MEDICAL MALPRACTICE

Contents

Overview

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Litigation

Doctors are now facing an increasing risk of legal action by their patients. Consumer enfranchisement, an emergent "compensation culture" encouraged by a growing personal-injury "industry," and a disenchantment with modern medicine's inevitable inability to keep apace with public expectations have all been ascribed a role in this incipient litigiousness.

This phenomenon has reached full maturity in the USA, where a "crisis" of excessive liability premiums, dwindling professional entry into high-risk disciplines, and reduced patient access now afflicts healthcare provision.

While figures indicate that civil suits in the UK have in fact been falling over the last decade, this ignores the considerable contribution made by settlements outside the legal arena in calculating overall costs.

The growing economic burden of servicing clinical negligence litigation in the UK, with the attendant repercussions of diverting funds from other areas of patient care, has been the focus of increasing political attention.

The Law of Negligence

Medical error is a constant, if not inevitable, companion to clinical practice; however, where iatrogenic harm is the result of negligence in the delivery of healthcare it is actionable at law.

The law of negligence is an instrument of corrective justice and a means of policing the exercise of proper care. It is concerned with the protection of private interests from the careless and unreasonable interference of others, and with the provision of financial compensation where such infringements have resulted in personal injury.

The common-law tradition, rather than undertaking the task of disentangling the complexities of subjective states of mind, concentrates instead on an examination of wrongdoing from an objective perspective. Negligent conduct is thus punished by a failure to meet court-determined standards based on a test of "reasonableness." In this way, the link between the related concepts of legal fault, moral blame, and the duty to make reparation is purportedly maintained.

Liability in negligence depends on the existence of a duty of care between the parties based on a proximate relationship (the "neighbor" test, initially formulated in *Donoghue* v. *Stevenson* [1932] AC 562, a breach of that duty by one of the parties' failure to take reasonable care, and injury caused by this breach.

The elements of this legal formula overlap to a greater or lesser extent, and their individual conceptual clarity is further clouded by a degree of judicial contrivance, employed to satisfy often covert policy considerations directed at limiting liability.

In the majority of cases, clinical negligence litigation can be distilled into disputes arising over an issue involving a breach of duty or an issue of causation.

Clinical Standards and Legal Standards

The notion of the "standard of care" is a matter of law to be determined by the court. It serves to define how individuals ought to behave and is a measure of the acceptability of conduct. A failure to attain this required level of conduct is the essence of an actionable breach of duty.

The seminal judgment in *Bolam* v. *Friern Hospital Management Committee* [1957] 2 All ER 118 established the general standard required of a professional exercising a particular skill to be that of the reasonably competent or skillful practitioner.

A clinician holding him-/herself out as possessing specialist medical skill will be judged by the objective standards of a person exercising that particular skill and occupying that specialist post. Tort has traditionally eschewed a variable standard, so in judging the actions of the neophyte practicing in a specialist environment, the court will make no allowance for inexperience (*Wilsher* v. *Essex Area Health Authority* [1987] QB 730 CA).

When adjudicating on an individual clinician's conduct, the court will invite expert testimony as to what constitutes accepted and prudent practice within the appropriate specialty. Liability will then depend on whether the clinician's conduct has failed to conform to this requisite clinical standard.

A departure from "customary" practice is, however, defensible at law if a responsible body of professional opinion can be found to support the propriety of the purportedly negligent conduct. Under these circumstances, the court is bound to find in an accused clinician's favor (*Maynard* v. *West Midlands Regional Health Authority* [1984] 1 WLR 634), even if an opposing body of opinion exists that is critical of the conduct in question. The court's preference for one body of opinion over another is not sufficient grounds to infer negligence.

This protectionist quality of the Bolam test creates an uneven contest, as claimants are doomed to failure if practitioners are able to find sanction for their conduct, albeit via a minority school of thought.

The introduction of national evidence-based guidelines on patient care may serve to inject an apparent degree of objective clarity into the courtroom provided there is an appreciation of their status as policy rules to control clinical behavior, and not necessarily as guarantees of customary practice. "Guidelines" are not directly admissible in court due to the common-law rules on hearsay. They may be introduced in order to support expert testimony, but in these circumstances will be accorded the same weight as other evidence. Critics of the Bolam test point to the undue reliance courts place on medical judgment when determining the standard of care, and therefore ultimately the question of negligent conduct. By way of contrast, it has been suggested that expert witnesses, whose tendency is to focus on ideals of clinical practice, rather than the commonly accepted, have artificially elevated the standard of care to a level unachievable by the majority of practitioners.

English case law appeared to signal a departure from the traditional reliance it placed on the conclusiveness of peer opinion (*Bolitho* v. *City and Hackney Health Authority* (1993) 4 Med LR 381 (CA)). Courts may now evaluate evidence that purports to be representative of a reasonable and responsible body of medical opinion and reject it as "unreasonable" if it is incapable of withstanding logical analysis.

Such departures from Bolam are likely to be rare, however, as the "illogicality" test is restrictive, but this novel judicial skepticism may represent a nascent release from the constraints placed on claimants. Courts may now exercise this inherent entitlement to invalidate "illogical" minority (or even "maverick") opinion that may hitherto have provided a successful defense under the Bolam test.

Causation

There is no liability in negligence if a direct connection between the negligent act and the injury complained of cannot be established (*Barnet* v. *Chelsea and Kensington Hospital Management Committee* [1969] 1 QB 428), even where the particular example of behavior can be shown to be demonstrably negligent by any measure.

Success on the issue of factual causation depends on an injured party demonstrating that, but for the defendant's negligent act, on the balance of probability, the injury complained of would not have occurred.

The burden of proving causation, which lies with the injured claimant, often presents insuperable problems. Clinical interactions may be complex, and where causal associations exist, expert medical evidence may be either unable to support the causative link or do so in a form that is not readily accessible to legal analysis.

Such problems are particularly acute where injury has resulted from two sources or from one of a number of potential causative agents. In certain circumstances the court may be willing to bridge the evidential gap and infer causation as a matter of law where particular insult can be shown to have exerted a "material contribution" to the injury complained of.

Tort Practice and Theory

The continued existence of negligence law despite reformatory pressure is perhaps a testament to its robustness and its explanative, deterrent, and retributive role in society. The effectiveness of tort law's principal function as an instrument of compensation has, however, been undermined by empirical evidence that indicates only a small proportion of patients who suffer injury due to negligence instigate formal legal action, and where claims are pursued, only a minority proportion are successful.

Such inefficiencies are accentuated by the costs of a system of civil litigation where, in over one-half of actions that proved successful, the injured party received no compensation because legal costs had consumed the damages awarded.

Civil procedure rules introduced in the UK aimed at remedying endemic problems of delay, and consequentially inflated costs, which had previously becalmed the litigation process, now require the courts actively to manage cases to ensure their timely disposal, and, where possible, to encourage mediation. State-sponsored legal aid has been withdrawn for most categories of clinical negligence and contingency fees have been introduced in its place.

Equally implicit is tort's relative deficiency at identifying and holding clinicians accountable for substandard care and, by extension, failing to deter careless practices. Undoubtedly fears of the personal and professional consequences of litigation are real, though the existence of state underwriting of civil liability, and the laws on vicarious liability, serve to divorce notions of fault from negligent conduct, and the effect of any financial deterrence is mitigated because compensation payments are not directly met by the wrongdoers.

To Blame or Not to Blame

The punitive and "blame-based" ethos of civil litigation has long been recognized as a disincentive to open admission and reporting of errors. The limited scope of the civil inquiry is concerned more with attributing individual fault than a quest for truth and, despite some limited success, is ill-equipped to expose systemic failure.

In addition, the civil forensic process does not provide a conducive environment for a full elucidation of the circumstances in which harm has been caused. The confrontational climate has been commonly regarded as responsible for breeding distrust rather than promoting resolution, and as injurious to the doctor–patient relationship.

Other jurisdictions have examined the entire notion of the role of "fault" in clinical negligence and have introduced no-fault (or, more accurately, minimal fault, as most have eligibility criteria) schemes founded on principles of proof of injury rather than proof of fault, irrespective of whether or not negligence can be demonstrated.

New Zealand has taken legislative action to abolish the right to take common-law actions in respect of personal injury, substituting this with a right to access to an administrative compensation scheme where injury has been suffered as a consequence of "misadventure." In Scandinavian countries, compensation is capped, and recourse to the tort system is retained.

Despite frequent calls for the introduction of a comprehensive no-fault system in the UK, its general introduction has recently been rejected by proposals that instead favor a system of "redress." Under this scheme eligibility will be founded on the nebulous concept of "serious shortcomings in the standards of care," and access to the courts is likely to be retained in deference to the right to a fair-hearing provision under Article 6 of the European Convention on Human Rights.

The challenge facing any no-fault system is the need to retain an incentive to ensure that appropriate clinical standards are maintained.

Preventive Medicine

While some jurisdictions have sought to tackle the burgeoning litigation by legislative means such as capping damages and reducing the limitation period, the UK proposes to approach the problem from a different angle.

A growing awareness of the need to minimize the risks of negligence occurring in the first place, and an understanding that injury may be the result of systemic or organizational failures, has resulted in the UK government instituting an array of proactive quality assurance initiatives with an emphasis on protecting and promoting patient safety.

It is anticipated that adherence to principles of clinical governance, risk management, and meaningful audit will assist in detecting, addressing, and eventually remedying failing standards. This in turn will, it is hoped, reduce the circumstances in which clinical error can flourish and in turn reduce the incidence of clinical negligence.

A greater understanding of the anatomy of clinical errors would undoubtedly contribute to their reduction. Key to this is the establishment of a system of reporting and investigation that encourages candor by guaranteeing anonymity or offering amnesty from legal censure.

The existence of institutions that collect anonymized information relating to adverse events is certainly not a novel concept; their future success in reducing errors will depend principally on their ability to look beyond epidemiology and into etiology.

See Also

Medical Malpractice – Medico-legal Perspectives: Negligence, Standard of Care; Negligence, Duty of Care; Negligence, Causation; Negligence Quantum

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Accident and Emergency

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Malpractice in Accident and Emergency in Context

Staff working in accident and emergency departments often face difficult challenges. These include attempting to treat a number of different patients with different conditions at the same time, but without the benefit of much background information and often with the added complication of patients under the influence of alcohol and/or drugs. Considering all of this, it is perhaps not surprising that on occasions, medical assessments and treatments do go wrong. Malpractice or negligence is relatively frequently claimed against those working in accident and emergency, when compared with other specialties – in one UK study, the two specialties quoted as being most at risk of receiving negligence claims were accident and emergency and obstetrics and gynecology. Historically, rates of claims have varied significantly between different countries, with those in the USA greatly exceeding those in the UK.

Malpractice Defined

The essence of malpractice (which for practical purposes may be regarded as being negligence) is that incorrect management resulted in definite patient harm. The term is understandably inextricably linked in a legal way to claims for (financial) compensation. The exact definition is therefore different in different legal systems and requires to be proved in slightly different ways. Under many legal systems, to prove negligence against a clinician, the patient needs to show the following:

1. the clinician had a duty of care
2. the clinician breached that duty
3. the patient suffered as a result.

Duty of Care

For those working in accident and emergency, there is often agreement that the clinician does have a duty of care to a patient. Difficulties arise when patients (for various reasons) refuse to comply with treatment, perhaps exhibiting aggressive behavior or leaving the hospital against medical advice. In these circumstances, other legal issues can cloud the simple issue of whether adequate care was provided.

Breach of Duty

A key component of proving negligence is showing that the clinician's care failed to reach minimum standards for the specialty. For some conditions, there are published and agreed national standards against which to compare treatment. However, most of the conditions that make up accident and emergency medicine do not have agreed standards. As a result, each case tends to be examined on its merits and the clinician may be judged or measured against what a

similarly experienced and expert clinician would be expected to do. In the UK, the clinician will try to defend him/herself by showing that he or she "acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art." This approach has underpinned the defense against negligence since the Bolam case in 1957.

Patient Harm Resulting

Having shown that a clinician did have a duty of care and that this care did not reach minimum standards, negligence did not occur unless the patient can be shown to have suffered as a direct consequence. In many instances, significant errors or omissions in management, whilst potentially harmful, do not actually result in any harm or damage to the patient.

The Background to Complaints and Claims

A significant proportion of patients and/or their relatives who complain about treatment are not primarily seeking financial redress. However, those who submit legal claims almost invariably are. There are common themes amongst published data relating to complaints and claims against accident and emergency departments. Complaints frequently relate to the attitude and failure of communication of accident and emergency staff, but claims for negligence more often cite failure to obtain X-rays or to interpret correctly those X-rays that have been obtained. Failures relating to obtaining or interpreting X-rays do not appear to cause serious problems frequently. However, claims relating to missed medical and surgical diagnoses are also quite common, and do frequently result in significant harm. For example, amongst patients discharged from accident and emergency after a failure to diagnose acute appendicitis, there were high rates of ruptured appendix and postoperative complications. Historically, a particular problem has been accident and emergency staff missing diagnoses of acute cardiac problems (myocardial infarction and unstable angina); with current pressures to discharge patients rapidly from hospital, this problem shows no sign of disappearing.

Risk Reduction

Improving care, resulting in a reduced number of claims, would benefit both patients and staff: the emotional cost of complaints being made against staff is not inconsiderable. There is some evidence that training may reduce rates of malpractice claims. Analysis of previous claims reveals areas worthy of consideration. Rates of missed fractures on X-rays analyzed by junior doctors in accident and emergency in the UK are acknowledged to be high and justify special focused training. The problem has also been tackled by an almost universal system of rapid reporting of X-rays by an appropriately trained expert, enabling errors to be quickly identified and patient harm minimized. In the fast-moving field of management of chest pain, emergency physicians are searching for ways of providing evidence-based treatment, allowing rapid discharge without compromising care (or risking litigation). Chest pain observation units, where patient care is determined by strict protocols, are emerging as a useful way forward.

The process of deciding whether or not negligence occurred almost inevitably relies heavily upon exactly what was documented in the medical notes. These comprise the crucial legal document in any dispute. The importance of making good contemporaneous notes cannot be underestimated. When subjected to scrutiny, observations and interventions that have not been documented will be assumed not to have taken place: all accident and emergency staff need to be reminded of this.

See Also

Medical Malpractice – Medico-legal Perspectives: Negligence, Standard of Care; Negligence, Duty of Care; Negligence, Causation; Negligence Quantum

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Anesthesiology

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Introduction

> Then the Lord God cast a deep sleep upon Adam and when he was fast asleep, He took one of his ribs and filled up flesh for it.
>
> Genesis, Chapter 2, verse 21.

In this article the processes involved in the practice of anesthesia and the associated common adverse events are described. Anesthesia is the discipline of pain relief. Pain may result from many different causes but the nonanesthetist immediately links the anesthesiologist with the relief of pain during surgery. Indeed, the relief of pain during surgery has made all the advances in surgery possible. It is therefore true to say that surgery stands on the shoulders of anesthesia. In this article the process of anesthesia is discussed and some of the common difficulties which may lead to litigation explained. Pain relief during surgery may be provided by general or regional anesthesia or by a combination of both.

General Anesthesia

General anesthesia may be considered in three sections: (1) induction; (2) maintenance; and (3) recovery.

Induction Induction is the start of anesthesia and may be by the inhalation of a gas such as nitrous oxide or of a vapor, classically ether or chloroform, but today the anesthetist may use sevoflurane, enflurane, or halothane. Halothane is now being used much less frequently as its use may result in a centrilobular necrosis of the liver and death. This occurs particularly when the patient has been "sensitized" by a recent exposure to halothane. Anesthetists are advised to avoid the use of halothane within three months of a patient's previous exposure to halothane. An important property of inhalation drugs used for induction, apart from an absence of side-effects, is that they should be nonirritant.

A significant advance was the introduction of the intravenous anesthetic induction drugs. The first of these were barbiturates. Thiopental, a thiobarbiturate, was introduced in 1935. Thiopental is still widely used but has been largely replaced by propofol, which was introduced in 1981. Members of the benzodiazepine family, initially diazepam but more recently midazolam, are also used to induce anesthesia.

Vasodilatation is an unwanted side-effect of intravenous anesthetic drugs. Great care is therefore required to avoid hypotension by introducing the induction drug slowly while monitoring its effect on the cardiovascular system. This is particularly relevant when a reduced blood volume can be expected, such as following a large-volume hemorrhage, or after heavy diarrhea or vomiting. Intravenous drugs are usually injected into veins in the back of the hand or in the antecubital fossa. The basilic vein in the antecubital fossa lies over the brachial artery, which is an end artery, that is, there is no collateral arterial

supply to the tissues supplied by the brachial artery. The accidental injection of thiopental into the brachial artery has resulted in precipitation of crystals of insoluble thiopental in small vessels in the limb and impaired circulation to the tissues supplied by the brachial artery, causing permanent loss of the peripheral regions of the fingers. Some drugs including thiopental are very irritant when injected into the subcutaneous tissues outside the vein and, if this occurs, the injection must cease immediately and the drug in the tissues must be diluted by the injection of 10 ml N-saline into the tissues. Failure to do this may result in significant tissue damage, irritation, and ulceration, litigation has followed.

Maintenance Maintenance is the period during which surgery takes place. The drugs used during this time are similar to those used during the induction process. Maintenance may therefore be by the use of inhalation or by intravenous anesthetic drugs. Propofol is the first intravenous drug suitable for both induction and maintenance and it is widely used for both purposes. Drugs administered by inhalation include sevoflurane, isoflurane, enflurane, and desflurane. Halothane may also be used but it is now increasingly restricted because of its association with liver damage. Nitrous oxide (laughing gas) and oxygen are used as the carrier gases for the vapors of the inhalation agents listed above.

A combination of nitrous oxide with oxygen and one of the vapors, with the patient breathing spontaneously constitutes a standard anesthetic formula. Other drugs may be given at this time and these include a muscle relaxant. The use of a muscle relaxant paralyzes the patient and therefore makes controlled ventilation mandatory. Potent analgesics such as morphine, fentanyl, sufentanil, alfentanil, or remifentanil may also be given.

Recovery Recovery is the period during which anesthesia is withdrawn and consciousness returns. Other drugs may be given at this time. These include the muscle relaxant reversal drugs, analgesics, and other miscellaneous drugs, including anticholinergics. These drugs will be mentioned later.

Local Anesthesia

The practice of local anesthesia may also be considered, though less commonly, under three headings of induction, maintenance, and recovery. The techniques of local anesthesia, sometimes called conduction blockade, may be considered under three headings: (1) infiltration anesthesia; (2) regional anesthesia; and (3) intravenous local blockade.

1. Infiltration is the injection of the local anesthetic drug directly into the tissues in the surgical area or through which the nerve supply to those tissues passes. This is experienced when visiting the dentist who infiltrates local anesthetic drug around the mandibular nerve and into the gum around the tooth which is to be the subject of the treatment. A similar technique, that is, local anesthetic drug infiltration, may be used for the repair of a hernia or the removal of a ganglion or other lump.
2. Regional anesthesia is typified by blockade of a large but defined area, as in the case of epidural or spinal injection of the drug. The various plexus blocks such as the brachial, lumbar, or sacral plexus block are also included under this heading.
3. Intravenous local blockade involves injection of a large dose of the local anesthetic drug into a vein in the arm or leg. This is known as a Biers block. A tourniquet must be used to reduce the amount of the drug that may escape, from the intended area of block into the general circulation lest a generalized toxic reaction and, of course, loss of blockade occurs. Local anesthetic may nonetheless escape through intraosseous capillaries, therefore, the use of toxic local anesthetic drugs such as bupivacaine for intravenous local anesthesia is forbidden.

The Process of Anesthesia

Preoperative Assessment

Many patients who present for surgery have intercurrent disease apart from the pathology for which surgery is required. For example, the patient requiring hip replacement surgery may also suffer from hypertension and angina. The same patient is likely to be taking medication to control blood pressure. Some of the medications may interact with some of the drugs used during anesthesia. Beta-adrenergic receptor-blocking drugs may precipitate heart failure and the bradycardia associated with their use may limit the heart's ability to respond to hemorrhage. The prolongation of the action of suxamethonium by ecothiopate eye drops and the interaction between monoamine oxidase inhibitors and opioid narcotic analgesics and sympathomimetic amines are well-recognized examples, but there are many more.

The drugs that the patient is taking reveal some of the patient's intercurrent diseases, and therefore, some of the likely pharmacological difficulties that may occur during anesthesia. The preoperative discussion and examination may identify various other problems such as untreated or inadequately treated hypertension, angina, previous myocardial infarction, upper

and lower airway disease, epilepsy, multiple sclerosis, or use of the contraceptive pill. Previous problems with general anesthesia include acute adverse reactions to drugs used during anesthesia (anaphylactic or anaphylactoid). A patient who suffered an anaphylactic reaction to pancuronium, but survived with slight brain damage, suffered a similar reaction to vecuronium and died. The similar chemical structures are illustrated in Figure 1. The life-threatening features of an anaphylactic reaction include bronchospasm, hypotension, and tachycardia.

Untreated or inadequately treated hypertension may result during anesthesia in a very unstable blood pressure, that is, marked rises or falls in blood pressure may occur. Furthermore, when hypotension occurs in a diabetic hypertensive patient, especially when associated with hemorrhage, ischemic optic neuropathy and associated blindness have resulted in litigation.

It is important to discuss the effect that anesthesia has had on other members of the patient's family, as some interactions with anesthesia are inherited. These include an inherited atypical cholinesterase that results in an unexpectedly prolonged paralysis following the muscle relaxant suxamethonium; some patients develop a malignant hyperpyrexia following injection of suxamethonium or inhalation of halothane; and patients with dystrophia myotonica are at very serious risk following the use of muscle relaxants. Sickle-cell anemia is a genetically linked condition common in patients with Afro-Caribbean roots. In this condition, hypoxia and hypothermia result in a change in shape of the normally spherical red cells. The red cells become sickle-shaped and thrombosis, severe pain, and hypoxia result. Acute hemolytic crises include fever, rheumatic pains, and abdominal symptoms. There may be severe anemia. The anesthetist must therefore identify whether a blood transfusion is required before surgery.

The preoperative examination provides the opportunity to anticipate the likely need for an intraoperative transfusion and to arrange for an appropriate volume of blood to be cross-matched. It is a wise practice in the case of patients who are more than 55 years of age to arrange for an electrocardiogram and for some patients, that is, when disease is suspected, a chest X-ray should be performed. Relevant blood analyses must be available before surgery begins, for example, a hemoglobin estimation is essential when bleeding has occurred, or when there is clinical evidence that suggests that the patient is anemic.

It is important to be aware of loose teeth which may be inadvertently dislodged and inhaled during anesthesia. It is essential to identify the patient who will be difficult to intubate, and to plan how control of the airway patency can be assured. The anesthetist must nonetheless be prepared to deal with unexpected life-threatening airway obstruction. In Figure 2 a large tumor which completely obstructed the airway can be seen rising from behind the tongue. The patient, who had no previous evidence of a tumor in her throat, was about to undergo surgery for a breast carcinoma.

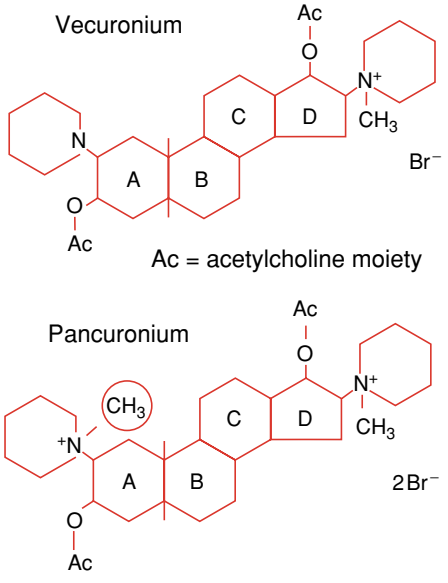

Figure 1 The chemical structures of vecuronium and pancuronium. A patient suffered an anaphylatic reaction to pancuronium and subsequently suffered a similar reaction to vecuronium and died.

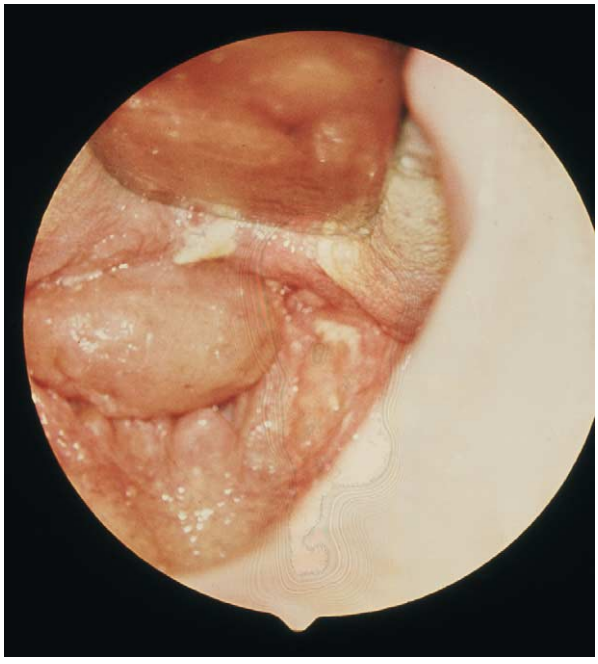

Figure 2 A large tumor can be seen rising up behind the tongue during attempted intubation.

The preanesthetic discussion can provide information that may be very important when planning postoperative care. Obstructive sleep apnea, a condition in which respiratory obstruction occurs during normal sleep, may occur following general anesthesia and lead to hypoxia and brain damage, or death. For these patients, great care must be exercised when selecting the dose and the drug to be used for postoperative analgesia and the analgesic drugs used during surgery, which affect the postoperative period. Indeed, in many cases postoperative care plans may be arranged before surgery starts. A patient with obstructive sleep apnea that required postoperative care in a high-dependency unit, but was sent back to the general ward, suffered respiratory obstruction, and died.

The examples given represent only the flavor of the investigations and clinical management required. The preoperative examination offers an important opportunity to identify the need for additional precautions. Nonemergency surgery for patients with uncontrolled hypertension, thyrotoxicosis, or an upper or lower respiratory tract infection should be postponed.

Premedication

Many patients desire sedation while others wish to remain fully awake during induction of general anesthesia, or during the injection of local anesthesia. Temazepam, an oral benzodiazepine, is an effective anxiolytic in a dose which has only minimal sedative action. Opioid drugs such as morphine or diamorphine may be used when the patient is in pain and to augment the analgesic effects of the anesthetic drugs.

Consent

Volenti nonfit injuria It is during the preoperative interview and examination that consent should be obtained. Great care is required to provide sufficient and appropriate information for the patient to make an informed decision. In providing information to the patient, it is necessary for the doctor to have identified those matters that are of maximum importance to each individual patient. Not all patients have identical priorities. Lawyers will know well the Australian case of Rogers and Whitaker. The patient, Mrs Whitaker, had only one sound eye but the surgeon suggested that he could give back the sight to the damaged eye. Mrs Whitaker requested that all care should be taken to protect her good eye. The surgeon failed to mention the possibility of sympathetic ophthalmia, a condition in which the eye that is not being subjected to surgery develops an inflammatory response in sympathy with the eye that has been the subject of surgery. This occurred in Mrs Whitaker's case and she lost the sight in her good eye, without gain in the previously damaged eye. The surgeon had considered the likelihood of damage from this cause to be 1 in 14 000 and therefore unimportant and not worth mentioning. It was however the type of information that Mrs Whittaker needed. Her most important interest was her good eye, and she had made this quite clear. Consent is a state of mind!

The Induction of Anesthesia

General The drugs to be used, the anesthetic machine, the monitors, and other equipment must be carefully checked. The patient's preinduction blood pressure, pulse rate, and pulse oxygen hemoglobin saturation should normally be measured and recorded. It is a standard practice to activate a continuous electrocardiograph display. These activities make some patients, such as children, very anxious by these activities and it may not be appropriate to make all these measurements until the child is asleep, but they must be introduced as soon as possible.

It is essential that an intravenous cannula is in place, usually in a vein in the back of the hand, before intravenous induction drugs are administered. The administration of multiple drugs is made easier by this, but more importantly the established venous access makes possible an immediate corrective response when an adverse reaction occurs. There are a number of local anesthetic creams that can be used to reduce the prick sensation and these are particularly valuable for children.

The intravenous anesthetic drug is then given slowly, and the patient is observed continuously. If given too quickly, the induction drug may, in those patients who are compensating for a reduced blood volume, cause vasodilatation and grave hypotension and even death. After induction a face mask may be applied to the face or a laryngeal mask passed into the throat. When a face mask is used, the lower jaw must be held forward in order to lift the tongue off the posterior pharyngeal wall to avoid respiratory obstruction (Figure 3). The laryngeal mask is an alternative to the face mask. The laryngeal mask is placed to lie behind the tongue and over the glottic opening. The primary advantage of the laryngeal mask over the face mask is that the anesthetist has both hands free for other tasks. It has been observed that the laryngeal mask is ideal when the patient is breathing spontaneously, but that it should not be used for positive-pressure ventilation, that is, when the patient's breathing is controlled by a ventilator. This is because there is the ever-present risk of anesthetic gases passing into the stomach, with the increased possibility of regurgitation or active vomiting. This

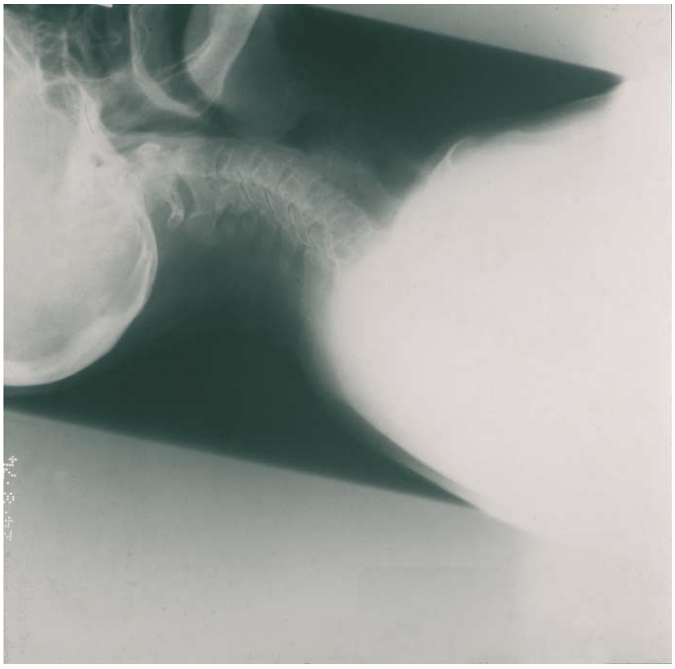

Figure 3 X-Ray neck shows the tongue obstructing the airway.

view has the support of many anesthetists, but by no means all. It seems to be a practice that may in due course require settlement by the judiciary.

The alternative approach is to intubate and ventilate the patient, that is, control the ventilation. Intubation involves placing a tube in the trachea, i.e., an endotracheal tube. An endotracheal tube with an inflatable cuff is usually used. When the cuff is inflated against the tracheal wall it forms an airtight fit. The tube may be passed through the mouth or through the nose. It is routine practice to paralyze the patient to facilitate intubation. The patient may also be intubated while breathing spontaneously under deep anesthesia, or if conscious, local anesthesia may be used. Intubation may be easy or exceedingly difficult. The anesthetist's view of the glottic opening during intubation can be seen in Figure 4. The tube can be seen lying in the trachea in Figure 5.

Before induction, the careful anesthetist will assess the degree of difficulty expected to achieve intubation by using a scoring system. The Mallampati system is most commonly used to identify the degree of difficulty that may be expected to achieve intubation.

When a difficult intubation is expected the anesthetist must be prepared to use a fiberoptic laryngoscope, or one of the special techniques such as passing a catheter through the cricothyroid membrane, just below the thyroid cartilage (the Adam's apple), up towards and behind the tongue and then passing the endotracheal tube over this and on through the glottis. The endotracheal tube may also be railroaded over a gum elastic catheter. It is absolutely essential, in all but emergency surgery, that the anesthetist confirms, using a face mask, that the patient can be ventilated before giving a relaxant drug. It must be remembered that the paralyzed patient cannot breathe; therefore, if the anesthetist cannot intubate

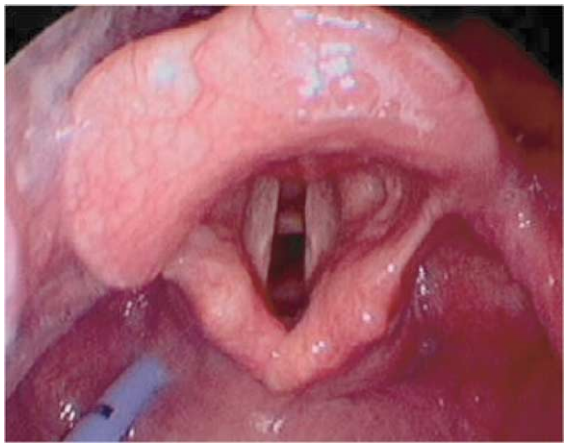

Figure 4 The anesthetist's view of the glottic opening during intubation. Reproduced with permission from Haslam N, Parker L and Duggan JE (2005) Effect of cricoid pressure on the view at laryngoscopy. *Anaesthesia* 60: 41–47. Copyright Blackwell Publishing 2005.

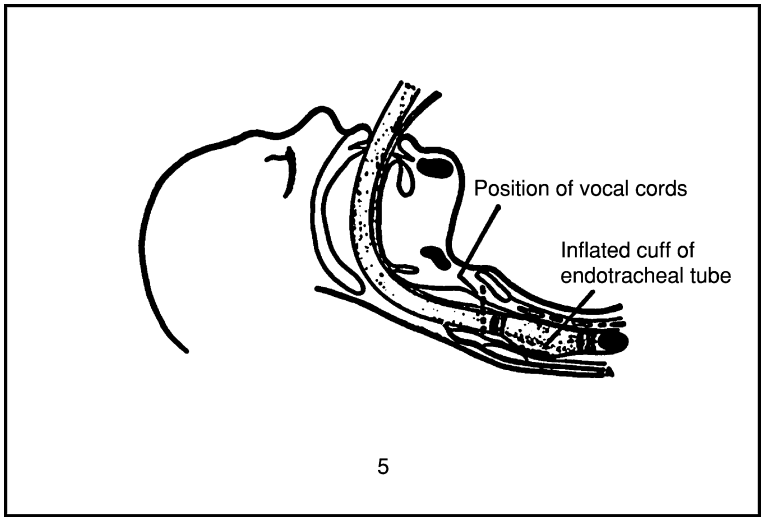

Figure 5 Endotracheal tube lying in the trachea.

and cannot ventilate using a mask, an immediate tracheotomy is required or the patient will die.

It is essential to confirm the correct placement of the endotracheal tube which is achieved most safely by the use of a capnograph to measure the expired carbon dioxide levels. Clearly, no anesthetic should be started until a capnograph has been tested and is included in the airway circuit. Unfortunately, while the use of capnograph is a requirement of the Royal College of Anaesthetists, in a recent anesthetic case no capnograph was used and this led to the death of a patient, a young healthy woman, following esophageal intubation. A failed tracheal intubation must be recognized immediately to avoid life-threatening hypoxia. The presence of breath sounds over the chest, while reassuring, may be heard when the endotracheal tube is in the esophagus. It is important nonetheless to auscultate over the chest after known correct intubation to confirm that the tube has not been passed in too far, that is, beyond the carina into the right main bronchus. This position would result in a hypoxic patient and, unless identified, a collapsed left lung (Figures 6 and 7).

The angles at which the main bronchi join the trachea are the reason why the right main bronchus is invariably the one that is entered by an endotracheal tube placed too deeply. Particular problems present when there is a partial laryngeal obstruction. In some cases, such as carcinoma of the larynx, it is essential for some patients first to perform a tracheotomy under local anesthesia to ensure that the airway is protected and the danger of a complete obstruction has been avoided. Deaths have occurred when this precaution has been ignored. Intubation may be used to prevent respiratory obstruction in young children with acute epiglottitis. In one case, it was agreed that if the patient had been intubated, the cardiac arrest and brain damage that followed would have been prevented. The careful anesthetist will always ensure that when there may be difficulty, the surgeon is scrubbed and ready to carry out an emergency tracheotomy if control of airway patency is lost during the attempted intubation of these patients.

It is usual to require that the patient has been fasting from food and drink for at least four hours, preferably six hours, to ensure that the stomach contents are reduced as much as possible before induction of anesthesia. The danger is that, during induction of anesthesia, esophageal regurgitation of gastric contents and their inhalation may occur. Even following anesthesia, the glottic protective reflex may be inactive for around two hours. In an emergency, this ideal may not be possible, and the risk that the patient may inhale gastric contents, regurgitated up the esophagus into the pharynx, must be guarded against. This protection may be achieved in a number of ways. The patient may be turned on his/her side with a few degrees of head-down tilt. If regurgitation or active vomiting occurs, the material will pass out of the mouth and not pool in the posterior pharynx and overflow into the glottis.

