Chapter 16: Legal and ethical matters

R. Hinchcliffe

Broadly speaking, the function of law is to maintain a framework of security and order and to do justice. Ethics enables people to live freely within that security, going beyond justice to benevolence (Dunstan, 1986).

Legal aspects

As David and Brierley (1968) pointed out, each political society in the world has its own law. In fact, it frequently happens that several laws coexist within the same state. Moreover, law is not static; it is in a state of flux, of evolution. The development of the law is shaped by logic, history, custom and utility, as well as the accepted standards of right conduct (Cardozo, 1921). It is therefore not surprising that the contributions of outstanding jurists, for example Kelsen (Tur and Twining, 1986), should have ranged over the whole field of international relations, justice, law and logic.

In view of this dependence on political, cultural, and historical factors, the law relevant to audiology will vary from country to country. This chapter will be concerned primarily with English law. Technically, as David and Brierly point out, the area of application of English law is limited to England and Wales. English law is neither the law of the United Kingdom nor that of Great Britain because Northern Ireland, Scotland, the Channel Islands and the Isle of Man are not ruled by 'English law'. However, because of historical ties this English law has applicability in various degrees to countries other than England.

The many facets of this English law which have a bearing on otolaryngological practice and research (Hinchcliffe and Hinchcliffe, 1976) are also applicable to audiology. In this chapter, it will be appropriate to restate some of these principles and mention some changes which have taken place over the last decade.

**General considerations**

There are two sources of law, that is case law and statute (code) law.

**Case law**

British case law comprises two systems of law, that is common law and equity. Equity was a peculiar development of the Middle Ages which sought to modify the rigidity of the common law by proceeding on flexible principles of 'good conscience'. Common law comprises the ancient unwritten law of the country. It developed tentatively and casually, based upon the decisions of judges in preceding cases. The common law doctrine of abiding by precedent is known as *stare decisis* (short for *stare decisis et non quieta movere*). However, the only thing in a judge's decision binding as an authority upon a subsequent judge is the principle upon which the case was decided (*Osborne to Rowlett* 1880). This principle on which a case is decided is known as the *ratio decidendi*.
Dias (1970) contended that the rigidity of *stare decisis* is largely mythical and judges have considerable latitude in evading unwelcome authorities. In the first place, a judge may lower the level of generality of a precedent when stating its facts and, in so doing, distinguish one case from another. Thus judges have much discretion in the handling of precedent. Moreover, as Stuttard (1969) points out, there is no test which can be applied to show which part of a previous case constituted the *ratio decidendi*. Anything which is not part of the *ratio decidendi* and which is not part of the facts of a case is referred to as *obiter dicta* (things said by the way). Consequently, the common law has the capacity to develop and to progress. As Lord Evershed said, the ancient rules of the English common law have the characteristic that in general they can never be said to be final and limited by definition, but have the capacity of adaptation in accordance with the changing circumstances of succeeding ages (*Haley v London Electricity Board* 1965).

**Tort**

The law of torts was a creation of the common law and it was evolved from the principle of providing a remedy for an unjustifiable injury done by one person to another. A tort is a civil wrong. As pointed out by Lord Denning, the province of tort is to allocate responsibility for injurious conduct. In the context of this chapter, the three most important torts are nuisance, negligence, and trespass to person.

**Nuisance**

A nuisance has been defined as 'an inconvenience materially interfering with the ordinary comfort, physically, of human existence, not merely according to elegant or dainty modes of living, but according to plain and sober and simple notions among the English people' (*Walter v Selfe* 1851). A nuisance is thus an unlawful interference with a person's use or enjoyment of land, or of some right over or in connection with it.

**Negligence**

Negligence is a failure to provide against reasonably foreseeable hazards. Indeed the concept of foreseeability is an essential element in all cases of nuisance and of negligence (Privy Council in the *Wagon Mound* case (*Overseas Tankship (UK) Limited v Miller Steamship Co* 1967 - *Wagon Mound No 2*, so-called because it refers to the ship SS *Wagon Mound*)). However, as Munkman (1985) points out,

'negligence as the criterion of liability involves the further test of reasonable foreseeability, which has been shown up as vague, capricious and subjective when applied to anything more complex than bows and arrows, or horses and carts.'

Some learned judges are able to foresee very little; others, by taking a complex succession of events step by step, are able to foresee almost anything. Moreover, the same court can reach opposite results on two cases based on the same happening. In the *Wagon Mound* case, different plaintiffs took action on the same occurrence. The lower court in one case held that a particular event was not reasonably foreseeable, while, in the second case, another lower court held that the same event might have been foreseeable.
In British courts, the concept of foreseeability is usually interpreted in the sense given to it by Lord Oaksey in the case of *Bolton v Stone* 1951 (the plaintiff was injured by a cricket ball hit over a fence onto a road; it was held that the cricket club was not liable as the possibility of injury was so slight). The reasonable man does not take precautions against everything which he can foresee, but only against those things which he can foresee are reasonably likely to happen.

In an action for negligence, the plaintiff must prove that the defendant was under a duty of care to him, that there was a breach of such duty, and that, as a direct consequence, the plaintiff suffered damage. Thus, the essential prerequisites have been given as the four Ds: Duty of care, Dereliction of duty, Damage, and Directness.

In practice, there is usually no doubt about the existence of the duty of care and it is then assumed to exist. However, in the case of *Donoghue (or M'Alister) v Stevenson* 1932, Lord Atkin formulated the general concept that 'you must take reasonable care to avoid acts or omissions which you can reasonably foresee will be likely to injure your neighbour.' He then defined 'neighbours' as 'persons so closely and directly affected by my act that I ought reasonably to have them in contemplation when I am directing my mind to the acts or omissions which are called in question.' Thus there will be a 'duty' situation wherever the relationship of the parties is such that the likelihood that the plaintiff would be affected by the defendant's conduct ought reasonably to have been contemplated by the defendant.

Defences available in an action for negligence are, apart from denying the alleged negligence, that:

1. it was an inevitable accident (mishap)
2. the negligence was that of someone else
3. the risk was assumed by the plaintiff (*volenti non fit injuria*)
4. there was contributory negligence by the plaintiff.

It is a defence to an action in tort that the defendant neither intended to injure the plaintiff nor could have avoided doing so by the use of reasonable care.

Until 1945, *contributory negligence* was a complete defence to an action in tort. However, in that year, the Law Reform (Contributory Negligence) Act was enacted. Section 1 of that Act states that

'Where any person suffers damage as the result partly of his own fault and partly the fault of any other person, a claim in respect of that damage shall not be defeated by reason of the fault of the person suffering the damage, but the damages recoverable in respect thereof shall be reduced to such an extent as the court thinks just and equitable having regard to the claimant's share in the responsibility for the damage.'
In two decisions (*Parnell v Shields*, 1973 and *Salmon v Newland and others*, 1983) 20% was deducted from damages awarded as the result of road accidents in which the plaintiff was not wearing a seat belt.

Associated with the concept of contributory negligence is the doctrine of 'hypothetical causation'. A steel erector had died following a fall from a tower. Although on the day in question no safety belts were available, it was held, from the evidence given, that the deceased would not have worn one. The plaintiff’s act of omission may therefore constitute a *novus actus interventiens*.

**Trespass**

Trespass (see later) to the person is any direct, intentional interference with an individual without lawful justification. Trespass to person encompasses both *assault* (the threat or attempt to use force against another person) and *battery* (the actual application of force). Unlike the law of negligence, the plaintiff need not prove that the defendant was negligent or had a duty of care to him. He need only prove that the act was harmful to him. He must, however, establish an intention. Where the battery does not amount to a serious crime, a defence of *volenti* can be maintained, as in the law of negligence.

**Statute law**

Statute law is enacted by the legislature which, in Britain, is Parliament. The unprecedented development of legislation in the nineteenth century owed much to the concepts and reforming zeal of Bentham (1789) who has subsequently been considered as one of the greatest analytical jurists of all time (Friedmann, 1949). In his theory of legislation, Bentham defined the main function of law as being to provide subsistence, to aim at abundance, to encourage equality, and to maintain security. From these concepts there emerges the increasing social legislation which reached its peak in the middle of the twentieth century.

