Mechanisms of Surgical Disease and Surgery in Practice

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Approaches to Surgical Problems

What Do Surgeons Do?

Surgeons are perceived as doctors who do operations, that is, cutting tissue to treat disease, usually under anaesthesia, but this is only a small part of surgical practice. The range individual surgeons undertake varies with the culture, the resources available, the nature and breadth of their specialisation, which other specialists are available, and local needs. The principles of operative surgery—access, dissection, haemostasis, repair, reconstruction, preservation of vital structures and closure—are similar in all specialties.

A general surgeon is one who undertakes general surgical emergency work and elective abdominal gastrointestinal (GI) surgery. In geographically isolated areas, such a surgeon might also undertake gynaecology, obstetrics, urology, paediatric surgery, orthopaedic and trauma surgery and perhaps basic ear, nose and throat, and ophthalmology. Conversely, in developed countries, there is a trend towards greater specialisation. GI surgery, for example, is often divided into ‘upper’ and ‘lower’, and upper GI surgery may further subdivide into hepatobiliary, pancreatic and gastro-oesophageal cancer surgery.

Surgeons are not simply ‘cutting and sewing’ doctors. The drama of surgery may seem attractive but good surgery is rarely dramatic. Only when things go wrong does the drama increase, and this is uncomfortable. Surgery is an art or craft as well as a science, and judgement, coping under pressure, taking decisive action, teaching and training and managing people skilfully are essential qualities. Operating can be learnt by most people, but the skills involved in deciding when it is in the patient’s best interests to operate are essential and must be actively learnt and practised.

Surgeons play an important role in diagnosis, using clinical method and selecting appropriate investigations. Many undertake diagnostic and therapeutic endoscopy including gastroscopy, colonoscopy, urological endoscopy, thoracoscopy and arthroscopy. Indications for laparoscopic surgery, supported by good quality clinical trials, continue to broaden as equipment and skills become more sophisticated.
A SHORT HISTORY OF SURGERY

There is no doubt that the first surgeons were the men and women who bound up the lacerations, contusions, fractures, impalements and eviscerations to which man has been subject since appearing on Earth. Since man is the most vicious of all creatures, many of these injuries were inflicted by man upon man. Indeed, the battlefield has always been a training ground for surgery. Right up to the 15th century, surgeons dealing with trauma were surprisingly efficient. They knew their limitations—they could splint fractures, reduce dislocations and bind up lacerations, but were only too aware that open wounds of the skull, chest and abdomen were lethal and were best left alone, as were wounds involving major blood vessels or spinal injuries with paralysis. They observed that wounds would usually discharge yellow pus for a time; indeed, this was regarded as a good prognostic sign and was labelled ‘laudable pus’.

The 15th century heralded a new and dreaded pathology—the gunshot wound. These injuries would stink, swell and bubble with gas. There was profound systemic toxicity and a high mortality. Of course, we now know that this was the result of clostridial infection of wounds with extensive anaerobic tissue damage caused by shot and shell. The surgeons of those times were shrewd clinical observers but surmised that these malignant effects were caused by gunpowder acting as a poison, for it was not until centuries later that the bacterial basis of wound infection became evident. At that period, the remedy was to destroy the poison with boiling oil or cautery. Boiling oil was the more popular since it was advocated by the Italian surgeon Giovanni da Vigo (1460–1525), the author of the standard text of the day, Practica In Arte Chirurgica Compendiosa. These treatments not only produced intense pain but also made matters worse by increasing tissue necrosis.

The first scientific departure from this barbaric treatment was by the great French military surgeon Ambroise Paré (1510–1590) who, while still a young man, revolutionised the treatment of wounds by using only simple dressings, abandoning cautery and introducing ligatures to control haemorrhage. He established that his results were much better than could be achieved by the old methods.

Ignorance of the basic sciences behind the practice of surgery was slowly overcome. The publications of The Fabric of the Human Body by Andreas Vesalius (1514–1564) and of The Motion of the Heart by William Harvey (1578–1657) in 1628 were two notable landmarks.

Surgical progress, however, was still limited by two major obstacles. First, the agony of the knife: patients would only undergo an operation to relieve intolerable suffering (e.g., from a gangrenous limb, a bladder stone or a strangulated rupture) and, of course, the surgeon needed to operate at lightning speed. Second, there was the inevitability of suppuration, with its prolonged disability and high mortality, often as high as 50% after amputation. Amazingly, both these barriers were overcome in the same couple of decades. In 1846, William Morton (1819–1868), a dentist working in Boston, Massachusetts, introduced ether as a general anaesthetic. This was followed a year later by chloroform, employed by James Young Simpson (1811–1870) in Edinburgh, mainly in midwifery. These agents were taken up with immense enthusiasm across the world in a matter of weeks.

The work of the French chemist Louis Pasteur (1822–1895) demonstrated the link between wound suppuration and microbes. This led Joseph Lister (1827–1912), then a young professor of surgery in Edinburgh, to perform the first operation under sterile conditions in 1865. This was treatment of a compound tibial fracture in which crude carbolic acid was used as an antiseptic. The development of antiseptic surgery and, later, modern aseptic surgery progressed from there.

So at last, in the 1870s, the scene was set for the coming enormous advances in every branch of surgery whose breadth and successes form the basis of this book.

What Sort of Patients Come to Surgeons?

Different types of surgeons practise in very different ways. In the United Kingdom, most patients are referred by another doctor, for example, GP, accident and emergency (ER) officer or physician. The exceptions include trauma patients who self-refer or arrive by ambulance. In some countries, patients can self-refer to the specialist they consider most appropriate. Regardless of the route, surgical patients fall into the following categories:

- **Emergency/acute**, that is, symptoms lasting minutes to hours or up to a day or two—often obviously surgical conditions, such as traumatic wounds, fractures, abscesses, acute abdominal pain or GI bleeding
- **Intermediate urgency**—usually referrals from other doctors based on suspicious symptoms and signs and sometimes investigations, for example, suspected colonic cancer, gallstones, renal or ureteric stones
- **Chronic conditions** likely to need surgery, for example, varicose veins, hernias, arthritic joints, cardiac ischaemia or rectal prolapse

The Diagnostic Process

To manage surgical patients optimally, a working diagnosis needs to be formulated to guide whether investigations are necessary and their type and urgency, and to determine what intervention is necessary. The process depends upon whether immediate life-saving intervention is required or, if not, the perceived urgency of the case. For example, a patient bleeding from a stab wound might need pressure applied to the wound immediately whilst resuscitation and detailed assessment are carried out. At the other end of the scale, if symptoms suggest rectal carcinoma, a systematic approach is needed to obtain visual and histologic confirmation of the diagnosis by colonoscopy and radiologic imaging. Tumour staging (see Ch. 13, p. 185) aims to determine the extent of cancer spread to direct how radical treatment needs to be. Treatment may be curative (surgery, chemotherapy, radiotherapy) or palliative if clearly beyond cure (stenting to prevent obstruction, local tumour destruction using laser, palliative radiotherapy).

