially when they become emergencies. Where rationing is achieved by waiting, as in the UK, the apparently random distribution of scant resources is not demonstrably less unfair. Implementing guidelines in a country such as the UK where the provision of cardiac services lags far behind most developed countries is going to be hugely expensive. The cost of the NICE recommendations, for example, cannot be met by the purchasers of healthcare.

The side effects of treatment recommended by guidelines is the second reason for caution in their interpretation. On balance, thrombolysis in myocardial infarction and use of warfarin in atrial fibrillation save lives. But both may result in catastrophic bleeding. This is particularly sad for those who were previously active and asymptomatic and whose infarct or arrhythmia was not particularly symptomatic. The complications of treatment instituted on the active recommendation of a physician also engender more heart searching than those that occur naturally. While the physician is less often blamed for the sins of omission, he is nevertheless just as guilty if he fails to recommend a treatment which has been shown to confer benefit overall. Junior medical staff in particular must pay careful attention to the exclusion criteria.

The third problem with guidelines is that many patients receive a treatment in order that a few may benefit. Most trials demonstrating benefit in the treatment of cardiovascular conditions report an absolute reduction in major adverse events of a few per cent per annum, although the results are often reported as a relative reduction in order to amplify the potential gain in the public mind. We cannot yet identify which patients will benefit from which drugs and hence the victim of a heart attack will be recommended to take aspirin, a statin, a β blocker, and an angiotensin converting enzyme inhibitor, in addition to other drugs for diabetes, hypertension, etc. No wonder the cupboards of the elderly are full of pills.

The analogy has been drawn with anaemia; a randomised trial of the use of iron supplements in all cases of anaemia would demonstrate that a percentage would benefit. So all cases would be treated, until we learned to select those whose anaemia was caused by iron deficiency. In our current state of knowledge we are overtreating patients with cardiovascular disorders and are encouraged to do so by well intentioned guidelines. The general practitioner often bears the blame, and the cost, of this polypharmacy, and seldom challenges the advice of panels of experts. Cardiologists have the authority and the knowledge to provide intelligent interpretation of guidelines and should do so more often in order to reduce the drug burden in the elderly.

Physicians should remember and teach their junior staff that our job is to advise, not insist. Any decision about treatment should be discussed with the patient and his or her relatives, wherever possible. Interestingly many older patients decline the offer of anticoagulation for atrial fibrillation. The existence of guidelines, however, means that we must record

our discussion and the reasons for our decision. We should remember that many guidelines are available on the internet so that patients will be aware of what our peers have recommended. Guidelines then should inform the practice of cardiology and can never replace the individual advice to a patient, taking into account his or her particular circumstances. The authors of guidelines will be reassured to know that none has yet been held liable for harm resulting from the application of a recommendation, although this is a possibility and a disclaimer might be advisable.³

REGULATIONS

Regulations carry greater authority than guidelines, but lack the force of the law. Many are devised by organisations allied to government—for example, the Army. Others are imposed by institutions on their workforce in order to ensure safe practices. Regulations for the management of medical conditions are called protocols and have the same authority; they may be imposed by managers. Regulations are intended to provide written, reasoned, and prospective policies for employees. In many industries where the incapacity of an individual compromises the safety of others, regulations relating to cardiovascular fitness are imposed. Compliance with regulations is guaranteed when the perpetrator of the regulations is also the employer, or is acting on behalf of a group of employers such as the airlines. The Civil Aviation Authority has set fitness standards for pilots of commercial aircraft which are now agreed internationally by the Joint Aviation Authority. Therefore, throughout the world pilots who have or are suspected of having heart disease are subject to similar regulations.

Workers with heart disease are treated more fairly nowadays, although many employers still discriminate against those with heart disease, mainly because of the risk of sudden incapacity, and death. This risk can be assessed and if the risk is judged unacceptable then permanent sickness benefit may be available. In some industries, a diagnosis of heart disease with its perceived increased risk of incapacity makes employment unacceptable. Tanker drivers are one current example. Others include drivers of main line railway trains and seafarers in UK registered vessels, although this last group is undergoing reappraisal and in the near future may be permitted to return to sea subject to the precise nature of their responsibilities and heart condition.