Another common approach is to have the patient lying supine with the anesthetist's assistant pressing down on the cricoid cartilage. The pressure prevents passive regurgitation but not necessarily active vomiting. This technique is sometimes known as Sellick's maneuver. Failure to prevent the inhalation of gastric material, which includes hydrochloric acid, results in damage to lung tissue with pulmonary edema (Figure 8), developing into pneumonia and frequently death. This syndrome is known as pulmonary aspiration or Mendelson's syndrome.

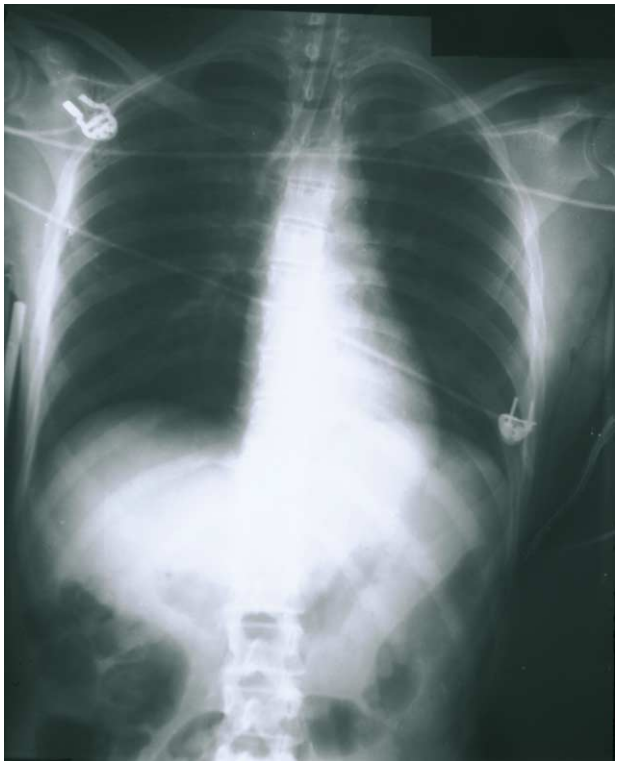

Figure 6 Endotracheal tube shown directed into the right main bronchus.

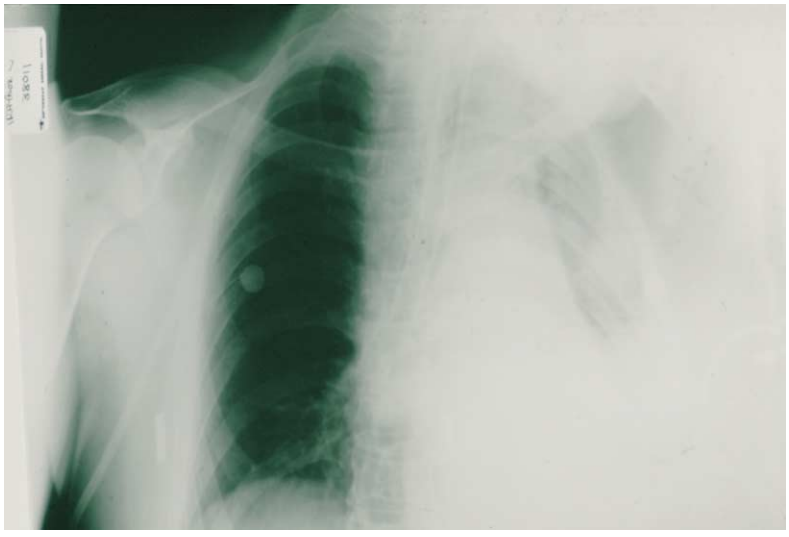

Figure 7 The endotracheal tube passing into the right main bronchus. The left lung is collapsed and airless.

Maintenance Naturally occurring opioid drugs such as morphine or diamorphine and synthetic opioids such as fentanyl, alfentanil, and remifentanil are frequently given to provide analgesia. These drugs are used in addition to the inhalation anesthetic drugs mentioned above or in addition to propofol during total intravenous anesthesia (TIVA). In patients whose breathing is controlled, a muscle relaxant is also used. Controlled ventilation may be without a muscle relaxant, though deeper levels of anesthesia are usually required. The muscle relaxant makes controlled ventilation easier at lighter levels of anesthesia. However, when the surgery is intraabdominal, muscle relaxation is essential to prevent

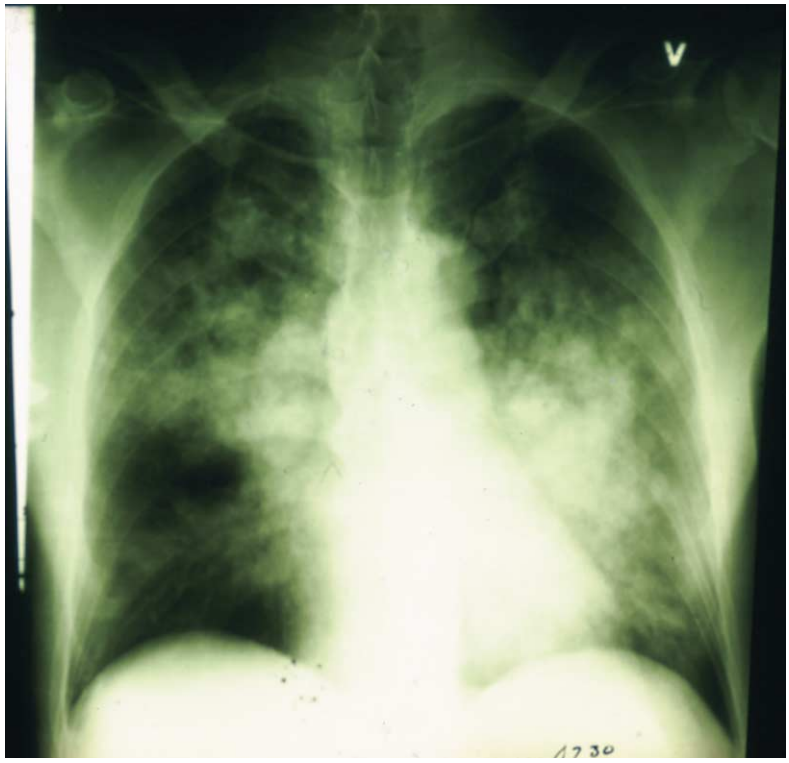

Figure 8 X-ray view of a patient's lungs following inhalation of gastric contents during intubation before cesarean section.

the abdominal contents from being forced out of the abdominal cavity and at the end of surgery to permit the easy closure of the anterior abdominal wall.

Nitrous oxide is usually used as the carrier gas for the anesthetic vapor. It also has strong analgesic properties. Patients are generally hyperventilated during the period of anesthesia. Hyperventilation ensures that the blood carbon dioxide does not rise and the patient gains from the analgesic effect of hypocarbia. Hypercarbia may result in vasodilatation with increased bleeding.

It is essential to monitor expired carbon dioxide continuously throughout surgery not only to ensure that the pulmonary ventilation is appropriate, but also to monitor anesthetic tubing disconnection. It is not surprising that ventilatory circuit disconnections occur, especially during head and neck surgery and when general changes in position are required. Of course, the anesthetist should confirm the security of the oxygen/anesthetic tubing connections, but disconnections can occur when least expected; hence, it is essential to use a capnograph. During a disconnection, no expired carbon dioxide reaches the capnograph, indicating that a disconnection has occurred.

Other standard monitors include an automated blood pressure-measuring device. Blood pressure may rise or fall during surgery. Falls in blood pressure may be due to an increase in the depth of the anesthetic or an interaction between the various drugs used. It may also indicate a sudden or progressive loss of blood. Loss of blood is usually but not always obvious. It must be remembered that the circulation depends on the heart rate, the venous return flow, myocardial contractility, and the peripheral resistance. The heart rate may be affected by surgical activity such as stretching of the bowel. The venous return is affected by hemorrhage and vasodilatation. Myocardial contractility is affected by the depressant action of drugs, including the anesthetic drugs. The peripheral resistance depends on the degree of vasodilatation, which is affected by anesthetic drugs. Bleeding may occur deep in the peritoneal cavity, or indeed be hidden in the tissues and, while not seen by the anesthetist, should be anticipated. A fall in expired carbon dioxide may indicate that circulatory failure has occurred. Cardiovascular stability may also be disturbed by cardiac rhythm changes, which may signify other pathologies, including myocardial infarction. It is therefore essential to follow the blood pressure changes continually. The five-minute intervals are generally considered appropriate, though more frequent recordings may be required. The heart rate may reflect changes in blood pressure, inadequate analgesia, and a response to hemorrhage or to some

drugs. In particular the anticholinergics increase heart rate, while the beta-blocking drugs slow the rate. Heart rate must therefore be monitored continuously.

Changes in cardiovascular performance influence excretion of carbon dioxide, hence the essential importance of capnography, but oxygenation may also be affected. Oxygenation also affects cardiovascular performance. It is essential therefore to display oxygen/hemoglobin saturation continuously. This is easily done by attaching a sensor to the finger or the earlobe. Gross changes in oxygen/hemoglobin saturation are visible in light-skinned Caucasians as a blue color of the skin and mucous membranes (cyanosis). The skin changes are not as visible in a dark-skinned people, but the mucous membranes and tissues inside the body such as the muscles show the same blue (cyanotic) changes in all peoples, as do the mucous membranes.

More sophisticated measurement of cardiovascular function includes central venous pressure (CVP) and pulmonary artery (PA) pressure measurements. CVP requires a catheter to be passed up a great vein such as the basilic vein in the arm, or the internal/external jugular veins in the neck, until the tip of the catheter is in the right atrium of the heart. The position is confirmed by the pressure waveform. The catheter is then withdrawn until the pressures fall, and changes in the pressure are related to breathing. Alternatively, a chest X-ray may be used to identify the position of the catheter tip. The CVP is frequently measured by passing the catheter into the subclavian vein. The common complication of this approach is a pneumothorax following penetration of the lung by the needle. Damage may also occur to the subclavian artery, leading to hemorrhage and hematoma formation. It is essential that both of these potentially serious complications are excluded by a chest X-ray following catheter insertion. Failure to X-ray the chest immediately has resulted in both hemorrhage and pneumothorax threatening the patient's life. The CVP pressures are, of course, much lower than the pressures in the atrium. CVP measurement should always be used when major hemorrhage is anticipated or is taking place and when cardiac failure is present or anticipated. The pressure measured is generated by blood returning to the heart and, while not a measurement of blood volume, it is an indication of over- or undertransfusion. It is therefore an indication that appropriate blood replacement has been or is being given. Rises in CVP may indicate overtransfusion or cardiac failure and therefore provide an invaluable window into cardiovascular function. PA measurement requires that the catheter be passed through the right atrium and right ventricle into the PA. This device provides extensive information about cardiac function.

It is now considered important to monitor continuously the inspired/expired anesthetic vapor concentrations. The term minimum alveolar concentration (MAC) of an inhaled anesthetic agent is used to describe the concentration of vapor in the alveoli at which only 50% of rats will remove their tails from a hot plate. The MAC value is obviously directly related to the brain concentration of the agent being used. The term, in clinical anesthetic practice, is used to describe the MAC value for any inhalation agent, that is, the alveolar concentration at which 50% of patients will be asleep. Clearly, at 2 MAC a greater percentage of patients will be asleep. The number of patients reaches 100% at 3 MAC. Other factors, such as the concentration of nitrous oxide used as a carrier gas and the doses of analgesics given, will alter the required MAC necessary to ensure that the patient is asleep. The measurement of the inspired and expired concentrations of the anesthetic vapor is therefore essential for good anesthetic practice. The measurement of the MAC value is not a measurement of the depth of anesthesia, nor even an indication that the patient is asleep, but it can be used with the measurement of other variables such as the pulse rate and an assessment of other patient social factors, such as alcohol intake and surgical stimulation, to judge the appropriateness of the anesthetic being given.

Position during general anesthesia is an important risk factor; in particular, avoidable nerve damage can result.

In the case of prolonged surgery, the patient's temperature, unless heat conservation or heating is used, is likely to fall. It is important in these cases to monitor core temperature. The use of skin temperature measurement is useless as vasoconstriction occurs in the skin during cooling and therefore skin temperature will not reflect core temperature. Esophageal or rectal temperature is therefore monitored. Intravascular temperature monitoring may also be used. Temperature may be maintained by infusion of warm fluid, blood, or crystalloid (salt solutions), by a water-heated mattress, and by blowing warm air around the patient. Hot-water bottles may cause skin burns and should not be used. Temperature measurement and control are essential for babies and small infants.

Recovery Essentially, recovery requires the anesthetic to be switched off and then breathed out, or in the case of a TIVA to be metabolized to nonanesthetic substances, or excreted to allow consciousness to return. It is important to reverse the residual action of the muscle relaxants and this is achieved by the injection of a drug with an anticholinesterase action.

The most commonly used drug is neostigmine and another is edrophonium. These drugs prevent cholinesterase, an enzyme present in the blood and in the region of the neuromuscular junction, from breaking down the acetylcholine. Acetylcholine is the substance secreted at the nerve endings, which activates muscle depolarization and contraction. The actions of acetylcholine are of two types: nicotinic and muscurinic. At the neuromuscular junction, acetylcholine is nicotinic, whereas it is muscurinic at the acetylcholine receptors in the heart and its action slows the heart. The muscurinic action of the acetylcholine is blocked by the use of anticholinergic drugs such as atropine or glycopyrollate. Failure to give the anticholinergic has resulted in a cardiac arrest. Bradycardia during surgery has also been treated, though not always effectively, by the use of an anticholinergic. Bradycardia which fails to respond to an anti-cholinergic drug is usually treated with epinephrine (adrenaline), isoprenaline or another inotrope and oxygen.

Following general anesthesia the glottic reflex may remain obtunded for about two hours and therefore following extubation the patient should be nursed on his/her side, at least until fully awake; otherwise vomiting or passive regurgitation, with the inhalation of gastric contents, and the serious complication of pulmonary aspiration syndrome are possible risks.

Patients may complain of pain during recovery and adequate pain relief must be given. Opioid drugs such as morphine are still the most commonly used analgesics, though there is an increasing use of nonsteroidal antiinflammatory drugs (NSAIDs), or combinations of an opioid and an NSAID. Diamorphine (heroin) is also widely used in the UK. It is common practice to inject a small dose of opioid drug intravenously to achieve a rapid onset of effect, but great care must be taken to avoid respiratory depression. Alternatively, the analgesic may be injected intramuscularly or administered rectally. The use of spinal and epidural anesthesia (analgesia) for postoperative pain relief is common practice, especially following lower abdominal and lower-limb surgery. A very popular technique is patient-controlled analgesia (PCA). This approach must be discussed with the patient. The patient is able to inject an intravenous bolus of analgesic in a preset dose by pressing a button when in pain. Lockout times are built into the computer program to prevent an overdose. The doctor may, when required and if judged safe, override the lockout and administer a separate bolus. The use of a PCA has proved to be one of the most significant recent advances in postoperative pain control. In some ways, it is analogous with the self-administration of a drug, by inhalation, such as nitrous oxide during labor. Care must be taken with elderly patients to differentiate between confusion and pain. Analgesics are not appropriate when confusion is related to hypoxia.

It is the responsibility of the anesthetist to detail the postoperative care instructions, that is, the variables to be monitored and the limits before medical advice is sought, and the analgesia and intravenous fluid prescriptions, in addition to any other drugs taken routinely.

Regional Anesthesia and Analgesia

Regional blockade may be considered under two sections – central and peripheral – and may be described as the use of a local anesthetic agent to block pain sensation from a defined region of the body.

Regional blockade may be used in conjunction with general anesthesia. Controversy continues concerning the placing of the local block after the start of general anesthesia, in particular, when the local blockade is central, that is, subarachnoid (spinal) or extradural (epidural), including caudal. The passage of the spinal needle may, on impact with a nerve root or nerve, cause an unpleasant sensation in the distribution of the nerve concerned. This is the signal for the anesthetist to withdraw the needle slightly or completely and then recommence the placement at a different vertebral level. The anesthetized patient cannot communicate that the needle placement caused pain and may therefore suffer serious damage if the injection of the drug is started while the tip of the needle is within the nerve. Disruption of the nerve may result in permanent loss of motor power and sensation in the region supplied by the damaged nerve or nerve root. The potential for serious damage is so great that central blockade should be established, or the catheter must be in position and tested before general anesthesia is induced.

Central blockade Central blockade is widely practiced. Many patients undergo cesarean section under spinal or epidural anesthesia. Neurological complications may also follow spinal ischemia associated with hypotension or air embolism, the neurotoxic effects of the drug, compression of the nerve root or the spinal cord by hemorrhage, and abscess formation. Some authorities have expressed the opinion that one area of unwarranted complacency is the belief among many experienced anesthetists that they can identify intervertebral spaces accurately by palpation. This is not the case. The usual clinical method for identifying the interspace is by a line that joins the two iliac crests, but this depends on the line being at a constant vertebral level, which it is not. The line, Tuffier's line, crosses the vertebral column with a maximal incidence at the L4–L5 disk but it may be higher and, if a higher level coincides

with an identification error, that is, a higher space is thought to be L4–L5, there is danger to the spinal cord. The lumbar subarachnoid space should be entered below the termination of the cord. Unfortunately, the spinal cord does not always end at or above the interspace L1–L2. Great care is therefore required in needle placement.

Other complications of spinal anesthesia include hypotension, bradycardia, spinal hematoma, nausea and vomiting, headache, urinary retention, and infection. An unexpected high block can result in respiratory difficulty and unconsciousness.

Other complications of epidural blockade include dural puncture; if this is unrecognized, a large dose of local anesthetic may be injected into the subarachnoid space, leading to hypotension and spinal ischemia, respiratory depression, unconsciousness, and convulsions following an intravascular injection. Even recognized dural puncture may, as a result of cerebrospinal fluid leak, result in a severe postdural headache. Hemorrhage may result in a spinal hematoma.

Peripheral blockade Peripheral blockade includes intercostal, intrapleural, paravertebral, inguinal, cervical, brachial plexus, and lumbar plexus anesthesia. Specific nerve blockade is also employed and includes ulnar, radial, and median nerve blockade, and the lower-limb femoral, obturator, and sciatic nerve blockade. Pneumothorax is generally considered to be the complication of an intercostal block, although this is not common. In the case of an intrapleural block, care must be taken to avoid a rapid injection of local anesthetic resulting in toxic blood levels. Paravertebral block may be associated with a pneumothorax, toxicity is associated with high volumes of drug, and damage to spinal nerves may arise from subarachnoid and extradural injection of local anesthetic drug. Great care is required for cervical blockade, which may result in vascular or dural puncture, leading to convulsions. In addition, the phrenic nerve, stellate ganglion, and the recurrent laryngeal nerve may be blocked depending on the approach to the brachial plexus. Intravenous regional blockade is a common blockade used for limb surgery but complications may occur, such as a toxic response to an overdose if the tourniquet cuff deflates. Anesthesia is limited by the duration of the circulatory arrest. Femoral blockade is associated with intravascular injection, hematoma formation and nerve damage. It is contraindicated in the presence of a femoral graft.

Conclusion

The term anesthesia is derived from the ancient Greek word "anaisthesia," which means "the want of consciousness or sensation." The possibility of operating without pain has been the most important step in the development of modern surgery, following the aseptic treatment of wounds. The desire to relieve pain is as old as human history but its consummation extended over many centuries, during which endless attempts were made to relieve human suffering. Such attempts were forcibly expressed by Hippocrates: "*Divinum est opus sedare dolorem*." (It is divine work to relieve pain.)

The countless attempts and failures over the centuries led Velpeau to express his thoughts using these rather melancholic words shortly before the discovery of anesthesia: "*Eviter la douleur dans les opérations est une chimère, qui n'est pas premise de poursuivre*." (To discover ways of avoiding pain during operations is an imaginary objective which it is not permitted "to us" to pursue.)

Anesthesia has been described as a reversible journey toward death, and it is for this reason that the evolution of modern anesthesia has been influenced by increasing concerns for safety. The immediate influence of the various agents on the cardiovascular and respiratory systems and their inherent toxicity, affecting hepatic and renal function, has influenced the direction and rate of progress. In spite of substantial advances, life-threatening anaphylactic or anaphylactoid responses still occur particularly during the induction of anesthesia. These require an immediate and correct response by the anesthetist to avoid serious damage or death. Surgery may be considered as minor or major depending on its complexity. However, anesthesia, both general and regional, always brings with it a threat to life or of serious damage.

The responsibilities of the anesthesiologist and the dangers through which he/she must guide the patient are well illustrated by the ancient words spoken by Hippocrates centuries ago: "Life is short – the art is long – opportunity is fleeting – experiment is perilous –decision is difficult."

See Also

Consent: Treatment Without Consent; **Medical Malpractice – Medico-legal Perspectives:** Negligence, Standard of Care; Negligence, Duty of Care; Negligence, Causation

Further Reading

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Child and Adolescent Psychiatry

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Introduction

Medical misconduct (the kinds of behavior that bring doctors before medical boards) is more commonly a problem in child psychiatry than medical malpractice (the kinds of behavior that bring clinicians before civil courts). The limited available data suggest that child psychiatrists may be at greater risk of being disciplined than their adult colleagues. Disturbingly, child psychiatrists appear to be at least as likely to commit sexual indiscretions as their adult colleagues. In determining whether medical misconduct has occurred in child and adolescent psychiatry, the guiding principle is that the best interests of the child are paramount. Because the child is not regarded as legally responsible for actions, more responsibility resides with the clinician than is the case with adult patients. The child's minor status also introduces a third-party decision-maker (usually the parents, but sometimes the state), and it is not uncommon for issues of responsibility to be further clouded by the child psychiatrist developing a therapeutic relationship with the parent.

Definition

Medical malpractice occurs when there is "dereliction" of "duty of care" that is the proximate cause of harm to a patient.

Duty of Care

Although duty of care requires that a therapeutic relationship be established, face-to-face contact is not required, so that telephone advice to a parent can establish duty of care. There may also be a duty of care to nonpatients (e.g., Tarasoff requirements to warn those who may be at danger from a patient). Nor do all face-to-face contacts necessarily impose a duty of care. It is usually accepted that a discrete child psychiatric assessment for forensic purposes does not impose a duty of care provided the purpose of the assessment is made clear to the family (but forensic assessment does carry the same mandatory notification requirements).

Dereliction of Duty

This requires a deviation from the ordinary standard of care, by commission or omission. Expert testimony is required to demonstrate negligence, but not "intentional tort" (where there is judged to be deliberate intent to harm, or that the psychiatrist ought to have known that his/her behavior was wrong, for example, sexual misconduct). An error of judgment does not constitute negligence. There is an expectation of ordinary competence, ordinary being defined in terms of national standards. However, even where explicit practice guidelines are available, these are generally not regarded as binding and a "respected minority" approach is usually acceptable. In addition, special

circumstances can be taken into account, for example, the requirement for an isolated practitioner to make decisions outside his/her core area of expertise because more expert services are not available locally.

Proximate Cause

To establish malpractice, the dereliction of duty needs to have made a substantive contribution to the harm done. Thus the child psychiatrist who provides a prescription that ultimately leads to a child's death by suicide would not be held responsible if it could be shown that the child was likely to commit suicide by some other means if the tablets had not been available.

In adult psychiatry, misconduct is sometimes mitigated by demonstrating that the patients themselves have contributed to their outcome by not suitably advising their psychiatrist of, for example, their suicidal intent. This mitigation would hold less in child psychiatry where children are not held responsible for their actions.

Harm

Malpractice claims usually involve compensatory damages for physical or psychological harm.

Malpractice in Child and Adolescent Psychiatry

There are no recent data, but surveys in the 1970s and 1980s suggested that fewer than 1% of medical malpractice claims concerned psychiatrists and of these only a small minority (5–20%) concerned child psychiatrists. These low survey figures get some confirmation from the fact that insurance premiums are low for child psychiatrists. There are few systematic data, but the commonest precipitants to litigation in child and adolescent psychiatry are probably suicidal behavior, physical or sexual assault by another patient in the inpatient unit, inadequate treatment, the commitment process (and, on the other hand, failure to hospitalize), diagnostic error, and failed supervision of a case.

Suicide

Guidance as to what constitutes malpractice in cases of attempted or completed suicide is compromised by the lack of a universal standard of care. It is important to document a history that identifies the severity of known risk factors, but this will provide only a limited guide to decision-making. There is a common assumption that hospitalization is the preventive response to suicidal intent but clinicians should bear in mind that hospitalization carries its own problems, both clinical and legal, and the aim should always be to respect individual freedom and offer the least restrictive alternative for care. What is sometimes forgotten is that death or injury are not the only dangers for a suicidal adolescent, and the risk of suicide needs to be balanced against the risk to the child of restrictive treatments such as inpatient care. Courts will support the decision to discharge patients from inpatient units even if they subsequently complete suicide provided that the discharge decision has been taken on sound clinical grounds. The clinician's position will be strengthened if:

- the decision-making process is well documented (thinking out loud)
- the case has been discussed with colleagues
- the duty to disclose possible risk to parents/guardians has been met
- appropriate care has been taken to minimize exposure to risky means
- a safety plan is in place which offers the child and parents clear pathways to gain further help and support if required
- documentation demonstrates that the clinician has more than a superficial understanding of what underpins the child's possible suicidal intent.

Inpatient Care

Medical negligence claims relating to harm done in an inpatient environment most commonly relate to failure to protect a child from adverse events in that setting. Seclusion and restraint are potentially risky activities, and must always be demonstrably in the patients' best interests. Inpatient units need to have explicit and conservative policies for the implementation, audit, and evaluation of restraint. Because it is common for admitted children to have been abused, and for this to affect their behavior, there is an increased risk of further abuse in inpatient units. Note that the treating psychiatrist will be responsible for the child's well-being even if care is primarily carried out by junior medical and/or nursing staff. Should an inpatient unit arrive at a wrong diagnosis and implement inappropriate and potentially harmful treatment, the nominated child psychiatrist could be held responsible even if he/she has not been actively involved in the inpatient setting.

Where one patient assaults another, action might be brought on behalf of the assaulted child against the psychiatrist managing the child who perpetrated the alleged assault. For such litigation to be successful, lawyers for the assaulted child are likely to need access to the medical record of the assailant. Courts will not always accede to such requests.

Drug Therapy

The most common drug involved in misconduct actions is methylphenidate (probably because of its image as much as its true dangerousness). However, with increasing acceptance of the view that newer antidepressants (perhaps particularly paroxetine) can increase the risk of suicide, more litigation about such drugs is expected. In obtaining informed consent from the guardian (and preferably also assent from the child) it should be borne in mind that the more experimental the drug, the more information needs to have been demonstrated to have been provided in gaining consent. Risk of litigation will also be lessened by proper monitoring of medication. Adverse events on a drug do not necessarily imply misconduct, and a clinician who has prescribed a damaging drug where no less disabling drug would have been as effective is unlikely to be held negligent. However, it is essential to show that prescribing has been for therapy and in the best interest of the child and not for others' convenience. This might particularly apply in children whose behavior is troublesome to others and prescribing could be argued to be for the benefit of those managing the child.

Confidentiality

Children rarely sue for unauthorized disclosure but the parents may, for example, for giving information without consent to a school. Care must be taken to ensure appropriate consent to use case histories and video recordings for research, teaching, or other publication. Some information has privileged status before the courts, that is, the psychiatrist may not be obliged to reveal information, even under subpoena. Conditions of privilege will vary according to the jurisdiction, and legal advice is recommended if the conditions are unclear to the psychiatrist.

There are situations in which confidentiality must be breached in order to protect some party, usually the child. These include: suspected child abuse; in some jurisdictions, access to firearms if there is suicidal intent; duty to warn others who are in danger from the patient; and unlawful sexual intercourse. Clinicians would generally be protected in making such notifications but care is required to ensure that mandatory requirements are not exceeded. For example, child abuse allegations by one parent against another should be reported to statutory agencies, but might not justify advice to that parent to withhold access from the alleged perpetrator.

Minimizing Risks

Good clinical practice is not driven by a preoccupation with reducing risks of litigation but rather is aimed at increasing opportunities for children and their families. Nevertheless, there are some principles that can be followed to reduce potential risk of litigation (these principles also apply to pediatric emergency physicians and community pediatricians, who play an increasing role in children's mental health):

- Ensure that all medical records contain a genogram (family tree) that clearly identifies living, custodial, and guardianship arrangements.
- Discuss patients with colleagues, and ask for second opinions (this is not an admission of lack of competence). Case conferences about difficult patients or families frequently enhance clinical outcomes as well as providing legal protection.
- Document thoroughly and preserve documents because the statute of limitations does not have force until the child reaches adult status. Note, however, that courts will accept a psychiatrist's recollection even if it is not documented. Data can be added to case notes at a later time (preferably before the notes are subpoenaed) but any additional entry should be clearly dated as to the time of the addition.
- Provide clear explanations of assessment (including uncertainties) and treatment plans, and clearly document informed consent. Where possible, also get consent (or at least assent) from the child.
- Provide clear (preferably written) guidelines for the use of medication and other treatments that the child is expected to engage in outside therapy sessions.
- Use safety plans; invite families to contact you again if they are concerned or if unexpected developments occur.
- Terminate treatment contracts if you believe that something unreasonable is being asked of you (but remember that you have continued responsibility for a patient after termination until the family sees another clinician, and terminating contracts unilaterally risks action for abandonment).
- Be mindful of conflict of interest. For example, the profit motive may influence admission and discharge decisions in inpatient units; managed care might pressurize premature discharge. Note that it is the psychiatrist who will be held responsible for the consequences of premature discharge if he/she cannot demonstrate that he/she has taken adequate steps to represent the child's needs for continued care.
- Avoid taking on a forensic role unless it is explicit to all parties that the purpose of the interview is court-related.
- In child protection cases, the responsibility of the child psychiatrist is to bring suspected abuse to the

attention of the appropriate authorities. Unless a child psychiatrist has had additional training in child protection, it is not appropriate to carry out any level of child protection investigation. In particular, Munchausen syndrome by proxy should be conceptualized as a form of child abuse so that the child psychiatrist has no investigative role except as coordinated by an appropriate child protection expert. The child psychiatrist should also avoid giving opinions about diagnosis in parents where they have not made a direct assessment of that person.

- Interactions with parents need to be documented at least as well as those with the child.

If litigation occurs or is thought to be likely:

- Notify insurer and seek advice early.
- A clinician who has little experience of court proceedings should seek supervision on how best to act in court. For example, learning that lawyers can be deliberately provocative can help clinicians respond more calmly to what seems to be unreasonable statements made in the court proceeding.
- Where a clinician believes that malpractice has occurred, he/she is required to advise the patient/family of this possibility. Otherwise the clinician might be regarded as having perpetrated a fraud on the patient by withholding information about potential misconduct.

See Also

Forensic Psychiatry and Forensic Psychology: Assessment; Forensic Interviewing; Personality Disorder; **Munchausen-Syndrome-by-Proxy**

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Colorectal Surgery

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Introduction

Colorectal and anal diseases are extremely common, particularly in developed countries. Hemorrhoids are a frequent source of irritating symptoms, and colorectal cancer is one of the three most common cancers in these countries. As a direct result, the treatment of these conditions often results in complications, which may be life-threatening or disabling and sufficient to give rise to profound resentment in the patient who subsequently may seek retribution via various legal agencies.

The public are protected, to a significant degree, by public bodies such as (in the UK) the General Medical Council (GMC) and the Royal College of Surgeons (RCS), who seek to monitor the professional abilities of those who propose and eventually carry out as individuals various treatments for colorectal disorders. Specifically, the Association of Coloproctology (AoC) is a society to which all who propose themselves as specialists in colorectal surgery are invited to apply and will be accepted for membership provided they meet the required criteria. The GMC is more usually concerned with ethical and moral issues, but its judgment may be invoked if there are serious issues of professional and technical malfunction or misjudgment. The RCS is more frequently associated with educational commitments rather than disciplinary matters. To be removed from the association of this august institution would not bar the individual from clinical practice. Similarly, the AoC provides an educational forum in the specialty and also frequently, as a consequence of peer activity, guidelines on management of complex issues within the specialty. It is the author's opinion that any patient seeking colorectal advice from a specialist should ensure that he or she is a member of this society (information can be obtained from the *Medical Directory*).

Anal Disorders

Anal disorders are extremely common, the majority of adults in the western population experiencing symptoms at some stage in their lives. The most common underlying cause of symptoms is hemorrhoids, but there are other disorders, that can be confused with hemorrhoids, which can lead to potentially serious errors in management.

The symptoms commonly associated with hemorrhoids are: rectal bleeding, anal discomfort, anal swelling, prolapsing anal lump, perianal itching, and anal discharge. Of these, rectal bleeding is the most prominent and troublesome. It is also the most common symptom from which serious clinical errors in misdiagnosis can arise. Because rectal bleeding may also be a clinical feature of colorectal cancer, it is imperative that the clinician should exclude this possibility before undertaking treatment of hemorrhoids. The decision as to in how much detail to investigate a patient with rectal bleeding is a complex one. The younger patient can be generally assumed to be bleeding from hemorrhoids and can be spared complex and unpleasant investigations. The older patient, or the patient who has a family history of colorectal neoplasia, needs to be investigated in more detail, including full colonoscopy or by computer tomography (CT) scanning. All patients presenting with anal or rectal symptoms should be examined by digital examination of the anus/rectum and by sigmoidoscopy. The latter is a simple and safe procedure whereby the lining of the lower bowel can be visualized directly and a malignancy of the rectum readily excluded.

Other anal pathologies (e.g., anal cancer) can be confused with hemorrhoids. Wherever doubt exists, any macroscopic lesion should be biopsied and subjected to histological examination. This is usually a minor procedure causing little discomfort or morbidity.

Investigation of Rectal Bleeding

Colonoscopy is a relatively safe and highly skilled visual examination of the colon and rectum employing sophisticated (and expensive) fiberoptic instruments. The examination may be uncomfortable for the patient, but this can usually be circumvented by the use of intravenous analgesia. The procedure's chief advantages lie in the accuracy of diagnosis and ability to biopsy any pathology seen or in some cases removal of polyps. The chief disadvantage, apart from expense, lies in the small but real risk of colonic perforation during the procedure. If this complication occurs, there is a significant probability of fecal peritonitis developing, and the patient's life is placed at risk. Often emergency major abdominal surgery has to be considered.

Recently, CT pneumocolons have been well established as a noninvasive method to investigate the colon and rectum. This technique suffers from the disadvantage of involving large doses of radiation to the patient; for this reason, it is an investigation only considered in the older patient, i.e., beyond reproductive age. There is also the additional disadvantage that no biopsy is possible if pathology is visualized. Such patients may then have no alternative but to proceed to colonoscopy in addition.

Anal Trauma

The clinician must always be aware that anal injury may be consistent with anal rape or damage sustained during childbirth (third-degree perineal tear) and careful documentation of the injury may be required for subsequent medicolegal needs. Clinical examination would include simple inspection to assess damage to skin and digital examination to assess damage to the underlying anal sphincter musculature. At a later stage, objective documentation of the presumed injury would include visualization of the sphincter complex by anal ultrasonography and magnetic resonance imaging (MRI) and possibly would also include a physiological assessment of the anal canal.

Rectal Disorders

The most important disease which the clinician needs to exclude in a patient suspected with rectal disease is rectal carcinoma. Often the diagnosis can be achieved by simple digital examination of the anal canal: the majority of rectal cancers have been shown to be "within reach" of an examining finger. Following digital examination, sigmoidoscopy, which is a simple and safe examination of the rectum, is performed without anesthetic in the outpatient environment. This simple instrument allows examination of the entire rectum and some of the colon just beyond. At the same time, if any pathology (e.g., rectal carcinoma or polyp) is identified, a small biopsy can be safely taken for histological examination. In the author's opinion, it would be considered negligent not to carry out these two simple investigations in a patient suspected of rectal disease.

Colonic Disorders

Simple clinical examination including digital examination of the rectum and sigmoidoscopy is mandatory in all patients suspected of colonic disorders. Again, the most important disorder which needs to be excluded is carcinoma of the colon. Since the diseased

area is likely to lie beyond the reach of the sigmoidoscope, more invasive methods are required, e.g., colonoscopy, to make the diagnosis. At the time of the colonoscopy, as discussed above, any pathology seen can be readily and safely biopsied.

Specific Complication of Colorectal Surgery

As with all other forms of surgery, many of the procedures employed to treat these diseases are invasive with attendant risks for the patient. For this reason, it is now mandatory to discuss the potential risks in detail with the patient (or relative) preoperatively and list the most important risks on the consent form prior to the patient's signing.