**Formulating a Diagnosis.** The traditional approach to surgical diagnosis is to attempt to correlate a patient’s symptoms and signs with recognised sets of clinical features known to characterise each disease. While most diagnoses match their ‘classical’ descriptions at certain stages, this may not be so when the patient presents. Patients often present before a recognisable pattern has evolved or at an advanced stage when the typical clinical picture has become obscured. Diagnosis can be confusing if all the clinical features for a particular diagnosis are not present, or if some seem inconsistent with the working diagnosis.

This book seeks to develop a more logical and reliable approach to diagnostic method than pattern recognition, by attempting to explain how the evolving pathophysiology of the disease and its effect on the anatomy bring about the clinical features. The overall aim is to target investigations and management that give the best chance of cure or symptom relief with the least harm to the patient.

Principal Mechanisms of Surgical Disease

Surgical patients present with disorders resulting from inherited abnormalities, environmental factors or combinations in varying proportions. These are summarised in Box 1.1, as a useful ‘first principles’ framework or aide-mémoire upon which to construct a
When considering the causes of a particular condition, it may be helpful to run through the range of causes listed here. This should only be a first step and not a substitute for thought. This approach gives no indication of the likely severity, frequency or importance of the cause.

**Congenital**
- Genetic
- Environmental influences in utero

**Acquired**
- Trauma—accidents in the home, at work or during leisure activities, personal violence, road traffic collisions
- Inflammation—physical or immunological mechanisms
- Infection—viral, bacterial, fungal, protozoal, parasitic
- Neoplasia—benign, premalignant or malignant
- Vascular—ischaemia, infarction, reperfusion syndrome, aneurysms, venous insufficiency
- Degenerative—osteoarthritis, glaucoma, osteoarthritis, rectal prolapse
- Metabolic disorders—gallstones, urinary tract stones
- Endocrine disorders and therapy—thyroid function abnormalities, Cushing syndrome, pheochromocytoma
- Other abnormalities of tissue growth—hyperplasia, hypertrophy and cyst formation
- Iatrogenic disorders—damage or injury resulting from the action of a doctor or other healthcare worker; may be misadventure, negligence or, more commonly, system failure
- Drugs, toxins, diet, exercise and environment
  - Prescription drugs—toxic effects of powerful drugs, maladministration, idiosyncratic reactions, drug interactions
  - Smoking—atherosclerosis, cancers, peptic ulcer
  - Alcohol abuse—personal violence, traffic collisions
  - Substance abuse—accidents, injection site problems
  - ‘Western diet’—obesity, atherosclerosis, cancers
  - Lack of exercise—obesity, osteoporosis, aches and pains
  - Venomous snakes, spiders, scorpions and other creatures—local and systemic toxicity
  - Atmospheric pollution—pulmonary problems
- Psychogenic—factitious disorder, unspecified (Munchausen syndrome) leading to repeated operations, problems of indigent living, ingestion of foreign bodies, self-harm
- Disorders of function—diverticular disease, some swallowing disorders

A differential diagnosis. This is useful when clinical features do not immediately point to a diagnosis. This approach is known as the surgical sieve; however, it is not a substitute for logical thought based on the clinical findings.

**Congenital Conditions**

The term *congenital* defines a condition present at birth, as a result of genetic changes and/or environmental influences in utero such as ischaemia, incomplete development or maternal ingestion of drugs such as thalidomide. Congenital abnormalities of surgical interest range from minor cosmetic deformities such as skin tags through to potentially fatal conditions such as congenital heart defects, posterior urethral valves and gut atresias.

Congenital abnormalities become manifest any time between conception and old age, although most are evident at birth or in early childhood. Some are diagnosed antenatally, for example, foetal gut atresias with grossly excessive amniotic fluid (polyhydramnios). There are expanding specialist areas involving intrauterine or foetal surgery, for example, for urinary tract obstruction. During infancy, conditions such as congenital hypertrophic pyloric stenosis come to light. In childhood, incompletely descended testis may become evident. Finally, some disorders may present at any stage. For example, a patent processus vaginalis may predispose to an inguinal hernia even into late middle age.

Whilst many congenital abnormalities give rise to disease by direct anatomical effects, others cause disease by disrupting function, with the underlying disorder revealed only on investigation. For example, ureteric abnormalities allowing urinary reflux predispose to recurrent kidney infections.

**Acquired Conditions**

Acquired surgical disorders result from trauma or disease or from the body’s response to them, or else present as an effect or side-effect of treatment. For example, bladder outlet obstruction may result from benign prostatic enlargement, from urethral stricture after gonococcal urethritis or from damage inflicted during urethral instrumentation. The classification detailed here is a framework, but conditions may fit more than one heading, and the mechanism behind some disorders is still poorly understood.

**Trauma**

Tissue trauma, literally injury, includes damage inflicted by any physical means, that is, mechanical, thermal, chemical or electrical mechanisms or ionising radiation. Common usage tends to imply blunt or penetrating mechanical injury, caused by accidents in industry or in the home, road traffic collisions, fights, firearm and missile injuries or natural disasters, such as floods and earthquakes. Damage varies with the causative agent, and the visible injuries may not indicate the extent of deep tissue damage.

**Inflammation**

Many surgical disorders result from inflammatory processes, most often stemming from infection. However, inflammation also results from physical irritation, particularly by chemical agents, for example, gastric acid/pepsin in peptic ulcer disease or pancreatic enzymes in acute pancreatitis.

Inflammation may also result from immunological processes, such as in ulcerative colitis and Crohn disease. Autoimmunity, where an immune response is directed at the body’s constituents, is recognised in a growing number of surgical diseases, such as Hashimoto thyroiditis and rheumatoid disease.

**Infection**

Primary infections presenting to surgeons include abscesses and cellulitis, primary joint infections and tonsillitis. Typhoid may cause caecal perforation, and abdominal tuberculosis may be discovered at laparotomy. Amoebiasis can cause ulcerative colitis-like effects. Preventing and treating infection is an important factor in surgical emergencies, such as acute appendicitis or bowel perforation. Despite the rational use of prophylactic and therapeutic antibiotics, postoperative infection remains a common complication of surgery.

**Neoplasia**

Certain benign tumours, such as lipomas, are common and are excised mainly for cosmetic reasons. Less commonly, benign tumours cause mechanical problems, such as obstruction of a hollow viscus or surface blood loss, for example, leiomyoma. Benign endocrine tumours may need removal because of excess hormone secretion (see Endocrine disorders later). Finally, benign tumours
may be clinically indistinguishable from malignant tumours and are removed or biopsied to obtain a diagnosis.