As Dias (1970) pointed out, there is now universal recognition that deliberate law making is indispensable to the efficient regulation of the modern state. The most important consequences of judicial acceptance of the supremacy of Parliament is the doctrine that no court can challenge the validity of an Act. As Ungoed-Thomas J said

'What the statute itself enacts cannot be unlawful, because what the statute says and provides is itself the law, and the highest form of law that is known in this country. It is the law which prevails over every other form of law' (*Cheney v Conn* 1968).

This contrasts with the position in some other countries where a higher court can declare statutes as 'unconstitutional' and therefore inoperative. However, with Britain joining the European Economic Community, the doctrine of unlimited supremacy of Parliament may have to be modified. This may well be the only legal safeguard for the possibility, envisaged by Dicey (1905), that Parliament could, if it wished, enact a law ordering all blue-eyed babies to be killed.
In respect of Acts of Parliament, the role of judges is limited to interpreting them. For this purpose, there are three rules, that is the literal rule, the golden rule, and the mischief rule. The *literal rule* states that the words in an Act are to be interpreted in their natural, ordinary, and plain meaning. Where such a literal interpretation would be absurd or ambiguous, the *golden rule* states that the statute should be interpreted such that it makes good sense. The *mischief rule* may also be applied to an otherwise ambiguous statute. This rule states that one should look to discover what 'mischief' an act was intended to remedy. It thus follows that decisions based upon an application of an Act and its interpretation by the courts are all important; the actual provision of the Act is less important.

Statute law may impose certain limitations on the common law. In particular, the Limitation Act 1939 stated that actions founded on tort shall not be brought after the expiration of a certain duration (six years) from the date on which the cause of action accrued. The Law Reform (Limitation of Actions) Act 1954 reduced this period to three years in connection with actions for damages for negligence, nuisance, or breach of statutory duty where personal injury was concerned. The time commences on the date on which the cause of action accrues. Thus, until 1963, an injustice might have arisen in a case where an injury was inflicted in a way that could become discoverable only after a lapse of time. Such a manner is, of course, characteristic of many occupational disorders, noise-induced hearing loss being an example *par excellence*. This injustice was removed by the Limitation Act 1963. This Act enables the plaintiff to bring a claim even though the three year limit is past, provided that he neither knew about the injury, nor ought to have known about it, and provided that he brings the claim within one year.

**Measures to protect against noise**

In the UK, the generation and the effects of noise are controlled both by common law and by statute.

That part of the common law known as tort deals with both the annoyance aspects of noise and the hearing-damaging aspect. The particular sections of the law of tort governing the annoyance and the damaging effect of noise are the law of nuisance and the law of negligence, respectively.

The Noise Abatement Society summarized the law on noise in its book on that theme in 1969. Although some time has passed since then, the law at that date is still relevant except for the fact that the 1960 Noise Abatement Act has been superseded by the Control of Pollution Act 1974. Part III deals with noise pollution.

It could appear from cases already decided under noise control Acts that statute law applies to noise and/or vibration made by mechanical processes. However, in the case of *Leeman v Montagu* 1936, the noise of cockerels crowing was held to be a common law nuisance.

The effectiveness of noise legislation in noise control has recently been summarized by the Noise Council (1986) in *Noise Legislation - its Effectiveness for Noise Control*. The
Noise Council was formed in 1986 to replace the Noise Advisory Council which fell foul of the British Government's 1981 quangicide campaign.

**Law relating to noise annoyance**

**Common law**

As Cusack (1969) has pointed out, English land law has for many centuries laid stress upon the entitlement of lawful occupiers to what is termed 'quiet enjoyment', meaning that they are to be protected against unjustifiable interference from outsiders. In modern times this ancient expression has been found to have a new and literal significance. Quiet enjoyment is increasingly menaced by intrusive noise.

That air-borne noise may constitute a nuisance was first established in 1867 in the case of *Crump v Lambert*. That structure-borne noise may constitute a nuisance was established in the case of *Hoare and Company v McAlpine* in 1923.

In *Vanderpant v Mayfair Hotel Co* 1930 it was made clear that intrusive noise need not be injurious to health. What matters is whether or not it interferes with ordinary comfort.

In contrast to the statute law on noise, it is no defence for the defendant to show that he has taken all reasonable steps and care to prevent the noise (*Rushmer v Polsue and Alfieri Limited* 1906). The judgment of Warrington in this case was expressly approved by the House of Lords on appeal. With respect to this case, Lord Loreburn stated that

'It would be no answer to say that the steam hammer is of the most modern improved pattern and is reasonably worked.'

This principle was upheld in the case of *Halsey v Esso Petroleum Company Limited* 1961. The plaintiff was granted both damages for loss caused by acid smuts from the defendant's depot and injunctions to restrain the making of noise at night and the emission of pungent smells at any time. The action was also of note because in evidence the plaintiff brought noise level measurements to court.

A landlord may be liable if he has authorized the creation of a nuisance expressly or by implication. This a landlord has been held liable for his tenant's blasting operations because he had let the property for that specific purpose (*Harris v James* 1876).

Gunfire, especially when malicious, can be a cause for nuisance. A fox farmer was granted an injunction restraining his neighbour from firing guns so as to frighten the foxes during the breeding season (*Hollywood Silver Fox Farm v Emmett* 1936).

As mentioned previously, the case of *Hoare and Company v McAlpine* 1923 established that structure-borne sound (vibration) may constitute a nuisance. Another case was in connection with pile-driving operations which set up vibrations that damaged the plaintiff's buildings (*Barette v Franki Compressed Pile Co of Canada* 1955).
Noises other than those due to gunfire or machinery can also constitute a nuisance. In the case of *Tinkler v Aylesbury Dairy Co Limited* 1888, it was held that noise resulting from moving milk churns when being loaded interfered with the personal comfort of the nearby residents and thereby constituted a common-law nuisance. Noise from carts and shouts from their drivers during the night, so that they made the plaintiff unable to sleep, also constituted a common-law nuisance (*Bartlett v Marshall* 1896). As mentioned previously, noisy animals can constitute a common-law nuisance. As well as the case of *Leeman v Montagu* 1936, there was, more recently, the case of *Harrison v Metropolitan Police* 1972. In the latter case, the plaintiff obtained an injunction with respect to howling and barking of dogs kept in a police station compound. These noises had disturbed his sleep and made it difficult for him to work in his study even when he wore earplugs and had installed both double glazing in the bedroom and internal shutters.

Malice may be a factor in an action for noise nuisance. In the case of *Christie v Davey* 1893, a music teacher was granted an injunction restraining a neighbour from knocking on the party wall and otherwise creating a noise to interfere with professional teaching.

However, temporary noise, for example that due to the demolition of a building, may not, if the operation is reasonably conducted and all proper reasonable steps taken to ensure that no undue inconvenience is caused to neighbours, form a basis for a successful action for nuisance at common law (*Andreae v Selfridge* 1938). Nevertheless, a teacher in New Zealand was successful in claiming damages in the New Zealand Supreme Court because nearby construction noise forced him to shout and this caused him to develop a tumour on the vocal folds (News Item, 1969).

At common law, prescriptive right is a defence in an action for nuisance. This arises after 20 years. However, the time begins only when the act in fact becomes a nuisance. Thus it was held that the defendant had no prescriptive right in a case where he had used the machinery for more than 20 years but the vibrations caused by it became a nuisance only when the plaintiff, a physician, put up a consulting room at the end of his garden near the noise (*Sturges v Bridgman* 1879). This decision thus also upheld the principle, established in the case of *Bliss v Hall* 1838, that it is no defence to show that the plaintiff came to the nuisance.

**Statute law**

Prior to the Noise Abatement Act 1960, noise control was vested in local authorities under provisions set out in, and effected principally by, bye-laws made under the Local Government Act 1933.

The Noise Abatement Act 1960 has now been superseded by the Control of Pollution Act 1974. Part III of the Act deals with noise. The first section (s. 57) of this part imposes a duty on every local authority to periodically inspect its area to detect noise nuisances and to establish noise-abatement zones.