Anal Surgery

Hemorrhoidectomy is the most common performed procedure within this speciality and also is the most common procedure which may result in profound patient dissatisfaction and possible litigation. In most cases, the procedure involves excision of perianal skin which is rich in sensory-nerve endings. Hence, the operation is often associated with severe perianal pain in the postoperative stage, the pain being greatly aggravated by defecation. Because hemorrhoids have a rich blood supply hemorrhage is a common postoperative complication.

Because of these major problems, it is extremely important to counsel any patient undergoing anal surgery (even minor surgery, such as excision of an anal skin tag) that they must expect symptoms which can be severe and can only be partially countered by the use of powerful analgesics and local agents. The patient must be warned that they will require a suitable period of convalescence and cannot expect to return to work after a short period.

In rare circumstances, the procedure may be performed negligently such that the anal sphincters may be damaged leading to permanent fecal incontinence. Under these circumstances, substantial damages are usually awarded against the surgeon concerned, justifiably.

The treatment of anal fissure is generally by local agents that carry no significant complications (e.g., dilitiazem, and glyceryl trinitrin). However, a small number of patients do not respond to these agents and require treatment by surgery: sphincterotomy. This procedure involves division of a small portion of the lower end of the internal anal sphincter. In some patients, this could lead to partial anal incontinence: namely, incontinence to liquid stool and to flatus. It is, therefore, vital to counsel such patients prior to surgery and warn them of the risks involved. The risks are minimized if the surgeon is careful not to divide the entire length of the internal anal sphincter.

The treatment of anal fistula may involve division of a portion of both the internal and external anal sphincters in order to achieve adequate drainage of the sepsis. The skill of the surgeon lies in the understanding of how much sphincter can be safely divided without rendering the patient fecally incontinent postoperatively. A preoperative MR scan of the perineum should be performed so that the fistula tract can be accurately mapped out preoperatively and a prognosis provided on the subsequent risk of functional problems resulting postoperatively. Where extensive division of the anal sphincter mechanism appears necessary to achieve satisfactory drainage (i.e., in high anal fistulas), it is sometimes possible to avert problems by the application of a ligature (seton) around the affected anal sphincter to promote drainage.

Rectal Surgery

Excision of the rectum, either total or partial, may be necessary in the treatment of malignant conditions of the rectum or in certain inflammatory disorders (e.g., Crohn's disease and ulcerative colitis). Dissection of the rectum may involve damage to the delicate sympathetic nerves which surround the rectum and subsequently innervate the bladder and penis (or vagina). Therefore, damage to these nerves may subsequently give rise to problems with micturition and/or sexual function (e.g., failure of ejaculation and failure of erection) postoperatively. It is therefore extremely important that patients are warned of the 5% risk of these complications developing. In the author's opinion, these complications are unfortunate and are not the result of negligence on the part of the surgeon.

Abdominal dissection of the rectum involves a pelvic dissection close to the anatomical site of the ureters and bladder. It is relatively common to damage either of these structures inadvertently. Wherever possible a preoperative CT and MR scan of the pelvis should be carried out so that the anatomical site of the ureters with reference to the rectum and relevant pathology (e.g., carcinoma) can be assessed so that the surgeon is prewarned if there is close proximity of the tumor to one of the ureters. During the operation, it is good practice to identify both ureters at an early stage and carefully exclude them from the dissection.

In the procedure of anterior resection of the rectum, the rectum is partially excised and an anastomosis constructed between the colon and lower

rectum. If the portion of rectum remaining is of short length, the reservoir capacity of the rectum is much reduced, with the result that these patients may experience considerable functional problems postoperatively. Commonly, these patients experience marked urgency of defecation, soiling, and in severe cases, frank fecal incontinence. Patients must be warned preoperatively of these risks, and it should be discussed whether or not they would prefer to undergo total rectal excision with the provision of a stoma as a preferable line of therapy.

Colonic Surgery

As a consequence of colonic resection, either ureter may be damaged and during dissection of the right side of the colon the duodenum may be inadvertently damaged with the risk of a duodenal fistula developing postoperatively. As with rectal disease, it is vital to carry out a proper and full preoperative assessment including a detailed imaging, such as CT scanning. Hopefully, this will allow the surgeon to be prewarned of possible technical difficulties and permit measures to reduce the risk of inadvertent damage. For example, if the CT scan shows proximity of the tumor to either ureter the risk of damage may be reduced by asking a urologist to insert a ureteric catheter preoperatively.

Stomas, which can be created from either the terminal small bowel (ileostomy) or the colon (colostomy), are frequently performed in colorectal surgery. They can be fashioned either as a permanent measure such as in the treatment of a cancer of the lower rectum or as a temporary measure. In the latter instance, this may be a measure instituted to divert fecal matter away from a technically difficult anastomosis below the stoma. The stoma would then be closed when it is judged safe and the anastomosis demonstrated to be fully healed.

Stomas understandably cause great anxiety to patients and are the principal cause for delay in seeking advice where rectal cancer is suspected. In practice, they are rarely a major problem for patients, most of whom rapidly adapt to their management. It remains vitally necessary that any patient being considered for a stoma should be fully counseled both by medical staff and by fully trained stoma therapists. The counseling includes discussion on the most suitable siting of the stoma for the individual patient, as well as general management and possible cosmetic and sexual problems they may experience. Ideally, the preoperative workup should include the availability of a volunteer ileostomist or colostomist, who would be prepared to discuss the implications of a stoma with the patient.

Summary

The potential for surgical accident and litigation in this specialty is high, but fortunately rare. This is largely the result of intensive and closely supervised training of the junior grades followed by rigorous examination before the trainee is permitted to apply for the part of a consultant. The activities of the RCS and the AOC have done much to improve the quality of training and, thereby, the public remain, to a large extent, protected from incompetent clinical practice.

See Also

Medical Malpractice: Overview

Further Reading

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Ear, Nose and Throat Surgery

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Introduction

Despite the importance of this topic there is a surprising dearth of related literature, no doubt due to the relative infrequency of complaints and litigation in the past. A Medline search revealed only ten articles related to informed consent or medical negligence in ear, nose, and throat (ENT) practice. However changing attitudes have led to an increasing number of complaints in recent years, while the scope of ENT surgical practice has broadened and encompasses facial plastic surgery as well as endoscopic and skull base surgery; dissatisfaction with the outcome of rhinoplasty and complications of endoscopic sinus surgery are common.

In this article a general consideration of malpractice in ENT surgery will be followed by specific problems in otology, rhinology, and head and neck surgery. All the outcomes described have resulted in complaints or litigation.

The term malpractice, like negligence, implies blame. The terms mishap or adverse event, however, do not necessarily imply surgical error. Many apparent errors originate primarily in system failures rather than solely in an individual's acts or omissions.

In ENT practice errors are common but few result in injury, and few of these lead to malpractice claims.

Good communication makes a claim less likely, as many complainants say they only want the truth and to ensure others are not similarly afflicted, rather than money.

Lack of time can lead to a failure of communication. The British Association of Otolaryngologists (BAOL) indicates that a 3-hour clinic should contain no more than 12–14 patients. In law being too busy is no defense, nor is fatigue.

Surgeons must ensure they are properly equipped, both technologically and personally, and have adequate trained nursing and ancillary staff. The tendency of some hospitals to lose medical records is lamentable. The records must be full, accurate, and contemporaneous.

Duty of Care

For a claim of negligence to succeed there must first be a duty of care. All medical practitioners are responsible for their acts or omissions, but consultant surgeons are also jointly liable for that which is done under their supervision. A consultant must ensure that appropriately trained or supervised individuals carry out all care. Trainees are more likely to err; for example, the incidence of adverse events after stapedotomy is less when only senior surgeons operate.

Training and Malpractice

Surgeons must be able to show that they have appropriate training for the work they do, otherwise an accusation of malpractice is difficult to defend. While most ENT surgeons undertake general ENT cases, subspecialist training is bringing greater experience and expertise to complex work. In pharyngeal pouch surgery for example, CEPOD (Confidential Enquiry into Perioperative Deaths) (UK) for 1996–1997 recommended that a single surgeon in each district should have responsibility.

The master and apprentice training model is applicable in head and neck surgery but in otology and rhinology much of the surgery is done single-handed, with the risk of error when the operator is inexperienced, even while the supervisor may be watching the monitor.

Otologists have always trained and practiced on human cadaver temporal bones; however these are now difficult to obtain. Regional temporal bone dissection courses are slowly evolving, and synthetic bones are now available. A recent British survey showed that an average ENT trainee comes to the end of six years of training with little experience of complex middle-ear surgery and is not therefore properly equipped to practice otology. Similar considerations apply to surgical residents in the USA and in other training programs. Subspecialism in the last two years of training should improve outcomes, and consultants wishing to take on subspecialist interests should undertake appropriate training or arrange supervision while performing new procedures.

Outcomes

On Florence Nightingale's wards, outcomes were measured as relieved, unrelieved, or dead. Nowadays any complaint is more defensible if surgeons can quote their own figures for outcomes rather than data published by others. A case series with limited numbers of a particular procedure or with poor results compared with the average can imply a poor standard of care. Such suppositions should however take into account the case mix: a series dealing with particularly complex cases is expected to have poorer results than those for routine or uncomplicated work. Currently data are routinely obtained for head and neck cancer outcomes but the continuing general failure to audit both in terms of quality of life and specific outcomes is surprising. It is however difficult to obtain meaningful data for such complex outcomes as those for ear surgery and basic data sets are now available to assist in this process, while similar data sets are evolving for rhinology.

How Errors Occur

Errors may be classified as an act of omission or commission.

Omission

- Failure to examine properly, investigate appropriately, or act upon the findings.
- Failure to refer either to a colleague in another specialty as appropriate or to a colleague with specific experience of the case in hand.
- Failure to institute mandatory treatment, for example, prophylactic antibiotics before neck surgery where the pharynx is opened. A fistula after this event would be grounds for a claim of negligence.
- Failure to monitor the facial nerve when it is at risk, for example, in mastoid surgery or parotidectomy. Surveys indicate, surprisingly, that this is not a standard practice.

Commission

- Lack of care or judgment in management, for example, taking on a case for which the surgeon is not adequately equipped.

Informed Consent and Negligence

Wide variations currently exist in the consenting process. It is clear that, unlike in the USA, UK law does not require a document describing the minutiae of every conceivable adverse event; however, worldwide it is negligent if common or serious complications are not discussed.

Complications may be regarded as avoidable and unavoidable. An example of the latter might be graft failure, while, of the former, a dislocated incus during a stapedotomy represents a poor standard of practice. In microsuction of the ear, it is unacceptable that a previously normal eardrum be perforated. Facial palsy during a straightforward superficial parotidectomy or mastoid exploration should not occur. In the USA and more recently in the UK, this event often leads to a successful claim for negligence. Consent does not necessarily exonerate surgical mishaps.

Patients should understand the normal postoperative course so that routine events, for example bruising after rhinoplasty, are not misinterpreted as adverse events.

Figures 1 and 2 show the relative frequency of complaints in various areas of independent ENT practice derived from claims dealt with by the UK Medical Defence Union. These are now discussed under the specialty headings.

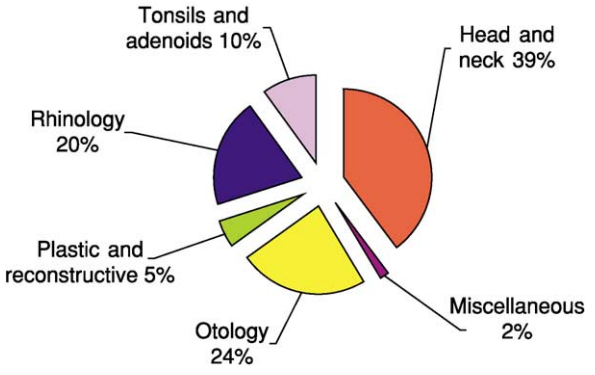

Figure 1 Complaints in ENT surgery (main area of practice).

Head and Neck

An accurate and documented history and examination must be carried out.

Fiberoptic nasendoscopes must be available in globus sensation to exclude tumor. Failure to diagnose carcinoma of the larynx is not uncommon.

In glue ear in an adult, it is important to exclude nasopharyngeal cancer, particularly in Chinese patients.

Failure to Investigate

If a neck gland is removed that is subsequently shown to be a metastasis from a squamous carcinoma, then the patient has at best had an unnecessary operation or at worst has a worse prognosis. Fine-needle aspiration prior to parotid or thyroid surgery may indicate the need for more or less radical surgical treatment.

Foreign Bodies

These can be missed, particularly if radiolucent, such as dentures. Foreign bodies must be ruled out in the case of unilateral rhinorrhea or recurrent chest infection.

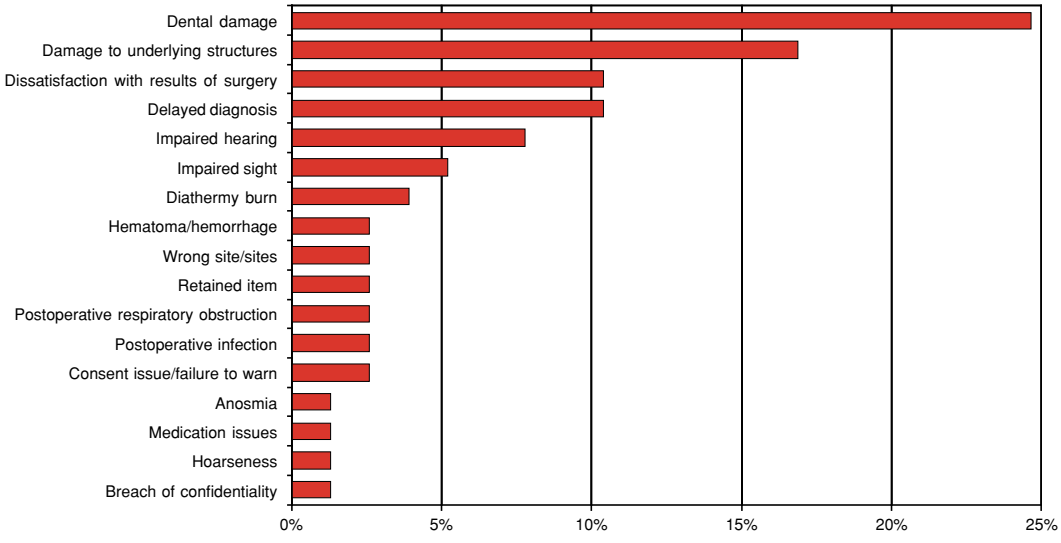

Figure 2 UK ENT settled claims in a 14-year period.

Failure to Stage Accurately

In head and neck cancer the existence of distant metastases must be investigated in addition to local staging and treatment.

Potential Neural Complications

Although always cut in a classical radical neck dissection, the spinal accessory nerve should be preserved in a conservative neck dissection unless it is close to involved nodes. Section of this nerve during a node biopsy is indefensible and is an occasional source of litigation.

The vagus and phrenic nerves are at risk, though they are rarely damaged.

With regard to the brachial plexus, it is essential to stay superficial to the deep fascia when dissecting in the root of the neck.

The facial nerve trunk is at risk if a neck dissection is taken very high to get above tumor, or during total parotidectomy.

The marginal mandibular nerve may potentially be injured at the time of a submandibular gland resection and will be sacrificed if forming part of a classical radical neck dissection.

The recurrent laryngeal nerves are at risk during thyroidectomy as well as the superior laryngeal nerves.

Frey syndrome and salivary fistula should be discussed before parotidectomy.

Dental problems are common sources of complaint following adenotonsillectomy as well as other transoral procedures. Secondary hemorrhage occurs in 5% of cases but is still a source of litigation.

Obstructed tube or displacements are potentially lethal complications of tracheostomy.

Operations in the floor of the mouth may result in airway obstruction due to edema: the UK Medical Defence Union has dealt with one death resulting in litigation from this cause.

Perforation should not occur in a straightforward upper esophagoscopy; it is debatable whether rigid endoscopes should be used in the lower esophagus where there is much greater risk. There is a risk of perforation when removing foreign bodies or dilating structures.

Otology

Failure to Examine

Attic disease may be missed if microscopy and suction clearance are not carried out.

Failure to Investigate

With regard to unilateral sensorineural hearing loss and tinnitus, a plethora of audiological techniques have been used to indicate the likelihood of a lesion in the cerebellopontine angle. However magnetic resonance imaging (MRI) is now the "gold standard;" failure of diagnosis where no MRI scan is requested is negligent.

Computed tomographic (CT) scanning in chronic suppurative otitis media is not yet mandatory, but CT shows erosions or fistulae, so that the patient can be advised of an increased risk of hearing loss or facial nerve injury.

The BAOL in the UK has published guidelines that ototoxic antibiotic eardrops may be used in discharging middle ears, however it is safer to use ciprofloxacin drops. These are licensed for that purpose in most countries but not in the UK, where eye drops can be used in the ear on a named-patient basis. Povidone-iodine solution is ototoxic and care must be taken when cleaning the skin prior to operations where the eardrum is perforated.

Ear syringing is usually carried out by general practitioners or their practice nurses. It is estimated that 1:1000 cause major complications. It is essential to rule out a history of preexisting ear disease and to adhere to protocols for safe practice.

In the surgery of chronic suppurative otitis media, patients must be aware of the failure rate in terms of a continued wet ear and worse hearing. The author has been involved with two medicolegal cases where sensorineural hearing loss and tinnitus have followed apparently straightforward myringoplasties. Cholesteatoma surgery does not necessarily avoid subsequent intracranial complications in chronic otitis media.

In stapes surgery, sensorineural hearing loss or tinnitus may result in a complaint. Facial palsy should not occur. Where a persisting stapedial artery is coagulated there is a small chance of blindness.

In corda tympani nerve section, contrary to traditional teaching there are more long-term symptoms if the nerve is cut rather than stretched. Corda symptoms are more likely in cases where there is no inflammatory disease.

It has traditionally been regarded as bad practice to operate on the only hearing ear; however, with conservative technique it is safe to operate in chronic otitis media on the only hearing ear where necessary.

In cases of congenital ear anomaly, unilateral canal atresia should not be operated. Bilateral disease should be managed in a specialist center.

Rhinology

While septal and turbinate surgery is within the province of the ENT generalist, the Hopkins rod endoscope has revolutionized the practice of sinus surgery.

With improved understanding of the pathophysiology of the sinuses, simple but invasive and traumatic procedures such as the Caldwell-Luc operation are rarely indicated. However, the advent of endoscopes and CT scanning has encouraged surgeons to take on more complex maneuvers close to the orbit and skull base with the potential for injury to the lacrymal apparatus, the optic nerve and ocular muscles, and the anterior ethmoidal artery or meninges. The incidence of complications is in fact no greater than before but the new litigation climate has led to an increase in the number of claims. It is important to stress that surgery is unlikely to help common complaints such as postnasal drip or facial pain.

Rhinoplasty is recognized by the medical defense organizations as an appropriate operation for the appropriately trained ENT surgeon. However, patient dissatisfaction with the results of this operation is relatively more common than for any other ENT procedure.

Failure of Diagnosis

Endoscopic examination in clinic is now mandatory for patients presenting with sinonasal symptoms.

CT scanning is mandatory prior to endoscopic sinus surgery.

Failure of Management

Training in endoscopic sinus surgery must include the avoidance and management of iatrogenic trauma to the skull base and orbit, including orbital hematoma.

Hyposmia may be present before surgery, although smell test kits are not customarily used and it is therefore difficult to defend an allegation that surgery has negligently resulted in this complication. The removal of the middle turbinate will by definition remove some olfactory fibers and an important landmark.

See Also

Drug-Induced Injury, Accidental and Iatrogenic; **Drugs, Prescribed:** Licencing and Registration; Product Liability; **Medical Malpractice – Medico-legal Perspectives:** Negligence, Standard of Care; Negligence, Duty of Care

Further Reading

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Facio-maxillary Surgery

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Definitions

The specialty of maxillofacial surgery is centered on the bones and soft tissues of the jaws and face but traditionally includes surgery from the clavicles to the skull vertex. Thus the specialty currently enjoys a position in the head and neck not dissimilar from that of the general surgery of yesteryear before subspecialization removed urology and vascular surgery from the generality of general surgery.

Maxillofacial surgeons might thus be viewed as the "general surgeons" of the head and neck region. Due to the dense complexity of the structures in the head and neck region, certain organs are excluded from this generality. The brain and cervical spine, globe and middle and inner ears are properly the domain of the neurosurgeon, eye surgeon, and ear, nose, and throat surgeon. However, inevitably, subspecialization within maxillofacial surgery is also possible with the evolution of cancer surgeons specializing in head and neck malignancy, orthognathic surgeons treating jaw disproportion, facial esthetic surgeons normalizing facial deformity, trauma surgeons dealing with head and neck damage, and even salivary gland surgeons.

Terms allied with maxillofacial surgery are "craniofacial surgery," in which serious facial deformity requires the combined surgical skills of the neurosurgeon and maxillofacial surgeon, or in which the maxillofacial surgeon facilitates the access of the neurosurgeon to the skull base by reflecting soft- and hard-tissue flaps. The term "head and neck surgery" tends to be used for major surgery in the region, particularly when malignancy is treated. The term "facial orthopedics" is occasionally used to describe the treatment of trauma to the facial skeleton or elective surgery to the facial bones due to disproportion.

The Nature of Maxillofacial Surgery

Maxillofacial surgery has a number of core areas of surgical interest and expertise. These include malignant diseases of the mouth, jaws, face and neck, orthognathic surgery, the surgical treatment of oral disease, orofacial trauma, salivary gland disease, surgery of the temporomandibular joint, orofacial reconstruction, and facial esthetic surgery.

Essentially, the specialty is concerned with investigation, diagnosis, and treatment of conditions of the head and neck. The work of senior surgeons will depend on their training and expertise in other specialties. While they will be competent to deal with most conditions within areas of core interests for the specialty, some surgeons will subspecialize and have greater competence in one discipline or another.

Malpractice

It is interesting that, despite the highly emotive nature of conditions around the face and mouth requiring treatment including surgery, the specialty of maxillofacial surgery is less beset by lawsuits than specialties such as neurosurgery or plastic surgery. In the case of neurosurgery, with its connotations of life and death, or more poignantly, life beset with tragic restrictions, it is perhaps understandable that legal redress will be sought for such major dissatisfactions. In the case of plastic surgery, the cosmetic element is frequently beset with litigation due to the highly charged and emotional nature of the expectations that are placed on such surgeries and the inevitable associated costs.

In this article maxillofacial surgical procedures most prone to malpractice suits are covered with a brief description of why the procedure might be required and how it is accomplished. The information and warnings that should be given in order to obtain valid consent are described along with common complications that might be associated with negligence or malpractice.

Surgical Procedures

It is important when dealing with surgical procedures that are of an intermediate or major nature to ensure that the information given to patients is not only what the surgeon feels is appropriate, but also what the patients need. Once the information is given, it is the responsibility of the surgeon to ensure that it is also understood and that patients have sufficient time within an encouraging atmosphere to ask further questions and explore their concerns. The development of a sympathetic relationship with both surgeon and patient should work toward the best possible outcome. It is also important for the surgeon to share with the patient his/her concerns with regard to the procedure and its possible complications. It is only in this atmosphere of mutual support and trust that best treatment will occur and that when problems arise, they may be understood by the patient to be unavoidable within a caring context, when this is the case.

Surgical Resection of Malignancy

The majority of malignant tumors in the head and neck region that require major surgery are squamous cell carcinomas. These tumors, in common with most cancers, are capable of metastasizing or spreading to other parts of the body. These secondary tumors, arising from a primary lesion from within the oral cavity or nasopharynx, spread via the lymph drainage system, blood, or directly through soft tissues.

Basal cell carcinomas of the facial skin are also commonly dealt with by maxillofacial surgeons, but these lesions characteristically do not metastasize and are usually dealt with by local resection and primary closure when small, although they may require large flaps and even free grafts on occasions.

Surgery is not the only option in the treatment of head and neck cancer, and in many cases, radiotherapy can offer an equally successful outcome, sometimes with a lower morbidity. Chemotherapy, although rarely curative for squamous cell carcinoma of the head and neck, can be a useful adjunct at certain stages of the disease. There are times when active treatment must give way to palliative care when a cure is impossible and further active treatment is unkind or inappropriate. It is therefore important that a maxillofacial surgery cancer patient is assessed on a combined clinic with a team of one or more surgeons with a special interest in head and neck surgery, a clinical oncologist, a radiotherapist, speech therapist, and dietician in order that the most appropriate treatment may be discussed with the patient.

Computed tomography or magnetic resonance imaging will usually be required to assess the stage of the disease which, with a detailed clinical examination, will be able to describe the disease by the TNM notation (tumor, node, and metastasis). The aim of cancer surgery is to resect the complete malignant lesion and reconstruct the surgical deficit in order to return the anatomy and function to as near normal as possible. When major cancer surgery has been carried out in the head and neck region, there is frequently some reduction in natural function and/or an orofacial deformity. The removal of an adequate and appropriate margin of healthy tissue around the carefully marked tumor is essential and unequivocal.

Once the resection has been carried out, the degree to which the patient is returned to a satisfactory cosmetic and functional state will depend upon the skills and experience of the surgeon, and thereafter, the further skills of the speech therapist and dietician. Potential complications of this type of surgery include: speech, swallowing, facial appearance, the presence of scars, and potential damage to nerves, including in particular, the lingual nerve providing sensation to the tongue, the inferior dental nerve providing sensation to the lower lip and chin, the hypoglossal nerve moving the tongue, and the facial nerve moving the muscles of facial expression, the patient should be warned of these in as supporting and caring a way as possible.

Despite the ravages of the malignant tumor and the inevitable destruction of the resection process, patients and their legal advisers are becoming increasingly concerned with the appropriateness of the surgery that has been provided and the quality of reconstruction. These are not as yet major sources of contention but may become so in the future.

Salivary Gland Surgery

The major salivary glands comprise the paired sublingual glands in the floor of the mouth anteriorly below the tongue, the paired submandibular glands in the submandibular fossae just below the horizontal rami of the mandible bilaterally, and the large parotid glands over and around the ascending rami of the mandible bilaterally.

The sublingual glands are removed due to the formation of ranulae or cysts associated with these glands which protrude into the floor of the mouth or due to concerns with tumors within the glands. The larger submandibular glands may require removal due to poor functioning associated with pain and swelling which may be occasioned by the formation of calculi or stones within the glands or ducts. The presence of a tumor within the gland will also necessitate its removal.

The parotid glands are frequently operated in order to remove a benign tumor known as a pleomorphic adenoma but may also require surgery if they are suspected of harboring other tumors or a malignancy or if the glands are functioning poorly with pain and swelling or prone to recurrent infection.

The sublingual salivary glands are usually removed by making an incision in the floor of the mouth and dissecting the gland free with its attachments. In contrast, the submandibular and parotid salivary glands require an incision in the neck for removal of the submandibular gland or an incision, usually anterior to the ear and extending into the neck, in order to remove the parotid gland.

Patients will be prone to soreness, swelling, and bruising after surgery. As well as warning patients of the relatively minor complications, it is important that they appreciate that the lingual nerve supplying sensation and taste to the tongue can be permanently damaged in the removal of the sublingual gland to which it is closely related. The lingual, hypoglossal, and lower branches of the facial nerve are closely associated with the submandibular gland and are at risk in its removal. Along with the damage to the taste sensation associated with the lingual nerve, the hypoglossal nerve allows movement of the relevant side of the tongue and the lower branches of the facial nerve control movement of the angle of the mouth and lower lip on the side of surgery. The trunk of the facial nerve closely abuts the parotid gland. All significant branches of the facial nerve pass through the parotid gland en route to the muscles of facial expression. Significant damage or transection of the trunk of the facial nerve will result in paralysis of the muscles of facial expression on that side, giving the appearance of a stroke. The great auricular nerve, which passes below and close to the parotid gland, frequently requires transaction, resulting in permanent numbness of parts of the external ear and, in particular, the earlobe.

It is important that the patient is warned of the important risks of nerve damage which, in the case of benign disease, are rare. Scarring on the face or neck is inevitable in removal of the parotid and submandibular glands, but the scars may be well disguised by the incisions being made into skin creases, as long as healing is uneventful. Temporary weakness after parotid gland surgery occurs in approximately one-third of operations but usually recovers within three weeks while numbness of the skin flap usually improves over four to six months. Frey syndrome (gustatory sweating of the face) can occur in up to 50% of parotidectomy patients. Sialocele and salivary fistulae can occur after parotidectomy and usually resolve spontaneously after some weeks. The removal of part or all of the parotid gland can result in an anesthetic hollowing of the facial profile.

When unwarned complications occur, or when the degree of complications is not commensurate with the level of disease, patient dissatisfaction and litigation are possible sequelae.

Orthognathic Surgery

This type of surgery to correct dentofacial deformity is so called as it straightens or normalizes the jaws and in so doing must also produce a balanced occlusion. It is usually necessary for realignment of teeth

before such jaw surgery, and it may even be necessary to continue realignment after surgery is complete. It is important therefore that patients for whom orthognathic surgery is contemplated should be seen in a combined clinic between a maxillofacial surgeon and an orthodontist.

Although the surgery is primarily functional in nature, in order to improve disproportion and occlusion as well as jaw position, the esthetic element must not be ignored. "Normalizing" the tooth position by orthodontics followed by "normalization" of jaw position by orthognathic surgery tends to "normalize" facial appearance to a great extent. It is important that patients are aware of changes that will be occurring in their teeth, jaws, and facial appearance before treatment begins as it may affect their decision to have surgery. It may be that additional surgical procedures need to be carried out in order to create a harmonious facial appearance after the planned jaw movements, and these must be agreed with the patient.

X-rays, predictive drawings, and computer-predicted images can be of help in allowing the patient to imagine the appearance the surgeons and orthodontists feel is likely. It is important that the patient realizes that such predictions generally indicate a trend rather than an absolute appearance and no guarantees should be made. It should be the goal of the surgeon to carry out the minimum of surgery to attain the required and agreed result and osteotomies, or cutting of the jawbones. Osteotomies are usually described as segmental (where sections of alveolar bone, usually bearing teeth, are sectioned) as well as LeFort 1, 2, and 3 osteotomies of the upper facial skeleton, depending on whether the bone cuts are made at the low, middle, or high levels. In the lower jaw, segmental surgery is also feasible, although sagittal splitting or vertical subsigmoid osteotomies of the mandibular ramus are more usual with or without genioplasty procedures to adjust the chin point position.

Once jawbone osteotomies are carried out, the bone is secured in its new position either by direct wiring or plating with screws or indirectly by wiring teeth together for around six weeks. There is a strong trend toward the increasing use of plates and screws in order that patients may open their jaws, thus protecting their own airway and to allow communication, eating, and drinking, all of which are easier when jaws are not wired together. Common complications include pain, swelling, bruising, and modest weight loss in the immediate aftermath of surgery. Patients must be warned however that a degree of relapse of the new jaw position can occur, although this is usually modest. In conditions where the jaw is open anteriorly (anterior open bite) there is a greater tendency for relapse to occur.

The inferior orbital nerves providing sensation to cheek and nasal skin, including the upper lip and associated gum, the inferior dental nerve giving sensation to the lower lip and chin skin, and the lingual nerves providing tongue sensation, are all closely associated with the osteotomy cuts usually required in this type of surgery and are therefore at risk of damage. Authorities vary widely regarding the frequency and degree of nerve damage that occurs in such surgery, but permanent and noticeable numbness probably occurs in less than 5% of patients undergoing such surgery.

The catastrophic loss of large portions of osteotomized jawbone is recorded in the literature as occurring rarely and is probably more prevalent in patients who have experienced cleft-lip and palate repairs where scar tissue and possibly abberant vascularization are present. This type of surgery is usually carried out electively and on young persons and, although considered functional, also has a strong esthetic element. For this reason such surgery is inevitably associated with optimistic expectations by the patient with reassurance, usually by the surgeon, that such surgery is normally "routine." It is therefore not surprising that when a desired result is not achieved or when a major complication occurs, dissatisfaction can deteriorate to litigation.

Facial Esthetic and Cosmetic Surgery

The surgical "normalization" of facial appearance when it falls significantly outside the mid-range might be considered as facial esthetic surgery while a convenient further division of surgery to improve facial appearance might be considered as "cosmetic" where surgery to mitigate the normal appearances of natural aging or to "improve" certain features already within the normal range is carried out. Such surgery, which is emotive, often patient-driven, and privately funded, will inevitably be associated with higher levels of dissatisfaction than when surgery is carried out to treat pathological processes. Such elective esthetic or cosmetic surgery includes blepharoplasty to improve the eyelids, rhinoplasty to adjust the appearance of the nose, rhytidectomy or facelift to mitigate the effects of aging on the facial skin, and a panoply of surgical procedures too numerous to mention here but amongst which are laser skin resurfacing, botulinum toxin injections to eliminate wrinkles, and collagen injections to bulk out lips.

There appears to be a trend toward lawyers and courts looking upon such elective and nonessential surgery as more a commodity than a medical

treatment, and it is inevitable that litigation will increase and the test for surgeons to satisfy in court will also escalate.

Trauma A major commitment in maxillofacial surgery is the treatment of facial trauma, usually occasioned by either interpersonal violence or road traffic accidents. There is tacit acceptance by both patient and surgeon that the surgeon will do his/her best in difficult circumstances to repair the damage done to facial tissues, while accepting that the circumstances and the emergency nature of surgery would allow for certain compromises.

There is a trend in trauma, as in other areas of surgery, for patients who are now better informed and empowered to replace blind gratitude with a discerning and occasionally litigious demeanor. In fact, this only serves to highlight the necessity for all professional healthcare workers to be aware of the latest and best accepted treatment for surgical conditions and to carry this treatment out in the patient's interest. The employment of sound audit, regular clinical governance, and continuing medical education is important as it will ensure that patients receive the best and most appropriate care and that surgeons are professionally satisfied and, of course, protected.

Temporomandibular joint surgery The temporomandibular jaw joint is heir to degenerative, traumatic, and psychosomatic conditions. Osteoarthritis and rheumatoid arthritis can affect and damage the function of the temporomandibular joint, as may trauma to the jaw joint, particularly where the bony or cartilaginous elements are badly damaged. In addition, conditions such as arthromyalgia and temporomandibular joint dysfunction are common conditions affecting one-third or more of the population at some time according to some authorities, but are rare in childhood or old age. The condition appears to be due in part to stress or anxiety and may generally be treated conservatively with reassurance, bite guards, physiotherapy, and other physical treatments such as ultrasound, mega-pulse, and manipulation. It is rarely necessary for surgery to be carried out, although minimally invasive techniques such as lavage of the jaw joint, manipulation, and jaw joint arthroscopy can be helpful. Surgery to the bone of the joint or the meniscus/cartilage is occasionally required for pain, locking, or unpleasant sounds and sensations which emanate from the jaw joint.

In medicolegal terms, deterioration in long-standing temporomandibular dysfunction symptoms or the development of such symptoms *de novo* are frequently the subject of litigation after road traffic accidents, particularly when there are whiplash injuries. Such claims must be dealt with on a patient-by-patient basis, although as a general rule if the condition has markedly deteriorated as a result of the alleged accident or assault or occurred as a new symptomatic condition, it would seem to form the basis for a valid claim.

Conclusion

In short, the maxillofacial region is an important and emotive part of the body and the surgeons who treat this region have, until recently, been spared the medicolegal attention given to their colleagues operating in different specialties. Although this is likely to change, it signals an excellent opportunity for the specialty to respond by ensuring that it is giving the best possible care and to continue to improve the healthcare partnership with the patient at the center.

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Medical Malpractice: Ear, Nose and Throat Surgery

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General Practice

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Introduction

This article describes the situation in the UK.

Negligence by a doctor in his/her professional capacity due to or following an action or inaction on his/her part is all too common. Substandard practice is unacceptable for general practitioners to the same degree as it is for any other doctor in medical practice. Because of the Bolam principle, albeit modified by Siddaway and Bolitho, the medical profession does appear to have a legal advantage over other citizens in the field of negligence. Negligent acts so carelessly and recklessly performed and leading to a criminal charge are rare. The Bolam principle is helpful to the medical profession by allowing the standards of care to be expressed as those exercised by the relevant medical peer group but at the same time other or minority views and opinions, if held by respectable peers, are acceptable. However, the opinions must be reasonable. In other words, the same legal rules apply to the general practitioner as to any other doctor. Negligence is governed by a duty of care to the individual concerned and a breach in that duty, which leads to damage that otherwise would not have happened. The civil system works on the balance of probabilities. If the probability is less than 50%, a claimant would not succeed.