**Malignant tumours** may present with signs and symptoms from the primary, the effects of metastases (‘secondaries’) and sometimes, systemic effects, such as cachexia. Malignant tumours are responsible for a large part of the general surgical workload.

**Vascular Disorders**

A tissue or organ becomes **ischaemic** when its arterial blood supply is impaired; **infarction** occurs when cell life cannot be sustained. **Atherosclerosis** progressively narrows arteries often resulting in **chronic ischaemia**, causing symptoms, such as angina pectoris or intermittent claudication. It also predisposes to **acute-on-chronic ischaemia** when diseased vessels finally occlude. Other common causes of acute arterial insufficiency are thrombosis, embolism and trauma. Arterial embolism causes acute ischaemia of limbs, intestine or brain; emboli often originate in the heart. If blood supply is restored after a period of ischaemia, further damage can ensue as a result of **reperfusion syndrome**.

When a portion of bowel becomes strangulated, the initial mechanism of tissue damage is venous obstruction, and this progresses to arterial ischaemia and infarction. An **aneurysm** is an abnormal dilatation of an artery resulting from degeneration of connective tissue. This may rupture, thrombose or generate emboli.

**Chronic venous insufficiency** in the lower limb causing local venous hypertension is responsible for the majority of chronic leg ulcers in the West.

**Degenerative Disorders**

This is an inhomogeneous group of conditions characterised by deterioration of body tissues as life progresses. In the musculoskeletal system, **osteoarthritis** decreases bone density and impairs its structural integrity, making fragility fractures more likely. Spinal disc and facet joint degeneration is common, causing back pain and disability, and osteoarthritis is widely prevalent in later life: the almost universal musculoskeletal aches and pains are probably caused by degeneration of muscle, tendon, joint and bone.

Other degenerative disorders include age-related retinal macular degeneration, glaucoma, the inherited disorder retinitis pigmentosa, and certain neurological disorders (Alzheimer, Huntington and Parkinson disease, bulbar palsy). Atherosclerosis and aneurysmal arterial diseases are often nonspecifically labelled degenerative.

**Metabolic Disorders**

Metabolic disorders may be responsible for stones in the gall bladder (e.g., haemyotic diseases causing pigment stones) or in the urinary tract (e.g., hypercalciuria and hyperuricaemia causing calcium and uric acid stones, respectively). Hypercholesterolaemia is a major factor in atherosclerosis and hypertriglyceridaemia is a rare cause of acute pancreatitis.

**Endocrine Disorders and Hormonal Therapy**

**Hypersecretion** of hormones, as in thyrotoxicosis and hyperparathyroidism, may require surgical removal or reduction of glandular tissue. Endocrine tumours, benign and malignant, may present with metabolic abnormalities, such as hypercalcaemia caused by a parathyroid adenoma, Cushing syndrome resulting from an adrenal adenoma or episodic hypertension caused by a phaeochromocytoma.

**Diabetes mellitus**, particularly when poorly controlled, causes a range of complications of surgical importance, for example, diabetic foot problems, retinopathy and cataract formation, as well as predisposing to atherosclerosis.

**Hormone replacement therapy** in postmenopausal women brings mixed benefits: it slows osteoporosis and reduces colorectal cancer risk whilst slightly increasing risk of breast and endometrial cancer. There is also evidence of an increased rate of thromboembolism, as with higher oestrogen-containing oral contraceptive pills.

**Other Abnormalities of Tissue Growth**

Growth disturbances, such as hyperplasia (increase in number of cells) and hypertrophy (increase in size of cells) may cause surgical problems, in particular benign prostatic hyperplasia, fibroadenosis of the breast and thyroid enlargement (goitre).

In surgery, the term **cyst** imprecisely describes a mass which appears to contain fluid because of characteristic fluctuance and transilluminaibility. A cyst is defined as a closed sac with a distinct lining membrane that develops abnormally in the body. A variety of pathological processes produce cysts. Most are benign but some cysts may be malignant.

**Iatrogenic Disorders**

Iatrogenic damage or injury results from the action of a doctor or other healthcare worker. It may be an unfortunate outcome of an adequately performed investigation or operation, for example, perforated colon during colonoscopy or pneumothorax from attempted aspiration of a breast cyst. These are termed **surgical misadventure**. However, if the damage results from a patently incorrect procedure, for example, amputation of the wrong leg or removal of the wrong kidney, then **negligence** is likely to be proven. Such wrong site surgery is termed a **never event** and is now rare because of mandatory preoperative site marking and comprehensive theatre staff briefing (World Health Organization [WHO] checklist). Other never events include retained foreign objects postprocedure (i.e., surgical swab, guidewire), transfusion of incompatible blood products or administration of medication via the wrong route. Prescription or administration of the incorrect drug or dose is usually iatrogenic. It is unusual for iatrogenic problems to be caused simply by one person’s failure. More often it is a **system failure**, with inadequate checks and balances in the system. Complications of bowel surgery, such as anastomotic leakage may result from poorly performed surgery but can occur in expert hands; audited results can demonstrate whether the surgeon is proficient.

**Drugs, Toxins and Diet**

Problems with prescribed drugs include unavoidable **toxic effects** of certain chemotherapeutic agents, for example, neutropenia, and the **side-effects** of drugs, such as nonsteroidal anti-inflammatory drugs (NSAIDs) causing duodenal perforation, or codeine phosphate causing constipation. Drug **allergy**, **idiiosyncrasy** or **anaphylaxis** may result from individual responses to almost any drug, and **interactions** between drugs cause adverse effects; in this respect warfarin is a prime culprit. Maladministration of drugs may also cause problems with, for example, the wrong drug given for intrathecal chemotherapy causing paralysis (a never event).

In many countries, venomous creatures, such as spiders, snakes or scorpions cause toxic and sometimes fatal harm.

Although major advances have now been made to discourage it, **cigarette smoking** has been the biggest single preventable
the principles of the Hippocratic Oath. This originated from the Greek School of Medicine around 500 bc and its essence is as follows:

- Doctors must be instructed and then registered to protect the public from amateurs and charlatans.
- Medicine is for the benefit of patients, and doctors must avoid doing anything known to cause harm.
- Euthanasia and abortion are prohibited.
- Operations and procedures must be performed only by practitioners with appropriate expertise.
- Doctors must maintain proper professional relationships with their patients and treatment choices should not be governed by motives of profit or favour.
- Doctors should not take advantage of their professional relationships with their patients.
- Medical confidentiality must be respected (see later).