Where a local authority is satisfied that noise amounting to a nuisance exists, or is likely to occur or recur, s. 58 requires the authority to serve a notice requiring the abatement
of the nuisance or prohibiting or restricting its occurrence or recurrence. The notice must specify the time, or times within which the requirements of the noise are to be complied with. Under s. 58(5) it shall be a defence to prove that the best practical means have been used for preventing, or for counteracting the effects of, the noise. Section 72(2) defines 'practicable' as 'reasonably practicable having regard among other things to local conditions and circumstances, to the current state of technical knowledge and to the financial implications'.

Section 59(1) says that a magistrates' court may act under this section on a complaint made by the occupier of any premises if he is aggrieved by noise amounting to a nuisance.

Sections 60 and 61 effect control of noise on construction sites. In connection with intended work, s. 60(2) enables the appropriate authority to serve a notice specifying the plant or machinery that is, or is not, to be used, specify the hours during which the work may be conducted and specify the level of noise which may be generated.

Section 62 governs noise in the streets. A loudspeaker may not be operated for any purpose between 2100 hours and 0800 hours, and for commercial advertising at any time.

Section 63 provides for the establishment of noise abatement zones. Section 64 requires local authorities to keep a noise level register. This records noise level measurements made of noise emanating from premises within such a zone. Section 66 provides for a 'noise reduction notice' to be served on persons responsible for exceeding permitted levels within the zone.

Section 68 provides for the fitting of silencers to machinery.

Section 73(1) says, among other things, that 'noise' includes vibration.

Section 74 provides a maximum penalty of £200 for first offenses and £400 for subsequent offenses, together with a fine of £50 for each day that the offence continues after the conviction.

There are also a number of other anti-noise provisions embodied in miscellaneous Acts. Section 28 of the Town Police Clauses Act 1847 prohibits the wantonly disturbing of residents by knocking on the door or ringing the door bell. Section 55 of the Metropolitan Police Act 1839 provides that

'no person other than persons acting in obedience to lawful authority shall discharge any cannon or other firearm of greater calibre than a common fowling piece within three hundred yards, or any dwelling house...'.

Section 1 of the Metropolitan Police Act 1864 provides that:

'any householders with the Metropolitan Police District, personally or by his servant, or by any police constable, may require any street musician or street singer to depart from the neighbourhood of the house of such householder on account of the illness of on account of the interruption of the ordinary occupation or pursuits of any inmate of such house, or for other reasonable or sufficient cause; and every person, who shall sound or play upon any
musical instrument or shall sign in any thoroughfare of public place near any such house, after being so required to depart, shall be liable to a penalty not more than forty shillings...'.

**Law relating to noise-induced hearing loss**

Occupational noise-induced hearing loss is covered by both the common law and the statute law. There are broadly two aspects of statute law which relate to the topic under discussion; that is occupational hygiene provisions (specifically, the 1961 Factories Act and the 1974 Health and Safety at Work Act) and social security provisions (specifically, the 1975 Social Security Act, under which noise-induced hearing loss is a prescribed occupational disease).

In 1974, noise-induced hearing loss became a prescribed disease under the 1965 National Insurance (Industrial Injuries) Act (the Social Security Act's predecessor).

In a 1978 judgment (*McIntyre v Doulton*), the judge said after referring to a Scottish case:

'I hold, therefore, that s. 29 (of the Factories Act) does cover the dangers created in a place of work by excessive noise.'

The same opinion was expressed by the judge in *Kellett v British Rail Engineering Ltd* 1984, although the judge in *McGuiness v Kirkstall Forge* 1978 and the judge in *Thompson and others v Smiths Ship Repairers* 1984 did not find, on the facts in those cases, any breach of the statutory duty.

Claims that defective hearing is attributable to an employer's negligence (blameworthiness) are therefore usually based on the dual claim that:

1. the employer is in breach of a common law duty
2. he is in breach of a statutory (s. 29 of the Factories Act) duty.

Consequently, individuals may claim compensation for damage to their hearing by actions for negligence as well as under social security legislation. (Under social security legislation, that is state insurance, the need to prove negligence or other default is removed.) In addition there are a number of compensation schemes for out-of-court settlements. These schemes are based on agreements between insurers and trade unions. Such agreements are, of course, governed by contract law. (Contract law is essentially the law relating to agreements. Together with the law of tort (under which the law of negligence comes), contract law broadly covers the law of rights and obligations. Apart from drawing on common law, contract law also draws on equity and statute law.)

The rules under which individuals may claim compensation for occupational or other damage to hearing will therefore depend upon which approach is being made. These differences also encompass differences in the nature and extent of the medical examination, although this is not often appreciated. Under the social security legislation, conditions are more circumscribed. There is therefore not much latitude for differences in medical
examination procedure in respect of DHSS (Department of Health and Social Security) claims. Moreover, under union/insurers agreements, the standard of proof required is fixed by agreements between the parties.

A more general approach to the problem of compensation has recently been presented by Stapleton (1986). She argues that there are serious distortions underlying the modern debate on compensation for personal injuries because it focuses on the victims of traumatic accidents. Alternative forms of support for the disabled are suggested. It is to be noted that Lord Devlin has said, in respect of compensation for loss of amenity:

'Limbs and faculties cannot be turned into cash as property can. If it were not that the objective element has already been given a place in the assessment by authorities, I should question whether it should be there at all. I think that deprivation should be measured mainly if not wholly by the sense of loss' (H. West and Son Ltd and Another v Shephard 1963).

**Measures to protect against unwanted effects of drugs**

The law of negligence affords some protection for a patient against the adverse effects of therapeutic substances or procedures. The doctor, the hospital, or the pharmaceutical manufacturer could be liable. Injury sustained as a result of being given a drug could be considered an aspect of product liability. Decisions in a given case would be based on *Donoghue v Stevenson* 1932 which has been referred to earlier. The plaintiff in that case had drunk ginger beer from an opaque bottle which was subsequently found to contain a decomposed snail. The plaintiff, who became ill, was unable to sue under the law of contract because another person had purchased the bottle. The law of contract may also not be applicable for other reasons. For example, in *Phizer v Ministry of Health* 1965, the House of Lords ruled that the supply of drugs under the NHS scheme was not a contract, even when a prescription charge had been levied. The patient has a statutory right to demand the drug; the hospital has the statutory obligation to supply it.

The case of *Watson v Buckley* 1940 showed that a plaintiff may sue (successfully) the distributors of an unsafe pharmaceutical product, in that case a hair dye.

Much of the legal interest in the adverse effect of drugs centers on thalidomide, alpha-(N-phthalimido)glutaramide. This was a psychotropic drug which was discovered in 1954, first marketed in West Germany in 1956 and in the UK in 1958. An ataxic polynueuritis was soon observed as an adverse effect. Widemann (1961) reported congenital abnormalities in cases where the mothers had taken the drug in the early stages of pregnancy. In the same year, the drug was withdrawn from the market. During the 5-year period that it was on the market, thalidomide probably produced 10 000 defective children, about 400 in the UK. The congenital abnormality was characterized by phocomelia, microtia and frequently, defective hearing. Legal proceedings began in 1962 but the case was never fully litigated. Instead, there were a series of settlements, beginning in 1968 and ending 10 years later (News Item, 1978). Nevertheless, as Teff and Munroe (1976) point out, the thalidomide catastrophe has had many repercussions and a profound influence on the law. It provoked an extensive assessment by the Law Commission on the Problem of Liability for Antenatal Injury. This culminated in the Report on Injuries to Unborn Children 1974. Based upon the Law Commission's recommendations, the Congenital Disabilities (Civil Liability) Act 1976 provided for the
unborn child to sue for negligence. At the time of the thalidomide catastrophe, doubts were expressed as to whether or not a right of action existed with regard to antenatal injury. This was exemplified by a decision in 1884 in the USA in which it was held that a child was part of its mother and had no independent legal personality (*Dietrich v Northampton* 1884). However, a British judge involved in the thalidomide settlements held that the mother had a right of action and was entitled to damages for 'grievous shock at seeing her child born deformed'.