General practitioners are expected to have a core of knowledge and skills common to general practitioners as a whole and be able to apply them in as effective and acceptable a manner as the next general practitioner, whether working in the National Health Service (NHS), that is the system of care provided largely through taxation and mostly free at the time in the UK, or privately, or both.

It has also to be recognized that complaints about a general practitioner's services may additionally be investigated by agencies outside the process of litigation, namely the contracting authority and subsequently the Health Service Commissioner and finally the General Medical Council (GMC). If a criminal charge involving negligence against a general practitioner is proven, this will be reported to the GMC.

The Problem

It has to be appreciated that changes in medical practice occur following new diagnoses or an increased understanding of disease and pathology, altering treatments and drug discoveries and changes in the natural history of disease. It is expected that doctors make themselves aware of these changes and modify their practice accordingly. Lord Donaldson in a judgment stated: "If a doctor fails to exercise the skill which he has or claims to have he is in breach of his duty of care. He is negligent."

For the general practitioner, the standard is that of other general practitioners, not specialists, but this holds whether the doctor is in year 1 or year 20 of practice. However, the general practitioner cannot or should not guarantee the results or outcome of his/her medical interventions as could an engineer building a bridge. Of course, even trained professionals make errors all the time but these tend to be trivial or easily reversible. Good training enables people to anticipate or quickly recognize problems so as to take evading action. The fact that general practitioners work in a medical environment that is uncertain and often at the early stages of the presentation of disease can create a climate where diagnostic errors may occur. It also has to be recognized that errors may occur not because of individual imperfections but because the system in which the practitioner works lacks processes or mechanisms that check organizational efficiency, detect errors, or provide sufficient resources.

Rules and Regulations

Technically speaking, self-employed general practitioners in the NHS do not have contracts with individual patients, be they registered under permanent, temporary, emergency, or other procedures. The general practitioner's own contract with a health authority is sufficient to establish a duty of care in respect of a registered patient, including those patients not registered with the general practitioner concerned whose conditions have to be considered in an emergency situation. The current General Medical Services Regulations (2004) make it clear that a practice providing general medical services under their contract is expected to act "with reasonable care and skill." This means in a like manner as would other practices under similar circumstances where partners or employees were exercising professional judgment requiring generally accepted knowledge, skills, and care but no higher. Of course, this would not prevent any general practitioner from exercising a higher standard. Clearly if the generality of general practitioners became more knowledgeable and skillful, this would affect the acceptable standard of care provided by increasing it.

Part 5, Section 12 of the General Medical Services Regulations sets out the general statement that the general practice shall provide essential medical

services to their patients. There are separate contractual arrangements for other specific services such as intrapartum obstetrics and minor surgery involving cutting or injections, but whatever contract or contracts are held, a general practitioner is expected to have the relevant knowledge and skills to undertake the required care. Employed doctors, such as assistants or general practitioner registrars or other employees such as nurses, receptionists, or secretaries in undertaking their relevant tasks may do so in a negligent manner but the employing general practitioner(s) have to be ready to take legal responsibility for their acts (or omissions). However, all these employees are or should be covered by separate independent indemnity cover to that of the general practitioner principals themselves. The position regarding locum practitioners is not clear. However, an employing general practitioner could be held responsible if he/she engaged a locum without checking that the locum was competent for the purpose and subsequently the locum injured a patient, amounting to negligence. It has to be remembered that general practitioners in partnership are or may be equally liable.

Factors Leading to Claims

1. There may be problems of communication. The medical notes and records or telephone messages may be incomplete or illegible. Reliance on memory is no substitute for recorded information. Communication amongst members of the practice staff (or from a deputizing service that is an organization providing locum doctor services) may be poor. Incomplete information may be conveyed to other outside agencies, especially in relation to hospital referrals, e.g., a history of anaphylaxis to penicillin or other drug reactions. Clearly, medical records must not be changed falsely. If changes can legitimately be made, these should be made clearly, initialed, and dated.
2. If, following a consultation or other medical intervention, circumstances arise or are noted in which follow-up, treatment, or referral to other agencies would be desirable or necessary, then the relevant option should be discussed with the patient and acted upon. This would also include considering or carrying out treatment advised by hospital specialists. It would be especially important to note in the records a patient's refusal for treatment or referral. It may well be that the general practitioner's examination was deficient and this had a direct effect on a harmful outcome. However, given an acceptable examination, a mistake in making or considering a diagnosis would not necessarily be negligent. If the failure to make a diagnosis is because an examination is not carried out, e.g., failure to visit and avoidable harm results, this may well lead to a claim being made. Telephone consultations do occur. There are advantages and disadvantages in relying on such proceedings but it has to be recognized that there may be avoidable risks in offering advice in the absence of a physical examination.

   Problems may arise if the general practitioner does not act on abnormal results of investigations which he/she has initiated or ordered. It is wise for the general practitioner (or nurse) to ask the patient to contact or visit the surgery to obtain the results. Failure of the patient to do so may not exculpate the general practitioner if he/she fails or fails to attempt to contact the patient. Abnormal results derived from hospital clinics would be expected to be acted upon by the responsible hospital doctor concerned.
3. If a patient suffers from an adverse drug reaction (whosoever had originally prescribed the drugs), the general practitioner should note this clearly in the medical records. Represcribing a drug that had previously resulted in an adverse reaction may be deemed negligent. Blind prescribing of a drug little known to the general practitioner at the behest of a hospital doctor, especially if clinical control is maintained by the hospital, resulting in harm to the patient, may not be excusable. It must be remembered that the prescribing doctor is or may be legally responsible for any mishap. He/she is certainly legally responsible for writing the prescription and, in the best of all worlds, the doctor who has and retains clinical responsibility for the patient should undertake the prescribing. Joint responsibility may occur, as in obstetric care, but each doctor must know what the other one is doing and prescribing. In other words, a general practitioner cannot escape legal responsibility for any harm by stating he/she was merely carrying out the orders or request of a hospital doctor. The general practitioner should always have an up-to-date *British National Formulary* (a comprehensive book describing the drugs in use, their indications, doses, side-effects, contraindications, interactions, and dangers) at hand and use it. Family doctors in other countries would no doubt have a similar publication to which to refer.

   In prescribing a drug or drugs, the general practitioner should do so in accordance with the manufacturer's data. Product liability may fall on the general practitioner if for example he/she mixes two incompatible liquid drugs in a syringe and harm results.

4. General practitioners must take care before or during procedures so as to minimize or avoid harm. Such measures include only using a single-use syringe once, sterilizing equipment, or properly taking a cervical smear so that abnormalities can be detected.
5. General practitioners would be expected to maintain their professional premises in such a way to safeguard the safety of staff and patients, e.g., safe electric wiring, correctly positioning carpets on stairs, or ensuring that drinking water does not become contaminated.

The Good and Bad Sides to the Equation

It is interesting to note that it is only within the past 15 years that the number of claims against general practitioners in the UK has risen dramatically. In 1992 Margaret Brazier in her book *Medicine, Patients and the Law* reported on the relative rarity of malpractice claims against general practitioners, citing as reasons that general practitioners were viewed with a high measure of esteem by patients (which is still the case), that long-standing personal relationships could lead to mistakes being overlooked, and that negligence could be more difficult to prove against general practitioners.

Furthermore, the NHS complaints procedures then in place could allow patients to have any problems concerning their doctor's services aired. Additionally, it was easy for a general practitioner to refer a patient into the secondary care system.

These factors still remain but the Medical Protection Society reported in 1999 that general practitioners were 13 times more likely to be sued successfully by their patients than in 1989 and were 33 times more likely to be pursued with what were described as "spurious" claims. Furthermore, the amounts paid in damages have risen considerably. Many reasons have been advanced for the increase in the number of claims, including the development of a compensation culture amongst members of society but this merely describes what has happened and does not provide reasons for it. Further consideration of this is outside the scope of this article.

The Proposed Solution

Problems can be minimized if the general practitioner listens, takes a proper history, conducts the required examination, makes full records in the correct folder (both of the consultation and other contact events such as phone calls), carries out any appropriate investigations advising the patient of options and outcomes, obtaining agreement for any actions, treats the patient, referring him/her to other agencies when necessary, and visits when required. He has a duty to keep up to date and now has to be prepared for reaccreditation.

The General Medical Council's advice is:

1. You must keep your knowledge and skills up to date throughout your working life. In particular, you should regularly take part in educational activities which maintain and further develop your competence and performance.
2. Some parts of medical practice are governed by law or are regulated by other statutory bodies. You must observe and keep up to date with the laws and statutory codes of practice which affect your work.
3. You must work with colleagues to monitor and maintain the quality of the care you provide and maintain a high awareness of patient safety. In particular, you must:
   a. take part in regular and systematic medical and clinical audit, recording data honestly. Where necessary you must respond to the results of audit to improve your practice, for example by undertaking further training
   b. respond constructively to the outcome of reviews, assessments, or appraisals of your performance
   c. take part in confidential enquiries and adverse event recognition and reporting to help reduce risk to patients.

Carrying out these activities is likely to reduce the possible danger to the health of patients (and others for whom the general practitioner bears a responsibility). General practitioners will still make mistakes, but hopefully ones that will not lead to litigation.

See Also

Medical Malpractice – Medico-legal Perspectives: Negligence, Standard of Care; Negligence, Duty of Care; Negligence Quantum

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Intensive Care

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Introduction

Critically ill adults are amongst the most vulnerable patients in the hospital. They suffer from serious diseases that in combination with the treatment render them defenseless and completely dependent on their carers. In addition, they are often unconscious or confused. The complete physical dependence along with mental incompetence makes them vulnerable to injury caused by criminal, accidental, or negligent acts.

Criminal Acts – Murder

All parts of society have their mad, bad, sad, and misguided members and the medical and nursing profession has its share. Unfortunately, attempts to murder patients continue to occur. Most, but not all, episodes of murder in the critically ill are performed by nurses and are usually multiple. The reason for this is the amount of time spent with patients alone. Nurses have the opportunity because they are alone with patients for long periods. They are also responsible for making up drugs and adjusting ventilators. Doctors are rarely alone with patients, drawing up or giving drugs, and so do not have the opportunity. When a doctor does look after a patient alone, a single death may be viewed as bad luck, two deaths are really bad luck, but three deaths would be suspicious. Conversely, nurses look after patients all the time and with the high mortality (about 20% in most intensive care units (ICUs)) death is not unexpected and this may allow murder of patients to go unnoticed for a long period.

Attempts at murdering patients may be from the omission of drugs. For example, the doctors may have prescribed a catecholamine infusion, such as epinephrine (adrenaline). The nurse making up the prescription may omit the drug from the infusion, i.e., just put saline in the syringe, but still sign to say the drug is in the syringe. The absence of the drug results in hypotension. This is more common than might be thought.

In one postal survey of American critical care nurses, Asch found that 17% of nurses had received requests from the patient or family for euthanasia or help with suicide. Euthanasia (most often using high-dose opioids) had been engaged in by 16% of the nurses. A much smaller percentage (4%) had pretended to give essential treatment ordered by a doctor.

Directly harmful acts do occur. Nurses have been known deliberately to give muscle relaxants to patients who are not on mechanical ventilators, thus paralyzing their respiratory muscle. Similarly, they may make up antibiotics and other drugs for doctors to give with potassium rather than sodium chloride. If the doctor is careless and fails to check all the ampoules, then injection will cause sudden cardiac arrest. Administering a large dose of morphine is a further way of killing patients. The other way that nurses can murder patients is by adjusting the ventilator so it delivers insufficient oxygen or malfunctions in some other way.

The motive for these criminal acts varies. For some, a cardiac arrest after injection of potassium chloride generates excitement as the cardiac arrest team is called, and perhaps the patient's life is saved, or not. Others may want to see an improvement in the service. One pediatric nurse gave the reason for administering suxamethonium (a muscle relaxant) to children as a means of increasing the mortality rate so that services could be improved to reduce it. More commonly, it is a desire to see suffering stop in a dying patient. In this case there may be poor leadership by the medical staff: dying patients are not recognized and futile treatment withdrawn, so the nurse decides to take matters into his/her own hands. This may be

by giving unprescribed doses of morphine, omitting drugs, or adjusting the ventilator improperly. Sometimes there is proper leadership, but the nurse just decides to end the patient's life because the patient is suffering.

Proving there was misdoing is very difficult. With this type of crime it is only after many patients have died that colleagues become suspicious. After that there is usually further delay while the hospital authorities decide what course of action to take. More delay occurs when the police decide whether or not to investigate. The patient is dead, there are usually no witnesses, and the ventilator has been used on many other patients. Toxicology is occasionally useful, but more often than not it proves impossible to interpret. The drugs that may have been used to commit a crime have been used therapeutically, their elimination is abnormal, and tolerance develops. Because of this tolerance high serum concentrations may not mean that poisoning has occurred. It should also be remembered that the high death rate may mean that clusters occur purely by chance, leading to a crime of just "being there" or "having a bad run."

Surprisingly, the patient record can be of value in investigating whether unprescribed opioids have been used. To give these drugs special records are needed and nurses often continue to complete the forms meticulously, even if the drugs are not prescribed. Other drugs are much more difficult. In one case, the author looked through nearly 200 records completed by one nurse who had allegedly killed patients. There were multiple differences between the prescription and the administration of all types of drugs. Multiple nurses had made these errors.

There are much rarer cases of doctors being accused of murder. In a Canadian case it was alleged that a consultant gave large doses of first an opioid (hydromorphone 500 mg h^{-1}) to relieve a dying patient's suffering, which is perfectly proper. However, the patient continued to live and the physician gave a large, intravenous undiluted dose of a vasodilator (nitroglycerine) and then went on to give undiluted, intravenous potassium chloride. Both drugs were injected through the same femoral venous catheter. The patient died. The police were subsequently informed, and the doctor tried. The doctor was acquitted because there was doubt that the venous catheter was in the vein.

Negligence

Negligent acts in the critically ill appear to be more common amongst doctors than nurses. This is simply because doctors do more invasive procedures and prescribe drugs. In many countries a reduction in doctors' working hours has led to the nursing staff doing more both in the ICU and on the wards. As they take on extended roles, they will be more likely to encounter these allegations.

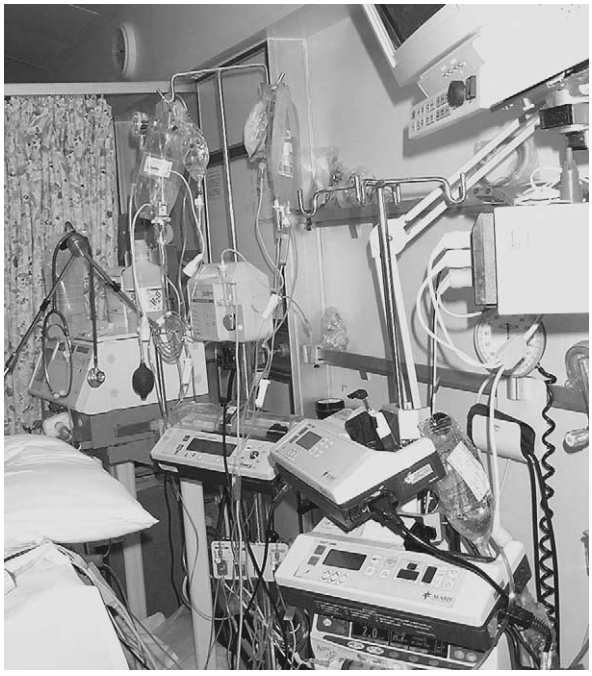

Figure 1 Multiple pieces of equipment in an ICU.

In the UK, litigation for negligence was rare in the critically ill, since most patients and their relatives were glad to have survived such an illness. This sentiment is now changing, and there has been a dramatic increase in litigation. However, because litigation was uncommon, medical note-taking was not as good as it is in other areas. Indeed, it is still common to find a medical intervention not recorded in the medical notes but recorded in the nursing record.

There is an adage that the more you do to a patient, the greater the risk of something going wrong. As a body fails, more and more needs to be done to the patient, increasing the risk of something going wrong. The ICU is a very technical environment and the complexity of the equipment makes it even more likely for equipment to malfunction or be misused. As the equipment becomes more complex, the corresponding level of experience in both the junior medical and nursing staff is decreasing. This is not just a UK problem, but a global one (Figure 1).

Some of the technologies and problems are described below.

Central Venous Lines

Central venous lines are one of the commonest causes of attempted litigation. Puncture of the carotid artery when the internal jugular vein is catheterized is an

accepted risk of about 2%, with a range of 0–30%. Usually, this leads to a hematoma and little else. Unfortunately, this type of accident is also associated with complete occlusion of the artery and the development of a stroke. So long as the central line was needed and inserted using the proper technique this is not negligent. Unfortunately, the situation has been complicated in some cases by the doctor using the line to infuse drugs that are irritant or cause thrombosis, and failing to remove the line for many hours. This method is not considered acceptable practice.

The National Institute for Clinical Excellence (NICE) has recently published guidelines indicating that these types of lines should only be inserted (except in emergencies and the like) using ultrasound guidance. Since monies have been made available for the purchase of this expensive technology; in the future if there is a complication during insertion, failure to use ultrasound may be considered substandard.

Perforation of the heart is another complication that may arise from this procedure. If the line ends above the heart, then perforation of a great vein results in a hydrothorax as fluids are infused. However, if the line tip is below the pericardial reflection, then perforation into the pericardium will result. If fluids are infused, they will cause tamponade, which may result in death. To prevent this complication a chest X-ray needs to be taken to confirm correct positioning of the tip before it is used for infusion, except in an emergency.

Nerve injuries may also occur as a complication. The recurrent laryngeal nerve may be injured after an internal jugular approach and similarly the femoral nerve after femoral vein catheterization.

Positioning

The critically ill patient is often semiconscious, either from illness or from the sedation and analgesia given to help the patient tolerate the interventions needed in the ICU. The resulting immobility, perhaps coupled with the need to use unusual positions and reduced arterial blood pressure, renders the patient more likely to suffer a pressure injury. These are varied and range from peripheral nerve entrapment through pressure sores to necrosis of the breast from turning the patient prone and pressure on a breast implant. It can be difficult to determine if the injury is caused by substandard care.

Peripheral nerve injuries in isolation most likely result from a failure to protect a vulnerable part of the body. However, the ulnar nerve may be injured, even if all precautions are taken, if its anatomy is unusual and it is outside the ulnar groove at the elbow. Multiple neuropathies occurring during a period of intensive care are usually caused by something other than poor positioning. These other causes may include critical care neuropathy or preexisting illness such as excessive alcohol consumption.

Pressure areas, such as the heel, may also be damaged if there is a prolonged period of immobility. Usually, there are other confounding factors, such as the use of catecholamine infusions causing poor skin perfusion in combination with hypotension. Some unusual pressure-relieving methods, designed to help, may worsen the situation. Diarrhea, a common complication of critical illness, may exacerbate a sacral sore.

Misuse of Drugs

As many as 20 drugs may be used in a critically ill patient at any one time. The potential for straying outside the recommended dose, duration of treatment, drug interactions, and adverse events is enormous. However, there are some relatively common problems with drugs of which both doctors and lawyers need to be aware and illustrations of these are given below.

Nonsteroidal antiinflammatory drugs (NSAIDs) These drugs are good at relieving some forms of pain, especially those where there is an element of inflammation. In addition, in severe pain they reduce the amount of opioids needed to treat severe pain. They have therefore found widespread usage in many areas of medicine. In the critically ill, two of their side-effects cause concern. The first is their effect on renal function. Because they all inhibit prostaglandin synthesis they prevent renal vasodilatation. In conditions of poor renal blood flow, such as shock, they add to the renal vasoconstriction and may precipitate renal failure after multiple doses (rarely one or two). If they are prescribed to the critically ill, then the renal function must be known and observed for toxicity of these drugs. Since the Royal College of Anaesthetists has published guidelines on their use (www.rcoa.ac.uk), failing to follow these guidelines in a critically ill patient may be considered substandard care if the patient develops renal failure as a consequence.

Deep-vein thrombosis (DVT) Immobility increases the risk of a DVT and a subsequent pulmonary embolus. The incidence of DVTs in the critically ill is between 13% and 30% and can lead to pulmonary embolism and death. In many areas of medicine, such as orthopedics, there is proven benefit from DVT prophylaxis. Some lawyers have suggested that failure to give DVT prophylaxis has resulted in avoidable pulmonary embolism and death. However, many

trials exclude the critically ill and only a few have shown benefit in some patients. The lack of this information makes it difficult to construct guidelines on which patients should receive prophylaxis.

Failing to give a drug The advent of life-saving, very expensive drugs has opened up a whole new era of potential negligence. In 2002, activated protein C (aPC: Xigress: Lilly Products) was introduced into clinical practice for the treatment of life-threatening sepsis. It has been shown to produce a 6% reduction in mortality from this condition. Its great expense (£5500) and the frequency of sepsis means that the cost pressure on some hospitals is large. Some have responded by not using it at all, arguing it has not been through the NICE procedure and recommended by NICE. (Once a drug has been approved by NICE, central funding to cover its cost is made available. It is also a requirement that the drug is introduced.) Others have introduced a system of rationing. There is no doubt for the majority of clinicians that this drug works, and it will be interesting to see if failure to give it will be considered unacceptable.

Starch solutions It is not just drugs that have adverse effects: common, everyday intravenous fluids also have adverse effects. Some fluids have a maximum amount that can be infused in a certain time. Starch solutions are used to replace intravascular volume, depleted either from sepsis or hemorrhage. Unfortunately, some starches interfere with blood clotting, causing an acquired lack of von Willebrand factor. This interference can increase the risk of hemorrhage in a susceptible critically ill patient.

Professional Problems

Doctors and nurses are expected to practice to the highest possible standards and failure to do so may result in allegations of professional misconduct. There are some common problems that affect ICU staff.

Sexual Hallucinations

About a quarter of patients suffer from abnormal dreams or hallucinations while they are in the ICU. Almost half of these abnormal dreams disturb the patient; many involve violence, death, attempted murder, and physical harm to him/her. It is easy to explain to the patient that this did not happen since he/she has no physical signs of violence. Much more difficult are the hallucinations that involve sexual assault such as rape and sodomy. A careful history and examination of the record may show precipitating events such as a vaginal examination or the insertion of a rectal temperature probe. Unfortunately, sometimes the patient will complain to the police or other authority first and an investigation may be started. Usually this is very damaging to the person against whom the allegation is made.

Patient Autonomy

Respect for the patient's autonomy is also expected. This becomes difficult when faced with an unconscious critically ill patient whose prognosis is poor. Issuing a do-not-resuscitate (DNR) instruction without consulting the patient or the family (as a surrogate) is expected of doctors. The same is true of a do-not-escalate (DNE) instruction. If the patient is competent then his/her wishes should be respected. As the case of Mrs. B in the UK showed, even if the patient wants life-supporting measures (such as mechanical ventilation) to be withdrawn, he/she has the right to that treatment being removed. However, it is important to draw the distinction between refusal of treatment and assisted euthanasia.

Organ Donation – Money for Organs

Transplantation of the heart, lung, and liver is life-saving. Unfortunately, the advances in this area have made it a victim of its own success. These organs can only be obtained from heart-beating cadaveric organ donors. This type of donor is only found in ICUs. There are organizations worldwide that offer transplants where the cost is many more times the cost of a transplant in the UK or elsewhere. Caution is needed by ICU doctors not to become involved in any trade of organs. It is strictly forbidden in most societies, although the matter is under debate.

Reporting of Deaths

Many of the deaths in an ICU need to be reported to a coroner, procurator fiscal, or medical examiner. Rules vary between countries and even regions of the same country (including within the UK) as to who should be reported. We have shown that directors of intensive care can be unaware of some of the regulations; but then the same study also showed that so were some of the coroners.

Record-Keeping in the Critically Ill

As in many areas of medicine, the patient record may be a central piece of evidence in a court case. The critically ill are often of interest to coroners, compensation lawyers, as well as criminal and civil lawyers. It is worth remembering that what you write in the notes may be read out in court. If you fail to record something, then you are unlikely to remember it later.

Do not criticize your colleagues and their treatment of the patient unless you are prepared to justify your criticisms later.

If you do find yourself giving evidence in court, always read the notes in advance of your appearance.

See Also

Complaints Against Doctors, Healthcare Workers and Institutions; **Expert Witness:** Medical

Further Reading

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Neonatology

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Introduction

The pediatric subspecialty of neonatology has advanced to a degree that public expectation of intact newborn survival, fostered by press coverage of "miracle" babies, could be considered unrealistic. Recourse to legal action following adverse outcome may have been suppressed in the past by the strong emotional ties that a family forms with their pediatrician during an infant's critical illness. Nowadays, neonatal death or complications with long-term sequelae are being increasingly subjected to medico-legal scrutiny. Claims of this nature are a justifiable means, and presently the only route in the UK, to securing large sums of money necessary to support a disabled individual appropriately for life. In as many as a quarter of such cases clinical negligence can be identified. That is not to say that all clinical negligence claims are successful, as the link to causation of an injury is often complex. Much neonatal morbidity is multifactorial in origin.

When considering any intervention in medicine the risk-to-benefit ratio has to be taken into account. This is no more so than when dealing with the fragility of life of a baby born 4 months prematurely and weighing between 500 and 750 g. Intact survival is possible but cannot be guaranteed. The parents have the right to be fully involved with decisions regarding viability and resuscitation at this early gestation. They must be aware that many of the innate complications of prematurity cannot be prevented, and that interventions carry the risk of iatrogenic injury.

Malpractice in neonatology covers failure of a medical or nursing professional to provide an

accepted level of duty of care through reprehensible ignorance or negligence or through criminal intent, especially when injury or loss follows. Negligence is a breach of duty of care, which causes damage. A doctor is in breach of his/her duty of care if he/she fails to provide a reasonable standard of care. Pediatricians, as in other specialties, can only be judged according to the state of advancement of their clinical field at the time of the plaintiff's injury. By contrast, deliberation on causation may benefit from discussion of the latest science. Recent therapies such as prenatal steroids to promote fetal lung maturation and postnatal surfactant replacement therapy for respiratory distress have halved mortality from severe hyaline membrane disease in the newborn. For a clinician to deprive a patient of the benefits of such treatments would constitute negligence if the breach of duty of care resulted in damage, such as death, chronic lung disease, or other complications attributable to the greater severity of lung disease.

In contrast to an adult patient of sound mind who is obliged to make a claim with respect to personal injuries within 3 years, limitation in the case of a child damaged by an injury in the newborn period is extended to his/her 21st birthday, or beyond. If the injured party remains incapable of managing his/her own affairs he/she is regarded by law as "being under a disability." In such cases, the right to sue continues throughout life and up to 3 years after death for the benefit of the claimant's estate.

Unlawful Killing and Manslaughter

Collective decisions on the withholding or withdrawing of care are regularly made by senior clinicians, parents, and nurses on delivery suites and neonatal units in the UK. The majority of deaths on neonatal units are directly attributable to withdrawal of care, in circumstances where the baby may or may not have succumbed to the underlying illness. The situation is unique to the newborn and only applies in cases of extreme prematurity, gross malformations, and in the context of profound brain damage. These difficult events need to be fully documented and second opinions should be provided. Approached with sensitivity, understanding, and flexibility according to parental wishes, it should be possible to act in the patient's best interests and prevent exposure of the parents or doctor to criminal law or the media. In legal terms, this remains a "gray area." Technically, the doctor who switches off a ventilator is committing a positive act that results in unlawful killing and is guilty of murder. Omitting to act where there is a duty to do so, such as at resuscitation, could legally be interpreted as manslaughter. The UK courts are sometimes used in individual complex cases to grant one-off "declarations of legality" to make lawful the decision to withdraw care.

The complexity of these issues is highlighted by a case in the USA where the medically qualified father was acquitted of manslaughter after taking his daughter (a 25-week gestation baby, weighing 780 g) off the ventilator on day one, despite the neonatologist's conviction that intensive care should be continued. In an era when babies born at 23 and even 22 weeks gestation are surviving, the majority of UK tertiary-level neonatologists would feel it appropriate to offer intensive care to a baby delivered at 23 weeks gestation, weighing more than 500 g, and born in a viable condition. They would do so in the knowledge that they hold joint responsibility with the parents for considering stopping intensive care if profound brain damage was identified, or a severe clinical deterioration meant that death was inevitable.

Iatrogenic Disorders in Neonatology

The invasive nature of neonatal intensive care and the fragility of many of its recipients result in a higher proportion of disorders arising from complications of procedures and treatment than in most other fields of medicine. These iatrogenic disorders are in many cases unavoidable despite optimal care. They should, however, be anticipated, recognized, and promptly treated. Malpractice occurs when there has been an unacceptable delay in recognizing or treating these disorders, or when the complication results from an unacceptable standard of care, such as a drug error or incorrect ventilatory settings (e.g., pneumothorax). Examples of conditions with potential iatrogenic causes or components are listed in Table 1.

Many drugs used in neonatology carry the risk of significant side-effects. For example, indometacin, used to encourage a patent ductus arteriosus to close, may cause gastrointestinal hemorrhage or perforation. The same complications can occur with the steroid dexamethasone when used to treat chronic lung disease, although this use of postnatal steroids

Table 1 Conditions with potential iatrogenic causes

Pneumothorax
Chronic lung disease
Subglottic stenosis
Retinopathy of prematurity
Necrotizing enterocolitis
Intestinal perforation
Gastric rupture
Conjugated hyperbilirubinemia
Periventricular hemorrhage
Periventricular leukomalacia

has been dramatically curtailed in the light of mounting evidence of an association with an increased risk of cerebral palsy.

Indwelling arterial lines placed either peripherally in the radial or posterior tibial arteries or centrally via the umbilical artery are invaluable for continuous blood pressure monitoring and atraumatic blood sampling. They do, however, carry the risk of hemorrhage and devastating ischemic injuries involving digit and limb loss (Figures 1 and 2). Umbilical artery catheters may also be associated with thrombotic or embolic obstruction of the renal arteries leading to renal failure, the mesenteric arteries causing gut perforation, and the lumbar arteries resulting in paraplegia. Buttock necrosis and sciatic nerve damage have also been described. As with intravenous infusions, regular nursing observations of arterial lines are essential for early detection of perfusion-related complications. As soon as there is evidence of compromised tissue perfusion an arterial line must be

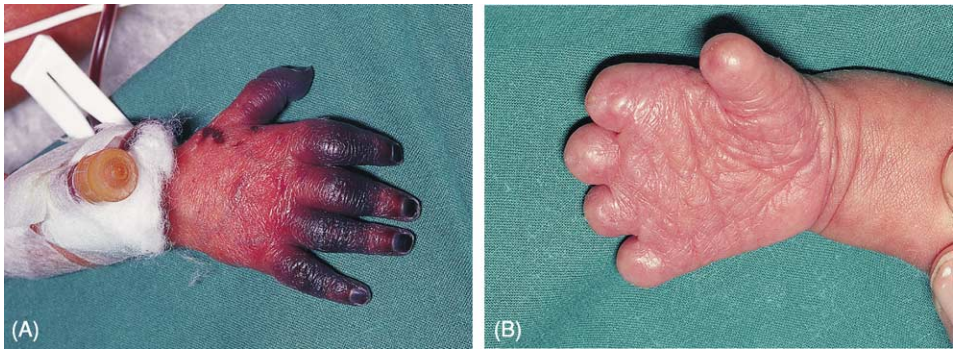

Figure 1 (A) Gangrenous fingers following radial arterial catheterization. (B) Subsequent loss of fingers and thumb. Reproduced with permission from Rennie JM, Roberton NRC (eds.) (1999) *Textbook of Neonatology*, 3rd edn. Edinburgh, UK: Churchill Livingstone.

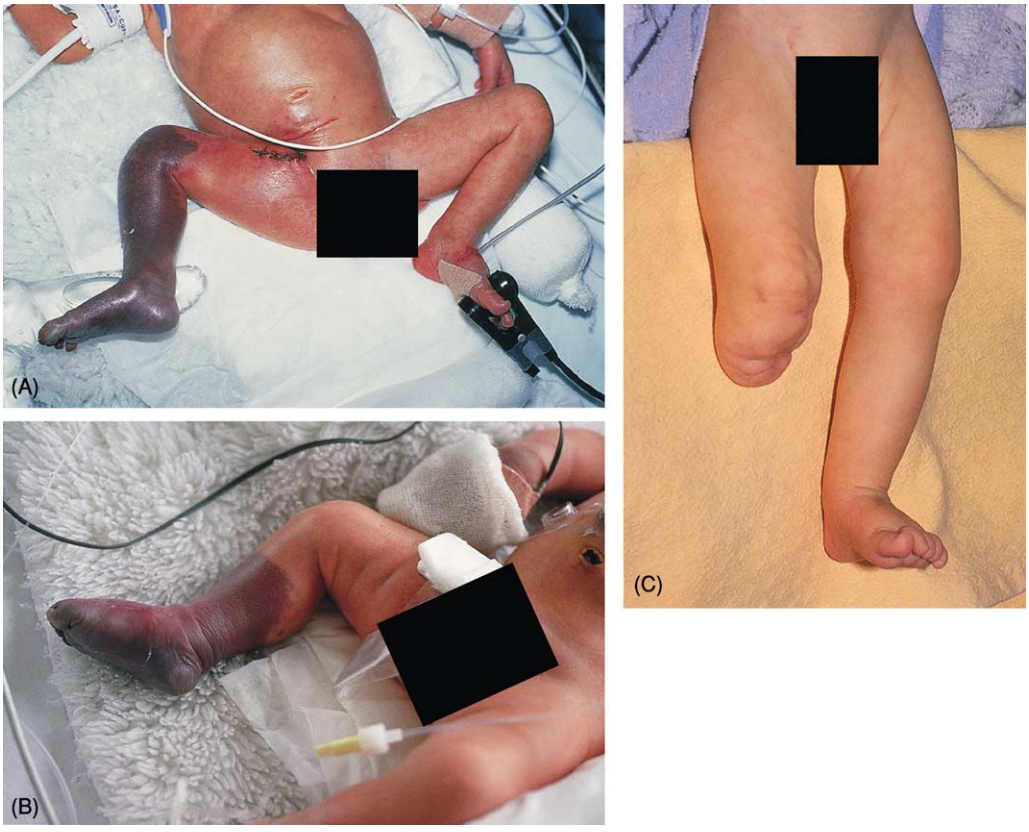

Figure 2 (A) Acute ischemia to the right leg following insertion of a femoral artery line. (B) Some recovery with the line of demarcation below the knee. This resulted in a below-knee amputation (C). Reproduced with permission from Rennie JM, Roberton NRC (eds.) (1999) *Textbook of Neonatology*, 3rd edn. Edinburgh, UK: Churchill Livingstone.

removed, and supportive measures to improve the circulation should be started. These measures may extend to thrombolytic therapy and surgical referral for embolectomy. In terms of malpractice, it is rarely the arterial line insertion technique that is open to question, but more often it is the delay in managing the complication that prompts legal scrutiny. When any arterial line is being used it is essential that pressure alarm limits are correctly set to alert staff to hypotension. This may be the first indication that hemorrhage is occurring from a line. Umbilical venous catheters carry complications of their own, such as hepatic necrosis and portal vein thrombosis when sited in the liver or cardiac tamponade if the tip perforates the right atrium. The ideal position for an umbilical venous catheter is at the junction of the inferior vena cava and the right atrium.

The incidence of iatrogenic injuries and errors in drug prescription and administration will tend to increase at times when a neonatal unit is at its busiest and the medical and nursing staff are overstretched. Monitoring of clinical incident reports and equating adverse events to staffing levels and staff mix has become an essential tool in risk management. In cases of injury that come to legal attention, some allowance is made for the grade of the doctor involved. However, it is to be expected that a junior doctor performing a neonatal procedure should be sufficiently experienced and competent to perform an allocated task, and to be able to recognize complications (*Wilsher* v. *Essex Area Health Authority* 1987. Queen's Bench 730). Perforation of the lung during chest drain insertion for a pneumothorax (Figure 3) may be considered clinical negligence if the operator was untrained and unsupervised.

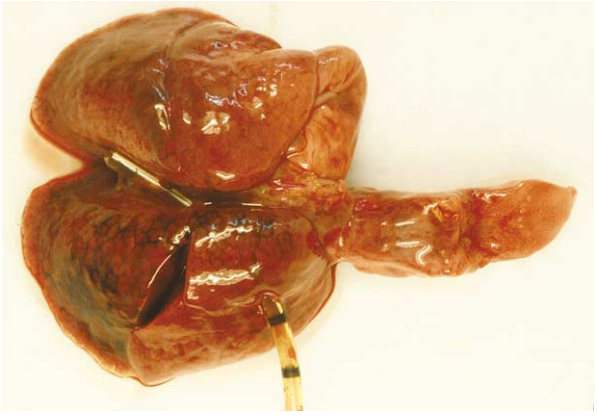

Figure 3 A postmortem specimen showing perforation of the lung by a chest drain that had been inserted with the intention of draining a pneumothorax. Photo courtesy of SJ Gould.