SECTION A  Principles of Surgical Care

Alcohol and substance abuse may have a surgical dimension: alcohol can lead to personal violence or road traffic collisions; cannabis smoke is carcinogenic and causes dysplasias and premalignant lesions of the oral mucosa, as well as contributing to mental health problems. Misdirected injection of opioids and other drugs may cause abscesses, false aneurysms and even arterial occlusion. Misuse of ketamine can cause intractable bladder pain, cystitis and urinary symptoms.

The so-called Western diet, rich in fat and calories and low in vegetables, fruit and fibre, is linked with a range of diseases including colorectal and breast cancers, obesity, dyslipidaemias, diabetes and hypertension. This is particularly so when combined with a lack of exercise. Dietary fibre protects against colorectal adenomas and carcinomas as well as diverticular disease.

Psychogenic Disorders
Psychogenic disorders are not often a source of surgical disease but factitious disorder (previously referred to as Munchausen syndrome) patients may present with abdominal pain and become subjects of repeated laparotomies, psychiatric patients living rough may suffer from exposure and frostbite, and others may repeatedly cause self-harm or swallow foreign bodies, even such items as razor blades or safety pins.

Disorders of Function
A range of common disorders are defined by the functional abnormalities they cause, although their pathogenesis often remains ill understood. The GI tract is particularly susceptible, with conditions, such as idiopathic constipation, irritable bowel syndrome and diverticular disease.

Medical Ethics and Confidentiality

The term medical ethics refers to the universal principles upon which medical decisions should be based, and governs the beliefs and actions that influence the day to day judgements of doctors. Whilst benevolence should govern all medical practice, other factors, such as self-interest, money, the distribution of resources and individual technical skills are important motivating factors.

To some extent, the practice of surgery is influenced by the need for self-protection but in trying to avoid litigation, a surgeon may over treat or overinvestigate in ways that are unnecessary and may even be unethical. A degree of self-interest is inevitable but the guiding principle should be that the patient’s interests are paramount. Desirable attributes in a surgeon are listed in Box 1.2.

Surgeons generally aspire to practise their craft in line with the principles of the Hippocratic Oath. This originated from the...
Do Not Resuscitate Orders

A do not resuscitate (DNR) order on a patient’s file means that doctors are not required to resuscitate a patient if their heart stops. It is designed to prevent unnecessary suffering and potential side-effects such as pain, broken ribs, ruptured spleen or brain damage. The British Medical Association and the Royal College of Nursing say that DNR orders can be issued only after discussion with patients or family, difficult though this may be. Decisions should not be made by junior doctors alone but in consultation with seniors. The most difficult cases are those involving patients who know they are going to die and are suffering pain or other severe symptoms but who could live for months.

All adult patients who are admitted to hospital should have documentation of their resuscitation status. A DNR order does not mean that patients cannot be offered any active treatment. Discussion should take place with the patient and family to set boundaries on acceptable treatment of potentially reversible factors (such as antibiotics for infection), but it may be agreed that it is not appropriate to escalate care to a high dependency unit if the condition significantly deteriorates.

**Guidelines for When a DNR May Be Issued**

- If a patient’s condition is such that resuscitation is unlikely to succeed.
- If a mentally competent patient has consistently stated or recorded they do not want to be resuscitated.
- If an advance notice or living will says the patient does not want to be resuscitated.
- If successful resuscitation would not be in the patient’s best interest because it would lead to a very poor quality of life.

In the United Kingdom, NHS Trust Hospitals must agree explicit resuscitation policies that respect patients’ rights and are readily available to patients, families and carers; policies must be regularly monitored.

**Communication**

**With Patients**

Doctor–patient relationships are best learnt by following good examples in the clinic and ward in an apprenticeship model. Patients are vulnerable, often with unpleasant symptoms and usually with little understanding of anatomy, physiology or pathology. They rarely understand the likely progress of a disease or its treatment and may have been conditioned by the media to expect miracle cures or to believe that the latest technology is what they need. Patients take in only about 10% of what is said during a consultation, but this can be improved in the right setting and with reinforcement. Important messages need to be given in comfortable surroundings, without giving the impression the doctor is in a rush, perhaps with family present and with a nurse who can later ensure messages have been understood.

Doctors are in a privileged position, able to make decisions on a patient’s behalf that can have dramatic effects on their life and that of their family. Patients these days generally wish to know more about their condition, but can then take greater responsibility for it than in the old days of the paternalistic doctor. Thus an effective doctor–patient relationship involves not only taking an accurate history but also intelligent listening to discover what patients know, or think they know, about their health and likely treatments, and responding to their concerns in ways they can understand. A good interview also involves imagining ‘the third eye’, how both sides of the consultation might appear to an observer. Patients frequently complain, with good reason, that they ‘don’t know what is going on’. They pick up bits of information that may be inaccurate, so doctors should anticipate what they should explain to patients and families and give information in a timely fashion.

During the process of diagnosis and treatment, there is often uncertainty and incomplete information, so it is valuable to explain at intervals the stage reached, both to the patient and, with the patient’s permission, to relatives. Where there are different treatment options, a balanced view of the alternatives should be given, perhaps with some statistics, but when the doctor has reason to prefer one approach, this should be explained too, and then the patient can make a considered choice. It can be easy to persuade patients to undergo treatment—after all, you are the expert in their eyes—but trust, respect and empathy teach that patients may wish to reflect at leisure. Except in emergencies, patients should be able to go away and consider options rather than having to sign a consent form just before treatment. They may even wish to take a second opinion if choices are uncertain or potentially life-changing; this should be welcomed rather than discouraged. By helping patients understand their condition, their self-management will be more effective. Similarly, key factors such as diet or smoking habits can be discussed in an atmosphere of trust with more hope of success.

**Palliative Care**

Sometimes cure is not possible. Then quality of life may become the goal, with palliative treatment being offered. Patients generally want to know what will happen, including their mode of dying. Whilst this can be hard to predict, they need to know their symptoms, particularly pain, will be managed effectively and that they will be looked after. Experience teaches it is usually impossible to say with accuracy when a patient will die except a few days before it will happen, so it is unwise to predict life span except in general terms.

**Breaking Bad News**

All doctors in clinical practice experience the need to break bad news, such as an unfavourable outcome, unsatisfactory care, a cancer diagnosis or a poor prognosis. It is an event doctors tend to remember and a moment in the patient or relative’s life they will never forget.

Ideally, bad news should be conveyed by the most senior member of the team but in reality, bad things often happen at night, often in the A&E department, and the most junior doctor is the one on the spot. Discuss what is to be said with your seniors even under these circumstances wherever possible. The following general points apply:

- **Bad news is private.** Find a quiet space, preferably an office with chairs (you do not need a desk).
- **Avoid hiding behind jargon:** ‘the metastatic nature of the neoplasm makes it inoperable’ is useless. ‘I’m sorry to say that the cancer has spread and an operation won’t help’ is better.
- **Give time and space;** turn off pagers and phones if possible.
- **Do not be defensive and do not be afraid to express regret.**
- **Avoid filling the silence of grief with continuous chatter.**
- **Allow time for questions.** If you do not know the answer, say so and try to find out.
- **Always offer another meeting,** ideally with the head of the team.
Many patients/families will wish to discuss what has been imparted with their family doctor, so it is vital that you get all information to the GP before that visit.