The likelihood of thalidomide claim to have succeeded also hinged, as it does in occupational noise-induced hearing loss cases, on the general state of medical and scientific knowledge at the time in question. The time in question was between 1956 and 1958 when the drug was being developed. The likelihood of success of a claim would also hinge on whether or not the pharmaceutical company could be held to have discharged their duty of care. At the time in question, teratogenicity tests were not part of standard screening procedures for new drugs. Risks which ought reasonably to have been known must be interpreted in the light of medical knowledge and experience prevailing at the time (*Roe v Ministry of Health* 1954).

As Teff and Munroe pointed out, public reaction to the thalidomide tragedy created an atmosphere in which both the medical profession and the pharmaceutical industry were prepared to accept controls. The result was the Medicines Act 1968. This Act provided for the legal control of various aspects of the advertising, manufacture, labelling, distribution, and use of medicines.

The 1968 Act also provided for the establishment of the Medicines Commission. Licences for new products. Certificates to subject these to clinical trials must be obtained from the Commission's Committee on Safety of Medicines. The Committee also monitors adverse reactions to drugs already in use. As a result the hazards of practolol, 4-(2-hydroxy-3-isopropylamino-propoxy)acetanilide, were detected and their frequency assessed. The drug, which is a beta-adrenergic blocker, was used for the treatment of angina pectoris, cardiac dysrhythmias, and hypertension. It produces an oculomucocutaneous disorder (Felix, I. and Dahl, 1974), which is sometimes associated with tinnitus and/or impairment of hearing (Wright, 1975). The hearing disorder may be conductive or sensorineural. Various audiometric patterns occur, including one that is similar to that of noise-induced hearing loss (McNab Jones et al, 1977).

Having discussed the present British position on product liability in respect of drugs, Diamond and Laurence (1985) concluded that a no-fault scheme for drug-induced injury is desirable, workable and need not cost so much as to render serious discussion on implementation a waste of time. Such a scheme would obviate unsuccessful plaintiffs being encumbered by crippling financial costs. For example, the plaintiff in *Vernon v Bloomsbury Health Authority* 1986 will have to sell the family home to pay not only her own lawyer's bills but also the defendants' costs, which have been awarded against her. This case and other cases of alleged negligence in relationship to ototoxic drugs are discussed later.
Measures to protect against health services and their personnel

Common law

Negligence

Health services and their personnel are liable for acts of negligence. In the Court of Appeal, Lord Denning has said that the hospital authorities are responsible for all of their staff (*Roe v Ministry of Health* 1954). However, a clinician is not liable because some other doctor might have shown greater skill and knowledge. In actions for negligence in respect of medical practice, the law is applied almost entirely on the expert evidence of medical witnesses - evidence from competent practitioners that, in the same circumstances, they would have done, or would not have done, what the defendant did.

It is normal for the plaintiff to establish that the defendant's negligence had caused him injury. However, the onus is on the defendant if the principle of *res ipsa loquitur* (things speak for themselves) operates. For example, a patient went into hospital with two stiff fingers (due to Dupuytren's contracture) and came out with four. In reversing the decision of the trial court, Lord Denning held it to be a case of *res ipsa loquitur* (*Cassidy v Minister of Health* 1951). Two conditions are required before this doctrine will apply. First, the even which caused the damage must have rested within the control of the defendant. Secondly, the mere occurrence of the event itself implies that the defendant has been negligent. One would also presume that this doctrine would be applied to cases of permanent complete facial palsy following a stapedectomy. Recently, a plaintiff underwent this operation and the stapes was replaced with a politef piston. The only unusual feature encountered at operation was a greater than usual amount of posterior meatal wall which had to be drilled before the stapes and foramen ovale were exposed. The patient developed a complete ipsilateral facial palsy 48 hours after the operation. A subsequent exploration showed that the facial nerve had been damaged in the horizontal portion of a facial nerve canal, at which site there was a dehiscence. The claim for damages was settled for £10 000 (*Annual Report and Accounts, 1978*).

In respect of the directness of the causation, actions for medical negligence may allow for a 'chain of causation'. Thus failure in the treatment of the infected finger of a pregnant woman was held to be the cause of a voice disorder. The chain of causation here was via a septicaemia and subsequent damage to the cranial nerves.

*Mishaps, mistakes and negligence*

In respect of medical practice, Lord Denning has said that a doctor was not to be held to be negligent simply because something went wrong. He was liable only when he fell below the standard of care of a reasonably competent practitioner in his field so much that his conduct might be deserving of censure or be inexcusable (*Cole v Hucks* 1968). However, this holds only when the mishap cannot be avoided by any such precaution as a reasonable man may be expected to take. Risks are inherent in most medical and surgical procedures but a practitioner must not take 'an unwarranted and unnecessary risk'. The 'broken needle' cases best illustrate the law relating to medical mishaps. When the needle of a hypodermic syringe breaks off during a diagnostic or therapeutic procedure, the plaintiff must produce evidence
of negligence as such. The evidence may be that the needle was not the appropriate one for the particular injection or that it was inserted wrongly.

Mistakes must be differentiated from mishaps. As a general rule in the law of torts, a mistake is no defence. However, the law has taken a different view in respect of medical mistakes. A mistake in diagnosis has been construed as an 'error of judgement'.

Thus, in an action for damages brought by a widow in respect of the misdiagnosis of her late husband's chest pain, the judge rules that the case was one of mistake and not of negligence because the doctor had examined the case carefully for an hour. However, failing to make a correct diagnosis must be differentiated from failure to examine a patient adequately. The latter may amount to negligence. Failure to use a stethoscope in a casualty department to diagnose fractured ribs in an intoxicated injured patient has been held to be negligent. Failure to request a radiological examination in possible bony disorders or injuries would probably be held to be negligent. But, surprisingly, failure to employ an endoscope which would have diagnosed a rare condition may not amount to negligence. If a doctor does not feel competent to diagnose a particular case, he may be held negligent for failing to refer the case to the appropriate specialist. Although, in cases concerning surgical treatment, the question of negligence hinges on what other competent practitioners would, or would not, have done, so often the principle of *res ipsa loquitur* (see above) is applied. This principle would hold where the wrong operation was performed or the wrong side was operated on. Lord Goddard held that the principle applied in 'swab cases' also (*Mahon v Osborn* 1939).

In a Court of Appeal decision, Lord Denning said that:

>'if medical men were to be found liable whenever they did not effect a cure - or whenever anything untoward happens - it would be a great disservice not only to the profession itself but to society at large. Heed should be taken of what had happened in the United States. There "medical malpractice" cases were very worrying, especially as they were tried by juries who had sympathy for the patient and none for the doctor - who was insured - and damages were colossal. Experienced practitioners refused to treat patients for fear of being accused of negligence. In the interest of all we must avoid such consequences. The courts must say firmly that, in a professional man, an error of judgment was not negligent (*Whitehouse v Jordan and Another* 1979).

However, the case went to the House of Lords where disagreement was expressed with this statement. Their Lordships nevertheless upheld the Court of Appeal's decision in reversing the trial judge's finding. In concurring with Lord Wilberforce, Lord Fraser stated that Lord Denning must have meant to say that an error of judgment 'is not necessarily negligent'. Another Law Lord, Lord Edmund-Davies, concluded by saying:

>'doctors and surgeons fell into no special legal category, and, to avoid any future disputation of a similar kind, his Lordship would have it accepted that the true doctrine was enunciated - and by no means for the first time - by Mr Justice McNair in *Bolam v Friern Hospital Management Committee* 1957. In words applied by the Privy Council in *Chin Keow v Government of Malaysia* 1967: "When you get a situation which involves the use of some special skill or competence, then the test as to whether there has been negligence or not is not
the test of the man on the top of a Clapham omnibus, because he has not got this special
skill. The test is the standard of the ordinary skilled man exercising and professing that
special skill". If a surgeon failed to measure up to that standard in any respect ("clinical
judgment" or otherwise) he had been negligent and should be so judged (Whitehouse v Jordan
and Another 1980).