What level of risk is acceptable for such workers? The answer depends on the industry in question. The cardiology advisors to the aviation industry were the first to develop the concept of acceptable risk. They proposed that the pilot could be likened to a part of the airframe. Engineers accept a risk of component failure of one per billion flying hours. Making a number of assumptions about the time the pilot spends in the air, and in particular during the critical phases of the flight—taking off and landing—then it can be calculated that this equates to an annual risk of incapacity of 1% per annum. A pilot may therefore be allowed to fly if his risk of a cardiovascular event is less than this. This happens to be the annual risk of a heart attack (myocardial infarction or sudden cardiac death) in healthy men aged 45–64 years based on data derived from the cardiovascular literature. Hence the 1% “rule” is tantamount to recommending that the pilot should continue at work provided he is at no increased risk as compared with his peers.⁷

Regulations governing drivers

Among the most widely used regulations in cardiological practice in the UK are those governing drivers with heart disease. They have been generally welcomed as striking a reasonable balance between the liberty of the individual and his or her potential to cause harm to others; hence they are widely used in other industries.

The regulations are drawn up by an honorary medical advisory panel currently comprising six cardiologists, one cardiac surgeon, representatives from the medical branch of the Drivers and Vehicle Licensing Authority (DVLA), the chief medical officer at the Department of Transport (currently linked with Local Government and Regions), and others. Following the Phillip's report into the BSE (bovine spongiform encephalopathy, or "mad cow disease") outbreak, government concern over the wisdom of the advice that it was receiving from expert scientific committees resulted in the recruitment of lay members to the medical panels—an initiative that was implemented in the cardiac panel in November 2001.

Other panels with similar constitutions and tasks are concerned with neurological disorders, diabetes, eyesight, psychiatric disorders, drugs, and alcohol. A panel's duty is to advise the secretary of state who formulates policy in conjunction with ministerial colleagues; DVLA is the agency responsible for implementing his policies. The UK is unusual in that the regulations do have their origin in law—the Road Traffic Act (1986). The relevant sentences for the cardiologist state that drivers must not suffer from "Sudden attacks of disabling giddiness or faintness", nor "Severe physical or mental handicap". The wording of both may be quaint but the intention of the first is clear and has been so since first promulgated in the 1930s.

Any driver who suffers from a disorder which might render him or her liable to such attacks is said to have a "prospective disability", and should stop driving until the risk has been assessed medically. Examples for the ordinary driver would include epilepsy, recent heart attack, or the implantable cardioverter-defibrillator.

The regulations governing drivers are the panel's interpretation of the law. Sudden incapacity, caused for example by a Stokes-Adams attack, obviously falls within the meaning of the Act and is a bar to driving. There are many more disorders in which the faintness is not so sudden or the mental handicap not so severe or merely transient. Neurocardiogenic syncope in the older driver, the onset of an arrhythmia, or severe cardiac pain are three common examples. The essential issue in each case is whether the disorder is sufficient to cause the driver to lose control of his or her vehicle. The term "cognitive distraction" nicely describes the effect that the disorder has on the driver and is the currently favoured wording. It is always a matter for individual judgment whether the prospective disability is sufficient to warrant suspension of driving. The regulations may on occasion be overridden if the cardiologist can show that there are very good reasons why that particular patient does not conform to the regulations formulated by the panel. One example might be a shortening of time off driving after a heart attack for someone who was at demonstrably low risk as compared with the average victim. In the event of an accident as a result of incapacity, however, the cardiologist would be required to defend his or her position.

The consequences of driver incapacity are much greater for vocational (group 2) drivers as compared with ordinary (group 1) drivers. The former include drivers of large goods and passenger carrying vehicles (LGV and PCV) and, in some traffic areas, others who drive for a living—for example, taxi drivers.

Taylor showed that the case fatality rates for accidents involving these vehicles, using the definitions in force at the time, were 3–4 times greater than those involving ordinary private motor cars.⁸ Vocational drivers also have longer occupational exposure. Hence more stringent criteria are justified.