**Communicating With Colleagues**

Communicating with colleagues involves speaking, both face to face and on the telephone (Box 1.3), and writing (handwriting, dictating, typing, emailing) patient notes, information letters to patient or family practitioners, for example, after an outpatient consultation, referral letters, discharge summaries, reports and presentations for local or larger scale medical meetings. All of these need to be honest, accurate and timely, particularly when communicating patient information. Remember, recipients are entitled to rely on what you have written in their later treatment of a patient. Also any written information may be called in evidence in a court of law should something go wrong later. Patient notes must never be altered later, although, rarely, amendments may be added provided they are signed and dated.

Hospital doctors work in teams where it is important to know one’s responsibilities and those of everybody else, and to understand when to call for help in good time. Changes in a patient’s condition usually need to be passed on to other team members. If you have made a mistake, admit it early and do everything you can to mitigate it.

With diminishing junior doctors’ hours, it is vital to have structured handover of patients to the incoming team at the end of shifts and at weekends and holidays, including especially details of ill patients and those with complex management problems and any agreed plans for them.

**Communication via the Clinical Record**

Reduced junior hospital doctors’ hours make it imperative to keep the written records for every patient up to date, including management plans and what to do if predictable changes occur. Date and legibly sign each entry giving your name in capitals and grade, record important test results and write instructions for antibiotic and deep vein thrombosis (DVT) prophylaxis. In high operative risk patients, seniors should discuss documents before surgery. After operation, write or type an operation note with clear postoperative instructions so these are immediately available to recovery and ward staff.

Document details of any discussions with patient and relatives—particularly about poor prognosis or withdrawal of active treatment and who has been told about this or about a diagnosis of malignancy. Regarding a discharge summary, ensure all investigation results have been checked and the diagnosis and future plans have been recorded and send it immediately on discharge. If the patient died, record the cause of death in the notes as it is written on the certificate and inform the family doctor.

**Evidence-Based Medicine and Guidelines**

Evidence-based medicine (EBM) as now understood really began when Professor Archie Cochrane, a Scottish epidemiologist, published his book *Effectiveness and Efficiency: Random Reflections on Health Services* in 1972 and continued with his later advocacy of its principles. EBM has gradually gained political support and acceptance within the medical profession. EBM calls into question the traditional belief that ‘we’ve always based our practice on science’. Cochrane’s work has been recognised by the proliferation of Cochrane Centres and the international Cochrane Collaboration, all devoted to meticulously evaluating evidence and promoting its use.

The aim of EBM is to apply best scientific evidence to clinical decision making. It relies on critical assessment of published evidence about risks and benefits of treatments (or lack of treatment) and of diagnostic tests. Only between 50% and 80% of the volume of medical treatments are evidence based, with better evidence available for more common treatments. Statements by medical experts are seen as the least valid form of evidence, but evidence-based practice is not relevant where imponderables, such as quality of life judgements are involved. Evidence-based guidelines (EBG) have an appeal to health economists, policymakers and managers as they help to measure performance and perhaps justify rationing or centralising resources.

Austin Bradford Hill, the grandfather of modern medical research, who was fundamental in discovering the link between smoking and lung cancer, produced a set of guidelines, as given in Box 1.4, for assessing *causality*, that is, the relationship between an exposure and an outcome, and these remain the foundation of EBM today.
Cherry-Picking the Evidence Versus Systematic Review

Cherry-picking is a dubious means of reinforcing what you already believe, the very opposite of systematic review. It involves relying only on published work that supports your view and finding reasons to ignore what goes against it. The solution is a process of systematic review as conducted by the Cochrane Collaboration. Their methodologies were largely established at McMaster University. The term EBM first appeared in 1992 and journals devoted to the subject have included the British Medical Journal’s Clinical Evidence, the Journal of Evidence-Based Healthcare and Evidence Based Health Policy, all co-founded by Anna Donald, an Australian pioneer.

EBM encourages clinicians to integrate valid and useful scientific evidence into their clinical expertise. Using systematic reviews, meta-analyses, risk-benefit analyses and randomised controlled trials (RCTs), EBM aims that health professionals make ‘conscientious, explicit, and judicious use of current best evidence’ in everyday practice. Systematic review of published research studies is a very important method of evaluating treatments. An explicit search strategy is used finding relevant data, both published and raw and unpublished. The methodological quality of each study is evaluated, ideally blind to the results. Alternative treatments are compared, and then a critical, weighted summary is given. This thorough sifting of information often reveals large knowledge gaps and sometimes grossly flawed ‘best practices’; it has saved numerous lives without undertaking new research studies. Sir Muir Gray, an internationally respected authority on healthcare systems, has commented ‘advances will be made through clean, thorough sifting of information often reveals large knowledge gaps and sometimes grossly flawed ‘best practices’; it has saved numerous lives without undertaking new research studies. Sir Muir Gray, an internationally respected authority on healthcare systems, has commented ‘advances will be made through clean, thorough sifting of information often reveals large knowledge gaps and sometimes grossly flawed ‘best practices’; it has saved numerous lives without undertaking new research studies. Sir Muir Gray, an internationally respected authority on healthcare systems, has commented ‘advances will be made through clean, thorough sifting of information often reveals large knowledge gaps and sometimes grossly flawed ‘best practices’; it has saved numerous lives without undertaking new research studies. Sir Muir Gray, an internationally respected authority on healthcare systems, has commented ‘advances will be made through clean, thorough sifting of information often reveals large knowledge gaps and sometimes grossly flawed ‘best practices’; it has saved numerous lives without undertaking new research studies. Sir Muir Gray, an internationally respected authority on healthcare systems, has commented ‘advances will be made through clean, thorough sifting of information often reveals large knowledge gaps and sometimes grossly flawed ‘best practices’; it has saved numerous lives without undertaking new research studies. Sir Muir Gray, an internationally respected authority on healthcare systems, has commented ‘advances will be made through clean, thorough sifting of information often reveals large knowledge gaps and sometimes grossly flawed ‘best practices’; it has saved numerous lives without undertaking new research studies. Sir Muir Gray, an internationally respected authority on healthcare systems, has commented ‘advances will be made through clean, thorough sifting of information often reveals large knowledge gaps and sometimes grossly flawed ‘best practices’; it has saved numerous lives without undertaking new research studies. Sir Muir Gray, an internationally respected authority on healthcare systems, has commented ‘advances will be made through clean, thorough sifting of information often reveals large knowledge gaps and sometimes grossly flawed ‘best practices’; it has saved numerous lives without undertaking new research studies. Sir Muir Gray, an internationally respected authority on healthcare systems, has commented ‘advances will be made through clean, thorough sifting of information often reveals large knowledge gaps and sometimes grossly flawed ‘best practices’; it has saved numerous lives without undertaking new research studies. Sir Muir Gray, an internationally respected authority on healthcare systems, has commented ‘advances will be made through clean, thorough sifting of information often reveals large knowledge gaps and sometimes grossly flawed ‘best practices’; it has saved numerous lives without undertaking new research studies. Sir Muir Gray, an internationally respected authority on healthcare systems, has commented ‘advances will be made through clean, thorough sifting of information often reveals large knowledge gaps and sometimes grossly flawed ‘best practices’; it has saved numerous lives without undertaking new research studies. Sir Muir Gray, an internationally respected authority on healthcare systems, has commented ‘advances will be made through clean, thorough sifting of information often reveals large knowledge gaps and sometimes grossly flawed ‘best practices’; it has saved numerous lives without undertaking new research studies.