There have been conflicting interpretations of the judgment in a more recent case
(Wilsher v Essex Area Health Authority 1986) which went to the Court of Appeal. Finch
(1986) points out that the headline of The Times Law Report on this case ‘Doctors
Inexperience no Defence to Negligence' is not supported by the full original transcript of the
judgment. An inexperienced senior house officer was acquitted of negligence by al three
Court of Appeal judges. However, the decision significantly qualified the ability of
inexperienced doctors. Finch argued that it is misinterpretations such as these that give rise
to medical misconceptions of legal responsibility. These have two results. First, defensive
medicine is practised. This is not 'defensiveness', it is defensivism, which is the enemy both
of doctors and of patients. Secondly, a cry goes up for a new type of compensation
independent of the need to prove fault. But such a system, as in New Zealand, has its defects.

Havard (1986) draws our attention to the views expressed by the dissenting judge (the
Vice-Chancellor) in the above case:

'Should the authority be liable if it demonstrated that due to the financial stringency
under which it operated it could not afford to fill the post with those with the necessary
experience? However, the law should not be distorted by making findings of personal fault
against individual doctors who were, in truth, not at fault, in order to avoid such questions
... the courts would not do society a favour by distorting the existing law so as to conceal the
real social questions which arise.'

Nevertheless, because of the increase in litigation, there is an increasing tendency to
practise defensive medicine. However, as Havard has pointed out, it is a criminal offence
under the penal code of most European countries outside the UK to fail to render assistance
in an emergency. Since 1983 in the State of New York, it has been an offence punishable by
a $1000 fine and a year in jail for any doctor or nurse to refuse emergency care when
requested.

There is now a mounting number of negligence cases of audiological interest. Of
particular concern are those associated with clearing the ear of cerumen and the use of
ototoxic drugs.

Cases involving ear syringing

A perforated ear drum following aural syringing in a 50-year-old man resulted in
otorrhoea which, in turn, resulted in inability to go swimming or take a shower, resulting in
an expensive holiday to the Canary Islands being ruined. The doctor who syringed the ear
recorded that 'unfortunately, the nozzle of the syringe slipped during the procedure and the
external auditory canal was lacerated'. The case was settled out of court for £4222. This sum
covered a 'profound sensorineural hearing loss' on the affected side as well as surgical fees
In another case of a perforated ear drum following syringing, the plaintiff was reported to have suffered a 'permanent 40-dB hearing loss and tinnitus' (James v SKF (UK) 1977).

In a third case of ear-drum perforation following syringing, subsequent treatment (repeated myringoplasties) by a consultant was considered to have made things worse rather than better.

'There was a 50 per cent hearing loss in the affected ear with vestibular function significantly diminished.'

The claim was settled after negotiation by payment of damages of £8000 and costs of £810 (Annual Report and Accounts, 1979).

However, not all claims in respect of ear-drum perforations due to syringing have been successful. An 18-year-old youth attended for a medical examination at a recruiting centre. Impacted wax in both ears required syringing. The youth denied any previous ear trouble. Syringing was successful in clearing the wax from one ear but

'the third and last effort to eliminate the wax from the other ear proved so painful that the doctor desisted, instilled more oil into the ear and told the young man to return a week later ... the boy reported at the examination centre a week later with a piece of lint over his ear on which there was some brownish-yellow discharge ... He had had some bleeding from the ear during the evening of the day when it had been syringed ... On examination, the ear was found to be cleared of debris and there was a small perforation in the tympanum.'

'The papers were submitted to two experienced otologists, both of whom were of the opinion that it is impossible to perforate a healthy ear drum by syringing.'

In view of this evidence, the judge gave a judgment for the doctor with costs (Taylor, 1971).

Cases involving ototoxicity

An Australian case mentioned by Lockhart (1980) is cited as an example of the duty of a doctor to use competent assistants. The plaintiff, who had been surfing, attended hospital complaining of 'a thundering noise in the ear'. After examination of the plaintiff's ear in the casualty department, a resident doctor asked a student nurse to provide the plaintiff with some glycerol and phenol ear drops. The nurse misunderstood and the plaintiff was given what was essentially pure phenol. As a result 'a part of his ear drum was destroyed, and his hearing was permanently impaired'. The judge said that:

'the real cause of the error was the giving of instructions in terms which were not as specific as they should have been to a pupil nurse who was not competent to take them. The doctor should not have given her instructions, or he should, before giving her the instructions, have satisfied himself that she was competent to take them and knew what was intended' (Henson v The Board of Management of the Perth Hospital and Another 1938).
A woman who had been admitted to hospital suffering from boils was prescribed a course of streptomycin. The day after the last injection, symptoms of damage to the vestibulocochlear nerve developed and the plaintiff was left with the loss of her sense of balance. The claim for negligence was based upon the fact that a total of 30 injections had been ordered by the house surgeon but 34 injections had been given. The judge considered that it was the last injection which had caused the damage. The defendants were therefore liable (Smith v Brighton and Lewes Hospital Management Committee 1958).

Another woman, after a holiday in Taiwan and in Australia, developed, first, a middle ear infection and then a subacute bacterially negative endocarditis. She was prescribed a 19-day course of benzylpenicillin in conjunction with gentamicin. Almost immediately after the end of the treatment she had symptoms of vestibular labyrinthine damage. The plaintiff's case was that there had been no monitoring of gentamicin blood levels in the last week of the treatment. However, the judge accepted the views of the expert witnesses called on behalf of the defendants. They gave evidence that the effect that the defendants' doctors treated the patient in a manner which conformed to a proper standard of medical treatment. Consequently, the defendants' doctors could not be held to be negligent (Vernon v Bloomsbury Health Authority 1986). Having regard to the judgment in the previous case, one wonders whether another judge at another time in another place would have come to the same decision. Unfortunately, the plaintiff cannot afford to go to the Court of Appeal.

**New medical or surgical procedures**

The institution of an experimental therapeutic procedure can be particularly hazardous - legally for the doctor as well as medically for the patient. The law governing the institution of new (experimental) treatments of patients was established over 200 years ago (Slater v Baker and Stapleton 1767). In that case, the plaintiff sued the then Head Surgeon (Mr Baker) of St Bartholomew's Hospital. Mr Baker had refractured the plaintiff's healed leg so that it could go through the 'operation of extension using a heavy steel invention with fearsome teeth'. On appeal, the Chief Baron held that:

'although the Defendants in general may be as skilful in their respective professions as any two gentlemen in England, yet the Court cannot help saying that, in this particular case, they have acted ignorantly and unskillfully contrary to the known rules and usage of surgeons.'

The law applicable to actions for negligence in respect of a new therapeutic procedure was systematized in a Scottish case (Hunter v Hanley) by Lord President Clyde in 1955. Three facts must be established. First, that there does exist a normal, usual practice. Secondly, that the defendant had not adopted that practice. Thirdly, that the course of management adopted was one that no professional of ordinary skill would have taken if he/she had been acting with ordinary care.

A defence of *volenti non fit injuria* in medical cases of actions for negligence can only be made if consent - informed consent - has been freely given. Any medical or surgical procedure, including the simplest diagnostic examination which is conducted without the patient's consent (expressed or implied) is a trespass to person (see later). For minor
diagnostic and therapeutic procedures, consent is usually implied. It is argued that, when a patient presents to a doctor seeking treatment, he/she has clearly implied consent to a physical examination and, at least, some minor therapeutic procedure. Sitting down in the examination chair or lying down on a couch may be taken as tacit consent. If an emergency operation is necessary to save a patient's life and consent cannot be obtained, the principle of 'agency of necessity' is invoked.

In a recent claim for damages arising out of an unsuccessful stapedectomy, the plaintiff claimed that he had not carefully read the consent form and was under the impression that it signified authority only for a general anaesthetic and an examination. The plaintiff was employed as a claims manager by an insurance company where careful scrutiny of forms and their small print is all important. Not surprisingly, therefore, the judge completely rejected the plaintiff's evidence.

In some experimental therapeutic procedures, actions for negligence have hinged, not on whether or not an unusual course of action was adopted, but on whether or not informed consent had been really given. In a case where a facial paralysis developed after an operation involving the insertion of an electronic device in the para-aural tissues to treat deafness, the judge held that there was inadequate warning of all the risks involved.