Acceptable level of risk

In an ideal world the risk of driver incapacity would be subject to objective appraisal, using data from the medical literature, as in aviation. Medical advisors can then define the risk for an individual. Society—that is, politicians—can independently decide what level of risk is acceptable. The medical profession is then absolved from deciding about that level. But the world is far from ideal and the medical literature, while helpful for some conditions such as coronary heart disease, does not generally provide sufficiently accurate data for individual decisions. Hence medical advice does tend to be based on the distilled wisdom of groups of specialists. And in seeking to define an acceptable level of risk, this should obviously be comparable whether the prospective disability be cardiovascular or neurological. A major difficulty in providing an objective basis for assessing the risk of incapacity at the wheel from a cardiovascular cause is that the risk of incapacity does not necessarily equate with the cardiovascular event rate, as described in the literature. The classic cardiovascular end point, namely death, may be sudden in epidemiological terms, yet may allow time for the driver to pull over safely to the side of the road. Conversely neurocardiogenic syncope may be sudden and incapacitating, but is not an event that would appear as an end point in the cardiovascular literature. A reasonable assumption that has been made is that the cardiovascular mortality rate is similar to the incapacity rate. This is tantamount to suggesting that for every cardiac death on the road that does not cause incapacity there is another survivor of a cardiac event who was transiently incapacitated by a non-fatal arrhythmia or hypotensive episode.

Society already accepts that drivers in their late 70s may hold a vocational licence by which age their annual death rate from coronary disease exceeds 2%. This is very similar to the recurrence rate agreed for the epilepsy guidelines which are a risk of recurrence of 2% per annum or less for vocational (group 2) drivers. This is, however, double the risk accepted by the Civil Aviation Authority for commercial pilots. The latter, more stringent figure is justified on the basis of the greater consequences resulting from pilot incapacity. Also pilots are required to retire at the age of 65 years; therefore, regulations do not have to accommodate the elderly pilot. For ordinary drivers suffering from cardiovascular disorders a greater risk of incapacity is acceptable.

A figure of 20% annual risk of an event has been arrived at by consultation, and has been accepted by neurologists for those drivers who have had a seizure. This sort of event rate is rarely encountered in cardiovascular disorders, except in those who had continuing symptoms of heart failure or a major heart attack less than one month ago—in keeping with the current guidelines. There is again no irrefutable logic behind this figure, but society places no restrictions on a young man who has recently passed his driving test, and whose annual risk of an accident is of this order.

The level of acceptable risk for driver incapacity is thus an event rate at or below 20% per annum for ordinary licences and 2% for vocational licences. Vocational (group 2) drivers with coronary heart disease, for example, may thus resume

driving six weeks after a coronary event provided that they are asymptomatic and can satisfactorily complete three stages of the Bruce treadmill test. This test does contain useful prognostic information but it tells us nothing about the ulcerated atheromatous plaque which was the cause of the event. The cardiologist therefore has to ask himself supplementary questions such as whether the plaque has had time to heal, and is the patient taking aspirin, and also satisfy himself that the risk of further thrombosis is minimal. Often the patient's own cardiologist is not the right person to do this because he will tend to act as his patient's advocate. An independent opinion may be advisable.

Regulations change

The guidance material published in *At a glance medical aspects of fitness to drive* is the panel's interpretation of those disorders which constitute a prospective disability. They are inevitably imperfect and may lag behind clinical practice. Regulations that affect medical practice change, for three good reasons. Firstly, our knowledge of the disease process and understanding of the natural history gets better; secondly, new diagnostic tools are introduced; and thirdly, new treatments improve the prognosis. Examples of each include our recognition of the benign nature of some cases of hypertrophic cardiomyopathy, tilt testing for the investigation of syncope, and the demonstrable benefits of implantable cardioverter-defibrillators. Officially any change in guidelines is effective from the moment of the panel's decision. Informing the profession and public remains a problem which has been partly resolved by the introduction of the DVLA website (www.dvla.gov.uk). Regulations necessarily lag behind changes in clinical practice because the regulators have to have a sufficient body of evidence to demonstrate that a change, generally a relaxation, is justified. The implantable cardioverter-defibrillator is a good current example. Treatments delivered by the early devices were potentially incapacitating. This is no longer so likely. So recommended times off driving have shortened. But there remain longer term anxieties about lead malfunction so the recommendations remain cautious, much to the frustration of some cardiologists.

Individual cases may sometimes appear unfair and drivers may feel aggrieved at the loss of their licence, which in the case of some group 2 drivers may mean the loss of their livelihood. They do, however, have the right of appeal. If the licence is not restored then they can pursue their claim through the courts. This has not happened in cardiology in the past decade, which may indicate that regulations are seen to strike a correct balance between the rights of the individual and the safety of others. Some drivers ignore medical advice. In this situation the doctor should first make sure of his reasons for giving the advice. An example might be a driver with blackouts, thought to be caused by an arrhythmia. The doctor should repeat the advice and make careful notes. He or she may seek a second opinion, and consult a defence organisation. If the driver persists then the doctor should tell the patient in writing that he is informing the medical branch at DVLA, who can then take any necessary action. If the doctor does not do this and the driver causes an accident then the doctor shares the responsibility. The patient may lodge a complaint against the doctor but when this has happened hitherto the ombudsman has found in favour of the doctor.