Malpractice in Neonatal Medicine

Examples of conditions that are most frequently cited in claims of neonatal clinical malpractice are listed in Table 2. The majority of perinatal litigation is centered on hypoxic–ischemic encephalopathy and the question as to whether obstetric malpractice was to blame for the suboptimal or depressed state of the newborn infant and subsequent cerebral palsy. Occasionally the brain insult in such cases may be compounded by or entirely result from inadequate neonatal resuscitation. There may also be comorbidity from failure to treat associated complications such as hypoglycemia or hypotension.

The forms of brain injury that are more likely to occur postnatally and in the preterm population are periventricular hemorrhage (PVH) and periventricular leukomalacia (PVL). Even in the context of high standards of obstetric and neonatal care, these potentially devastating cerebral lesions can occur unpredictably as complications of prematurity. There is increasing awareness that many cases of PVL result from chorioamnionitis (*in utero* infection). A claim of malpractice may be invoked in cases of PVH if, for instance, a malplaced endotracheal tube (ventilation tube) or a pneumothorax had not been recognized

Table 2 Conditions frequently cited in cases of neonatal malpractice

Condition	*Context*
Hypoxic–ischemic encephalopathy (HIE)	Standard of resuscitation
Periventricular hemorrhage (PVH)	Standard of ventilatory support
Periventricular leukomalacia (PVL)	Hypotension or hypocarbia
Retinopathy of prematurity (ROP)	Hyperoxia. Failure to monitor/treat
Chronic lung disease (CLD)	Standard of ventilatory support
Hypoglycemia	Monitoring and treating risk groups
Neonatal infection	Delays in diagnosis and treatment
Extravasated infusions and scarring injuries	Delays in recognition and treatment
Severe jaundice leading to kernicterus	Failure to recognize and treat
Hemorrhagic disease of the newborn	Failure to provide vitamin K
Drug errors	Failure to take remedial action

and promptly corrected. Similarly, in a case of PVL, it can be shown that there was a failure to recognize or sufficiently promptly treat known causes such as hypotension and severe hypocarbia (resulting from overventilation).

Infection in the newborn (e.g., pneumonia, septicemia, necrotizing enterocolitis, and meningitis) can be rapidly overwhelming even when antibiotics and supportive therapy are commenced as soon as clinical suspicion is raised. Neonatal malpractice arises in such cases when there has been a failure to recognize risk factors for infection and there has been an unacceptable delay in treatment.

The majority of newborns will develop mild jaundice in the first week of life, but in a small proportion the level of the jaundice pigment bilirubin will reach potentially brain-damaging levels that can lead to cerebral palsy. This form of cerebral palsy, referred to as kernicterus, is preventable with phototherapy and exchange blood transfusion. Failure to recognize cases of severe jaundice or to intervene with treatment at published recommended levels represents malpractice.

Retinopathy of prematurity is a complication usually confined to infants born at extreme low birth weight (less than 1.0 kg). Whilst strict monitoring of oxygen therapy may reduce the incidence of this condition, there are several etiologies at play and the retinal disease cannot always be avoided. What can be prevented in the majority of cases is progression of the disease to its end-stage of macular disruption, retinal detachment, and blindness. There are national guidelines for screening preterms with eye checks and for instituting timely treatment with laser or cryotherapy. Failure to provide such a service constitutes a breach of duty of care.

Hypoglycemia, defined for newborns as a blood sugar level less than 2.6 mmol l^{-1}, is not an uncommon finding. Otherwise, healthy term infants usually have alternative brain fuel supplies that prevent them becoming symptomatic. Higher-risk groups, such as preterms, growth-retarded babies, infected babies, infants of diabetic mothers, and some cases of inborn errors of metabolism are at greater risk of developing signs such as convulsions, coma, and apnea from which they may go on to develop neurological sequelae. Failure to assess and maintain the blood sugar adequately in these at-risk categories to the extent that a baby develops neuroglycopenic symptoms would be considered clinically negligent.

Unfortunately, some scarring injuries are an inevitable hallmark for graduates of neonatal intensive care. Intravenous lines, blood sampling, and chest drain insertion are all inclined to leave their mark. The injuries from infusions occur when extravate is aggravated if they contain hypertonic solutions or toxic drugs and electrolytes (Figure 4). It is a fact that drip extravates do not reflect negligent practice, but if this event, which signals the need for a replacement cannula, goes unheeded for more than 1 hour, the nursing care can be called into question. Nursing observation charts provide for hourly documentation of the condition of intravenous sites, and the perfusion of limbs and extremities if indwelling arterial lines are being used. In the case of extravasation injuries, malpractice occurs if there has been inadequate surveillance of the infusion site and a consequent delay in recognition of the injury. Since it is now a textbook-recommended practice that in cases where there is ischemia of the overlying skin, the tissues should be flushed as soon as possible with a hyaluronidase solution, it may be considered malpractice if there is a failure to offer such treatment.

Skin preparation with concentrated iodine and alcohol solutions will reduce invasive sepsis during procedures, but if not rinsed off with milder solutions, and particularly if a baby is allowed to lie in a pool of such agents, chemical burns may ensue.

Prior to being discharged home, babies born in hospital should receive a routine screening examination.

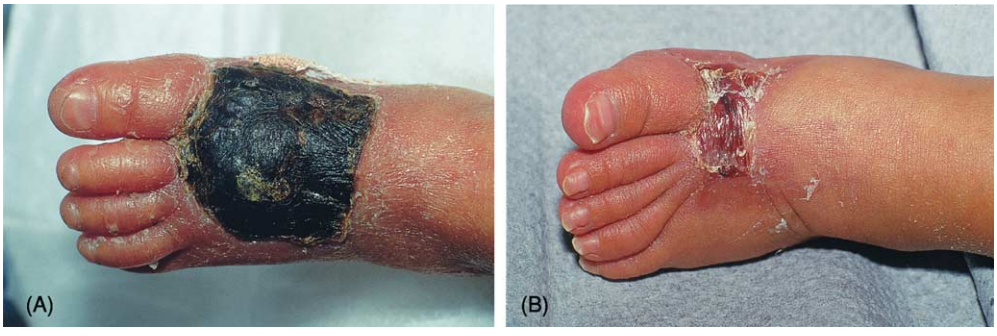

Figure 4 (A) Tissue damage to the dorsum of the foot following extravasation of total parenteral nutrition. (B) Healing, with a time interval between (A) and (B) of 5 weeks, has resulted in an extensor contracture. Reproduced with permission from Rennie JM, Roberton NRC (eds.) (1999) *Textbook of Neonatology*, 3rd edn. Edinburgh, UK: Churchill Livingstone.

Table 3 Failures leading to potential neonatal malpractice

Failure to detect an obvious and significant abnormality on newborn examination
Failure to follow up appropriately an abnormality found on newborn examination
Failure to adhere to published guidelines for the management of neonatal jaundice
Failure to maintain the blood sugar in babies at risk of symptomatic hypoglycemia
Failure to give vitamin K at birth as prophylaxis against hemorrhagic disease
Failure to screen for or treat progressive retinopathy of prematurity

Whilst this is designed to pick up significant conditions (such as heart disease, developmental dysplasia of the hip (DDH), or head growth abnormalities), a number of conditions can be understandably missed. For instance, it is recognized that up to half of DDH is not detected on clinical examination of the hips. Similarly, it is not always possible to detect the milder forms of cyanotic congenital heart disease. But, as Roberton points out in his *Textbook of Neonatology,* there is no legal defense if the examination has not been performed and DDH is subsequently detected, or if an abnormal finding on routine neonatal examination is inadequately reviewed. These are examples of failures leading to potential neonatal malpractice, as listed in Table 3.

Conclusion

Neonatology encompasses a wide spectrum of ethics, the law, and clinical situations with heightened potential for malpractice. Decision-making on withholding resuscitation or withdrawal of care places neonatologists in a legal "gray area," bordering on unlawful killing and manslaughter. Successful outcome of neonatal intensive care can be hindered by complications, and a large proportion of these will be iatrogenic. Conditions with potential iatrogenic causes are highlighted in this article, along with complications frequently cited in cases of neonatal malpractice. Also emphasized are omissions of disease detection and treatment provision that constitute breach of duty of care.

See Also

Medical Malpractice – Medico-legal Perspectives: Negligence, Standard of Care; Negligence, Duty of Care; Negligence, Causation; Negligence Quantum

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Neurosurgery

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Introduction

Neurosurgery is undoubtedly a high-risk surgical discipline, but shares a number of common medicolegal problems with other branches of medicine. It also has a number of problems peculiar to itself. This article deals with malpractice in its broadest sense, outlines areas where medicolegal problems may develop in neurosurgical practice, and suggests strategies for their avoidance.

Frank Furedi, an academic sociologist at the University of Kent at Canterbury, has coined the term "litigation culture." Essentially he described the concept that, if a person gets hurt, it must be the fault of somebody rather than being just a chance event to which no culpability should be attached or, in other words, bad luck. Moreover, within this mindset the injured party assumes that compensation will not

only be due, but will be his/her inalienable right, and there is often an expectation of a large payout, along the lines of the damages payable in various cases in the USA.

Often, the desire for pecuniary gain may be veiled behind apparently altruistic motives, such as a desire to "stop it from happening to someone else," but the bottom line is invariably financially driven.

In the USA, litigation culture has, in fact, brought about a national crisis in medical practice. This has been encouraged by a legal system in which conditional fees operate, under which as much as 50% of any award may go to the lawyer. Furthermore, US juries, in addition to awarding economic damages, can award "punitive damages" and can use their powers to inflate awards in the knowledge that if they do so, the plaintiff will still receive a substantial sum, in spite of the legal top-slicing of the award.

The mean award for damages from malpractice in the USA is $3.5 million. It is therefore no surprise to find that malpractice insurance premiums have risen by as much as 45% in certain high-risk specialties, such as neurosurgery, obstetrics, and orthopedic surgery.

The effect of this is for some practitioners in these disciplines to retire early, move to another location (state), or to confine their practice to low-risk procedures, e.g., neurosurgeons not undertaking intracranial surgery and only performing carpal tunnel decompressions.

The ripples of this litigation culture have spread out from the USA. In the UK, litigation culture currently costs 1% of the gross domestic product, which equates to approximately £10 billion per annum.

Neurosurgery is a relatively new discipline and seeks to diagnose and treat disorders affecting the central and peripheral nervous systems. Many of the disorders that fall within its compass are life-threatening and may require emergency surgery of a highly skilled and specialized nature.

Malignant cerebral tumors are associated with a poor prognosis and their surgical treatment may be associated with the risk of death or the production or worsening of a neurological deficit. Similarly, benign skull-base neoplasms such as meningiomas, which may have an intimate relationship to important neurovascular structures, demand the highest degree of surgical skill yet their removal may be associated with neurological deficit.

The management of aneurysmal subarachnoid hemorrhage is another area where the poor natural history of the disease has to be set against the not inconsiderable management morbidity and mortality. Even if a technically perfect operation is performed, the patient may still die or be disabled because of delayed ischemic neurological deficit consequent upon vasospasm. In such circumstances, criticism of the treatment received by the patient may follow, despite there being no grounds for complaint.

Communication and Consent

A recent study examined the reasons why doctors were sued and concluded that communication is an important reason. Adverse events are inevitable in medical practice but should not necessarily result in litigation. Factors that tend to result in litigation are, for example, a preexisting adversarial relationship between doctor and patient, or the development of one following the occurrence of such an event. It has been shown that litigation tends to occur when the patient or his/her family believe that the doctor has been economical with the truth and may have "covered up" important information.

It has also been shown that the surgeon's tone of voice may be a deciding factor in the decision to complain or seek redress at law when outcomes have been perceived as being adverse. If the surgeon does not sound concerned or is imperious, litigation is more likely to follow.

It will thus be readily appreciated that good communication skills are vital for good practice. Good communication skills should be seen as one of the important building blocks of good medical practice. They can be used to build a framework for dealing with patients when it comes to obtaining consent for treatment.

Consent is now a complex topic but one with which the neurosurgeon must be familiar. The simple rule for consent laid down in 1914 by Judge Cardozo has had to be developed to suit an enquiring and well-informed society as well as for the protection of the medical profession against individuals who would take the opportunity to sue.

Missen in 1992 proposed that "consent" is inadequate, as it implies that the patient is "doing the doctor a favor" by signifying agreement. In this era of patient participants, Missen felt that the term should be replaced by "request for treatment." The request for treatment emphasizes that there may not be a "cure," but that a "treatment" may be all the doctor can ultimately provide. Understanding that a definite cure may not be forthcoming may facilitate a move away from the bitter disappointments and legal actions that patients do take when their expectations are not fulfilled.

A recent investigation into the practice of obtaining consent sought to establish the frequency with which potential complications were discussed with the

patients. The results indicated that a wide range of discussions took place with some surgeons emphasizing every conceivable complication, while others emphasized very few. The authors concluded that a "checklist" should be drawn up emphasizing the informed aspects of consent that were discussed. There should be a clear explanation of the indications for the proposed surgery and that an open discussion of the principles and risks of the procedure should take place. They also recommended that an honest discussion of the consequences of not undergoing treatment should take place. Furthermore, a discussion about alternative treatments should occur.

There is clearly a dichotomy between enumerating all the risks of surgery and failing to obtain informed consent. The naming of all possible complications will increase the anxiety and stress levels of a patient, but balanced against this is the duty of the doctor to explain the nature of the disease, the available treatments, as well as the risks and benefits of the proposed procedure.

In neurosurgical practice, litigation is likely to be caused by lack of informed consent, delays in the definitive diagnosis being made, and unrealistically high expectations on the part of the patients and relatives. McManus and Wheatley suggest that the consent should be more patient-centered, as it is in Australia with the patients demanding more information before undergoing surgery. They imply that there is a simple equation in which the higher the amount and quality of information the patient receives, the lower will be his/her level of anxiety. They conclude that hospitals should design skeleton websites and leaflets, clearly setting out the risks and benefits of various procedures in order to help patients make informed decisions about their treatment.

In neurosurgical patients, the problems of obtaining informed consent can be greatly exacerbated by difficulties in communication due to dysphasia or impaired consciousness. Furthermore, the complications from intracranial surgery can be so devastating that it may be difficult for patients to make a clear judgment about the benefit of undergoing a procedure, if the natural history of the disease from which they are suffering is particularly unfavorable and the risks of complications are high. Particular attention must be given to ensuring that there is a match between the explanations given to the patient and his/her ability to understand them. It is vital in neurosurgical practice to explain the nature and consequences of serious complications, even if the likelihood of their development is remote. In the Australian case of *Rogers* v. *Whitaker* (Australian Law Reports (1992); 109: 625–637), an Australian ophthalmologist was found to be negligent of not warning his patient of a 1 in 14 000 chance of the development of sympathetic ophthalmitis. This judgment clearly suggests that there is a case for warning patients about devastating complications even if the risk of their development is very small.

The principal way in which problems centering on consent can be avoided is to spend time with the patient and his/her relatives and enter into a frank and meaningful discussion with them about the proposed treatment, the natural history of the disease in question, and alternative therapeutic strategies. Time should be allowed for questions to be asked and the doctor obtaining consent should in general be the person performing the procedure.

Withdrawal of Treatment

Issues of consent and the patient's autonomy are highly pertinent when considering the question of withdrawal of treatment. Advanced techniques of resuscitation and life-preserving technology that allow the life of a patient to continue in the presence of devastating neurological deficit now exist. Dilemmas arise when patients, doctors, and relatives struggle to decide whether to prolong and sustain life where the life in question is of very poor quality and there is no prospect for spontaneous recovery.

The ethical problem of deciding whether the quality of life for the patient in a persistent vegetative state (PVS) is worth continuing is highly contentious. It is impossible to know exactly what someone else is experiencing and doctors cannot merely impose their own values on those of an incompetent patient. A recent review entitled *Withdrawing of Life Sustaining Treatment* attempts to address this problem and points out that a patient's autonomy and values can conflict with the responsibility of the attending clinicians.

The case of Miss B, who had a hemorrhage into a cavernous hemangioma in the upper spinal cord in 1999, is particularly pertinent (*Ms B* v. *an NHS Hospital Trust* 2002 EWHC 429 (Fam)). She recovered from this hemorrhage but rebled in February 2001 and became tetraplegic. She was dependent on artificial ventilation and was unable to do anything for herself. She had no control whatsoever of her limbs and sphincters and had no hope of recovery. Miss B felt her life was intolerable and wanted to be removed from her ventilator.

Dame Elizabeth Butler Sloss found that Miss B was competent to decide upon her treatment and stated *inter alia*: "a mentally competent patient has an absolute right to refuse to consent to treatment for any reason, rational or irrational or for no reason at all, even where that decision may lead to his or her own death." Her judgment also emphasized that "the right

of the competent patient to request cessation of treatment must prevail over the natural desire of the medical and nursing professions to keep her alive."

Competent patients have the right to decide on the benefits, burdens, risks, and overall acceptability of treatment. They have the right to refuse treatment, even if this results in death.

Good surgical practice published by the Royal College of Surgeons of England in September 2002 also endorses this policy and advises surgeons to consider advanced statements or living wills very carefully.

Negligence

Negligence is defined very aptly by Alderson in the case of *Blyth* v. *Birmingham Waterworks Company* ((1856); 11 Exch 781). "Negligence is the omission to do something which a reasonable man, guided upon those considerations which ordinarily regulate the conduct of human affairs, would do or doing something which a prudent and reasonable man would not do." Emphasis is placed upon the reasonableness and the ordinariness of the "prudent man," although experts are expected to be skilled and competent in their work.

In medical cases, the appropriate standard of care is determined by a legal standard ratified by the courts and not by the medical profession.

Thus, McNair J summarized the question of the standard of care in his speech to the jury during the *Bolam* v. *Friern Barnett Hospital Management Committee* case of 1957 (2 All ER 118):

> A doctor is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a reasonable body of medical men skilled in that particular art. Putting it the other way around a doctor is not negligent if he is acting in accordance with such a practice, merely because there is a body of opinion which takes a contrary view.

It is important to consider some of the general legal principles that cover the tort of negligence. For an action of negligence to succeed, three components must be present, and the burden of proof rests upon the plaintiff. First, he/she must show, on the balance of probabilities, that there exists a duty of care which was owed to him/her by the defendant. Second, he/she must show that the defendant was in breach of that duty. Finally, that damage resulted to the plaintiff as a result of that breach.

One of the more difficult concepts to appreciate is that of causation. Although it can be established that a duty of care existed and that the defendant was in breach of that duty of care, the outcome may have been the same even if that breach had not taken place. Medical negligence cases can be extremely complex and there may be competing reasons why a particular problem develops which may have nothing to do with the alleged negligent act of the defendant.

Thus, the relationship between a hypoxic perinatal event and the subsequent development of learning difficulties or deafness may be far from clear and there may be other competing causes which could equally explain the problems later experienced by the child.

Again, the plaintiff must be able to prove, on the balance of probabilities, that the alleged negligence was the cause of the subsequent problem or that it made a material contribution to the extent of the disorder. In many medical negligence cases, the defendants may admit liability but deny causation. The seminal case on causation is *Bolitho* v. *City and Hackney Health Authority* (4 Med LR 381 (1993) and 39 BMLR 1 (1998)).

Two illustrative cases demonstrating the problems associated with causation in neurosurgical practice are now outlined.

Case 1

A 68-year-old woman presented to an Accident and Emergency department with a two-week history of headache and unsteadiness. She received a cursory examination, and a diagnosis of a viral infection was made. Her relatives were concerned when she was allowed to go home without investigation. Her condition deteriorated and she returned to the same hospital 5 days later. Again, she was told that she was suffering from a viral infection, but now her relatives insisted that she should have a computed tomography (CT) brain scan, but this was refused. Three days later, following increasing headache, she represented to the same hospital but on that occasion was seen by a different doctor. A CT head scan was performed: it showed a mass lesion in the right cerebellar hemisphere, the radiological appearances of which were suggestive of metastasis. Further investigation showed the presence of a right upper-lobe bronchogenic carcinoma with hepatic and adrenal metastases. She died 3 days after palliative resection of her cerebellar lesion. Her relatives issued legal proceedings against the hospital.

Although it was conceded that the hospital was in breach of its duty of care to this woman, causation could not be established, as expert evidence held that, even if a scan had been performed at the time of her first attendance, the outcome would still have been the same, as her disseminated carcinoma was incurable and rapidly fatal.

Case 2

A 38-year-old man, who had not previously suffered from headaches, developed a headache of sudden onset associated with a brief loss of consciousness. His general practitioner was called and a diagnosis of wry neck was made. His headache failed to improve

over the next few days and he attended his general practitioner's surgery; he was sent for an X-ray of his cervical spine and prescribed diclofenac.

Six days later, he had a further episode of headache, this time associated with aphasia and a right hemiparesis. He was taken to hospital where a CT head scan was performed that showed diffuse subarachnoid blood and an intracerebral hematoma within the left sylvian fissure.

He was transferred to a neurosurgical unit where cerebral angiography was performed. This revealed a left middle cerebral artery aneurysm which was treated by craniotomy and clipping.

He remains disabled with impairment of fine movement in his right hand and has some speech difficulties.

Expert advice suggested that no reasonable general practitioner would have failed to consider the diagnosis of subarachnoid hemorrhage when confronted with headache of sudden onset associated with loss of consciousness. Moreover, if the diagnosis had been made at that stage, on the balance of probabilities, he would have been investigated and found to have a left middle cerebral artery aneurysm. This would have been treated before a second hemorrhage occurred, producing a profound neurological deficit.

The case thus succeeded not only on the grounds of breach of duty of care and liability, but also on causation. These cases are relatively straightforward examples of the problems of causation, but in neurosurgical practice it is not uncommon for the issues of causation to be extremely complex and, in analyzing a case, several experts with specific subspecialist skills may need to be instructed.

Although the burden of proof in negligence cases lies with the plaintiff, the legal principle known as *res ipsa loquitor* may be applied, in which case the burden of proof is lightened. The expression means "the thing speaks for itself." When invoked, the argument on negligence shifts to the defendant and he/she has to explain how the matter in question could have occurred in the absence of negligence. Typical instances where this legal maxim might be applied would include matters such as operating on the wrong side of the head or doing the wrong level in a spinal procedure without taking steps to ensure that the correct level was treated.

It should be remembered that negligence can occur as a result of poor communication between medical experts. In neurosurgery, the telephone has been said to be the most commonly used "instrument" and instructions between referring clinicians and neurosurgeons must be absolutely explicit and irrefutable. Furthermore, adequate arrangements should be made for the safe discharge or transfer of patients back to referring hospitals once neurosurgical intervention has taken place.

Good Practice

Good practice in medicine is a fine balance between providing the absolute best service for each patient and providing a cost-effective service that is financially supportable. Economic stringency puts pressure on doctors and governments alike. Centrally funded health services are constantly put in the position of having to make compromises as expensive medical technology and drugs evolve. Financial restrictions on centrally funded health providers who are forced to economize inevitably mean that there will be cuts in training new doctors, as well as in research and development.

A large amount of medical practice is now protocol-driven, as purchasers of medical care believe that this provides an efficient use of resources. The obverse of this is that clinical freedom is limited and litigation is encouraged in cases where there are even minor departures from the protocol.

In this rapidly changing environment in which surgeons are now working, what constitutes good surgical practice and how can this be achieved? It is established that good surgical practice is not merely dependent upon the technical or clinical skills of the surgeon, but also upon effective team-working and appropriate use of time and resources. The General Medical Council highlighted seven core headings in its document *Good Medical Practice* which set out the standards required of all doctors. Observation of these principles would certainly decrease the likelihood of a doctor becoming the subject of a serious complaint. In the context of surgical practice it is important for surgeons to realize that they are responsible for the standards of clinical care they offer patients and should bring to the attention of their employing authority any deficiencies in resources that impact upon the safety of their patients. Patients should be treated according to the priority of their clinical problems. When providing emergency care for patients, neurosurgeons should carry out procedures that lie within the range of their routine practice.

Unfamiliar procedures should only be performed if there is no clinical alternative, or a more experienced colleague is unavailable, or transfer to an alternative specialist unit is considered to be a greater risk. Surgeons working in private practice should demonstrate a high level of probity and transparency. They should have the same indications for treating patients in the public sector as in the private sector and should not "invent the need to operate because there is a fee." Furthermore in private practice, surgeons should not

Table 1 Problems that may occur in neurosurgical practice: errors in diagnosis

1. Headache of sudden onset – missed aneurysmal subarachnoid hemorrhage
2. Cauda equina syndrome – delay in diagnosis and treatment of central disk protrusions
3. Subdural empyema
4. Epilepsy of late onset with apparently normal scan with subsequent development of a glioma
5. Failure to appreciate that neck pain may be a presenting symptom of a posterior fossa space-occupying lesion
6. Remember that bilateral leg weakness can be due to a parasagittal meningioma in the presence of normal spinal imaging
7. Remember to obtain informed consent when dealing with patients who have had an aneurysmal subarachnoid hemorrhage. The relative merits of craniotomy and clipping and GDC therapy should be discussed
8. Particular care should be exercised when dealing with psychosurgery. Consent is vital, as is collaboration with the referring psychiatrist

Table 2 Potential problems that may occur during surgery

1. Operating on the wrong side of the head Avoid by checking the side of the lesion on the scan with a colleague and ensure that the surgeon operating is the person positioning and draping the patient. Do not make an incision on a patient who has been draped by an assistant without being absolutely certain about the side
2. Operating on the correct patient but using the wrong patient's scan Always ensure that the patient's name, date of birth, and hospital number are the same as those on the scan
3. Operating on the wrong level in spinal procedures Always take preoperative and intraoperative marking films and retain these in the patient's notes. With disk surgery, an X-ray with a marker in the disk space is irrefutable evidence that the correct level has been treated
4. Do not delegate operative procedures to trainees inappropriately Always ensure that an appropriate degree of supervision occurs at all times
5. Never let ''the sun set'' on a blocked shunt If a diagnosis of shunt failure is made, it should be operated on as soon as possible. The possibility of respiratory arrest and death should never be forgotten in cases of shunt blockage
6. Do not forget that aspirin can cause problems with hemostasis Unless the problem is immediately life-threatening, defer surgery for 10 days

carry out unusual or complex procedures that they would not normally perform in the public sector.

Neurosurgeons who are involved in medicolegal work should keep their clinical and medicolegal practices separate. They should not treat a patient who has been referred for a medicolegal opinion. Moreover, surgeons would be advised not to operate on patients in personal injury litigation at the expense of the defendant's insurers.

Finally, Tables 1 and 2 suggest some obvious pitfalls that may occur in neurosurgical practice and some strategies for their avoidance. Remember, the majority of problems can be circumvented by paying "attention to detail" as well as by effective communication.

See Also

Medical Malpractice – Medico-legal Perspectives: Negligence, Standard of Care; Negligence, Duty of Care; Negligence, Causation; Negligence Quantum

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Nursing Issues

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Introduction

Given that there is wide variation in nursing practice and procedure worldwide, this discussion centers on nursing practice in the UK. Malpractice can be defined as "any unjustified act or failure to act upon the part of a doctor or other healthcare worker which results in harm to the patient." When reading current media and professional journals, one could be forgiven for believing that professional misconduct, malpractice, or negligence amongst healthcare professionals is of epidemic proportions. Investigation of official facts and figures suggests that, for nursing in the UK at least, this is not the case. There were 632 050 nurses registered to practice in the UK as on March 31, 2001. At some point in their professional career most will make a potentially serious mistake. The Nursing and Midwifery Council (NMC) received 1240 (0.002%) allegations of misconduct against registered nurses in 2001, 221 (18%) of which were referred to the Professional Conduct Committee (PCC). This resulted in 104 (47%) nurses being found guilty and removed from the register – 0.0002% of the total registered. It is clear that most cases of nursing malpractice do not reach the NMC. However, should a nurse be reported to the NMC, and find himself or herself facing the PCC, there is an almost even chance that the right to practice will be removed.

In recent years the UK government has paid specific attention to the increasing rates and costs of medical negligence litigation. Annual expenditure for clinical negligence in the National Health Service (NHS) has risen from £1 million in 1974–1975 to £446 million in 2001–2002. This increase in costs is not reflected in the number of nurses disciplined by the NMC. Does this mean that malpractice is not an issue for nurses? Malpractice is an issue for everyone, but the prevention of malpractice should be the overriding issue for all healthcare professionals.

Widely publicized scandals such as Shipman (a general practitioner) and Allitt (a hospital nurse) have led to the formalization of clinical governance principles throughout the NHS. There is a strong focus on both the individual and collective accountability of all healthcare practitioners. All cases of medical negligence claims have to be reported to the NHS Litigation Authority, all cases of Serious Untoward Incidents – including "near-misses" – have to be reported to the National Patient Safety Agency (NPSA). A great deal of work has been undertaken to try and understand the conditions that lead to adverse events, to minimize them through risk management processes, and to deal with them fairly and effectively when they arise. The aim of this activity is to move toward a "fair blame" culture where people are accountable for their acts and omissions, and learn from their mistakes.

In the light of clinical governance, nurses now face two distinct issues with regard to malpractice: (1) personal professional accountability and (2) from the nursing Code of Professional Conduct: A duty "to act quickly to protect patients and clients from risk if you have good reason to believe that you or a colleague, from your own or another profession, may not be fit to practice for reasons of conduct, health or competence."

In short, now all nurses are the keeper of their fellow healthcare professionals.

Professional Conduct and Accountability

It is accepted that nurses deliver the greatest part of healthcare to individual patients and clients. The nurse today, can give traditional basic bedside care or continue their professional development to become nurse anesthetists or endoscopists, for example. The range and scope of nursing intervention is potentially limitless and certainly complex. Regardless of the nursing role undertaken, a nurse's professional conduct in the UK is governed and regulated by the NMC. This regulatory body was created under the Nursing and Midwifery Order 2001 and is governed by statute (see Table 1).

In the USA, Nursing Practice Acts are laws in each state that are instrumental in defining the scope of nursing practice, and each nurse must practice according to the rules and regulations of the State Nursing Board.

The International Council of Nurses has issued general guidelines for nurses and states: "Nurses and their organizations, such as national nurses associations (NNAs), must understand the legal context within which they work."

The NMC issued a new Code of Professional Conduct in June 2002. It is a clear and concise document

Table 1 UK legislation and legal cases relating to nursing

Bolam v. *Friern Hospital Management Committee* [1957] 2 All ER 118
Bolitho v. *City and Hackney Health Authority* [1997] 4 All ER 771
Mental Health Act 1983. Section 2(2) (b)
Nursing and Midwifery Order 2001
Public Interest Disclosure Act 1998. Chapter 23

that outlines the principles that govern all nursing practice in the UK. It is explicit in terms of professional accountability – no one else can answer for the actions of a nurse:

> You are personally accountable for your practice. This means that you are answerable for your actions and omissions, regardless of advice or directions from another professional.

The highly skilled, professional nurse has long since replaced traditional images of the nurse as the doctor's handmaiden. A nurse can now make decisions, and take full responsibility for the care and treatment that is delivered. As a nurse is also personally responsible for her own professional development and continuing education, it is now imperative that nurses are competent in their own right:

> To practice competently, you must possess the knowledge, skills and abilities required for lawful, safe and effective practice without direct supervision. You must acknowledge the limits of your professional competence and only undertake practice and accept responsibility for those activities in which you are competent.

Clearly any idea of a nurse simply carrying out instructions from a senior colleague or doctor does not negate her or his personal responsibility for the care delivered. This differs from the medical profession where a consultant can be held accountable for the actions of a junior doctor in certain circumstances.

When things go wrong and, inevitably at some point they will, much depends on the outcome of the event. If no harm is done, there is no requirement for a legal remedy; however, this does not mean that malpractice has not taken place. A nurse can face disciplinary proceedings from both an employer and the NMC. The flow chart (Figure 1) outlines the various routes, within the UK, to sanctions for nursing malpractice which are not mutually exclusive.

As stated above, it appears that relatively few nurses are reported to the NMC. Anyone can report a nurse, although in reality the majority of reports come from employers. Directors of nursing in NHS Trusts (primary, community, or secondary care) have a duty to report nurses who, in their opinion, present a danger to patients and the public. Whilst there is a certain amount of discretion involved in the decision to refer a nurse, a director of nursing, who fails to report a nurse who then subsequently causes harm, will find that they too will be subject to professional disciplinary proceedings. The police also have a duty to report a nurse who has been convicted of a criminal offence, including driving offences, regardless of whether the offence has any relation to professional conduct. Where there is a potential for public confidence to be undermined, the NMC will take a view. Cynically, the more high profile the event, the more likely a hearing before the PCC.

However, being reported does not mean a nurse will face the ultimate professional sanction of being removed from the nursing register. It is actually very difficult to be struck off; malpractice has to be of a high and dangerous level. It can be both professional and personal; a conviction for rape or assault, for example, will justify removal from the register.

In the USA, complaints against registered nurses are investigated by the State Nursing Board. An assessment is made, by a sworn police officer, whether a crime has been committed or not and the case can be referred to the District Attorney. In cases of "minor" violation of the Nursing Practice Act, "a nurse can be personally fined"; in more serious cases a nurse can be placed on probation and be monitored through an

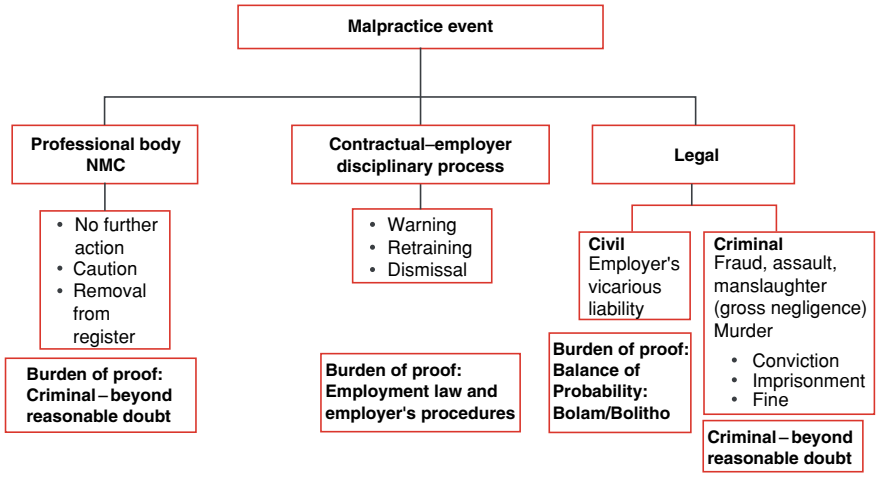

Figure 1 Malpractice – routes of accountability.

enforcement program. Ultimately, a nurse could lose the license to practice.

It is apparent that a nurse has a clear code of professional conduct to follow; however, nurses like other healthcare professionals are human beings and they do make mistakes. In the current climate of litigious claims for medical negligence, a nurse requires, as a minimum, thorough knowledge and clear understanding of the Code of Professional Conduct.

Professional Accountability for Others

It is clearly stated in the code of conduct that the behavior of other healthcare professionals is a nursing issue. If a nurse suspects that a colleague is "unfit" to practice, there is an obligation to report it in the interests of patient safety. This appears to be a reasonable diktat – patient safety must come above all other considerations. However, the reality of reporting a colleague is a far more personal dilemma, involving sensitive moral, ethical, and ultimately painful decisions. There is a contradiction in the current national drive within the NHS for a "fair blame culture" to encourage open and honest disclosure of genuine mistakes, and the unpalatable policy of "whistleblowing." Doctors are also expected, through their own codes of professional conduct, to whistleblow on their colleagues where there are concerns for patient safety. However, disclosure is a difficult decision to make and despite protection offered by the Public Interest Disclosure Act 1998, which a nurse is under a duty to be aware of, making serious allegations against colleagues is not an easy issue. It is, however, an issue that nurses increasingly have to face. It is the nurses who are in the unique position in relation to the whistleblowing expectations of the NHS. They work exclusively in the front line seeing and delivering the daily activity of the wards and clinics. It can be argued that they have far more direct contact with patients and other healthcare professionals than any other discipline, and as such are in a position to monitor, evaluate, and "police" professional standards of healthcare.

The introduction of the National Institute of Clinical Excellence (NICE) has formalized the test of reasonableness established by Bolam, and subsequently by Bolitho, with the publication of clinical guidelines that healthcare professionals are expected to follow (Table 1). NICE guidelines have yet to be tested in law, but there is an expectation that they will be implemented nationally into all clinical practice. Therefore, healthcare professionals now have publicly defined standards of care and treatment, established by a body of professional opinion by which to judge the actions or omissions of themselves and their colleagues. As implementation of such guidelines now forms part of the NHS assessment process through the Commission for Health Improvement (CHI), they will become an important aspect of everyday clinical care and eventually medical law. NICE guidelines apply to nurses and they are expected to identify and deliver evidence-based care.