However, in non-experimental therapeutic procedures, the courts will admit to the necessity for 'therapeutic misrepresentation'. In an action for negligence arising from damage to the recurrent laryngeal nerve during a thyroidectomy, the trial judge said:

'on the evening before the operation, the surgeon told the plaintiff that there was no risk to her voice, when he knew that there was some slight risk, but he did that for her own good because it was of vital importance that she would not worry. He told a lie, but he did it because in the circumstances it was justifiable. The law does not condemn the doctor when he only does what a wise doctor so placed would do' (Hatcher v Black 1954).

Similarly, a surgeon advising a patient on the risks of undergoing a major operation was under a duty to inform the patient according to the practice adopted by substantial body of medical practitioners competent in a particular field, but not under an absolute duty of full disclosure (Hills v Potter and Another 1983). The case concerned a woman who underwent an operation to relieve torticollis. Subsequent to the operation she was paralysed from the neck downwards.

The Medical Protection Society offers the following recommendations to doctors for a successful defence in negligence cases:

(1) keep clear and accurate records

(2) report early to the Society any incident which might give rise to a possible claim, setting out full details of the incident while it is fresh in the memory and giving the names and addresses of anyone who witnessed the incident
(3) seek the advice of the Society before replying to a letter of complaint which might lead to an allegation of negligence or breach of terms of service or an accusation of professional misconduct

(4) reply promptly to letters from the Society or its solicitors requesting comments or instructions

(5) keep the Society informed of any change of address, so that letters do not go astray. If a principal witness goes overseas without leaving a forwarding address and cannot be traced when a trial is imminent, the defence is embarrassed (Annual Reports and Accounts, 1978).

**Trespass**

It is not a battery to make a medical examination of a patient who consents to it. But a battery does take place if a person is examined against his/her own will (*Latter v Braddell and Sutcliffe 1881*). However, Lord Justice Winn's Committee on Personal Injuries Litigation concluded (Cmd 3691, 1968, para 312) that it:

'entertained no doubt that every claimant for personal injuries must be bound to submit himself to medical examination of a reasonable character which is reasonably required, subject, of course, to proper safeguards and to the claimant's right to object to any particular doctor'.

Nevertheless, Mr Justice Lawson condemned the procedure whereby a person could be compelled to submit to a medical examination by indirectly staying proceedings as not being conducive to respect for the administration of justice (*Baugh v Delta Walter Fittings 1971*). Mr Justice Lawson pointed out that a requirement to submit to a medical examination could be justified only where Parliament had specifically authorized it. Compulsory medical examinations are required by various statutes, for example of school children under the Education Act 1944. Even then, the examination can only be done after the requisite notice has been served on the parent.

The Court of Appeal has held that:

'if a defendant in a personal injuries case made a reasonable request for the Plaintiff to be medically examined by a doctor whom the Defendant had chosen then the Plaintiff should accede to such a request unless he had reasonable ground for objecting to that particular doctor and was prepared to disclose his reason to the Court' (*Starr v National Coal Board 1977*).

In giving judgment in this case, Scarman said that:

'the Defendant is not to be regarded as making an unreasonable request merely because he wishes to have the Plaintiff examined by a doctor unacceptable to the Plaintiff ... it can only be the interest of justice that could require one or other of the parties to have to accept an infringement of a fundamental human right cherished by the common law. The Plaintiff can only be compelled, albeit indirectly, to an infringement of his personal liberty if justice
requires it. Similarly, the Defendant can only be compelled to forego the Expert Witness of his choice if justice require it.'

A particular forensic audiological case concerned attempts to impose constraints on the nature and extent of the medical examination to be conducted by an expert witness. The plaintiff alleged that he was suffering from impaired hearing as a result of exposure to an occupational noise hazard. He had a partial hearing loss on one side, a total hearing loss on the other side, and he also suffered from tinnitus and recurrent episodes of vertigo. The defendant's expert witness proposed to conduct a medical examination that would have included tomography of the internal acoustic meatus, caloric tests and transtympanic electrocochleography. The patient refused to submit to the examinations and the defendant applied to stay the proceedings. The application first came before a registrar who was also furnished with an affidavit sworn by the expert witness for the plaintiff. The affidavit stated, among other things, that the radiological examination would

'involve considerable radiation dosage to the brain and eyes' ...

'My experience is that the caloric test is frightening to some patients, causes giddiness to most, nausea to many and vomiting to a few.'

Transtympanic electrocochleography

'is somewhat unpleasant and frightening for many patients. It is not without danger; very occasionally it has punctured the inner ear membranes and damaged the ear; or caused infection.'

The registrar accepted these statements and concluded that it would not be appropriate to grant a stay as asked by the defendant. However, he did say, in referring to the X-ray examination:

'it seems to me that this is an infringement of his (the Plaintiff's) liberty which, if it were the only test proposed, and subject to it not involving the Plaintiff in more than the safe dosage limit of X-rays, the Plaintiff could be obliged to accept.'

The defendant appealed and the case was heard by Mr Justice Webster on July 22 1980. The judge refused to choose between the conflicting evidence produced by two expert witnesses.

'For the reasons for the decisions I have already reached it has not been necessary for me to determine any factual conflict between the evidence of the Plaintiffs and the Defendants. All it is for me to determine is a reasonableness of the Defendants' request as reasonably seen by them and the reasonableness of the Plaintiff's objection as seen by him, and then to compare the weight of the reasonableness of the request with the reasonableness of the objection. For that purpose it does not seem to me (at any rate, in this case) to be necessary to involve such conflicts as there are between the various deponents, and I accordingly dismiss that application' (Prescott v Bulldog Tools Limited 1981). (An extended discussion of this case and related matters is given in Hinchcliffe, 1987.)
In an interlocutory action, Mr Justice Mais ordered an action to be stayed unless the plaintiffs submitted to caloric testing and polytomography. Liberty to apply for electrocochleography was also provided (Bird v Cadbury Schweppes Overseas Ltd 1981; Pearson v Cadbury Schweppes Overseas Ltd 1981).

In a subsequent interlocutory action (Holt v British Aerospace 1983), the plaintiff’s solicitors had endeavoured to constrain the medical examination which two medical examiners instructed by the defendants had proposed to conduct. It was a case of alleged noise-induced hearing loss. The case was heard before the district registrar who ruled

'So long as the Defendants choose a professional man with obviously good qualifications, then it seems to me that he should be given the right to make the decision (regarding which tests to do).'

The Registrar distinguished this case from the one of Prescott v Bulldog Tools 1981 on the grounds that in Holt 'nothing is really known about the Plaintiff's deafness'.

It is within the discretion of a judge to admit the evidence derived from a specimen of blood that has been unlawfully obtained (R v Trump 1979).

Surgical operations which are technically successful may amount to a trespass if consent has not been obtained. Thus, during an operation on an ear, a surgeon in the USA found that the other ear was more extensively diseased. He therefore operated on both ears. Although he did so skillfully and successfully, the court, on appeal, found for the plaintiff.

In a recent English case (Chatterton v Gerson and Another 1980), the plaintiff claimed that consent to a therapeutic procedure, which was associated with complications, was vitiated by a lack of explanation of what the procedure entailed and what were its implications. Consequently, the plaintiff had given no real consent. The procedure was therefore a trespass to her person. There was no claim that the doctor had been negligent. The judge said that the duty of a doctor was to explain what he intended to do, and its implications, in the way that a careful and responsible doctor in similar circumstances would have done. His Lordship was satisfied that the doctor had told the plaintiff what the procedure (an intrathecal phenol injection for pain relief) was all about. The plaintiff’s consent was not vitiated by any lack of information. The judge also said that it would be very much against the interests of justice if actions which were really based on a failure by the doctor to perform his duty adequately to inform were pleaded in trespass. The action therefore failed.