Regulations, even the Queen's regulations, may be challenged in law. There are instances where well intentioned

regulations have contravened the more basic rights, relating to employment and discrimination, for example. This is a further reason why regulations have to change; in cardiology, however, the various sets of regulations governing the medical fitness of drivers, aircraft pilots, offshore workers, railwaymen, and many others in industry have not needed to be changed as a result of litigation—yet.

Cardiologists are also commonly asked to give advice about fitness to work. If the individual's job is subject to regulations, such as those outlined above, then clearly the cardiologist should acquaint himself with these. If not, then the cardiologist would still be well advised to obtain a job description and propose that the question of continuing employment should also be referred to an expert—that is, an occupational health physician. Cardiologists and cardiac surgeons who assert that their patient is now cured and can return to full employment are liable to end up in conflict with the employer's representatives and may find themselves and their patient disadvantaged.

THE LAW

General Medical Council (GMC)

This statutory body is responsible for ensuring that the standards of professional conduct are maintained. Disciplinary powers were conferred on the GMC by the Medical Act of 1858, which also established the register. A doctor's name may be struck off the register if he is found guilty of "serious professional misconduct". Long before that ultimate sanction, members of the profession are required to comply with the standards set by the GMC whose advice (protecting patients, guiding doctors) is contained in a series of publications and on their website (www.gmc-uk.org).

The booklets which are of particular relevance to the cardiologist include those on *Training* (1997), *Good medical practice and maintaining good medical practice* (1998), *Seeking patient's consent: the ethical considerations* (1998), *Management in health care: the role of doctors* (1999), *Confidentiality: protecting and providing information* (2000), and the *Annual review of the work of the GMC*. Additional publications which cover some of the same ground are available from the Royal Colleges and medical defence organisations. In all these publications practical advice on daily problems may be found. Some issues are necessarily devolved to others, such as clinical governance which is a function of the cardiologist's institution.

All cardiologists and trainees must be very aware of the duties and responsibilities of a doctor. Issues such as informed consent, confidentiality, death certification, living wills, etc, are generic and not specific to cardiology. For further reading the aforementioned texts are recommended. The issue of what constitutes informed consent has also been discussed recently in this journal.⁹ Cardiologists need to remember that truly informed consent can only be obtained by a doctor or a nurse who is fully familiar with the procedure and that nowadays any risk should be brought into the open; in practice a complication rate in excess of one in several hundred must be noted, as should the rarer but very important complications of cardiac catheterisation such as stroke. Although a patient's consent for clinical and non-invasive examinations is being discussed in some specialties, this is unlikely to be necessary in cardiology. A potential defence in the event of a complaint is that attendance for a predefined purpose implies consent.

Medical negligence

No cardiologist or indeed cardiac surgeon is above the law, and sooner or later a letter will arrive threatening legal action as a

result of a patient's perceived misfortune. Such is the climate in which we live. No longer is free healthcare a privilege. People have been led to believe that they have a right to perfect health and if this is not achieved then someone has to take the blame and compensate the victim.

Governments and guidelines encourage this attitude. Doctors, however, lack the resources to deliver ideal health care and currently take much of the blame. Inevitably we will all fail in our duty of care towards individual patients occasionally and in the UK there have been some recent notorious examples. The tide of dissatisfaction runs deep and is exemplified by the fact that in March 2000 the National Audit Office stated that 23 000 claims amounting to a total value of £2.6 billion were outstanding against the NHS.¹⁰ Settlements of a further £1.3 billion were expected for claims not yet received. In 1998 it was estimated that £84 million was spent on clinical negligence claims by hospitals in England although the confidence intervals were wide. The increasing cost of medical negligence may not be as alarming as the above figures suggest; after allowing for hospital activity the annual rate of increase for closed claims during the 1990s was 7%. Most claims are legally aided and of those only 17% are successful. The Medical Defence Union (MDU) experience indicates that only 1% of cases end up in court, 70% do not proceed or run out of time, and in 29% of cases some sort of settlement is reached. It is difficult to escape the conclusion that the unregulated granting of legal aid is currently propelling the tide of litigation and that other approaches such as mediation and/or no-fault compensation merit re-examination.