Malpractice: The Nurse and the Law

Nurses are subject to the same laws of the land, any land, as other citizens. They do have statutory powers in some areas of healthcare that effectively protect them from prosecution in certain circumstances, such as the power to detain under the UK Mental Health Act 1983. Other recent legislation, such as the Human Rights Act 1998, also impacts on nursing practice in areas such as consent and withdrawal of treatment. Whilst a nurse cannot be appraised of every aspect of the law, there is an expectation that nurses will be aware of the legal implications of their practice.

In English law, there are two routes that can be taken in response to malpractice that causes harm – civil and criminal. It is rare for criminal action to be taken against a healthcare professional, especially a nurse. Whilst indictments for manslaughter by gross negligence have increased in the UK in recent years, these cases have been brought against doctors, not nurses. There have been cases where a nurse has been convicted of manslaughter, but these are rare.

When a nurse murders, or attempts to murder, the criminal justice system is activated and, if found guilty, the nurse will be punished accordingly. Manslaughter charges are far more difficult to ascertain, the most difficult issue being the intention (*mens rea*) behind the event. Risk is inherent in all aspects of healthcare, and there will be times when risks materialize through human error, as well as malpractice. In some cases the result will be the death or serious injury of a patient. The level of malpractice required for a criminal case to be brought is that of gross negligence and/or recklessness – the action has to be so reckless that intent to do harm (*mens rea*) can be implied. Thankfully, to date this is a rare occurrence in nursing. Therefore, the legal remedy in most cases of malpractice where harm results is the civil justice system. The burden of proof in a civil case is that of the balance of probability and the injured party must prove three conditions:

1. There was a duty of care owed – this is largely taken as established in the case of NHS treatment.

2. The duty of care was breached.
3. The breach of duty either directly led or substantially contributed to the injury sustained.

In the majority of cases, the nurse is protected by the vicarious liability of the employer. It is wise to ensure that the hospital where one practices has adequate professional liability insurance. American nurses have found, to their cost, that in some instances they are not covered by their employer's insurance.

It is difficult to establish how many cases have been brought specifically against nurses, as law reports cite cases against hospital trusts rather than individuals. This does not mean that a nurse can afford to dismiss the possibility of repercussions of malpractice; the emotional impact of being involved in a civil case for medical negligence should not be underestimated.

Conclusion

In conclusion, malpractice is difficult to define and can occur at many levels, all of which are serious, but not all of which will result in harm to a patient or sanctions against a nurse. An awareness of professional and legal responsibilities, effective risk management processes, and potential sanctions should now be part of every nurse's daily activity and education wherever they work. As with all aspects of the law, ignorance is no defense.

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Oncology

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Introduction

Oncology is the study and treatment of cancer, including research, surgery, radiotherapy, and treatment with drugs, including chemotherapy. Since different medical specialties and professions are involved, the diagnosis and treatment of cancer are usually managed by specialized multidisciplinary teams. In the UK, clinical oncologists have expertise in both radiotherapy and drug treatment, whereas medical oncologists specialize in chemotherapy and other medical treatments. When cancer becomes incurable, care is often provided by specialists in palliative medicine, in collaboration with general practitioners.

This article concentrates on the diagnosis of cancer and its treatment with drugs, and it should be seen in the context of the overall management of patients with cancer (including the support of other clinicians who may contribute, for example, in medicine, surgery, palliative care, and general practice).

Natural History of Cancer

Cancer develops as a result of a harmful mutation (change) in a chromosome of a cell, which continues to multiply out of the control of the host and eventually causes death if untreated. Tumors grow undetected for many months until they are about 1 cm in diameter, when they contain approximately 100 000 million cells. Therefore, many cancers have spread before the primary tumor is diagnosed, although the metastases may not become evident until several months or years later. As a result, it may be difficult to demonstrate that a delay in diagnosis has altered the eventual prognosis.

In the following sections, the diagnosis and staging of cancer are explained, and two important medicolegal issues in oncology are considered: (1) the consequences of a delay in treatment of cancer; and (2) the harm caused by errors in chemotherapy.

Diagnosis

It is important to discover as much as possible about the nature and extent of cancer in order to be able to advise on treatment. The size and spread of a tumor can usually be determined by physical examination supplemented by X-rays, scans, and blood tests. Computed tomography (CT), magnetic resonance

imaging (MRI), and ultrasound scans provide cross-sectional images that show the cancer in relation to other organs as well as any metastasis more than 1 cm in diameter. A bone scan uses radioactively labeled chemicals to detect spread to the skeleton, and positron emission tomography scans help to determine if a mass shown on CT or MRI scan is likely to be active cancer.

Histological examination is very important because the optimum treatment will depend on the type of cancer. A biopsy should be taken from the edge of the tumor if possible because the center may be necrotic (dead tissue). Alternatively, a core of tissue may be obtained for histology using a wide needle, or cells may be withdrawn by a fine needle for cytology. Malignant cells may also be found by cytological examination of scrapings, brushings, or washings from the site of the tumor or fluid (sputum, urine, or fluid from chest or abdominal cavities).

Staging and Grading

Cancer is described by its histological appearance and extent. Internationally standard classifications are helpful when considering treatment based on past experience, and they enable a valid comparison of the results of treatment in different hospitals.

The TNM (tumor, node, metastasis) staging is commonly used for solid tumors. The exact definition of each stage is different for each cancer, but Table 1 summarizes the general principles. The grade or degree of histological or cytological abnormality seen under the microscope also influences prognosis (Table 2).

Table 1 Tumor, node, metastasis (TNM) staging

T is	Noninvasive, premalignant, carcinoma-in-situ
T1	Superficial, small, early, usually less than 2 cm diameter
T2	Early, but beginning to invade more deeply, 2–4 cm diameter
T3	Moderately advanced, invading deeply, but confined to the organ
T4	Locally advanced, invading adjacent structures and organs, fixed
N0	No detectable spread to lymph nodes (glands)
N1	Spread to immediately adjacent lymph nodes
N2	Regional lymph nodes involved
N3	Extensive involvement of fixed nodes, or more distant nodes affected
M0	No distant metastases detected
M1	Distant metastases present
Alternatively, a simpler system of four stages may be used.	
Stage I	Local disease only (T1 N0 M0)
Stage II	Spread to local lymph nodes (T1–2 N1 M0)
Stage III	Locally advanced (T3 N1–2 M0)
Stage IV	Disseminated (M1) or locally extensive

Table 2 Grading of tumors

Grade I	Tumor cells mostly appear differentiated, similar to normal
Grade II	Both differentiated and undifferentiated (abnormal) cells
Grade III	Mostly abnormal undifferentiated (anaplastic) tumor cells

When the staging has been confirmed after surgery by histological examination, the letter "p" is inserted (e.g., pT1, pN0) to show that this is the pathological and not just clinical stage. If it is not possible to determine the stage, "X" is inserted (e.g., T1, NX, MX).

Effect of a Delay in the Treatment of Cancer

Cancer growth and spread are uncontrolled, and it is therefore important to avoid unnecessary delays in diagnosis and treatment. Since tumors have been growing for many months or even several years before diagnosis is possible, it may be difficult to show that a delay of a few months has affected the prognosis or outcome of treatment. The effect of the delay will depend on the overall curability of the tumor (e.g., the majority of lung cancers have spread before the diagnosis can be made) and its rate of growth. A rapidly growing cancer, such as in the head and neck, may progress considerably within 3–6 months to a higher stage and become more difficult to cure. On the other hand, bowel cancer usually grows more slowly, and it is often not possible to prove that a delay of 6–12 months affects treatment or prognosis. Nevertheless, it is important to consider each patient individually to decide whether or not, based on probabilities, the delay has had a detrimental effect using published evidence about the rate of growth of tumors and what is known about the natural history and treatment of different cancers.

Treatment

Until the end of the nineteenth century, surgery was the only treatment available. Since many cancers spread before they are detected, the majority of patients with cancer died of metastatic (disseminated) disease.

Following the discovery of X-rays and radium, treatment with ionizing radiation has been developed and has become important in the cure and palliation of many cancers. Drug treatment for cancer has developed rapidly in recent years; it is the primary treatment of some malignant diseases, and is used in conjunction with surgery and radiotherapy in other cancers.

Surgery is the initial treatment for the majority of localized cancers (e.g., cancer of bowel, breast, and skin) and may be followed by radiotherapy (breast, head, and neck) or chemotherapy (ovary and breast). Treatment is usually based on nationally standard guidelines, developed with the benefit of clinical trials.

Chemotherapy

Cytotoxic (cell-killing) drugs affect cells that are multiplying, for example, in the bone marrow, skin, intestine, and other proliferating tissues as well as the cancer. Cytotoxic chemotherapy must therefore be given in such a way as to poison the maximum number of cancer cells while allowing the normal tissues to recover from the inevitable damage. Fortunately, normal tissues are stimulated to regenerate after chemotherapy, whereas malignant tumors lack the normal regulatory mechanisms. Therefore, drugs are usually given in pulses every 3 or 4 weeks to allow sufficient recovery of the normal cells (bone marrow in particular).

Some forms of cancer are cured by chemotherapy, such as leukemia, lymphoma, testicular teratoma, and choriocarcinoma (a rare tumor of placental tissue). Breast, ovarian, and bowel cancer are moderately sensitive, and although not curable by chemotherapy alone, the prospects of cure may be improved when chemotherapy is added after the complete surgical removal of the tumor. Although many other tumors are relatively resistant to chemotherapy, such as the majority of lung and prostate cancers and melanoma, selected patients may benefit and a trial of treatment may be considered. Chemotherapy may therefore be recommended to relieve symptoms due to advanced, incurable cancer without a prospect of increasing survival.

Risks Associated with Chemotherapy

Excessive Dose

In order to achieve the most benefit, the maximum dose that can be tolerated is given, calculated according to the patient's weight, height, general medical condition, and age. Some patients are more sensitive than the average patient (especially the elderly and frail), and doses have to be adjusted according to the response to treatment (e.g., as judged by its effect on the full blood count). Some patients will experience serious side-effects even if the correct protocol has been used, but too high a dose will increase the chance of serious problems and can prove fatal. For example, one patient died after double the correct dose of chemotherapy was prescribed in error. Another patient was given repeat prescriptions by his general practitioner for a drug that should have been taken for only 4 days. By the time the mistake was recognized 6 weeks later, his bone marrow was severely suppressed and he did not recover.

Extravasation

Most cytotoxic chemotherapy is given into a vein by a short (bolus) injection over 10–15 min or by slow infusion over several hours, days, or even weeks. If chemotherapy leaks outside the vein, it may cause serious damage to the local tissues. Some drugs, such as vincristine and Adriamycin, are particularly "vesicant."

Sometimes, extravasation, leakage of the drug outside the vein, occurs and the infusion should be stopped immediately it is noticed. The harmful effect of concentrated chemotherapy on the tissues may be ameliorated by medical treatment (such as the injection of steroids), but sometimes tissue destruction leads to the formation of an ulcer at the site of injection. For example, an elderly woman developed a large ulcer on the inside of the elbow after an injection of Adriamycin. Veins at the elbow should not be used for chemotherapy because it is difficult to check the cannula. Moreover, vesicant drugs should be given via a fast saline drip so that it dilutes the drug (and it is apparent if the cannula is misplaced).

Organ Failure

The serious toxic effects of chemotherapy include kidney failure (e.g., cisplatin), lung fibrosis (e.g., bleomycin), heart failure (e.g., Adriamycin), and nerve damage (e.g., vincristine and taxol). It is important to monitor organ function carefully in order to be able to modify treatment appropriately.

For example, a patient receiving Adriamycin for breast cancer had an abnormal ultrasound heart test after three doses, and Adriamycin should have been stopped. After a fourth dose, the patient developed severe heart failure and died.

Wrong Diagnosis

Sometimes, patients receive chemotherapy for what is presumed to be a malignant tumor but that is later found to be benign, and they have therefore suffered the side-effects of treatment unnecessarily. For example, following a liver scan that showed multiple cystic areas (thought to be due to the spread of cancer), chemotherapy was given to a patient without further scans or a biopsy. After several months of treatment, a more detailed scan confirmed that the cysts were benign.

Wrong Site

There are more than 20 reports of the injection of vincristine (instead of another less toxic drug) into the spinal canal, resulting in fatal outcomes. Guidelines have been issued to ensure that this error is prevented. The UK National Patient Safety Agency has carried out research on the use of a unique connector for spinal injections to prevent the injection of drugs designed for intravenous use.

Conclusion

Treatment of cancer requires accurate diagnosis and prompt treatment. However, since many tumors spread early, it may be difficult to demonstrate that delays of a few months affect the outcome. Chemotherapy is a potent treatment for cancer, but failure to take appropriate precautions may lead to unnecessary serious harm.

See Also

Medical Malpractice: Radiotherapy

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Oral Surgery

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Definitions

For the purposes of this article, oral surgery may simply be considered to include the diagnosis and surgical treatment of diseases of the oral soft and hard tissues, including the lips and teeth and their supporting structures. The surgery will normally be at a minor or intermediate level, usually conducted as an outpatient procedure, under local analgesia, or as a day-stay procedure under general anesthesia, rarely requiring an overnight stay in hospital.

Included within the ambit of oral surgery here are entities such as dentoalveolar surgery, minor oral surgery, and surgical dentistry.

Oral surgery may be undertaken in independent dental practices, community clinics, and within hospitals. Practitioners of oral surgery will be dentally qualified with additional expertise and training in oral surgical procedures. Increasingly, further qualifications and the requirement to be included on specialty lists are required.

The normal patient anxieties associated with routine dentistry and other procedures within the oral cavity make oral surgery a particularly challenging discipline when conducted under local analgesia. In view of the restricted access and the inevitable intimate juxtaposition of important structures, it is a form of surgery requiring meticulous and skilled practice in all its forms. When practiced on the conscious patient it is also the branch of surgery requiring the highest level of patient support and management skills.

The Nature of Oral Surgery

Oral surgery may be considered to be essentially a subspecialty of dental surgery and more broadly of surgery generally.

The subspecialty concerns itself primarily with the diagnosis and treatment of diseases of the oral cavity and associated structures. Whilst oral surgeons can be involved in the diagnosis and treatment of oral infections and oral lesions, they can equally become involved in the diagnosis and treatment of orofacial pain. However, most of the surgical procedures carried out will involve the surgical removal of teeth and roots, surgical endodontics, and the removal of oral lesions, usually for diagnosis.

Some oral surgeons will also become involved with orofacial trauma, particularly when working within hospitals, and will repair facial lacerations and facial bone fractures. They may also become involved in orthognathic surgery to realign jaws. The treatment of orofacial trauma and orthognathic surgery is dealt with in elsewhere.

Malpractice

Malpractice in oral surgery, in common with other medical specialties, is usually due to an omission to obtain valid consent, for whatever reason, or due to the commission of negligence. Malpractice in general

will be dealt with elsewhere in this encyclopedia and in numerous medicolegal texts.

In this article, the common oral surgery procedures will be covered, including a brief description of why the procedure might be required and how it is accomplished. Importantly, the information and warnings that should be given to obtain a valid consent will be discussed and the common complications, which might be associated with negligence or malpractice, detailed.

In hospital practice generally, and no less in oral surgery, it is apparent that allowing junior or inexperienced members of staff, who may be incapable of actually undertaking a surgical procedure, to take consent is a potential reason for invalidating the consent. Such a practitioner can neither be relied on adequately to appreciate and explain the general benefits and disadvantages of a procedure nor be reliable in adapting this information to a patient's particular situation, let alone answer a patient's detailed question or concerns. The lack of appropriate and relevant information about a surgical procedure and a failure to allow patients adequate time to fully understand the implications of that information are areas of concern when attempting to obtain valid consent.

Surgical practice is inevitably contextual, and the context will include the complexity and vagaries of surgery and the interaction between the patient and clinician on a background of what is considered good practice. Damage to the inferior dental nerve and subsequent permanent anesthesia of half of the lower lip would be considered malpractice in the simple surgical removal of a mildly impacted wisdom tooth far from the nerve bundle. The same complication would be considered acceptable in the complicated removal of a deeply buried wisdom tooth, intimately associated with the nerve bundle and perhaps with related bony pathology, if the patient had received adequate warning.

The principal areas for malpractice in oral surgery are incompetent diagnosis or incompetent conduct of a surgical procedure, particularly where it needlessly damages adjacent structures.

Radiography

There is heavy reliance on X-ray imaging in oral surgery in order to assess dental and bony structures and associated pathology. Numerous radiographs are employed, including periapical and bitewing small films, occlusal medium-sized films, and those larger films that are used for rotational tomography to examine the jaws. Meticulous labeling of such radiographs with regard to patient name, side, and even the individual tooth (on smaller films) is required to prevent mistakes happening. It is important that radiographic images are of good quality in order that an accurate diagnosis may be made and an appropriate procedure may be properly planned and carried out efficiently. Poor inappropriate radiographs or even the total absence of radiographs provide fertile ground for the growth of litigation.

Surgical Procedures

It is not possible or desirable to cover all procedures carried out by the oral surgeon.

The common procedures, which encompass the majority of the work done, will be covered along with a description of the procedure, why it is necessary and, briefly, how it is done. The appropriate warnings and common complications, which will form the basis of most putative suits in negligence, will also be covered.

Surgical Removal of Teeth or Roots

Symptomatic or unrestorable teeth and roots retained in the jawbone once the crowns are lost frequently require removal in order to prevent symptoms (usually pain and infection), but may also be removed to facilitate the restoration of a deficient occlusion.

The removal of impacted and symptomatic third molars (wisdom teeth) is one of the most common operations undertaken by oral surgeons and advice on the indications for this surgery is offered by the National Institute for Clinical Excellence (NICE) in the UK, and similar bodies in other countries. The guidelines for removal include pain and infection, tooth decay, and any other associated pathology that the removal of the third molars would obviate.

Clinical and radiographic assessment is required along with treatment planning prior to reflecting gum flaps, removing bone with drills or chisels, and removing the teeth or roots with elevators or forceps sometimes after surgical division of roots. These procedures may be carried out under local analgesia or general anesthesia where the patient or the procedure demands it.

It is usual to warn the patient routinely prior to these procedures of pain, swelling, bruising, and a transient limitation in mouth opening due to muscle spasm in the aftermath of surgery. In the case of the removal of wisdom teeth it would be considered normal practice also to warn of a risk of permanent anesthesia or paresthesia of the inferior dental and lingual nerves. In the event of a higher risk, this should be indicated to the patient and this may be due to an intimate association of the tooth with the inferior dental canal, for example, or due to the presence of associated pathology such as a large cyst.

Although the risks of damage to the inferior dental or lingual nerves are frequently bundled together, as was made clear in the UK court case *Heath* v. *Berkshire Health Authority* (1991), coincidental surgical damage to the lingual nerve during lower wisdom tooth surgery will generally be considered to be negligent. In addition, if an intimate relationship exists between the surgical site and the inferior dental nerve, along with evidence of having appraised the patient of this, a charge of negligence should be avoided.

Fracture of the lower jaw during removal of teeth or roots, although the subject of much apocryphal concern, is rare and would be likely to form the basis for a charge of negligence, unless the presence of an atrophic or pathological mandible had been drawn to the patient's attention.

Damage to adjacent teeth or restorations (crowns, bridgework, fillings) during the removal of teeth or roots when an especial vulnerability had not been drawn to the patient's attention would be likely to lay the surgeon open to an accusation of malpractice.

The displacement of teeth or portions of teeth during surgery into the pharynx, pterygoid space, or antrum, although rare, is a common cause for concern and precaution. It would depend on the exact circumstances as to whether negligence would be apportioned.

The risk of creating a communication between the mouth and antrum in removal of an upper tooth (oroantral communication) closely associated with the floor of the antrum (usually upper premolar and molar teeth) should be signaled to the patient prior to surgery. It is likely that many such occult communications occur and heal uneventfully, with both patient and surgeon blissfully unaware. On the occasions that such communications continue and the communication epithelializes to form a persistent fistula, a patient unaware of the risk might understandably become aggrieved and pursue compensation for the inconvenience of requiring a second surgical procedure to close the communication.

The likelihood of patient bewilderment deteriorating to dissatisfaction and on to litigation will be greatly influenced by their relationship with the surgeon and the support that they receive in the aftermath of any problems.

Surgical Endodontics

Conventional or orthograde endodontics (root canal therapy) is frequently required when the pulp of a tooth becomes inflamed and undergoes necrosis due to a carious lesion or thermal or chemical damage. Removal of the necrotic pulp tissue with debridement of the pulp chamber and root canal followed by obturation of the chamber and canal with a filling material will allow conservation of the tooth in the majority of cases.

On the occasions when an infection involving the apex of the tooth persists or recurs despite a satisfactory orthograde root filling, the procedure known as surgical endodontics or apicectomy with retrograde apical seal is carried out. The apices of teeth are accessed via a mucoperiosteal flap or, when possible, via a less intrusive semilunar incision over the root apex. The tooth apex is exposed by removal of overlying alveolar bone, usually from the buccal aspect, any soft-tissue lesion curetted, and the apex of the tooth is prepared minimally to receive a retrograde apical seal. The procedure is carried out in the expectation that discomfort or bony pathology associated with the tooth will resolve and the tooth remains functional. It would be normal to warn the patient that the procedure is not invariably successful and is frequently associated with some pain, swelling, and occasional bruising.

It is likely that the tooth will be uncomfortable for a week or so after surgery and that the use of a flap bordering the cervical margin of the tooth could be associated with a small element of gum recession in the healing process. The patient should be warned that this can expose the margin of a prosthetic crown, giving a less pleasing esthetic appearance than before surgery.

There is a risk of apicecting the wrong tooth root in a situation where roots of adjacent teeth are closely clustered together, but this is rare. Gum recession and the risk of the procedure failing should be mentioned to the patient.

An apicectomy and apical seal without a satisfactory orthograde root filling in place is more likely to fail and would only be contemplated in exceptional circumstances when the patient has been entirely appraised of the poor chance of success.

The technique and materials utilized in surgical endodontics have developed and improved in recent years, and the failure to use magnification (loupes or an operating microscope) during the procedure or a failure to use up-to-date techniques and materials might be grounds for concern. As always, damage to adjacent structures, including nerve bundles, adjacent teeth, and the antra, without adequate presurgical warning and good reason will make the surgeon vulnerable to an accusation of malpractice.

Dental Implantology (Osseointegrated Dental Implants)

The development of dental implants has revolutionized the concept of dental and occlusal reconstruction over the last 30 or so years. Missing or lost tooth units

may now be replaced with implant-borne suprastructures (crowns, bridges, or dentures), which attach to dental implants that are firmly fixed in the bone. The implants are usually similar in length and width to the tooth roots they replace and are usually cylindrical and constructed of titanium, although other shapes and materials have been used. The success rate of dental implants can be very high and, if they are carefully placed and well maintained, can last for in excess of 30 years, although the suprastructure may require replacement every 7–10 years. Dental implants are therefore capable of providing rigid support for the replacement of single teeth, several teeth as a fixed bridge, or even overdentures, which are attached less rigidly but can be removed for cleansing.

Dental implants may be placed under local analgesia or general anesthesia and constitute intermediate surgery. A mucoperiosteal gum flap is reflected, a hole is carefully made within the bone to receive the implant, and the flap is closed for up to 6 months to allow osseointegration. The implant will usually become rigidly fixed due to the close apposition of bone with the implant. At this time a further minor surgical procedure is made to expose the head of the implant, followed by abutment placement, which will culminate in placing the definitive suprastructure.

This treatment will have been planned and agreed between the patient, oral surgeon, and restorative dentist (who will construct the suprastructures). It is important for the oral surgeon to discuss all the various restorative options with the patient before embarking on implant surgery. The patient should be aware of the advantages and risks of this treatment modality along with cost and timescale.

In view of the complexity and length of treatment allied with high cost and a number of surgical procedures, it is most important that the patient is aware of the implications of this form of treatment and that the restorative dental practitioner, as well as the oral surgeon, have the necessary experience and skills to be likely to produce a good result. Thorough planning, along with any necessary presurgical treatment, X-rays, study models, implant placement templates, or computed tomography scans should be carried out in order to give implant placement the best chance of success. Failure to discuss other treatment options such as dentures and bridgework or the cost or timescale will lay the oral surgeon open to criticism.

It is most important to plan the patient's implant treatment adequately with the restorative dentist and the dental laboratory in order that implant positioning and loading minimize disadvantage to the patient and maximize function and esthetics.

In the event that bone grafting is required to provide a sufficient foundation for dental implants, this requires detailed discussion and agreement with the patient, particularly if products derived from animals rather than inorganic materials are used.

Failure to use a high standard of sterile technique in surgery and to have available good-quality X-rays and planning templates will lay the practitioner open to accusations of malpractice on the occasions when a procedure does not proceed as it should.

Biopsy/Excision of Oral Lesions

Careful explanation with valid consent, albeit frequently verbal, allied with careful competent treatment minimizing damage to adjacent structures will make claims for negligence unlikely. Patients must be warned of pain, swelling, bruising and the placement of sutures, and any risks of recurrence.

General Considerations

The removal of a wrong tooth or fracture of the jaw during routine surgery or damage to adjacent teeth and restorations are complications likely to lead to accusations of malpractice.

Although discomfort from the temporomandibular joints, even when allied with clicking noises, can come to the patient's attention after oral surgery, it is usually an acute exacerbation of an underlying temporomandibular joint dysfunction. There does not appear to be good evidence that routine oral surgery causes temporomandibular joint dysfunction.

Great care should be taken not only to protect structures immediately adjacent to the surgical site but also the lips, face, and eyes: the eyes should usually be protected with safety spectacles during surgery.

An oral surgeon would be considered culpable if, whilst treating a patient for one condition, a more serious pathology was ignored. The efficient removal of a wisdom tooth in ignorance of a carcinoma on the lateral border of the tongue would be difficult to defend. The oral surgeon would also be expected to take adequate precautions with regard to providing antibiotic cover for those patients who require it (e.g., those with heart valve lesions) and to assess and treat correctly those patients on anticoagulation.

As a general maxim, an oral surgeon who practices the standard of care required by professional colleagues and hoped for by patients and who combines this care with humanity and gentle humor is least likely to disturb the repose of legal colleagues.

See Also

Medical Malpractice: Facio-maxillary Surgery

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Plastic and Cosmetic Surgery

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Introduction

Plastic and cosmetic surgery covers a wide range of surgical procedures. There has been a significant increase in litigation against surgeons performing such procedures, and it is likely that this trend will continue. Cosmetic surgery is different from other surgical specialties as the benefits of surgery are mostly psychological rather than functional. This difference raises ethical issues and vulnerability of plastic surgeons to litigation. The causation and genesis of plastic and cosmetic surgery claims are discussed, including issues of consent before surgery. The pros and cons of plastic surgeons using computer-generated images and the internet for marketing and communication are also discussed.

The Scope of Plastic and Cosmetic Surgery

Plastic surgery can be defined as the branch of surgery concerned with restoration of form and function by reconstruction of congenital, traumatic, and acquired conditions. Plastic surgery covers a very large field and deals with patients with congenital conditions such as breast and chest-wall defects, cleft lip and palate, and other facial deformities, including craniofacial defects, hand defects, skin defects, and urogenital defects. It also deals with patients who have sustained burns, face, hand, and lower-limb trauma, scars, and tattoos. Plastic surgeons also deal with patients requiring reconstruction following mastectomy for breast cancer, head and neck conditions, patients with benign and malignant skin conditions, pressure sores, venous ulcers, degenerative hand conditions, and patients requesting cosmetic surgery. Variable amounts of reconstructive surgery are carried out in collaboration with other surgical disciplines, for example orthopedic, ear, nose, and throat (ENT), and maxillofacial surgeons.

Plastic surgery means the molding of the surface and sometimes deep structures of the human body. Techniques developed in plastic reconstructive surgery have been adapted for the purpose of rejuvenation and esthetic enhancement of the patients. Cosmetic surgery includes surgery to improve, alter or change the appearance in the absence of disease, trauma or congenital deformity. Cosmetic surgery has developed rapidly since the 1970s and involves surgery for facial rejuvenation such as facelifts; blepharoplasty; rhinoplasty; body-contouring procedures such as liposuction and abdominoplasty; esthetic breast surgery, including breast reduction and enhancement; and laser surgery. Cosmetic surgery is carried out not only by plastic surgeons but also by ENT surgeons, maxillofacial surgeons, and dermatologists.

Trends in Medical Malpractice in Plastic and Cosmetic Surgery

In the USA, there has been a significant increase in claims related to medical malpractice in plastic, reconstructive, and cosmetic surgery. In the 1950s one claim per every 100 doctors was filed. By the early 1990s that figure had increased by 1000% to more than ten medical malpractice claims being filed per 100 doctors. Physicians have seen their medical malpractice insurance premiums increase by as much as 500% since the 1970s. The likelihood of an incident for a plastic surgeon has been estimated at once every 2.5 years.

The Medical Defence Union (MDU) in the UK in a recent 12-year period settled 241 claims that arose from plastic, cosmetic, and reconstructive surgery (**Figure 1**). This resulted in expenditure of just under £6.7 million (US $12 million). This included

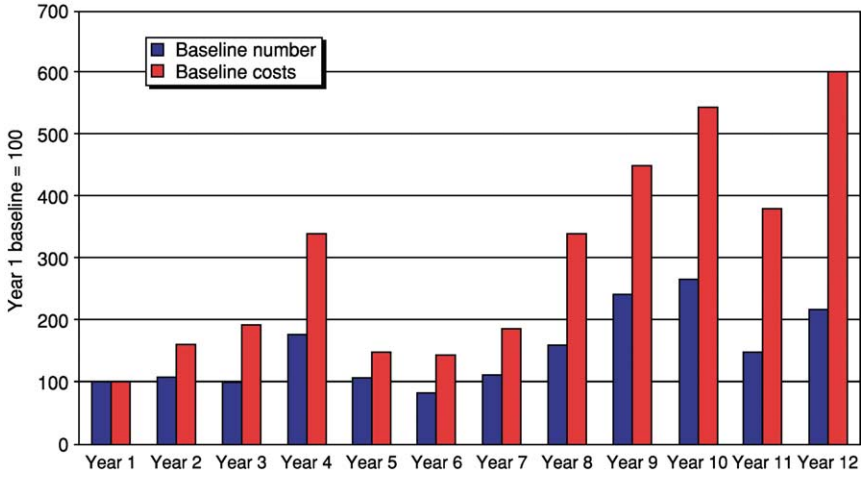

Figure 1 Number and cost of plastic and reconstructive surgery claims settled in a 12-year period. Reproduced with permission from the Medical Defence Union.

legal costs and the indemnity awarded to the patient. The size of claims ranged from £200 to £250 000 (US $360–450 000). This figure does not include those cases that were dropped by the claimant or won by the MDU. It also does not encompass the advisory matters that arose from this type of surgery such as complaints or referrals to the General Medical Council. The majority of these claims arose from consultations in the private sector and not from the National Health Service (NHS) as the NHS indemnity scheme was introduced in 1990.

Cosmetic Surgery: A Specific Problem?

As compared to other surgical specialities, cosmetic plastic surgery is one of the specialties most vulnerable and prone to litigation. This may be due to several reasons; for example, people who tend to seek cosmetic surgery are so concerned with enhancing their appearance that they may be less likely to tolerate imperfections, some patients may be receiving less than adequate care, and some patients are more willing to sue. There is also a growing emphasis on personal gratification and youth and a tendency on redress if things go wrong. People are requesting cosmetic surgery not only to look younger and sexier, but also because of dissatisfactions with life that are vague and diffuse.

The benefits of cosmetic surgery tend to be psychological, not necessarily functional, and difficult to evaluate. This form of surgery therefore raises the ethical problem of balancing risks and benefits of operations without functional benefit. If a patient has an injury such as a broken arm, the expected benefit of operative intervention is obvious whereas in cosmetic surgery the benefit is somewhat harder to assess. It is therefore necessary to weigh the risks and complications of the procedure including that of the anesthetic against a benefit for the patient that may be difficult to evaluate. Unlike other surgical specialists, the plastic surgeon assessing a patient who requests esthetic surgery is not trying to make a sick patient better but rather a well patient better. This not only puts a much heavier burden of responsibility on the operating surgeon, but also subjects him or her to a much broader range of possible reasons for unhappiness. Sources of dissatisfaction can range from a catastrophic result to something as unpredictable as a patient's hidden agenda.

Causes of Malpractice in Plastic and Cosmetic Surgery

A survey of claims in the USA has shown in 700 cases over 15 years that esthetic breast surgery, both augmentation and reduction, has been responsible for most claims. Approximately 37% of all elective esthetic surgery claims involved breast augmentation surgery. The main complaints of dissatisfaction have been encapsulation with distortion and firmness, wrong size (too little or too much), infection, repetitive surgery and attendant costs, and nerve damage with sensory loss. For breast reduction surgery, complications included unexpected ugly scars; too little or too much breast tissue being removed; partial loss, distortion or misplacement of nipples; and dissatisfaction with the resulting breast shape. If the primary complaint was back and shoulder pain and those complaints were relieved postoperatively, the dissatisfaction quotient lessened considerably (Figure 2).

Facelift surgery and blepharoplasty cases accounted for 19% of claims in this series, and the complaints

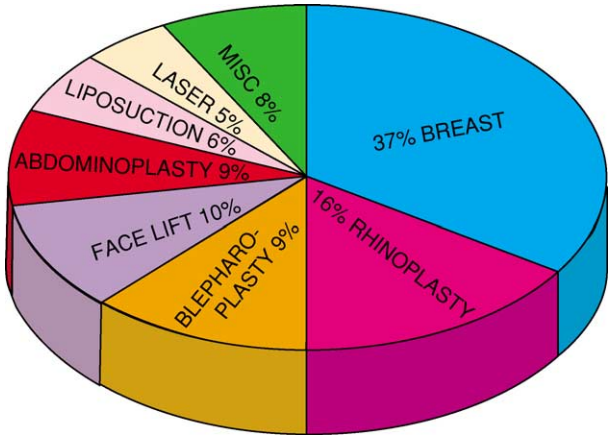

Figure 2 Total percentage of claims for elective esthetic surgery. Reproduced with permission from the Medical Defence Union.

with blepharoplasty included excessive skin removal, resulting in a starey look, dry eyes, the inability to close the eyes, and ectropion or scleral show, with resultant exposure keratitis. Visible scars, real or alleged visual impairment, and change of expression were also causes for complaint. In the rare but devastating postoperative blindness cases, the typical expanding hematoma commonly were not diagnosed and decompressed immediately.

Complaints with facelift surgery included visible or hypertrophic scars, sloughs or wound disruption (most often in smokers), facial nerve damage, inadequate result from insufficient or excessive tightening, persistent pain or numbness, and skin slough resulting in excessive scarring.

Rhinoplasty cases accounted for 16% of claims. Complaints with this procedure included unhappiness with disappointing results, airway obstruction, visible irregularities and scars, asymmetry, and emotional distress.

Abdominoplasty with or without suction-assisted liposuction represented 9% of claims with allegations of skin loss with poor scars, nerve damage, inappropriate surgery, and infection with or without appropriate postoperative management. The combination of liposuction and abdominoplasty increases the morbidity as this can affect skin circulation, leading to skin sloughs.

The most common allegations following liposuction were waviness, lumpiness, asymmetry, irregularities, disappointment with the degree of changes achieved, persistent numbness and pain, and the attendant cost of revision. In the techniques that entail superficial subcutaneous liposuction, skin circulation may be impaired. This can lead to major sloughs requiring extensive revisional surgery with substantial scarring. There were a number of undetected abdominal wall and intestinal perforations that led to major secondary operations and in several cases death. Tumescent liposuction procedures have also produced problems secondary to volume exchanges, leading to profound physiological disturbances and pulmonary edema. There were also cases involving overdoses of local anesthetic. The necessity for revisional surgery with its attendant costs was a common theme in all categories.

Chemical peels/laser resurfacing accounted for 5% of claims, allegations included blistering or burns with significant scarring, infection, and permanent pigmentary changes. Approximately 8% of all complaints against plastic and reconstructive surgeons have to do with miscellaneous allegations such as untoward reaction to medications or anesthesia and improper use of pre-op or post-op photos.

There is a continual flow of avoidable claims that are directly linked to smoking. In surgery involving wide tissue undermining, such as facelift and breast surgery, the patients who were heavy smokers suffered sloughs or poor wound healing which subsequently caused poor scars. These problems could have been predicted preoperatively.