The Cochrane Collaboration is perhaps the best known, most rigorous and respected organisation providing systematic reviews. Once the best evidence has been assessed, treatment is rated as ‘likely to be beneficial’, ‘likely to be harmful’, or ‘evidence did not indicate benefit or harm’. A 2007 analysis of 1016 systematic reviews from all 50 Cochrane Collaboration Review Groups found 44% of the interventions beneficial, 7% harmful and 49% where the evidence did not support benefit or harm. Ninety-six percent recommended further research.

When it comes to new or radical ideas, well-trained experts using clinical common sense should be able to make rational judgements about what is likely to be true; the more unlikely the claims for a new treatment, the higher must be the standard of proper evidence.

Longitudinal or Cohort Studies

For predicting prognosis, the highest level of evidence is a systemic review of inception cohort studies, that is, groups of patients assembled near the onset of the disorder. These groups are followed over years to determine how variables, such as smoking habits, exercise, occupation and geography may affect outcome. Prospective studies take years to perform but are valued more than retrospective studies, which are more likely to generate bias.

Ranking the Quality of Evidence (Box 1.5)

The strongest evidence for therapeutic interventions is by systematic review of randomised, double- or triple-blind, placebo-controlled trials with allocation concealment and complete follow-up, in a homogeneous patient population and medical condition. In contrast, patient testimonials, case reports, and even expert opinion have lesser value because of the placebo effect, biases inherent in observation and reporting, and personal and institutional biases.

A series of classifications of the strength of different types of evidence have been fashioned, grading them according to their freedom from biases that plague medical research; all are based around the same descending hierarchy:

- Systematic reviews of RCTs
- Individual RCTs
- Controlled observational studies—cohort and case control studies
- Uncontrolled observational studies and case reports
- Established practice and expert opinion (not to be confused with personal experience, sometimes dubbed eminence-based medicine). Expert opinion may be the best guide in the absence of good research evidence

Other Classifications of Quality of Evidence

For a review of classifications of evidence, see: https://patient.info/doctor/Different-Levels-of-Evidence

For access to the GRADE system of assessing the strength of recommendation and quality of evidence in systematic review see: https://www.jclinepi.com/article/S0895-4356(10)00330-6/abstract
Quality and Limitations of Clinical Trials

Trials must now be registered in advance: the Declaration of Helsinki 2008 requires that every clinical trial be registered in a publicly accessible database before recruitment of the first subject. The International Committee of Medical Journal Editors refuses to publish clinical trial results if the trial was not recorded in this way. This should eliminate the bias inherent in the failure to publish negative trials.

In 1993 30 medical journal editors, clinical trialists, epidemiologists and methodologists met in Ottawa to develop a new scale to assess the quality of RCT reports. This eventually resulted in the Consolidated Standards of Reporting Trials (CONSORT) Statement, published in 1996 and now largely adhered to by respected medical journals (http://www.consort-statement.org/). Cochrane adheres to similar standards and uses software ‘RevMan’ to help reviewers evaluate published studies.

Resources

• Cochrane Library: http://www.cochranelibrary.com/
• UK National Institute for Health and Care Excellence (NICE): https://www.nice.org.uk/
• NHS search engine for Evidence in Health and Social Care (from NICE): https://www.evidence.nhs.uk/

Guidelines

Clinical guidelines, practice policies, protocols and codes of practice are locally or more widely published mechanisms aimed at harmonising processes of care using best practice. Some are produced by surgical societies, such as the Association of Surgeons of Great Britain and Ireland (ASGBI). Guidelines should be just that—providing a structure rather than absolute ways to proceed in every case; they may be varied if clinical conditions dictate. Guidelines should have an evidence basis or be of proven clinical effectiveness and need regular review as evidence accumulates. Local guidelines are a natural outcome of clinical audit studies (see p. 11, later).

Keeping Up to Date: Continuing Professional Development (CPD)

Clinicians are quite properly expected to keep up with current developments and to demonstrate this to be revalidated. Surgical knowledge and wisdom can be acquired by reading, from seniors in clinic and on ward rounds, by discussion at local and regional meetings and by attending courses. Meetings may include journal clubs, case presentations, reviews of specific topics, and presentation of research or audit projects. Broad national update meetings are valuable and in the United Kingdom, include the ASGBI and speciality meetings, such as the Vascular Society and the British Orthopaedic Association. Meetings are a forum for trainees to present their work, learn from other presentations and find out what is current from colleagues. Surgeons in the United Kingdom are required to keep a log-book record of their educational activities to demonstrate their continued learning and this document forms part of regular appraisal and revalidation.

Consent to Treatment

Treatment against a patient’s will is only rarely justifiable. Clearing the airways of someone about to choke to death who is irrational because of impaired consciousness can easily be justified on the grounds that the patient would have wanted it if fully rational. UK common law holds that an adult of sound mind has the right to determine what is done with his body and a surgeon who performs an operation without consent commits an assault in the eyes of the law. The General Medical Council (GMC) guidance on consent can be accessed via: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/consent

When Is Consent Necessary?

Ideally, medical treatment should not proceed without first obtaining the patient’s consent. Consent may be expressed, or it may be implied, as when a patient presents for examination and acquiesces in the suggested procedure. Express permission can be based on an oral or a written agreement. Most invasive investigations (such as upper GI endoscopy or arteriography) and any surgical operation should be preceded by written consent, ideally well in advance to give the patient time to think it over. If oral consent alone has been obtained, then a note should be made in the patient’s record.

A doctor may proceed without consent if the patient’s balance of mind is disturbed or if the patient is incapable of giving consent because of unconsciousness. The same principles apply if the patient is a minor, but it is sensible to seek consent from responsible relatives or to check with colleagues that the planned action is in the patient’s best interest. Opinions should be recorded in the notes before action is taken.