**Statute law**

There is one statute that has been designed with the exclusive purpose of protecting hearing-impaired people. This is the Hearing Aid Council Act 1968. For the purpose of the Act, a body termed the 'Hearing Aid Council' was set up. The Council has the function of securing adequate standards of competence and conduct among persons engaged in dispensing hearing aids. It also advises on methods for improving training facilities for hearing aid dispensers. Section 1(3) requires the Council to draw up both standards of competence and codes of practice for dispensers. Section 1(6) provides for the Council to receive complaints
from members of the public and to investigate such complaints. Section 2 requires the Council to establish a register of dispensers of hearing aids. A person may be registered if, prior to the commencement of the Act, he had acted as a dispenser of hearing aids for a period of at least six months in the two years prior to the Act, or he satisfies the standards of competence laid down by the Council. The Council was also empowered by s 5(1) to set up a committee termed the 'Investigating Committee' to investigate disciplinary cases. The function of the Investigation Committee was to decide whether a disciplinary case (a case being investigated) ought to be referred to the Disciplinary Committee. If a person is judged by the Disciplinary Committee to have been guilty of serious misconduct in connection with the dispensing of hearing aids, the Committee may direct his name to be erased from the register.

Section 14 of the Act defined a 'dispenser of hearing aids' as 'an individual who conducts or seeks to conduct oral negotiations with a view to effecting the supply of a hearing aid, whether by him or another, to or for the use of a person with impaired hearing'.

A 'hearing aid' was defined as

'an instrument intended for use by a person suffering from impaired hearing to assist that person to hear better but does not include any instrument or device designed for use by connecting conductors of electricity to equipment or apparatus provided for the purpose of affording means of telephonic communication'.

**Law relating to information**

Broadly speaking, the law relating to information as it relates to our subject can be classified as that relating to confidentiality, copyright, and evidence of legal purposes.

**Confidentiality**

Confidentiality (also see later under Ethics) can be considered as one aspect of the right to privacy. Specifically, it can be considered the right to the privacy of personal information. The Younger (1972) Committee on privacy concluded that the main concern about what is termed 'invasions of privacy' involves the treatment of personal information. The Committee considered that, in medicine, the question of privacy was a matter for ethics and not for legislation. As a result of information which the Medical Research Council submitted to the Younger Committee in 1971, the MRC published a Code of Practice on 'Responsibility in the Use of Medical Information for Research'. The Council accepted that medical information about identified patients could be made available for medical research without the patients' explicit consent. However, all medical information that could be related to an identified individual should be treated as confidential and should be communicated only to medical research workers who are engaged in investigations in the interests of the health of the community. Even then, the MRC expressed great fears that confidentiality would break down with the increasing use of computers. At the same time, as a result of the active discussion in the Parliament on privacy, the British Psychological Society's Standing Committee on Test Standards produced an interim report (1970) which was then subsequently amended in respect of the section on 'Relevant Information'. The amended section read:
'How much personal information should be sought from an individual, even by those who have good reasons for doing so, is a difficult question which faces psychologists. Almost any information will, in certain circumstances, be relevant but the use of some information is controlled by law. The decisions of psychologists would be expected not to contravene the Universal Declaration of Human Rights adopted by the United Nations General Assembly 1948.'

The desire to protect computerized data resulted in the Data Protection Act 1984. As Elbra (1986) points out, the eight principles, which are the keystone of the legislation, state that data must be:

1. obtained fairly and lawfully
2. held only for registered lawful purposes
3. not used or disclosed except as registered
4. be adequate, relevant and not excessive
5. be accurate and, when necessary, up to date
6. not kept longer than necessary
7. be available to the individual concerned
8. be kept secure.

The Act was primarily introduced to enable the UK to conform with an EEC directive and thus allow British companies to continue to transfer computerized information across national boundaries. Some lobbyists saw it as a means of introducing 'freedom of information' but they have been disappointed by the narrowness of the Act (Anon, 1986).

As Black (1984) points out, there is something of an anomaly in concern being focused on protection of data held in mechanically processed systems than on the much larger amount of information held in manual records. However, as just pointed out, the prime purpose of the Data Protection Act 1984 was to enable the UK to conform with an EEC directive and thus allow UK companies to continue to transfer computerized information across natural boundaries. Nevertheless, certain doctors (Baldry et al, 1986; Bird and Walji, 1986) have argued for giving patients access to their own medical records.

**Copyright, design and patent law**

There are laws protecting designs, inventions and writings.

Copyright is defined as the exclusive right to do, or to authorize other persons to do, certain actions in relation to original literary work. That also covers medical literature. Copyright exists in the way that ideas are expressed rather than in the ideas themselves. It is not necessary to use an author's actual words to infringe copyright. Literary work related to case reports which use X-ray films and other records relevant to a patient's case record is the copyright of the employer.

The Registered Design Act 1949 regulates designs, with the exclusion of artistic work protected by the Copyright Act 1956. It has been held that 'anything worth copying is prima facie worth protecting'.
The term 'patent' is defined as a privilege granted by Letters Patent from the Crown to the first inventor of any newly manufactured contrivance that he alone be entitled to benefit, for a limited period, from his own invention.

Evidence

As Martin (1979) pointed out, an expert, when giving evidence in court must state the reasons for his opinions, how they were reached and by what criteria his conclusions can be tested. It is for the court to determine whether or not it wishes to accept his opinion, or which of conflicting opinions, if any, it prefers. The court is not bound to accept any opinion, even if undisputed.

The standard of proof in civil cases is that of the balance of probabilities (Cooper v Slade 1858).

According to s 1 of the Perjury Act, if any person lawfully sworn as a witness or as an interpreter in a judicial case wilfully makes a statement material in that proceeding, which that persons knows to be false or does not believe it to be true, that person should be guilty of perjury.

Confidential information communicated to medical practitioners is not protected by privilege (Garner v Garner 1920). However, a witness may refuse to produce a document or give evidence until ordered by the court to do so. In any claim for damages for personal injury, the court has the power under ss 31 and 32 of the Administration of Justice Act 1970 to order the disclosure and production of documents. Section 31 relates to legal proceedings which are contemplated; s 32 relates to legal proceedings which have been commenced. It entitles either party to the action to apply for an order for the production of relevant documents in the possession of a third person who is not a party to the action. Documents which may be the subject of an order under either section include medical correspondence, records, reports and X-rays. As a result of three decisions in the Court of Appeal in the early 1970s, it had become the practice in applications under both ss 31 and 32 for medical records to be disclosed only to a medical expert nominated by the applicant, and not to the applicant himself or to his solicitors. In the case of McIvor v Southern Health and Social Services Board 1978, a hospital submitted that the consequences of not confining production of hospital records to the medical advisers of the applicant would in some cases be so dire that Parliament must have intended to confer on the courts a power so to do. The hospital's appeal to the House of Lords was dismissed. The House of Lords held that the Act meant what it said. However, the medical protection societies strongly advise their members to consult with them before complying with any request for the disclosure of records. It does not follow that every application from solicitors for the disclosure of records in the possession of a doctor must automatically be complyed with, for the applicant has to satisfy the court on affidavit that there are grounds for making an order (Annual Report and Accounts, 1978).

It has been held that an expert medical report is meant for the impartial assistance of the court and not simply to buttress one party's case. A doctor is right in refusing to amend a report at the behest of the solicitor requesting it (Medicolegal, 1979).
Concern has indeed been expressed in recent times regarding the manner in which expert evidence comes to be organized by lawyers. Comments have been made both in the Court of Appeal and in the House of Lords. In a House of Lords' judgment, Lord Wilberforce has said that

'while some degree of consultation between experts and legal advisers was entirely proper it was necessary that expert evidence presented to the Court should be, and should be seen to be, the independent product of the expert, uninfluenced as to form or content by the exigencies of litigation. To the extent that it was not, the evidence was likely to be not only incorrect but self-defeating (Whitehouse v Jordan and Another 1980).

There is a curious notion among some medical men that they must, as well as presenting their expert evidence, also dwell on the rights and wrongs of a legal case. As Martin (1979) points out, a witness, however distinguished, cannot assume the mantle of a judge; he does not relieve the court of its responsibility for the judicial decision. Lord President Cooper has clearly distinguished between the separate roles of the expert and of the court (David v Edinburgh Magistrates 1953).