In the UK, the MDU in a recent 12-year period found that the largest group of claims settled (100 cases = 42%) was related to surgery performed on the face. Thirty-five of these claims resulted from rhinoplasty procedures and 27 from facelifts. Common themes in the expert reports for rhinoplasty claims were the lack of pre- and postoperative photographs and establishing the specific patient requirements during the counseling stage. There were numerous other types of procedures involving the face, including blepharoplasty, cheek and chin implants, chin reduction, and chemical face peel (Figure 3).

There were also a number of lip augmentation claims resulting in successful litigation. Of the cases arising from breast surgery, over half arose from breast augmentation procedures, mainly as a result of dissatisfaction with the cosmetic result. Approximately a quarter arose from breast reduction procedures. A vast majority of these procedures were performed purely for esthetic reasons, although some arose following reconstruction after mastectomy for breast cancer. The claims that arose from abdominal procedures followed either liposuction or abdominoplasty. Those citing the thigh were, apart from one case, related to liposuction. Claims where the site of operation was the arm were mostly related to tattoo removal, either by surgical excision or by using laser treatment.

The group marked “others” encompassed several types of procedures, none of which led to more than

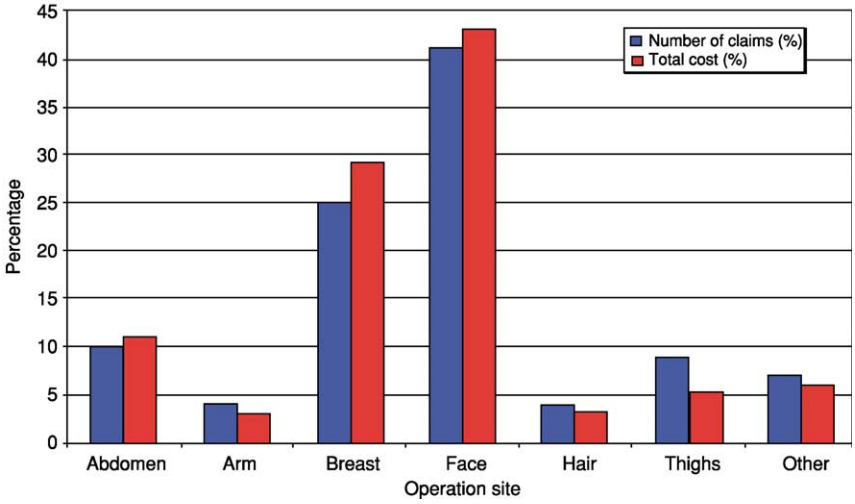

Figure 3 Distribution of claims by operation site. Reproduced with permission from the Medical Defence Union.

a handful of claims over the period. Sclerotherapy for veins on the face and leg was the only type of surgery in this category that gave rise to more than five claims over this period. There were three involving phalloplasty. This group included some of the less commonly performed procedures, including gender reassignment.

The most expensive claim resulted from dissatisfaction with the results of liposuction and fat transfer to the face. Breakdown of cost by anatomical region shows that claims resulting from breast surgery have been more expensive, although there is very little difference between those to the face and abdomen.

The Genesis of Malpractice Claims in Plastic and Cosmetic Surgery

There are certain issues that lead to malpractice claims against plastic and cosmetic surgeons. These include unexpected scarring, general dissatisfaction, and lack of adequate explanation or discussion that is not appropriate for the patient's level of understanding, resulting in poor consent. The patient's expectations may have been unrealistic. The patient's expectations may not have been known preoperatively and subsequently not have been met, or the patient's expectations may have been known preoperatively and were still not met. There are also patients who are more likely to pursue litigation claims in cosmetic surgery. These are patients with great expectations, excessively demanding patients, and those who may be indecisive, immature, and secretive. Patients who lack familial approval, those who have repeated cosmetic surgery procedures, and patients with psychological problems are also more likely to sue. It is therefore important to know the patient before surgery and to screen out those patients with unrealistic expectations. If the patient has such unrealistic expectations the procedure will not be successful even if it was performed well, and the doctor may be blamed for a perceived poor result. A condition that is important for plastic surgeons performing cosmetic surgery to be aware of and assess patients for is dysmorphobia. Dysmorphobia is a psychological condition in which the patient suffers from a subjective feeling of ugliness despite having a normal appearance or a minimal cosmetic defect. Patients requesting cosmetic surgery may also suffer from psychiatric problems such as eating disorders for which surgery would not be indicated. It is essential for the surgeon to identify these traits preoperatively. Informing patients in great detail of the potential complications of the procedure as part of the consent process will not be enough if the expectations of the patient were unrealistic. Insisting on a referral from the patient's general practitioner, a cooling-off period before surgery and, if appropriate, referral to a psychiatrist may be helpful to deal with these issues.

The survey of claims in the USA showed evidence of the same generic problems in esthetic surgery claims such as substandard documentation with missing or poor preoperative photographs, inadequate informed consent, poor patient selection, and substandard operative results. The genesis of claims implicates improper patient selection or overly enthusiastic treatment. A trend was found among plastic surgeons to try to combine several procedures at one sitting. It is not appropriate to perform several major procedures combined in one long surgery in an office facility. Staged treatment sessions are

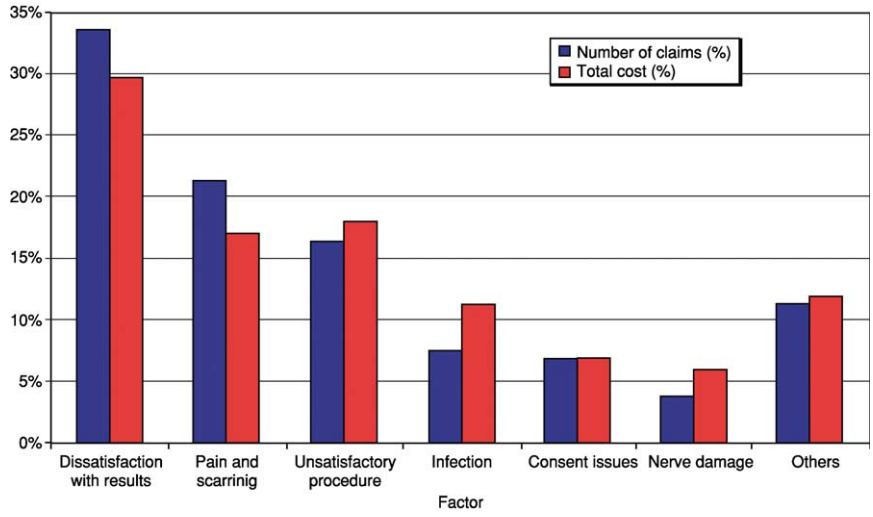

Figure 4 Factors leading to settled claims. Reproduced with permission from the Medical Defence Union.

preferable to trying to do as much as possible in one session. There were also a rising number of malpractice claims in which it was clear that economic consideration was put ahead of sound surgical judgment. This includes cases in which the patient did not need the proposed procedure, he/she was the wrong patient on whom to perform the procedure, and the surgeon was inexperienced.

The actual reason why patients pursue litigation is complex. Around half of all settled claims in this specialty by the MDU resulted from either dissatisfaction with the result of surgery and/or unsatisfactory procedures (Figure 4). Although similar, there is a subtle difference between the two groups. Claims arising from dissatisfaction with the results of surgery tend to arise from unrealistic patient expectations, and a successful claim will often result from deficiencies in preoperative counseling and poor clinical record-keeping. The unsatisfactory procedure group refers to problems arising directly from the surgical procedure and includes deficiencies in the surgical procedure, surgical technique used, or inadequate arrangements for postoperative follow-up. Another reason is where the main allegation was performing the procedure without the express consent of the patient. The "others" category includes a number of uncommon reasons, ranging from retained liposuction tubing and diathermy burns to brain damage resulting from hypotensive anesthesia. Interestingly, while dissatisfied patients have the largest number of successful claims, the most costly average claims arose from problems such as nerve damage and infection. The value of successful claims arising from pain and scarring was small.

Surgeons with lower claim rates may be more likely to manifest exemplary modes of professional peer relationships and responsible clinical behavior. A study has shown that the personal, educational, and professional characteristics of surgeons may contribute substantially to the incidence and outcome of malpractice claims. Common denominators of malpractice claims regardless of underlying cause are surprise, disappointment, and anger, followed by a breakdown in communications.

Issues Surrounding Consent and Basic Medical Legal Principles

Many malpractice claims are preventable. Most are based on failure of communication and poor selection criteria rather than on technical faults. Regardless of the technical ability of a surgeon, someone who appears distant or arrogant is far more likely to be sued than someone who has the ability to communicate well. Similarly, a surgeon who has a warm, sensitive, and caring personality is much less likely to be the target of a claim for negligence. An issue that may precipitate a complaint against a surgeon may not be a technical error made during the procedure but a failure by the surgeon to establish a reasonable rapport with the patient at the time of consultation. Exemplary surgical skills and good clinical judgment by the surgeon may be obscured in the patient's mind by what is felt at the time of consultation to be an offensive and arrogant attitude. The role of informed consent in cosmetic surgery is to try to ensure that patients know and understand what lies ahead if they want surgery to improve their appearance.

Surgeons should, as part of the informed-consent process, before any invasive procedure is performed explain to the patients the details of what is proposed, its purpose, potential risks, and any reasonable alternatives that may include no treatment at all. At the time of consent patients should not only be adequately informed but also should be capable of assimilating that information and thereby be competent to consent, and should be able to give that consent voluntarily without coercion, manipulation, or constraint on the part of the surgeon.

At the end of a comprehensive and detailed consultation it is difficult to know to what extent the patients have understood the details and potential complications of the procedure in question. A study performed 20 years ago has shown that simple written information increases the proportion of patients who understand their diagnosis from 31% to 70%. This was not at a level that matches the detail that applies to the consultation on cosmetic surgery today. A more recent paper has reported the outcome of a prospective randomized trial of patients' recall of verbal versus written preoperative warnings. Patients given verbal warnings were less able to recall them than those with written warnings.

Although a detailed consultation supplemented with written information, such as patient information sheets and copies of correspondence to the patients' general practitioner, would seem to be comprehensive, patients may still not assimilate the information that has been provided. It is therefore prudent to allow a cooling-off period during which the patient has the opportunity to dwell on the issues that have been raised. Patients should also be given the opportunity and encouraged to attend for further consultations to discuss any further issues that may arise.

In the UK, consent is based on a professional standard of disclosure or what a doctor believes a patient should know, whereas in the USA, consent is more patient-centered: the doctor owes a duty to disclose not only the inherent potential risks of treatment, but also any alternatives to that treatment and the likely consequence of nontreatment. Surgeons should, in respect for patient autonomy, give information over and above that required simply to protect them from the liability of battery. The physician must adhere to an applicable standard of care. In general this standard of care is that which would be rendered by a reasonable physician under like or similar circumstances. In order for a valid claim of negligence to be proven the physician must have owed a duty of care to the patient, the standard of care must have been violated by the physician, this violation of the standard of care must have proximately occurred, and a loss or injury must have occurred for which the patient can be compensated. The standard of care is evaluated in light of the state of medical knowledge and skill available at the time of the allegedly negligent conduct. In a medical malpractice case, the standard of care will be delineated by the medical experts' testimony. Therefore, the defendant's and plaintiff's medical experts play a crucial role in any medical malpractice case.

Issues Surrounding the Use of the Internet and Computer-Generated Pictures

Computer imaging allows surgeons to manipulate digital photographs of patients to project and predict possible surgical outcomes. Some of the benefits these techniques provide include improving doctor–patient communication, improving the education and training of residents, and reducing administrative and storage costs. Despite the many advantages that these computer imaging systems may offer, surgeons are concerned that these imaging systems may expose them to legal liability. Surgeons may face possible claims of implied contract, failure to instruct, and malpractice from their use or failure to use computer imaging. A study, however, has revealed that surgeons who use computer imaging carefully and conservatively and adopt a few simple precautions substantially reduce their vulnerability to legal claims.

It is recommended that computer imaging be used primarily as a tool for improved communication between physician and patient. Its use for the selling of an operation and marketing of various procedures is not appropriate. A computer image cannot exactly replicate an image based on the surgeon's technical abilities and patient's preexisting conditions. The digital projected result should therefore be understated and patients should also be shown images of the possible unexpected and unfavorable outcomes of the procedure. The computer images should be used to enhance the informed-consent process and consent should be documented such that the imaging session is only a simulation and is in no way meant to be a guarantee or warranty of a surgical result.

Over the last few years many plastic surgeons have set up their own personal website pages to provide information about themselves and to inform prospective patients of the range of procedures they may provide. Also included is usually an electronic mail link to communicate with and educate prospective patients. These services are provided without actually meeting patients face to face. Some of the positive aspects of personal website pages revolve around

their use as a marketing tool and as a tool in patient education. Physicians can advertise procedures that they commonly perform and this will probably expand their patient base. From a patient education point of view, one can depict actual procedures and place pre- and postoperative instructions for a procedure on the site.

It is recommended that a broad disclaimer of liability is used when posting medical information on a website. One should also not use information on the Internet in place of standard consent procedures. Surgeons should be aware of the implications of intellectual property/copyright infringement in the set-up of their website. If photographs of patients having undergone a surgery are used, then appropriate consent should be taken. It should be emphasized that the results depicted in the photographs may not represent the result another patient may achieve following the same procedure. An e-mail link on a personal website should be used for administrative tasks such as patient scheduling. Changes in medical information on privacy confidentiality laws and guidance from the General Medical Council on advertising should be followed.

Regulation of Cosmetic Surgery in the UK

Cosmetic surgery overlaps with a number of specialties in the UK, and it has no minimum standards of training leading to a certificate of completion of specialist training. The government was facing a problem in regulating this rapidly expanding market and responded by enacting the Care Standards Act following its response to the Health Committee's fifth report on the regulation of private and other independent healthcare, published in December 1999. This created a new body – the National Care Standards Commission (NCSC), which, with effect from April 1, 2002, took responsibility for the regulation of private healthcare throughout the UK in place of local authorities and health authorities.

In cosmetic surgery certain national minimum standards have been set, to which surgeons need to adhere. Some of these standards are that patients should always be given full details of the treatment they are to receive, they must not be admitted for treatment on the same day as the initial consultation, and referral for psychological counseling is available if clinically indicated. Surgeons performing cosmetic surgery must belong to the relevant professional body, which provides continuing medical education and adheres to the principles of the General Medical Council's good medical practice. They must maintain a comprehensive outpatient service; and must assess the appropriateness for receiving cosmetic surgery and record that in the patient's health record. There should also be written procedures for the safe use of equipment for cosmetic surgery within the hospital and all staff using the equipment should have completed training in the safe clinical use of this equipment and have demonstrated competence documented to this effect. In April 2004, the role of the NCSC was taken over by a new body, the Healthcare Commission, which is now responsible for reviewing the quality of care with reference to national minimum standards in the NHS and private sector.

See Also

Complaints Against Doctors, Healthcare Workers and Institutions; **Consent:** Confidentiality and Disclosure; **Medical Malpractice:** Ear, Nose and Throat Surgery; Facio-maxillary Surgery; **Medical Malpractice – Medico-legal Perspectives:** Negligence, Causation

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Police Surgeon

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Introduction

In today's increasingly litigious world, doctors are only too aware of their vulnerability to claims of alleged medical malpractice. Forensic physicians are not exempt from these risks and, indeed, are exposed to certain particular dangers because of the unique nature of their work. Although this article considers medical malpractice in relation to forensic physicians in the UK, many of the principles and considerations are equally applicable to other jurisdictions.

The Role of the Independent Forensic Physician

Forensic physicians (also known as forensic medical examiners and police surgeons) are usually general practitioners who provide clinical forensic medical services to the police in the UK on a part-time basis, although in busy metropolitan areas doctors may work exclusively as forensic physicians.

The doctors are self-employed and contract independently with the police to provide medical care to detainees and to conduct forensic assessments of both suspects and victims of crime. Thus, by the very nature of their work, forensic physicians are more likely than most doctors to end up in court giving professional or expert evidence. However, when things go wrong, forensic physicians may also find themselves as defendants in civil and even criminal proceedings.

Negligence and the Forensic Physician

Just as in any area of medicine, forensic physicians are expected to exercise proper care in their work. If they neglect to do so and their patients are harmed as a result, they can expect to be criticized and may face claims for compensation arising out of alleged clinical negligence. In a series of 100 consecutive files that were opened by one of the UK medical defense organizations to advise and assist forensic physicians, there were a total of 28 such claims of negligence. The vast majority (81%) of these cases were in relation to a delay in diagnosis, usually a fracture, while the remaining (19%) related to a prescribing error. A breakdown of these cases is shown in Table 1.

Alcohol intoxication is extremely common amongst detainees in police custody, and the anesthetic effect of the drug may explain some of the difficulty in establishing an early diagnosis of a fracture sustained during the commission of an alcohol-related offense. Intoxication may also adversely affect an individual's demeanor and this can lead to delays in diagnosis because of difficulty in establishing effective communication. However, problems with delayed diagnosis can also arise because of a failure on the part of the doctor to take a careful history and conduct a comprehensive examination. In particular, an uncritical acceptance of police assertions that a detainee is feigning illness has been highlighted as an important factor in a number of cases where delayed diagnosis has resulted in a death in police custody.

Deaths in police custody are hugely expensive both in terms of the emotional cost for the individuals and families involved and also financially, in relation to the formal inquiry that inevitably ensues. Research evidence has shown that the main causes of deaths in police custody in the UK involve deliberate self-harm, substance misuse, and delayed diagnosis of medical problems, particularly head injuries. Unfortunately, justifiable criticism is occasionally leveled at the standard of care provided to the deceased by the forensic physician involved and, rarely, the doctor may face a charge of manslaughter following a death in police custody. To reduce the numbers of these deaths, it is important to recognize clinical forensic medicine as a distinct medical specialty and ensure that doctors practicing the craft are properly trained and forensically aware.

Gross Negligence Manslaughter

When a patient dies as a result of alleged gross negligence on the part of a doctor, the UK Crown Prosecution Service may consider that a charge of

Table 1 A breakdown of 28 consecutive claims against forensic physicians

Reason for claim	*Number of cases*
Delayed diagnosis	23
Fracture of hand	5
Fracture of skull	2
Other fractures and trauma	6
Myocardial infarction	3
Suicidal depression	3
Diabetes	1
Other	3
Prescribing error	5
Total	28

Data from Schutte P (2000) Pitfalls in police work. *The Journal of the MDU* 16: 16–18.

manslaughter is justified. The threshold for determining criminal liability was established by the Court of Appeal in a case involving Dr. Percy Bateman, who was convicted of manslaughter in the 1920s after the death of an obstetric patient in his care. The Court of Appeal stated that:

> To establish criminal liability the facts must be such that, in the opinion of the jury, the negligence of the accused went beyond a mere matter of compensation between subjects, and showed such disregard for the life and safety of others as to amount to a crime against the State, and conduct deserving of punishment.

The suggestion that, to establish criminal liability, a jury must be satisfied that the doctor's actions were criminal, is somewhat tautologous. Fortunately, greater clarity can be found from the case of Dr. Adomako, where the Court of Appeal listed four states of mind, any one of which may be grounds for a finding of criminal negligence. These states of mind are:

1. indifference to an obvious risk of injury to health
2. actual foresight of the risk, coupled with the determination nonetheless to run it
3. appreciation of the risk, coupled with an intention to avoid it, but also coupled with such a high degree of negligence in the attempted avoidance as a jury may consider justifies conviction
4. inattention or failure to advert to a serious risk which went beyond mere inadvertence in respect of an obvious and important matter which the defendant's duty demanded he/she should address.

The number of doctors actually charged with and convicted of manslaughter increased appreciably in the 1990s, and there is strong anecdotal evidence that the police now routinely consider the potential criminal liability of forensic physicians involved in the care of individuals who die in custody.

Medication errors appear to be the single most common cause for a charge of medical manslaughter, whether in relation to deaths in police custody or elsewhere. A review of all medical manslaughter cases occurring in the UK between 1970 and 1999 revealed a total of 17 deaths involving 21 doctors. Only two doctors were charged in each of the first two decades during this period, compared to 17 in the decade 1990–1999 (this eightfold increase in cases of gross negligence compares to only a twofold increase in cases of civil negligence between 1990 and 1998). Forensic physicians appear to be disproportionately overrepresented, accounting for three (14%) of all doctors charged.

One of these cases involved a 23-year-old prisoner who was transferred to a provincial police station after having spent eight weeks in custody elsewhere. During this period, he had been weaned off heroin and, on transfer, was considered to be "fit and healthy." Notwithstanding this, two forensic physicians prescribed an alarming cocktail of drugs to him over the next 11 days, including temazepam (160 mg at night), diazepam (80 mg a day), chlorpromazine (300 mg daily), and methadone (30 mg daily). The man "was changed into a zombie-like figure" and subsequently died from drug toxicity.

In the other case, a forensic physician was charged with manslaughter after prescribing what was alleged to be a "lethal dose of methadone" to a 22-year-old man who, it transpired, was intoxicated with benzodiazepines at the time.

Although these are the only three reported instances of forensic physicians being charged with manslaughter, the author is aware of several other cases where similar charges have been considered. Taking a careful history, conducting a thorough examination, and keeping meticulous contemporaneous notes are the readily identifiable means of ensuring that such a charge cannot be substantiated.

Malpractice and the Expert Witness

Forensic physicians frequently appear in court as either professional or expert witnesses. When doctors come to court to give evidence, they have the benefit of absolute immunity. This immunity is regarded as necessary in the interests of the administration of justice and is granted to doctors, and indeed all witnesses, as a matter of public policy. It extends to anything said or done by them in the ordinary course of any proceeding in a court of justice and protects them from any action that may be brought against them even if things that are said or done are false, malicious, or negligent. The case of *Darker* v. *Chief Constable of West Midlands* appears to extend this immunity to reports and statements that may be produced by forensic physicians in the knowledge that, if proceedings were brought, the report would form part of the evidence in those proceedings.

Not only do doctors have immunity from civil action in relation to the evidence they give in court, but, also it seems that they have only a limited duty of care to the victims of crimes that they examine during the course of their work. Thus, the Court of Appeal ruled that Dr. Agrawal, a forensic physician who examined an alleged rape victim, owed the victim no duty of care to attend as a prosecution witness at the alleged rapist's trial, even if the failure to attend court resulted in the collapse of the trial and an exacerbation of the victim's psychiatric trauma. In such circumstances, the court ruled, the doctor is carrying

out an examination on behalf of the police and does not assume any responsibility for the victim's psychiatric welfare. The doctor's duty was simply to take care in the course of the examination not to make the patient's condition worse.

Whether the apparent immunity of forensic physicians to actions brought against them in relation to their work as professional and expert witnesses is as watertight today is open to debate. Certainly, in one recent landmark case, the Court of Appeal has ruled that children (but not their parents) can sue healthcare trusts and local authorities that wrongly conclude that they have been the victims of abuse. The three judges hearing the case held that the public policy considerations barring claims of wrongful diagnosis have been swept away by the Human Rights Act, which came into force in the UK in October 2000. It seems probable that this ruling will lay individual doctors, as well as healthcare trusts, open to negligence claims for wrongful diagnoses made in the course of legal proceedings.

Conclusion

Detainees in police custody represent a particularly vulnerable group of individuals by virtue of the high prevalence of substance misuse, mental illness, and previous episodes of deliberate self-harm amongst their number. Because of this vulnerability, forensic physicians involved in the clinical care of detainees expose themselves to an increased risk of civil and even criminal claims of medical malpractice if they fail to apply especial vigilance in the course of their examination and treatment of these individuals. Furthermore, it seems that forensic physicians may also be at risk of civil claims if they fail to exercise proper care when formulating forensic advice for the courts, if this advice is subsequently shown to be wrong.

See Also

Custody: Death in, United Kingdom and Continental Europe; Death in, United States of America; **Detainees:** Care in Police Custody, United Kingdom; Care in Prison Custody, United Kingdom

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Psychiatry

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Introduction and Definitions

Psychiatric malpractice falls under the general heading of medical malpractice and the same principles of tort law apply. The USA is the forerunner of psychiatric malpractice litigation with other industrialized countries lagging behind. Since the USA is farther along in legal malpractice evolution, the US system will be the focus of this article.

The physician who engages in a doctor–patient relationship owes a duty to the patient to provide care within the acceptable national standard, that is, what an average or competent psychiatrist would have done in similar circumstances. A breach or dereliction of this duty resulting in direct causation of damages to the patient is considered malpractice. These four malpractice elements must be proved by a preponderance of the evidence (i.e., tilting the scales) for the plaintiff to obtain a monetary award from the physician. Medical expert testimony is almost always needed in malpractice litigation.

Psychiatric malpractice claims in the USA and in other countries have been steadily rising over the past 30 years. Traditionally psychiatrists were less likely to be sued since they had fewer patients and closer relationships with them than other specialties. As practice patterns have changed and society has became more litigious, the number of malpractice cases is likely to continue to rise.

There are many potential causes of action against psychiatrists, including breaches of confidentiality, lack of informed consent, inadequate medication management, negligent psychotherapy, inadequate suicide assessment and prevention, duty to warn or protect third parties from harm by psychiatric patients, and doctor–patient boundary violations.

These areas are the focus of this article since they are the most common causes of action.

Breach of Confidentiality

Psychiatrists, with some exceptions, are expected to protect patient confidentiality. Confidentiality is an ethical obligation imposed on psychiatrists by themselves and their professional organizations. Specific statutes and case law may also require certain patient information to remain confidential. Many federal and state statutes have codified this obligation. Some courts have held that protection of confidentiality is an inherent part of the therapist–patient relationship.

The most common bases of recovery for breach of confidentiality are breach of contract, invasion of privacy, negligent infliction of mental distress, and loss of employment. Recovery for invasion of privacy generally requires a public disclosure of a private fact, not a disclosure to an individual or small group such as spouse or family. Recovery in breach of contract suits is limited to economic losses that were a direct result of the breach and does not include losses stemming from subsequent mental suffering or loss of employment.

Defenses for breach of confidentiality are dependent on valid consent for the release of information. To be valid, the consent must be knowing and voluntary. It is prudent to have patients sign release forms or document their oral consent in progress notes. Physicians should consider having patients sign progress notes where the consent to release information is documented. Another defense is that the breach was necessary due to an overriding public interest. This usually involves warning third parties about potential harm such as violence. State law may require some notifications, such as warning sexual partners about human immunodeficiency virus (HIV) status or reporting child abuse.

When treating adolescents aged 14–16 years, psychiatrists should not generally release information to families without their consent. An exception is the protection of the basic welfare of the patient or family members.

Lack of Informed Consent and Inadequate Treatment with Psychotropic Medication

Claims involving psychotropic medication comprise a significant portion of malpractice claims against psychiatrists. Reasonable care should include a thorough medical history, physical and psychiatric examinations, past medication history, history of adverse reactions to medications, and appropriate laboratory testing. It is the psychiatrist's responsibility to explain the risks and benefits of medication, alternative treatments, and risks of no treatment so that a patient can give informed consent. Informed consent should be obtained whenever a new medication is started and may be required whenever dosages are changed. Proper documentation of informed consent and treatment decisions is an essential component of malpractice prevention.

There are many different causes of action in cases involving medications. In addition to the areas mentioned above, selected areas of potential litigation include: prescriptions of improper dosage or of improper duration; failure to recognize drug–drug or drug–food interactions; creating a dependence on prescribed drugs; failure to recognize, monitor, and treat side-effects; and improper record-keeping.

The decision for off-label (not approved by the Food and Drug Administration) use of drugs or exceeding recommended dosages of drugs should be based on reasonable medical judgment and supported by available literature. The rationale for the decision should be clearly documented, and informed consent should also be heightened.

Tardive dyskinesia (TD) is an area of particular concern with the use of psychotropic medication. Several large judgments have been awarded in the USA for malpractice involving TD. The American Psychiatric Association has developed guidelines for the prevention and management of TD, and these may be helpful to clinicians.

Negligent Psychotherapy

Negligent psychotherapy has historically been difficult to prove due to the lack of established practice standards. There are hundreds of schools of psychotherapy. Successful claims of negligence have been raised in cases where there has been evidence of physical assault by the therapist, inadequate referral upon termination (abandonment), or failure of the therapist to offer pharmacological treatment as an alternative to psychotherapy.

A therapist has a duty to reassess or terminate treatment that is harmful or ineffective. When therapy ceases to be beneficial, the therapist should get a second opinion from a colleague or seek supervision. If this does not work, the therapist should offer to refer the patient to another colleague after processing termination with the patient. If a psychiatrist is concerned about dangerous behavior upon termination, such as suicide, he/she should consider transferring the patient to another psychiatrist in a hospital setting. Patients may claim negligence if their therapy has been terminated without adequate

referral options. Adequate procedures for termination should include providing the patient with reasonable notice of decision to terminate, assistance in finding another psychotherapist, emergency contact information, and an adequate supply of medication.

A psychiatrist has a duty to offer patients both psychotherapeutic and pharmacological treatment. Patients should be told that medication might hasten their recovery. They should also be given the option of psychotherapy without medication. Patients may claim negligence if they receive extended psychotherapy without a response and then improve soon after starting medication if they were not offered medication at the beginning of treatment.

Suicide Assessment and Prevention

Half of the patient suicides in the USA will result in malpractice litigation. Inpatient suicide carries the greatest liability, because the patient is in a controlled environment. Most *Diagnostic and Statistical Manual*, 4th edition (DSM-IV-TR) Axis I disorders, as well as some of the personality disorders, are associated with increased suicide risk. Suicide risk evaluation is a difficult task that involves the identification of specific risk factors for a given patient. Suicide prevention involves designing a treatment plan to address and minimize the patient-specific dynamic risk factors (Table 1).

The law recognizes that there are no absolute standards for the prediction of suicide because suicide results from a complex array of risk factors. Courts assume that a suicide is preventable if it is foreseeable; however, foreseeable does not equate with preventable in clinical practice. The term foreseeable is a legal term with no clear clinical equivalent. An action is foreseeable if there is reasonable anticipation that harm or injury is a likely result from certain acts or omissions. The standard of care for patients at risk for suicide includes the reasonable physician's ability to make a thorough assessment, to recognize relevant risk factors, and to design and implement a treatment plan that decreases the risk of suicide. No assessment is foolproof, and the patient determined to complete suicide may succeed despite a comprehensive prevention plan.

When a lawsuit is filed, the chart will be examined to determine whether the physician recognized the risk factors and considered limiting the risk by exerting greater control over the patient through hospitalization or other means. Documentation of encounters with actively suicidal patients should include a psychiatric evaluation with risk factor analysis, attempted discussions with family members, and a treatment plan with recommendations for ways to reduce the risk of suicide. Liability may also result from unforeseeable suicides if there is failure to assess suicide risk properly.

Table 1 Suicide risk factors

Epidemiological (static)
- Males > females
- Age: adolescents and geriatric population (males peak at 75 years, females peak at 55 years)
- Race: Caucasian and American Indian
- Marital status: single > divorced; widowed > married

Psychiatric (dynamic)
- Mood disorders, alcoholism, drug abuse, psychotic disorders, personality disorders
- Family history of suicide
- History of previous suicide attempt: assess lethality of intent
- Medical diagnosis of terminal illness (cancer, acquired immunodeficiency syndrome (AIDS)), chronic intractable pain, chronic and disabling illness (renal dialysis patient)
- Hopelessness

Psychosocial (dynamic)
- History of recent loss (loved one, job)
- Loss of social supports
- Important dates (holidays, birthdays, anniversaries, etc.)
- Access to weapons or lethal means
- Suicide plan: assess lethality of intent

The key to a favorable course and prognosis is early recognition of risk factors, early diagnosis and treatment of psychiatric disorder, and appropriate interventions for specific dynamic risk factors

Injury to Third Parties

If a psychiatric patient poses a potential risk to a third party, it may be incumbent on the psychiatrist to manage the patient via notification or hospitalization. This principle was demonstrated in the case of *Tarasoff* v. *the Regents of the University of California* (529 P.2d 553 (Cal. 1974) 551 P.2d 334 (1976)). The Tarasoff decision made physicians in California responsible not only for warning potential victims of their patients, but also for protecting them. Psychiatrists may be expected to protect third parties and society at large by hospitalizing patients or petitioning for commitment. The patient should remain hospitalized until he/she is no longer considered imminently dangerous.

Psychiatrists have also been found liable to protect society when their patients injured third parties while driving automobiles (*Naidu* v. *Laird* 538 A.2d 1064 (Del. 1988)). The holdings in these cases contradict the American Psychiatric Association, which took the position that psychiatrists have no special expertise to assess driving ability. Such cases put psychiatrists in a precarious position since they have been found liable in situations where they have no special training.

Another area where psychiatrists have been found liable to third parties is in recovered-memory cases. In *Ramona* v. *Ramona*, a father was awarded a $475 000

settlement when his daughter's therapists had negligently induced false memories that her bulimia was a result of being sexually abused by her father (*Ramona* v. *Ramona* (judgment on jury verdict), no. 61898 (Napa City Superior Ct, July 11, 1994). The therapists had told the patient that the abuse was confirmed during an amobarbital interview. The Ramona court felt that Mr. Ramona was a direct victim of the therapist's negligent psychotherapy.

Doctor–Patient Boundary Violations

The concept of boundaries between psychiatrist and patient initially developed in the context of the psychotherapeutic relationship and has subsequently been influenced by ethical principles set forth by mental health professional organizations, legal statues, and case law. These principles apply to all psychiatrist–patient relationships. Boundaries in the doctor–patient relationship provide a set of rules and expectations that allow the patient to develop trust in the physician and to know what to expect from the relationship. It is the responsibility of the psychiatrist to establish clear and consistent boundaries. The basic principle of these limitations on physician behavior is that physicians have a fiduciary duty to their patients. This duty is to put the best interests of the patient above the physician's interests.

Boundary violations involve clear-cut transgressions of the accepted relationship between psychiatrist and patient. Examples include having sex or sexualized conduct with patients, exploiting patients for financial gain, and engaging in social relationships with patients.

Physician–patient sexual contact and other forms of patient exploitation may be the basis for discipline by physician regulatory bodies. The American Psychiatric Association has adopted ethical guidelines which declare it unethical for a psychiatrist to have a sexual relationship with a former or current patient. Even when patients engage in behaviors that may be considered seductive, it is the physician's responsibility to maintain appropriate boundaries. In the USA, a number of states have enacted laws that make it a criminal offense to have sexual relations with patients. The first state to enact such a law was Wisconsin, followed by Minnesota, North Dakota, Colorado, and Maine, as well as a growing list of states. Criminal charges may include sexual assault, rape, and adultery. Some states, such as Minnesota, Wisconsin, California, Illinois, and Texas have civil statutes that incorporate a standard of care that makes malpractice easier to pursue by finding a civil cause of action for the sexual exploitation of patients by therapists. Some insurance companies have refused to pay for defending physicians in sexual boundary violation cases. Professional sanctions may include ethical complaints, expulsion from professional organizations, and loss of licensure.

Summary

Psychiatric malpractice litigation is a growing field and will likely continue to grow as society becomes more and more litigious. The claims against psychiatrists fall into several general categories, including lack of confidentiality, lack of informed consent for treatment, inadequate medication management, inadequate suicide assessment and prevention, injury to third parties, and doctor–patient boundary violations.

Psychiatrists should recognize that the best protection against malpractice litigation is the provision and documentation of good care. The physician who takes an adequate medical and psychiatric history, performs an adequate physical/mental status examination of the patient, renders diagnoses, and prescribes medication or psychotherapy in a reasonable manner is at much less risk for successful malpractice litigation. Finally, all physicians should be aware that the documentation of the above care is essential for communication with other physicians and to create a record of the appropriate care provided. The best defense against a malpractice claim is a well-written record documenting treatment plans and rational decision-making.

See Also

Forensic Psychiatry and Forensic Psychology: Suicide Predictors and Statistics; **Medical Malpractice:** Child and Adolescent Psychiatry; **Medical Malpractice – Medico-legal Perspectives:** Negligence, Standard of Care; Negligence, Duty of Care; Negligence, Causation; Negligence Quantum

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Psychology

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Introduction

In many countries the term psychologist is not protected by law – in other words, anyone practicing "therapy," even if they have no qualifications, can effectively refer to themselves as a "psychologist." However, those with appropriate qualifications, that is, a psychology degree and in many instances a postgraduate qualification in an academic or applied aspect of the discipline, choose to belong to their national society and hence to abide by the rules of conduct of that society. In countries where the term "psychologist" is not protected, as long as those using the term are reasonably accurate in their claims relating to expertise and experience and assuming they abide by the normal rules of everyday relationships, seeking redress in relation to perceived incompetent practice or poor record-keeping may be difficult to achieve. The only route for complaint would be directly through the legal process, and the only possible redress would be financial compensation, assuming that real and quantifiable harm has been suffered by the complainant. As practitioners in this instance would not be licenced or registered, there is no professional body from which they can be removed.