The Unconscious Patient

Under the necessity principle, a surgeon is justified in treating a patient without expressed consent if what he seeks to protect is more valuable than the wrongful act, that is, treating without consent, provided there is no objection to treatment. Treatment must be no more extensive than is essential and procedures not needed for the patient’s survival must not be performed. For example, a diseased testis could be removed during a hernia repair but sterilising a patient during a Caesarean section without consent constitutes assault.

Ambiguous wording on consent forms requiring a patient to agree to any operation the surgeon considers necessary is regarded by the courts as completely worthless. For this reason, a model consent form was produced by the NHS Executive in 1990 to be used throughout the health services.

Practical Aspects of Consent for Treatment

In British law, there is no such thing as informed consent. Surgeons like to feel they obtain informed consent after explaining to the patient in nontechnical language the nature, purpose and risks of the proposed investigation or treatment, together with alternatives and the likely outcome of treatment. It is good practice to provide a printed information leaflet on the specific operation detailing the procedure, alternatives, risks and recovery. The patient must be capable of understanding the explanation and if this is not the case then informed consent has not been obtained. It follows that consent cannot be obtained from patients who are unconscious or of unsound mind.

Obtaining Consent (Box 1.6)

There has been a significant change in UK law following the case of Montgomery versus the East Lanarkshire Health Board whereby the process of consent must stand the test that a reasonable body of patients and relatives would understand the benefits and disadvantages of all possible treatments for the particular condition.
The informed consent process should include:

- a description of the procedure or operation and anaesthetic;
- why the procedure is recommended and the risks and benefits;
- the degree of severity and likelihood of complications;
- treatment alternatives with related risks and benefits;
- probable consequences of declining the recommended or alternative therapies;
- name of doctor conducting the procedure and the anaesthetic;
- other doctors performing tasks related to the procedure.

Consent in Children

Consent can be obtained from children aged 16 years and over and occasionally in those under 16 years. It is always sensible to liaise with parents wherever possible in young people aged 17 and 18 years. In the absence of parents, another relative or person ‘in loco parentis’ can give consent for children.

For children in care, the local authority usually has full parental rights and the director of social services or deputy needs to sign the consent form. If the child is in voluntary care, the parents still act as guardians and their consent should be obtained.

Jehovah’s Witnesses

Adult Jehovah’s Witnesses usually refuse blood or blood product transfusion even in an extreme emergency because of their interpretation of part of the Bible. If permission to transfuse is withheld, then blood should not be given. Failure to respect the patient’s wish may result in an accusation of battery. The moral dilemma of allowing a patient to die when blood transfusion is likely to prevent death is uncomfortable but the law is clear. General advice is that a surgeon cannot refuse to treat simply because the patient imposes conditions on that treatment, although it may be possible to transfer the patient to a compliant surgeon’s care. In these circumstances, it is wise to interview the patient in the presence of a witness and explain the risks. The discussion should be noted and the witness should sign the hospital record.

In elective cases where anaemia needs to be treated to optimise the patient preoperatively, they may accept synthetic (recombinant) erythropoietin, which stimulates bone marrow to replace red blood cells. Some may consider the use of a cell saver during major surgery (anticipated to experience high blood loss) to harvest blood, process it and then reinfuse back into the body if required.

In children of Jehovah’s Witnesses the position is different. If a blood or blood product transfusion is needed to save the life of a child or to prevent harm, the transfusion can be given and defended in law by claiming that the decision was taken in the best interests of the child. If parental consent is withheld and there is ample time, the child can be made a ward of court, but this is not essential to obtain consent. If the decision to give blood is made, a second medical opinion confirming the need should be obtained if time allows. It is important to realise that a child subjected to transfusion against parental wishes may be rejected by the parents.

Clinical Governance and Clinical Audit

Clinical governance is a systematic approach to preserving and advancing the quality of patient care within a health system. Since the 1970s, there has been a growing realisation that looking critically at the way we run our clinical practice, and then taking active steps to move ahead, is much more effective than simply following time-honoured practices or even opening new avenues of research. In the United Kingdom, this movement is now universal but with varying degrees of success. Clinical governance starts with the mindset that the quality of care matters; it embodies a range of activities described here and elsewhere in this chapter.

Management Attitude to Quality of Care

Health service managers have to keep quality of care high on their long list of priorities and facilitate clinicians’ initiatives.

Education and Training of Clinical Staff

Thorough and well-rounded teaching in medical and nursing school, including anatomy and surgery, is the starting point. Training posts then need to offer a wide range of experience in an apprenticeship model, including step-by-step learning of procedures to back up continuing medical education, as well as specific courses, such as Advanced Trauma Life Support (ATLS). During training, good behaviours, attitudes and judgement can be acquired (see attributes of a good surgeon, earlier). All clinicians need to remain open-minded to change and remember it is their professional duty to remain up to date.
Clinical Audit

Clinical audit reviews clinical performance against agreed standards, refining clinical practice and then reauditing—a cyclical process of improving quality.

Clinical Effectiveness

Clinical effectiveness studies evaluate the extent to which an intervention works, its efficiency, safety, appropriateness and value for money. Studies of this type can be instructive and worthwhile for trainees to undertake.

Research and Development

Professional practice can change in the light of good research evidence, provided it can be implemented effectively. EBM involves critical appraisal of the literature and development of EBGs, protocols and implementation strategies from research.

Clinical Performance

Poor performance and poor practice often thrive behind closed doors but can be revealed by a local climate of openness; this also demonstrates the organisation meets the needs of its population. In surgery, trouble may come to light through morbidity and mortality meetings, clinical audit, via patient complaints or by ‘whistle blowing’, and these should provide the motor for change. Critical incident meetings, for example, can thoroughly examine particular adverse events and recommend change.

Nationally in the United Kingdom, the National Patient Safety Agency (http://www.npsa.nhs.uk/) ‘informs, supports and influences healthcare organisations and individuals’ by handling patient safety incidents, by running national independent Confidential Enquiries (NCEPOD in surgery and anaesthesia), by encouraging ethical research, and by developing and implementing safety recommendations, advice and strategies. Through the Practitioner Performance Advice Service (https://resolution.nhs.uk/services/practitioner-performance-advice/), it endeavours to solve concerns about the performance of health practitioners short of referral to the General Medical Council.