Data from the Physician Insurers Association of America and the MDU indicate that missed heart attacks are the third most expensive type of claim, after brain damaged babies and breast cancer. Of 349 claims analysed over 10 years, 160 were against general practitioners, 70% involved patients with no previous evidence of coronary heart disease, 47% were under 50 years of age, and 77% died; the average cost per case in the UK was £27 000. Invasive and interventional cardiologists are potentially liable to larger claims against them and this is reflected in their medical insurance premiums.

What can the cardiologist do to avoid litigation? The first rule is to keep good records. "No notes = no defence" is a well tested aphorism. The second is to maintain competence. History shows that this is best achieved by practising in an environment where audit, peer review, and related activities are the norm. The single handed or isolated practitioner is the most susceptible to error. In undertaking procedures the cardiologist or institution with low volumes is vulnerable, especially if these fall below the numbers recommended by advisory bodies such as the British Cardiac Society.

Publications by the GMC explain what to do when things go wrong which, in essence, boil down to a frank explanation to the patient and/or relatives in the first place. All NHS hospitals nowadays have a department devoted to the handling of complaints who must be informed as soon as possible. If the matter cannot be resolved locally, the complainant then has two options. The first is to go to an "independent review" in which senior staff from an unrelated hospital examine the allegations, interview those concerned, produce a report, and make recommendations. In the author's experience these are a rather cumbersome and time consuming method of giving the complainants a chance to express their grievances. This is often all that is required. Sometimes it is difficult to escape the conclusion that the complainants are motivated by a desire, not just for an apology and a wish to see that the mis-

take will not be repeated, but rather by a desire to humiliate senior medical staff. Some doctors find this difficult to accept but they should remind themselves that humility is a virtue.

Sadly the implementation of any recommendations—for example, faster access to coronary artery bypass surgery—may be frustrated by lack of resources.

The complainant's second option is take legal advice, and then action. Nowadays the first clue that such action is being contemplated is a request for release of the patient's notes. In order to succeed the complainant must first show that harm has been done—"but for the cardiologist's action I would be alright now". Death is generally indisputable. Chronic leg pain and immobility following a femoral haematoma are, however, more difficult to evaluate unless there are convincing neurological signs, which might persuade a judge. Secondly, the complainant has to show that the doctor "failed in his duty of care" and that his action or negligence caused harm (liability). In order to succeed a complainant does not have to prove a causal relationship beyond all reasonable doubt as in criminal law, but merely to show that it was "more likely than not" (causation). Thirdly, when it comes to a settlement, the complainant must be able to show that he has been disadvantaged by the harm and to what extent (quantum).

These steps in the process of litigation explain why so few cases proceed. Most cardiologists should have little to fear. But even the threat of litigation is a very unsettling experience. A few doctors find it difficult to carry on but, with help, most do, and most find that patients still have enormous confidence in the profession. The tide of litigation may ebb somewhat because complainants are now subject to closer scrutiny before being granted legal aid, and the register of solicitors permitted to undertake medicolegal work is diminishing the availability of the opportunistic solicitor.

In defending an action a doctor will rely on the Bolam test. This was a case in which the defence successfully argued that the doctor's actions were in keeping with a reasonable body of medical opinion, as follows: "In the realm of diagnosis and treatment, there is ample scope for genuine difference of opinion and one man clearly is not negligent merely because his conclusion differs from that of other professional men, nor because he has less skill or knowledge than others would have shown. The true test for establishing negligence in diagnosis or treatment on the part of a doctor is whether he has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty of acting with ordinary care".

This judgment has not been challenged for 45 years but there is a rider, as a result of a judgment handed down in the Bolitho case in 1997, since when it has also been necessary to demonstrate that the doctor's action would "stand up to analysis". It is thus not necessary to demonstrate that the cardiologist practised perfect medicine but simply that he acted rationally and logically according to a body of opinion among his peers.

The concept of the "non-negligent loser" should be familiar to all doctors. This is the case in which liability is not admitted but a financial settlement is negotiated with the complainant's representatives, because it is the cheapest option. No fault is admitted by the defendants and the doctor's professional status is unimpaired. Some doctors find this difficult to accept and want to fight on. The only gainers in that event are the lawyers.