The logic adopted by judges in handling evidence has been studied by Williams (1982). He concludes that judicial argument can often be translated into intuitional inductive logic. In a more extended approach, MacCormick and Birks (1986) have explored the patterns of thought peculiar to lawyers and the forces which influence the concepts, methods and preoccupations of the legal mind.

Conclusions

It is clear that there is a plethora of enactments and a considerable body of the common law which governs the practice of audiological medicine. With the notable exception of the Hearing Aid Council Act 1968, however, the relevant case law and statute law is not specific to audiology. Moreover, as indicated by the incorporation of the provisions of the Noise Abatement Act 1960 into the Control of Pollution Act 1974, there is a tendency to provide non-specific legislation.

Ethical aspects

The ethical aspects of medicine have recently been reviewed and re-analysed by Gillon (1985).

Philosophy can be considered to be 'the critical evaluation of assumptions and arguments'. Moral philosophy is then defined as the philosophical enquiry about norms, values, right and wrong, good and bad, and what ought and ought not to be done (Raphael, 1981). Gillon equates ethics with moral philosophy but immediately seeks to distinguish philosophical medical ethics from what might be called traditional medical ethics, that is the long and honourable tradition in which doctors have established and promulgated among themselves rules and codes of behaviour considered to be morally binding. The purpose of philosophical medical ethics is to make medico-moral decision-making a more thoughtful and intellectually rigorous exercise. Its ultimate purpose is to construct and defend comprehensive and moral theory for medical practice based on universal principles applying to all and
capable of justifying particular lines of conduct in individual cases. In a series of articles he then proceeds to conduct such an analysis. A prominent issue concerns: 'What are rights?' The answer to this question immediately elicits the fact that there are two major types of ethical theory. One type is based on rights and duties (so-called 'deontological theories of ethics', from the Greek word for duty; much religious moral theory is deontological). The other is based on the consequences of actions (consequentialist theories of ethics, for example utilitarianism).

As Dunstan (1981) pointed out, the ethics of medicine are as old as the profession itself. In Western civilization history goes back to the Hippocratic tradition. The foundation for modern ethical standards in Britain are derived from the Code of Professional Conduct produced by Thomas Percival in Manchester nearly 200 years ago (1789). His proposals 'Medical Ethics or a Code of Institutes and Precepts adapted to the Professional Conduct of Physicians and Surgeons' were published in 1803 (British Medical Association, 1984). The British Medical Association's Handbook points out that, while other European countries' ethical systems have been codified and incorporated in national civil and criminal law, the UK has proceeded along a different path. The General Medical Council, whose powers derive from the Medical Acts and which is responsible to the Privy Council, has enforced professional standards on the basis of guidance rather than through a codified system. The General Medical Council's (1983) booklet Professional Conduct and Discipline: Fitness to Practice, should be consulted regarding the broad aspects of etiquette, professional discipline and the law.

Research on human subjects

As pointed out by the Council for International Organizations of Medical Sciences (1982), the generalized application of the experimental scientific method by medical research is a product of the present century. Consideration is required in developed and developing countries alike as to whether prevailing legal provisions and administrative arrangements ensure that the rights and welfare of subjects involved in research are adequately considered and protected in conformity with the ethical principles prescribed in the Declaration of Helsinki by the Eighteenth World Medical Assembly 1964, as revised by the Twentyninth World Medical Assembly, Tokyo, 1975.

In Britain, the concept of local ethical research committees developed with a recommendation of the Royal College of Physicians (1967) that clinical research investigations should be subject to ethical review. Subsequently, the Royal College of Physicians (1984) produced Guidelines on the Practice of Ethics Committees on Medical Research. These guidelines attempt to provide detailed guidance on how the principles and the declarations of the World Medical Assembly should be applied to individual research proposals. The College of Physicians' guidelines make it clear that research ethical committees should concern themselves, not only with experimental research but also with non-experimental research, for example use of case records. They also indicate that there should be a mandatory review of all research projects affecting human subjects, including fetal material and the recently dead, in an institution. In the case of adverse decisions, the Committee is empowered, at the request of an investigator, to appoint referees by mutual agreement or, in the case of special difficulty, to ask the appropriate Royal College to appoint
referees, who will consider the views of both the investigator and the ethics committee in the presence of both. Local ethical research committees have no direct sanctions but, in the event of their discovering that their advice is not heeded or that clinical investigations are being conducted without reference to them, then they should report the facts to the body that set them up.

The extent of the remit of the local ethical research committees has yet to be defined. A gradual clarification will occur over the passage of time. In particular, one might consider the investigator experimenting on himself, and medical practice.

In the case of an investigator wishing to experiment on himself, particularly when he is conducting research in his own field of expertise, it could not be argued that there was no informed consent nor could there ever be a charge of breach of confidence. However, it could be argued that the subject was in a dependent relationship with the investigator. But perhaps the investigator could take refuge in the right to privacy as defined by Judge Cooley (1888) of the right to be let alone. Or take refuge in the right to decide what is to be done with one's body.

The routine treatment of an individual patient, using a procedure which has not yet been validated by an experimental comparative study, and which is not part of a research project, is in effect an uncontrolled experiment of a sample size of one and where the study is frequently not replicated; that is the antithesis of a good experimental comparative study.

The Scientific Affairs Board of the British Psychological Society (1978) enumerated 12 ethical principles which should govern research on human subjects. These principles can be applied equally well to research in audiology (particularly, because studies of auditory function can be formally equated with studies in psychoacoustics).

Particular groups, for example children (Nicholson, 1986) and healthy volunteers (Royal College of Physicians, 1986) have been the subject of special studies.

The first study stemmed from the fact that, in the UK, four sets of guidelines for medical research in children had been produced. The four proposals were in conflict. Some children's rights activists argue that children should never be used for research. But, how can the health of children be improved without the possibility of doing research on children? A Working Group of the Institute of Medical Ethics has sought to resolve these conflicts.

Among other things, the Report of the Royal College of Physicians recommended that there should be no financial inducement or any coercion that might persuade a volunteer to take part in a study against his better judgment.

Faden, Beauchamp and King (1986) have approached the matter of informed consent from a historical perspective, reasoning from a background of both moral philosophy and law.

The French approach to setting up ethical standards for experimental comparative studies is well set out by Arpaillange, Dion and Mathe (1985).
Confidentiality

Confidentiality and the use of medical records for research has recently been discussed by Knox (1986). As Knox points out, Hippocrates was the first to set out the confidential basis of medical practice. However, he said nothing about the conflict between the needs for confidentiality and the communication of data for research. The EEC has recently considered the matter (Commission of the European Communities, 1984). Two principal points emerged. First, modern reformulations of the Hippocratic Oath, such as the Declaration of Geneva, assert a joint concern for the good of man as an individual and for the corporate benefit of mankind. In a competitive world, the two principles sometimes come into conflict. Secondly, appeals to broader principles, for example contractual agreements, property rights and the right to privacy, do not solve the dilemma. The rules of personal contract demand secrecy, but the integrity of the society that sanctions and supports such contracts, demands a broader view. The EEC study concluded that there was no formal solution to the dilemma. A positive statement of all legitimate uses, including for research, to which medical records might be put, was preferred. It was considered that any strictly enforced legislation on confidentiality would almost always be harmful in one way or another. Consequently, they recommended a code of practice. This would provide a set of interpretable rules which could be applied in day-to-day decisions.

Conclusions

The ethical aspects of the two principal areas of applications of ethics to medicine, that is the doctor-patient relationship and research, have perhaps been best summarized by Dunstan (1986) and by Pappworth (1978), respectively.

Dunstan argues that the basis of the doctor-patient relationship is trust and confidence. The patient had to be given sufficient information so that consent to treatment could be grounded in trust. The patient did not need to understand everything that the doctor said to him, but he did have to trust him.

Pappworth pointed out that there are basically two ethical problems in respect of medical research. First, is there valid consent? And in this context, consent to an action which is basically wrong cannot change it into a rightful one. Secondly, do the ends justify the means? To these two basic problems, one should add a third problem. Is the confidentiality of the required data safeguarded?