In many countries then, it remains incumbent upon the person seeking psychological therapy to ensure that the therapist they approach is a *bone fide* member of the regulating society within that country and, ideally, to verify the credentials that the person holds.

Codes of Conduct

Psychologists who are members of their national society are then bound by the rules of conduct of that society. For example, in the USA this is the American Psychological Association's (APA's) Ethical Principles of Psychologists and Code of Conduct (2002). In the UK it is the British Psychological Society's (BPS's) Code of Conduct, Ethical Principles and Guidelines (2000). Much of the material presented in this article will be drawn from their codes of practice.

Core principles relate to questions of competence, the advertising of services, confidentiality and record-keeping, personal conduct and interpersonal relationship issues, the conduct of research, assessment, and the use of test results. Each of these areas will be addressed in the following sections. Unfortunately, both legal action in relation to malpractice by psychologists and complaints made to psychological societies are increasing. In spite of this there is a striking absence of research relating to psychological malpractice in a general sense. However, there is an abundance of research relating to specific aspects of professional practice, particularly "dual and exploitive relationships" and a substantive literature relating to ethical dilemmas faced by psychologists, including issues of confidentiality and competence to practice.

Competence

Psychologists work within a variety of settings, which include educational, healthcare, and occupational environments. Many also hold various postgraduate qualifications, including neuropsychological and clinical, counseling, health, occupational, educational, and forensic psychology, which provide them with the necessary background to gain the expertise in order to practice in such contexts. As the APA code of conduct states: "Psychologists provide services, teach, and conduct research with populations and in areas only within the boundaries of their competence, based on their education, training, supervised experience, consultation, study, or professional experience." As such they should "recognize the boundaries of their own competence and not attempt to practice any form of psychology for which they do not have an appropriate preparation or, where applicable, specialist qualification."

In short, psychologists should only provide services for which they have obtained appropriate training and/or of which they have appropriate experience or expertise. It is also important to recognize that competence can erode over time. It is thus incumbent on the psychologist concerned to ensure standards of practice are maintained through continuing professional development. Psychologists offering services for which they are not appropriately qualified or for which they do not have suitable experience may be liable for malpractice.

Advertising of Services

As with issues relating to competence, advertising should reflect the qualifications and expertise of the psychologist concerned; advertisers should endeavor to present a truthful and accurate picture of themselves and their work. In any such advertisement, as a matter of principle, psychologists should not denigrate the services of other psychologists, should not make claims about the certainty of a "cure," nor should they offer to make a refund in the event that the "cure" fails, nor should they play on clients' fears in order to seek to generate work. Any psychologist so doing would be open to a complaint of malpractice.

Confidentiality

As a guiding principle, psychologists are expected to keep and maintain adequate records of any consultation or meeting with those to whom they provide services. Steps should also be taken to ensure the confidentiality of any information obtained or stored in any medium. Issues relating to confidentiality should be explained to the recipients of the service at the outset and any limitations of confidentiality made explicit. In certain instances, for example within criminal justice settings, the psychologist's duty is to the service rather than the inmate, and hence information obtained from the latter cannot be confidential. However, institutional guidelines should make clear how information obtained would be handled. Similarly, when a psychologist prepares a report for, or provides evidence to, a court he/she will be expected to divulge information within such a context that has been obtained from the litigant. However, if information has been obtained from a third party, such as relatives, spouse, friends, or colleagues, then the consent of the litigant must be obtained.

A further issue central to the question of confidentiality concerns risk assessment, that is, an assessment of the likelihood that a particular behavior will occur and a consideration of the consequences of such an occurrence. This can refer to a variety of behaviors, including sex offending, violence, or suicide. In criminal justice settings both open reporting and monitoring of the client's behavior are likely to occur. It is of interest to note that the disclosure of previous offenses increases according to the degree of confidentiality offered. However, if a client is seen in a mental health setting rather than a criminal justice setting, then care should be exercised when establishing with the client the boundaries of confidentiality. It would not be good practice to promise absolute confidentiality to a client when it then becomes apparent during the course of the assessment that the client poses a serious risk either to the client or to others.

Confidentiality issues are a frequent dilemma for psychologists, and in many instances it can be unclear whether confidential information should or should not be disclosed. Disclosure to appropriate others may be necessary, for example, when there are serious safety concerns either about the recipient of the service or those with whom they may come into contact or in instances of child abuse reporting. In relation to malpractice issues, it is clearly important to make the correct decision about revealing confidential information. If there is any doubt, it is incumbent upon the psychologist concerned to seek appropriate advice from colleagues or their professional body.

Issues pertaining to confidentiality apply across a variety of domains, from clinical practice to research settings. In the latter context, information should be stored and communicated in a way which will not allow identification of any one individual. The same is true in relation to material used in lectures or published material.

Personal Conduct and Interpersonal Relationship

As a general rule, the only relationship the psychologist should have with the recipients of the psychologist's services is a professional one. This applies to both personal nonsexual as well as sexual relationships. While this is true of professionals in general, many psychologists have longer periods of contact with their clients, often on a one-to-one basis, than is true of many other practitioners. Blurred, conflictual, dual, or multiple relationships may, however, present problems of varying magnitude. A blurred or conflictual relationship is one where professional and personal boundaries are not absolutely clear. Dual and multiple relationships are those in which the psychologist is in a professional role with a person while either at the same time being in another role with the same person, with a person closely associated with or related to that person, or if the psychologist promises to enter into another relationship in the future with the person or a person closely associated with or related to the person.

At one end of the continuum it may not always be possible to avoid blurred or dual nonsexual relationships with clients or former clients. For example, there are occasions when the psychologist may have a remote relationship with the client outside his/her professional contact, perhaps as acquaintances in small, rural communities. Whether this is a perfect situation is a matter of debate but may be inevitable in certain instances. However, there are other occasions when boundaries become blurred which can and should be avoided. As a general rule, professionals should not invite clients to social events at which they will be present, lend them personal possessions, focus on nontreatment-related issues during therapy, or allow the treatment session to become a "social event."

At the other end of the continuum are instances of therapist–patient, supervisor–supervisee, and lecturer–student sexual involvement. Research studies suggest that between 0.9% and 3.6% of male therapists and between 0.2% and 0.5% of female therapists self-report sexual involvement with their patients. There is some indication that the incidence of such behavior has declined over the years. This may be due in part to the efforts of professional bodies and in part to a number of highly publicized multimillion-dollar malpractice awards. In one case in the USA a plaintiff was awarded $1 million despite the psychologist's defense that he had waited until after termination of therapy to engage in sexual relations and that he had then married his former patient and remained married to her for five years!

It is generally recognized that patient–therapist, supervisor–supervisee, and lecturer–student sexual involvement is damaging for patients/supervisees/students. Most cases involve a male therapist/supervisor/lecturer and a female patient/supervisee/student with intimacy occurring during therapy, training, or study. However, patients engaging in sexual relations with the treating psychologist after the termination of therapy also report being harmed by the relationship. Negative effects can involve a range of problems, including feelings of ambivalence, guilt, emptiness and isolation, sexual confusion, impaired ability to trust, emotional lability, suppressed rage, increased suicidal risk, and problems with attention and concentration.

The Conduct of Research

There are a number of guidelines that psychologists should apply in relation to the use of participants in research. Participants should be informed about the purpose of the research, their right to withdraw from participation or to decline to participate and, should they choose to do so, that there will not be any implications with regard to their treatment, education, and so on. Particular consideration should be given to the deception of prospective research participants. If deception is felt to be scientifically justifiable, then care should be exercised to ensure that it does not result in undue emotional distress for the participants concerned. The study should be followed by prompt debriefing to inform participants about the nature of the study and to discuss any concerns that might arise.

Although it is almost always necessary to secure ethical approval for research, either from one's own institution or the institution from which the participants are to be recruited if it differs from the former, this does not *de facto* imply that participants are protected from unethical practice.

Unethical practice includes not only that which might be directed toward research participants, but also behavior relating to one's peers, for example, claiming someone else's work as one's own or failing to give appropriate credit to others who have contributed substantially to the work.

Use of Test Results

Assessment provides the cornerstone for much professional practice in a range of settings, including forensic contexts. As a guiding principle, psychologists, including those working in forensic settings, should only administer tests for which they have been trained, should be competent in the use of

standardized tests, should use tests which fit the task and which fit the individual, should administer them correctly, should make appropriate use of computers in assessments, and should assess and report on factors which may affect the meaning of the test findings. In short, psychologists should administer only those tests that are appropriate for the task and whose validity and reliability have been established with the population to be tested.

Normal practice would be to provide the test-taker or other authorized person with feedback about the results in a manner which allows that person to understand the meaning of the results. If it is deemed that such release may cause harm or that the results may be misused or misrepresented or if confidentiality were to be compromised, then the psychologist may withhold the results unless required to do so by law.

Conclusion

Codes of conduct provide a set of minimum standards with which chartered or registered psychologists are required to comply. These professional codes are designed to protect the public from poor or incompetent practice and from those who misuse their professional status. The ideal is that "psychologists shall conduct themselves in a manner that does not bring into disrepute the discipline and profession of psychology." Unfortunately, there will always be a small minority who lay themselves open to complaints of malpractice.

See Also

Forensic Psychiatry and Forensic Psychology: Forensic Psychology, Education, Training and Certification; Ethics

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Radiotherapy

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Introduction

Radiotherapy, or radiation oncology, is the use of ionizing radiation (usually X-rays) to treat cancer and a few benign conditions. This article gives a brief outline of the nature of radiation and how it is used in treatment. The patient pathway is used as a basis for illustrating how problems can arise at any time during preparation and treatment.

Radiation

X-rays and radium were discovered just over 100 years ago and treatments of both benign and malignant tumors were developed during the first half of the twentieth century.

At first, only relatively low-energy radiation was available, which penetrated the tissues poorly and gave the maximum dose to the skin. Since the 1950s, high-energy "megavoltage" radiation has enabled the treatment of deep-seated tumors with a relatively lower dose to the overlying skin. Radioactive sources can also be inserted into accessible tumors, such as the cervix, to give a high dose of radiation locally, with a much smaller contribution

to the adjacent normal tissues than from external treatment.

Effect of Radiation

Ionizing radiation damages the DNA and hence may affect the vital genetic code of the cell, causing it to die when it tries to multiply. With low levels of radiation, the damage may be repaired by the nucleus of the cell, and cells killed by radiation may be replaced by multiplication of the undamaged cells. Normal tissues have a greater ability to regenerate than malignant tissues, therefore radiotherapy is usually given in small doses daily over 4–6 weeks, which allows recovery of the normal cells. This gives a high total dose to eradicate the tumor while allowing the adjacent organs to survive.

Modern Techniques

Radiation oncology has become a sophisticated and highly technical specialty using the latest diagnostic methods and computerized planning and delivery of treatment.

Computed tomography (CT) and magnetic resonance imaging (MRI) scans have enabled oncologists to localize the tumor and adjacent organs accurately in three dimensions. Precise treatment plans can be prepared using this information to focus the radiation on the cancer and minimize the dose received by the adjacent normal tissues. Subsequent positron emission tomography (PET) scanning allows the metabolism of tissues to be studied, and helps to establish more accurately the extent of the cancer to be treated. The improved accuracy in planning treatment has permitted the safe delivery of higher doses of radiotherapy, resulting in a better chance of cure, without increasing the risk of damage to normal tissues.

The delivery of radiotherapy has also become more precise, as the penumbra at the edge of the radiation beam of a "linear accelerator" is relatively narrow. The correct localization can be checked by simulation and verified by images taken during treatment. Techniques and doses have been improved through experience, particularly by clinical trials which compare a new treatment with the current standard. In view of these continuing improvements, it is important to consider what techniques were in use at the material time when considering a standard of care.

The Patient Pathway

The treatment of cancer usually involves several medical specialties and professional disciplines and the majority of patients are cared for by a multidisciplinary team of doctors, nurses, radiographers, and other paramedical staff.

First an accurate diagnosis and staging is essential, including biopsy and histological examination of the tumor tissue to discover its type and likely behavior. A detailed picture of the extent of the cancer is derived from physical examination and imaging using X-ray, CT, MRI, or ultrasound scans. The results of all investigations are often reviewed by the experts in a meeting of the multidisciplinary team and a treatment plan discussed with the patient and relatives.

Patients who are to receive radiotherapy are seen in a planning clinic where the details of treatment can be explained and preliminary steps taken, such as making a mask for accurate localization in the head and neck region, or CT scans for pelvic tumors. A simulator (a diagnostic X-ray machine that can show the area to be treated) is often used to delineate the radiation field or check that the prepared plan is accurate.

Many radical (curative) treatments now require complex calculations by medical physics technicians using elaborate computer planning systems and it is therefore usual for treatment to start several weeks after the planning clinic.

Treatment normally lasts only a few minutes each day, Monday to Friday, and most patients will not notice any immediate effect. There are both early (acute) and delayed effects of radiotherapy. Early effects, beginning in the first few weeks after starting treatment, include tiredness, occasionally sickness, temporary soreness of the skin (in the area being treated), and diarrhea if the abdomen is included. The acute effects last for several weeks after the end of radiotherapy and may require treatment.

The delayed effects of radiotherapy, more than 6 months later, include thickening of the tissues under the skin (radiation fibrosis), a reduced blood supply (which may not be apparent unless there is a need for surgery), and bowel damage (permanent diarrhea and/or narrowing of the bowel in 5–10% following pelvic irradiation). Since delayed effects are irreversible, the problems persist and are often difficult to treat. It is therefore important to keep the dose of radiation below what is known to be the tolerance level for that particular organ or tissue.

Errors in Radiation Oncology

Incorrect Diagnosis

Radiotherapy is sometimes given before the diagnosis of cancer has been confirmed. In an emergency this could be life-saving, but may lead to unnecessary

harm. For example, in 1986 a 63-year-old woman, who had completed chemotherapy and radiotherapy for lung cancer 2 months previously, developed weakness and tingling in her legs. This was thought to be due to the tumor pressing on the spinal cord, but at that time it was not possible to arrange an immediate MRI scan to confirm the diagnosis. Radiotherapy was given urgently to prevent deterioration, but the MRI scan subsequently showed no evidence of cancer. The radiotherapy given to the lung cancer 2 months previously had probably caused the symptoms, and the additional radiotherapy sadly caused further damage to the spinal cord.

Delayed Diagnosis

Sometimes the failure to make a diagnosis of cancer or a premalignant condition can result in extra treatment and its consequent side-effects.

A 58-year-old auctioneer suffered from hoarseness for 5 years before an advanced cancer of the vocal cords was discovered, necessitating urgent surgery. If he had been referred for investigations about a year previously, it is likely that an early cancer could have been cured by radiotherapy alone, thus avoiding the loss of his larynx.

A 32-year-old woman had an abnormal cervical smear, which was erroneously reported normal. Three years later she had abnormal bleeding during pregnancy, and a month before her first baby was due, cancer of the cervix was found. After cesarean section, she had a course of radiotherapy combined with chemotherapy, which cured the cancer but resulted in troublesome bladder and bowel symptoms. If the original smear had been reported correctly, the abnormal areas on the cervix could have been ablated, thus preventing the subsequent development of cancer, and avoiding the side-effects of radiotherapy and chemotherapy.

Failure to Obtain Informed Consent

It is important to discuss the treatment options and side-effects, warning a patient of any serious consequences of treatment (even if very uncommon).

A 70-year-old man developed an ulcer on his lower lip and biopsy showed cancer. There was no evidence of spread and he was advised to undergo surgery, which left an unsightly scar. Radiotherapy would probably have given a better cosmetic result with an equal chance of cure, but this alternative was not discussed when seeking his consent for surgery.

Some tissues are particularly sensitive to radiotherapy; for example, low doses of radiation enhance cataract formation in the eye and sterilize the testes and ovaries.

Informed consent should include a signed statement indicating that the patient has understood the potentially harmful consequences of radiotherapy.

When a new afterloading device was installed for giving radiation internally to the cervix, the dose rate was higher than the previous manual system. To compensate for the higher dose rate (which would be expected to have a greater effect than low-dose-rate radiation), the total dose was reduced by 20%. However, a careful study of the patients treated on the new machine showed that their side-effects were greater than had been expected, and the dose was later reduced further. Patients who were being treated first on the new machine should have been warned about the possibility of worse side-effects when signing a consent form.

The risk of developing cancer in the future may be increased by radiotherapy, especially in children and young adults. For example, it is important to warn young women of the increased risk of developing breast cancer following radiotherapy to the chest (for example, in the treatment of Hodgkin's disease).

Errors in Planning

Since planning involves several members of the multidisciplinary team (oncologist, radiographer, physicist, technician), mistakes by one member are usually noticed by another. A plan to treat the left tonsil was incorrectly marked on the right-hand side of the scans, but this error was recognized by the physicist before starting planning.

The medical records of one patient were not available while she was being prepared to receive a second course of radiotherapy. Fortunately, before radiotherapy was given, it was noted that there was an overlap with the previous treatment which could have led to a serious overdose.

Misidentification

Patients may sometimes come forward when another name is called. As in any other branch of medicine, it is important to confirm the identity of a patient so that the prescribed treatment is given to the right area of the correct patient.

A single dose of radiation to the wrong patient or wrong area may do little harm during a 6-week course of radiotherapy, but if a single large treatment is given incorrectly there may be more serious consequences.

Errors in Dose

The accuracy of the planning calculations on computer depends on using the correct information. After a new

planning system was installed, a member of staff used an incorrect method for calculation, which meant that doses were about 25% lower than intended, resulting in a failure to cure some patients.

In another center, the radiotherapy equipment was incorrectly calibrated, which resulted in over 100 patients receiving 25% more radiation than prescribed.

Calculations and doses should be carefully checked by at least two qualified members of staff. Sometimes an overdose is due to a poor technique, which may have been the standard at the time.

A 55-year-old man with lung cancer was treated in 1988 with six large fractions of radiotherapy, as this was standard management in several centers. Radiation damage to his spinal cord caused paralysis a year later. It was subsequently recognized that the risk of damage was greater with large fractions compared with smaller fractions, and such treatment would now be regarded as negligent.

Over 100 women given radiotherapy for breast cancer suffered damage to the nerves in the armpit, since a technique being used until the late 1970s resulted in an overlap between radiation fields. Although it was recognized that the women had severe problems due to excessive radiation, their claims failed since the technique and doses were in common use at that time. Improved accuracy in positioning the treatment now avoids this problem.

Superficial radiation is sometimes used for benign skin disorders. A 75-year-old man was given low-energy radiation to the front and back of his hands, but no correction in dose was made for the radiation penetrating through the skin. He effectively received nearly double the dose intended, and suffered severe burns and damage to his fingers.

An accurate diagnosis and careful planning of treatment will optimize radiotherapy and reduce the risk of harmful effects. Improvements in equipment and techniques have reduced the likelihood of harm. Careful checking by at least two qualified staff usually identifies any potential errors.

See Also

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Rheumatology

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Definition

Rheumatology is the study and management of disorders and diseases of the joints and surrounding tissues – muscles, tendons, and ligaments. There may also be involvement of blood vessels and other organs, such as eyes, gastrointestinal system, kidneys, lungs, nervous system, and skin.

Rheumatology may be divided into two broad fields: (1) the diagnosis and management of inflammatory diseases that affect the joints and surrounding tissues. These are conditions that may also affect the rest of the body, constituting generalized disorders; (2) osteoarthritis, mechanical and degenerative spinal disorders, and soft-tissue conditions affecting the muscles, tendons, and ligaments around joints.

Neurologic conditions such as carpal tunnel syndrome and other nerve entrapments may fall into either of these groups.

Noninflammatory Disorders

These conditions constitute the bulk of rheumatologic practice, affecting virtually all the population at some time in their lives.

A rheumatologist should know the natural history of such disorders and their relationship to trauma; be able to comment on treatment and the likelihood of symptom relief; and know the potential for adverse effects of drugs and physical means of treatment.

Inflammatory Disorders

In clinical medical practice, inflammatory disorders are considered more important than noninflammatory disorders, as they have a significant effect on mortality and morbidity. An expert rheumatologist

should be able to provide information on the natural history and variability of these conditions, and on their prognosis.

Litigation

An expert may provide a report after interviewing and conducting appropriate examinations on a claimant. This clinical assessment would usually be supplemented by examination of medical records.

In cases of work-related trauma, the occupational records may give further information about pre-accident performance and capabilities. These are sometimes important when assessing car crash or medical negligence claims.

In medical negligence claims it is sometimes necessary to give an opinion after examining the records. This opinion may form part of a preliminary assessment but also happens when there is a claim of failure of care from surviving relatives when the patient has died.

In the field of litigation, rheumatologists can provide information and opinion about the effects of trauma on the disease process. They can give an opinion on drug treatment and its likely consequences, including adverse effects.

Rheumatologists will be able to give an opinion on the standard of care; give expert guidance on disability; and recognize the potential for rehabilitation and methods used. The rheumatologists should also be well informed about physical means of treatment and the techniques of therapists providing it.

Rheumatologic Experts

Most consultant rheumatologists have a special interest, which may be broadly divided into conventional rheumatology and musculoskeletal medicine. Conventional rheumatologists may give expert opinions on more generalized disorders, such as rheumatoid disease and systemic lupus erythematosus and vasculitis. Musculoskeletal medicine specialists concentrate on noninflammatory disorders, in particular road traffic and work-related accidents producing neck or other spinal injuries and work-related upper-limb disorders (repetitive strain injury). Either group may have an interest in sports medicine or pain relief treatment.

Rheumatologists with a special interest in musculoskeletal medicine (and musculoskeletal physicians) should have expert knowledge in the field of spinal manipulation and injection. They often have personal experience in using these methods of treatment. Therefore, they may be ideally suited to prepare reports on physical methods of treatment such as physiotherapy, osteopathy, and chiropractic. Rheumatologists who use these methods of treatment may be preferred to consultants in pain relief for preparing reports on claimants with chronic musculoskeletal pain, as they are trained in diagnosis as well as treatment. Pain relief consultants have considerable skill in treatment, but many do this based on the diagnosis made by others.

Most rheumatologists who act as expert witnesses should provide an appropriate report on inflammatory diseases. However, some experts will have a particular interest and experience in the more complex disorders. These include systemic manifestations of rheumatoid arthritis, systemic lupus erythematosus and pregnancy, and the relationship between trauma and arthritis. Other connective tissue diseases and vasculitis may be complex and sometimes require an expert with particularly specialized knowledge.

There are differences of opinion among experts on the relationship between trauma and arthritis. A significant number of rheumatologists do not accept the diagnosis of fibromyalgia. Posttraumatic fibromyalgia is even more contentious. It is reasonable in such cases to request an expert opinion on these subjects before instruction.

In medical negligence cases it may be preferable to instruct an expert working in a similar unit to the defendant.

Virtually all physical complaints have a psychological component. Rheumatologists are trained to recognize the effects of injury and disease on a person's psyche. They should also be informed about the effects of preexisting or concurrent psychological and psychiatric disorders on physical problems.

A rheumatology expert would be expected to comment on the likelihood that psychological or psychiatric factors could contribute to symptoms and disability. In particular, the expert should comment if there are complaints or physical signs that cannot be explained on a physical basis. Sometimes the rheumatologist may be able to differentiate between a psychological component or overlay, and deliberate exaggeration or malingering. Usually, this is a matter for judgment under legal examination. The rheumatologist may recommend appropriate management such as cognitive behavioral therapy. However, the expert does not provide detailed expert reports on either diagnosis or detailed management of psychiatric conditions.

Special Investigations

In noninflammatory disorders, there are no blood tests that assist with diagnosis. However, tests may be done to exclude other conditions. Failure to test

Table 1 Conditions appropriate for rheumatologic expert reports

Accidents
Ankylosing spondylitis
Arthralgia
Behçet's syndrome[a]
Brachial neuritis
Bursitis
Carpal tunnel syndrome
Cervical spondylosis and disk disorders
Complex regional pain syndrome (CRPS)[a]
CREST (Calcinosis, Raynaud's, Esophagus, Sclerodactyly, Telangiectasia)
Dermatomyositis in children[a]
Fibromyalgia
Gout
Hughes disease in pregnancy[a]
Intervertebral disk prolapse
Joint hypermobility
Juvenile arthritis[a]
Lumbar spondylosis and disk disorders
Osteoarthritis
Osteoporosis
Polymyositis
Pseudogout
Psoriatic arthritis
Raynaud syndrome
Reflex sympathetic dystrophy (RSD) – Sudeck atrophy
Rheumatoid arthritis
Road-crash injuries
Sarcoid arthritis
Sciatica
Septic arthritis
Shoulder capsulitis (frozen shoulder)
Spinal injuries
Spondylolisthesis
Spondylolysis
Sprains and strains
Systemic lupus erythematosus in pregnancy[a]
Systemic sclerosis
Tendinitis
Ulnar neuropathy
Vasculitis[a]
Wegener granuloma[a]
Work injuries
Work-related upper-limb disorders (WRULD)[a]

[a]Need for expert with special interest.

may be appropriate, but in some cases indicates negligence. The results of blood testing may be significant in inflammatory conditions. They are important in diagnosis and for monitoring disease progress and drug treatment.

There are guidelines suggesting which tests are appropriate and frequency of testing for monitoring drug therapy. These should not be taken as absolute, but a clinician would need clear reasons for not adhering to them.

Radiology may include simple X-ray films, isotope scan, computed tomography, and magnetic resonance imaging scans. Radiologists provide definitive expert reports on these investigations.

A rheumatologist interprets the findings in the clinical context. Normal films do not exclude disorder or dysfunction. Abnormalities shown may be irrelevant or even misleading.

Conditions Appropriate for Rheumatologic Expert Reports

Rheumatologic expert reports might be necessary for the conditions listed in Table 1.

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www.rheumatology.org.uk (publications/library – guidelines; information on drug monitoring).

Vascular Surgery

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Introduction

Vascular surgery is the discipline which deals with peripheral arteries and veins. Throughout the world it is largely distinct from cardiac surgery, but vascular surgeons vary in the extent to which they deal with blood vessels in the thorax. In many countries, general surgeons still undertake small numbers of vascular procedures. There is a well-documented trend for poorer results from low-volume practice, which is likely to present a higher risk of medicolegal problems, particularly for surgeons working outside specialist groups.

Variation in the practice of vascular surgeons with regard to venous disease is important, because this is a major area for medicolegal activity. Many vascular surgeons deal largely with arterial work, which has traditionally been regarded as more serious and more challenging. This is reflected in the jargon "peripheral vascular disease," which is commonly used to refer only to arterial disease. Varicose veins (which are very common) have therefore often been dealt with by somewhat reluctant arterial specialists, by their trainees, and by nonspecialist general surgeons. This kind of approach is not universal and is gradually changing, but it has contributed to the high rate of medicolegal actions for treatment of varicose veins.

The margins and scope of vascular surgery as a specialty have become increasingly blurred by rapid dissemination of minimally invasive techniques such as angioplasty, stenting, and stent grafting. These techniques demand either a team approach (with interventional radiologists) or the acquisition of new skills: they can also precipitate "turf wars" between different specialties (including some cardiologists who engage in peripheral arterial work). All this can provide fertile ground for controversy and medicolegal problems.

Difficulties in Describing the Frequency of Medicolegal Claims

There are a number of difficulties in describing the numbers of medicolegal claims in any medical specialty, particularly for an international readership.

- Terminology varies, from the American use of "malpractice" to the fundamental British legal principle of "negligence." In this article the term "claim" will be used for a legal action against a doctor or hospital.
- Medicolegal claims may be initiated (or notified) but subsequently discontinued because they have no merit; they may be settled without admission of negligence or liability; or (in a minority) there may be a judgment that the responsible clinicians were indeed negligent. Any collation of claims must make clear which of these categories is being described.
- Some countries have seen considerable changes in the organizations dealing with claims. In the UK, for example, claims in private practice are dealt with by three defense societies. National Health Service (NHS) claims (the majority) were handled similarly until 1990; then at regional level until 1995; and since 1995 by a central litigation authority (even then, many smaller claims were still handled locally).
- There is no central database of claims in many countries so doctors have no way of knowing the details for their specialty.
- The scope of "vascular surgery" may be poorly defined in any review of medicolegal activity (does it include vascular surgeons only, general surgeons, arterial work only, amputation, varicose veins?).

Vascular Surgery Compared with Other Specialties

Arterial and amputation surgery is often required for patients who are elderly, who have multiple comorbidities, and whose arteries present difficult technical challenges. The incidence of adverse events is therefore high: 16% in the Harvard Medical Practice Study – higher than any other specialty. Aortic aneurysm repair and lower-limb bypass grafting had higher adverse event rates than any other operations in a study of 15 000 hospital admissions in Utah and Colorado, which judged 8% and 11%, respectively, of the adverse events to have been preventable. The Australasian Quality in Healthcare Study judged 49% adverse events in vascular surgery to be preventable. By implication, clinicians might be liable medicolegally for these events, but the Harvard study considered only 18% of the adverse events in vascular surgery to be due to negligence – a lower proportion than any other specialty studied.

Vascular Claims in the UK

The first collation of vascular claims in the UK was done in collaboration with the NHS Litigation Authority (using the data since its inception in 1995) and the Medical Defence Union (which handles the majority of private practice claims, using its data since 1990). The number of notified claims (claims notified to the defense organizations, but not settled or closed) was higher for varicose veins (244: 58%) than for treatment of arterial disease (174: 42%). Other data from the Medical Defence Union have shown that claims relating to varicose veins outnumber those for any other condition dealt with by vascular or general surgeons. Reasons for claims relating to varicose veins are shown in Table 1. The main reasons for claims relating to treatment of arterial disease are shown in Table 2.

The Medical Defence Union also indemnifies general practitioners (primary care physicians) and had on record 299 notified claims relating to vascular surgical problems during 1990–1999. Two-thirds alleged that mismanagement of limb ischemia resulted in amputation (80%) or death (16%) and one-third

Table 1 Notified claims (legal actions initiated) against surgeons in the UK relating to treatment of varicose veins. Surgeons were classified as ''vascular'' or ''general'' on the basis of the information they gave when notifying each claim. These claims cover the period 1990–1999, when much vascular surgery was done by ''general surgeons with a vascular interest.'' The subdivision does, however, give some indication of the degree of specialization, and the proportions of claims contrast with those for arterial work (**Table 2**)

	Vascular surgeons	*General surgeons*	*Total*
Nerve damage	22	54	76
Incorrect/inadequate/ unsatisfactory surgery	11	25	36
Discoloration/scarring after sclerotherapy	5	16	21
Femoral vein damage	2	14	16
Infection	0	15	15
Femoral artery damage	3	10	13
Deep-vein thrombosis	5	6	11
Tourniquet damage	4	1	5
Miscellaneous	11	40	51
Total	63	181	244

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Table 2 Claims relating to management of arterial disease notified by surgeons in the UK during 1990–1999 (see additional information in the legend to **Table 1**)

	Vascular surgeons	*General surgeons*	*Total*
Complications of aortic surgery	24	21	45
Failure to recognize/treat ischemia	27	9	36
Bypass grafting problems	22	6	28
Nerve damage at operation	9	7	16
Failure to diagnose/treat aneurysms	2	8	10
Miscellaneous/unclear	23	16	39
Total	107	67	174

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alleged misdiagnosis of aneurysms. Vascular specialists therefore receive a significant number of referrals in which diagnosis has been delayed and this prompts legal action. Even though the underlying delay was not theirs, their management of the patient may be scrutinized aggressively during legal proceedings.

Treatments for Cosmetic Problems and ''Lifestyle'' Symptoms

Vascular surgery provides a good example of treatments for a range of conditions of different severity, with inherently different medicolegal risks. At one extreme many patients with varicose veins request treatment for cosmetic reasons only. Even minor complications may therefore cause dissatisfaction and lead to legal action. The most common is sensory nerve damage – specifically damage to the sural nerve during short saphenous surgery. Very thorough explanation and counseling about the likely benefits and potential risks are essential (and this ought to include written information). Trainees are taught two aphorisms: "The patient's expectations should be the same as yours" and "The smallest veins can cause the biggest problems."

Treatment of intermittent claudication is a major part of the work of vascular specialists: it restricts walking ability, which is inconvenient but not medically dangerous. Use of bypass grafting to relieve symptoms carries a risk of significant complications, including failure or infection of grafts and limb loss. If these possibilities are not dealt with thoroughly during decision-making, there may be great difficulty defending a legal action if one occurs. In addition, medical control of risk factors is fundamental for patients with arterial occlusive disease, and vascular surgeons should beware of failing to advise patients about medical measures to prevent myocardial infarction or stroke. In an increasingly litigious world they may face legal action if they do not do so and a patient goes on to suffer such an event.

Treatments to Save Life or Limb

At the other extreme, patients with leaking aortic aneurysms are often in great pain, hypotensive, and, without an operation, they will die imminently. Any kind of detailed counseling is out of the question, and discussion of the many risks of surgery is both medically and pastorally inappropriate. Involvement of relatives is important, and this may include discussions about palliative care.

Patients with critical limb ischemia need limb salvage procedures or major amputation. Some of them are frightened, elderly patients who do not want to know about all the risks. That is their right (under British law) but it should always be assumed that they want to be informed until they state otherwise. If patients have asked specifically not to be told about the risks of treatment then the situation must be clearly recorded in their case notes.

Some patients with unsalvageable limbs or leaking aneurysms may be treated most humanely with good analgesia and terminal care. The cultural approach to this decision varies between countries, as do the medicolegal implications. In the USA, for example, relatives more often expect heroic treatment for the dying

than in the UK. In a survey of UK vascular surgeons only 22% were influenced by medicolegal concerns when making the decision not to operate on a patient with a leaking aortic aneurysm.

Prophylactic Interventions

Many vascular interventions (in particular, elective treatment of aortic aneurysms and treatment of carotid artery stenoses) are prophylactic. They guard against serious risks – aneurysm rupture causing death or cerebral embolism causing stroke – but nevertheless, procedures are done on people who feel quite well and who are usually asymptomatic. These procedures have potentially very serious risks and absolutely clear discussion (accompanied by written information and well recorded) is essential to defend subsequent claims for negligence if adverse outcomes occur. It is particularly important to involve relatives in discussion, not least because it is they who may sue if the patient dies or suffers a disabling stroke.

Involving Relatives

Involving relatives is always good practice and helps to protect against legal action, as described in the sections above, but there are national differences in the legal requirements to do so. In the USA relatives have some legal rights to be informed and to participate in decision-making. This contrasts with the UK, where only the patient can give consent. If the patient is incapable, then it is the duty of doctors to act in the patient's best interests. The relatives have no legal right to participate in the consent.

Special Aspects of Risk Management in Vascular Surgery

Written Information and Records

These tenets are basic, but so important they are worth rehearsing. Written information, including a thorough description of benefits and risks, should be given to all patients considering vascular interventions. This information must be recorded in the notes and copies of the information must be archived for future legal use. Explicit letters about decision-making can be copied to patients. Letters are helpful in the consent process and provide a good record that the patient was well informed. These considerations are particularly important when the patient is being managed by more than one discipline – for example, vascular surgery, vascular radiology, vascular medicine, and anesthesiology. Comprehensive medical and nursing notes and prescription charts are indispensable as evidence.

Guidelines and Protocols

Guidelines and protocols are common in some countries, but less so in others. They are particularly important for ward-based treatments such as thrombolysis, in which a variety of staff are involved, some of whom may be unfamiliar with management. It is worth pointing out, however, that guidelines and protocols are not legally binding. There may be good reasons to depart from them for particular patients, but this should always be clearly recorded.

Prophylaxis

Omission of prophylactic antibiotics (to protect against graft infection) or of prophylactic anticoagulants (to reduce the risk of thrombosis) are particular matters which feature in medicolegal proceedings. There is little defense for having neglected antibiotics if a graft becomes infected, but scientific evidence is poor about the requisite number of doses.

Clear evidence is still more elusive about anticoagulant prophylaxis, and this may cause legal argument. There is no compelling evidence that heparin protects against arterial thrombosis during or soon after procedures, although it is usual practice and would be recommended by most experts. Anticoagulant prophylaxis against venous thromboembolism in varicose vein surgery is also a dilemma. Varicose veins feature in national and international guidelines as a risk factor for deep-vein thrombosis, but thrombosis after varicose vein surgery is uncommon and use of prophylaxis varies considerably. It is in areas like this that the results of large surveys of surgical practice may help to provide evidence which can be used in legal proceedings.

Summary

Vascular surgery is associated with many adverse events and has great potential for medicolegal action. Treatment of varicose veins is particularly prone to litigation. The keys to risk management and robust defense are thorough counseling of patients and their relatives; attention to detail (such as routine prophylaxis against infection); and meticulous record-keeping.

See Also

Medical Malpractice – Medico-legal Perspectives: Negligence, Standard of Care; Negligence, Duty of Care; Negligence, Causation

Further Reading

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