Heart disease, guidelines, regulations, and the law: key points

- ▶ International (European) influences are playing an increasingly important role in the practice of cardiology
- ▶ Guidelines are intended to help practitioners and must be read with care; in specialist practice such as cardiology their application can be difficult
- ▶ Regulations and protocols are imposed by institutions; any violation must be supported by a very good reason
- ▶ Regulations that affect drivers are an interpretation of the law that states that you must not drive if you are liable to "sudden attacks of disabling giddiness or faintness"
- ▶ The GMC's booklets should be kept near to hand
- ▶ To establish that a cardiologist was medically negligent the plaintiff must prove causation and liability

Witnesses and experts

Solicitors approach doctors for assistance in two circumstances. The most common reason is for a factual statement relating to an involvement in a case. This should be prepared with professional help, should state who you are, be set out in short numbered paragraphs, should stick to the facts, and not offer an opinion.

Many cardiologists offer themselves as expert witnesses. The British Cardiac Society keeps a register. When this was set up in 1992 the legal and ethical committee was surprised that so many cardiologists wished to undertake this sort of work. The Society did not wish to impose restrictions on individuals who wished to provide expert opinions, but the committee did advise that cardiologists should not be over the age of 70 years and/or retired from active practice for more than five years.

Those who wish to provide a service as an expert will generally have been consultant cardiologists for 15 years or so because the courts and lawyers expect experts to have experience and standing. Expert witnesses must undergo further training, must acquaint themselves with the evolving literature on the subject, and should examine their motives. The profession is best served by those experts who are motivated by a desire to see justice done, rather than those whose interests are pecuniary. Serious experts will usually submit their names to the Law Society's register.

The duties of the expert lie beyond the scope of this article. The standard reference works^{11 12} should be consulted. The initial and often sole task of the expert is to prepare a medical report. This must be impartial. The ultimate responsibility of the expert witness is to the court. Medical reports which are biased and which encourage the complainant or defendant to believe that an action may succeed do a disservice and are unhelpful in the long run. It should be unnecessary to point out that an expert should only give an opinion which is within his field of expertise, and can only comment with authority on his peers—for example, a cardiologist should not pass comment on a general practitioner.

The reform of the civil procedure rules recommended by the report of Lord Woolf came into force in 1998.¹³ The aims are to improve access to justice, to speed up the process of litigation, and to reduce costs. Part 35 deals with experts and assessors; 35.1 describes the court's duty to restrict expert evidence; 35.4 describes its power to achieve this; and 35.7 describes its ability to instruct a single joint expert. This reform therefore reinforces need for impartiality in the preparation of expert reports.

Human Rights Act 1998

The impact that this legislation will have on the practice of cardiology is uncertain. The Act is likely to affect practice in several ways. A fundamental tenet is that humans have an absolute right to life. This may be at variance with sensible cardiological opinion—for example, a decision not to resuscitate. Consent to treatment protocols may have to be amplified. The allocation of scarce NHS resources may become subject to judicial review—for example, a patient who dies while awaiting coronary artery bypass grafting might be said to have been denied his basic right to life which he would have been afforded had he lived in another country.

The difficulty in predicting the effect of this Act is that English law has been built on precedents and piecemeal legislation, not the grand and sometimes internally inconsistent principles of the Act. We can only wait and see what view our judiciary will take when interpreting the Act in the light of our considerable body of case law.

Social security law

This is a little known but important aspect of legal practice. The law is mainly concerned with issues related to social security, but this includes accidents at work which may entitle the victim to compensation. These are not obviously matters for the cardiologist, but there is one important exception, namely an event that might have triggered a heart attack. This stems from a case in 1967 when unaccustomed strenuous work was judged to be such a trigger. Since then this judgment has usually been upheld, and compensation been granted, although there are continuing areas of uncertainty.¹⁴

Social security law has established precedents which find application in insurance medicine. Victims of heart disease commonly discuss the option of retirement on grounds of ill health, and indeed may be encouraged to do so by their medical advisers, and personnel manager. Most permanent sickness policies, however, state that an employee should be "wholly incapable of continuing their former employment" in order to claim benefit. This is a difficult argument for the cardiologist to sustain if, for example, the individual has made a full recovery following a coronary bypass procedure. These policies were originally devised to compensate victims of accidents at work, not those whose illness results from natural causes. Hence there are insufficient funds to meet all claims and each is scrutinised both at the time of application, and subsequently. Patients may find themselves financially disadvantaged if they retire on medical grounds without first checking the terms of their policy.

CONCLUSION

Despite the foregoing, cardiologists still have immense freedom to interpret guidelines, regulations, and the law provided that they always act in the best interests of their patients and record the reasons for their actions.

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