Risk Management

This is a prospective process to identify hazards that could cause harm, decide who might be harmed and how, then evaluate the risks and decide on precautions. Risks in a health service include risks to patients, risks to practitioners and risks to the organisation itself. Recognising in advance where particular risks lie is the first step to minimising those risks. Areas of potentially high risk include:

Older people: surgeons deal with an increasingly elderly population. The likelihood of comorbid disease is higher, although chronological age by itself is less important than biological age

Emergency surgery: this carries a higher risk of complications and death than elective surgery. Patients may be more physiologically disrupted or not fully resuscitated, intervention may be required out-of-hours when the ideal mix of staff is not available; investigations, such as computed tomography (CT) scanning may also not be so readily available

Day surgery: preoperative assessment can preselect patients for day surgery and minimise risk

Critically ill patients: these patients need optimising before surgery, often with shared care with a senior anaesthetist, physician or other specialist. More preoperative investigations and resuscitation may be needed, perhaps in an intensive care unit or high dependency unit. The initial surgical approach may become a damage limitation exercise with more realistic expectations about outcome

Operative risk assessment: the American Society of Anaesthesiologists grade scheme gives anaesthetist and surgeon a subjective idea of how sick the patient is and the likely outcome.

Information Management

Information management is vital to facilitate good, effective and economic practice. For example, high quality and available patient notes, systems for ordering laboratory and imaging tests and receiving results, accurate and prompt discharge summaries, easy outpatient booking, good feedback to family practitioners and reliable A&E systems. Hand-written methods have been used for many years in the United Kingdom, however because of advances in many hospitals, electronic (‘paperless’) systems are now flourishing, following success in the United States. In addition, the use of individual smart cards for patients to hold their own records, and easily portable devices, such as the iPad, hold promise for the future use in patient care, provided clinicians take sufficient interest in their development.

Surgical (Clinical) Audit

Research is concerned with discovering the right thing to do; audit with ensuring that it is done right.

RICHARD SMITH, FORMER EDITOR BMJ

There is a tendency to be overoptimistic or even defensive about one’s own practice. Yet patients, referring doctors, medical defence organisations (who defend the professional reputations of members when their clinical performance is called into question) and those paying for health care (governments and their agents and private insurers) are entitled to know that the quality of care provided in a given unit is up to standard. Examining morbidity and mortality at regular meetings within a unit (‘significant event’ reviews) are important but suffer from inherent weaknesses, such as defensiveness, incomplete data and rivalry. These meetings usually fail to address overarching problems, such as wound infection rates, or aspects of care from the patient’s point of view, such as delayed treatment, off-hand consultations, poor pain control and failure to give explanations. It is well established that medical errors are generally more likely to be caused by a system failure than an individual error and system errors are unlikely to be discovered by these morbidity and mortality meetings.

Clinical audit is a means by which clinicians can be collectively accountable for the care they provide and demonstrate its quality to outsiders. It requires a mechanism for scrutiny of each other’s work in a nonthreatening and constructive manner or else it would not function. In brief, a group of clinicians examines a topic of concern and agrees in advance what are acceptable standards of practice or outcomes, ideally based on published norms (‘the gold standard’). In other words, they establish and sign up to a set of standards for indicator based audit. The process embodies specific objectives, accepting peer review and being committed to change should weaknesses be revealed.
Once a topic is agreed, an audit cycle can begin with a pilot project on a small number of subjects, perhaps 20. A questionnaire is designed which ideally is capable of being completed retrospectively by nonclinical staff from hospital notes. With the pilot results, methods are refined and a larger scale project undertaken. Results are analysed by the group and necessary changes, and how these should be implemented, agreed. This is the most thorny aspect of clinical audit and the most difficult to achieve. Once the necessary changes have been implemented, the same audit needs to be repeated after a defined interval (completing the audit cycle) to bring the process up to a quality assurance mechanism.

Clinicians do need to be trained in audit methods and helped to design audits that are useful and sound. It is best to start with a simple project, such as, for example, what proportion of the entries in the notes is clearly signed.

**Medical Research Versus Medical Audit**

Medical research is used on a one-off basis to determine scientifically how interventions affect outcomes. Clinical audit measures how effectively aspects of good health care are put into practice. Every doctor can improve the way patients are cared for by critically examining local practices against current standards using audit methods.

Clinical audit and research share common features including defining explicitly what is to be measured and analysing and interpreting the data without bias. Audit can improve understanding of system failures, help develop guidelines and identify areas for education and training.

**Carrying Out an Audit (Box 1.7)**

Selecting topics for audit means taking into consideration how frequent the condition or treatment is, how high the risk to patients is, whether there is doubt about which treatment is the best, where care crosses specialty boundaries and finally, any topics of particular concern to clinicians or professions allied to medicine.

Single subject audits usually require no more than 50 patients to reveal problems and plan improvements. Subjects focus on aspects of the process of care (including resources used), appropriateness of tests or treatments or outcomes of treatment. They may include subjects, such as adequacy of pain relief from the patient’s point of view or, from the family doctor’s point of view, how long a discharge summary takes to be received.

The group then develops an audit indicator, which has objective, measurable standards of care and specifies a percentage of cases expected to reach the standard. For example, perhaps 100% of patients referred for palliative radiotherapy for lung cancer should receive their first treatment in less than 10 days after referral, or wound infection rates after appendicectomy should be no more than 3%. These indicators (known as criteria) can be based on published results, on previous local results or on standards the group hopes to achieve after running a pilot study.

Deficiencies usually turn out to be caused by system failure, such as poor coordination between departments (e.g., preassessment between anaesthesia and surgery) or poor communication between clinicians, with people not being informed about what is happening when. These factors are usually more important than lack of resources or personnel or poor individual performance. Improvements may result from simple organisational changes.

**Peer Group Review of Medical Audit Data**

Using audit indicators has advantages over raw data analysis or informal morbidity meetings. As standards have of necessity been agreed, any numbers of cases can be screened to select out for further discussion only those that vary from the standard. In itself, the process of refining and employing audit indicators is an educational experience that encourages self-analysis by individuals, departments, units or regions.

**Examples of How Clinical Audit Can Improve the Quality of Care**

- Reduction of risk of morbidity or mortality
- Improved effectiveness of care, such as streamlined processes of treatment
- Improvement in diagnosis—availability, appropriateness or quality
- Improved timing of care—reduced delay, better planning, efficient use of facilities
- Better use of resources—equipment, beds, support services, money
- Consumer satisfaction—patients and referring doctors
- Access to care—availability of diagnostic services and treatment
- Documentation and records—improved recording of the process of care
- Identifying educational needs by audit activity—for example, pain management

**Confidential Enquiry Into Perioperative Deaths (CEPOD)**

The pilot study was designed in 1983 jointly by the ASGBI and the Association of Anaesthetists to examine perioperative deaths and the delivery of surgical and anaesthetic care in Britain. This was followed by a review of all deaths within 30 days of surgery (all specialties) in three English Regions for the whole of 1986: 500,000 operations were reviewed with 4000 deaths (0.8%); 79% of deaths occurred in patients over 65 years of age. More information is available from: [http://www.ncepod.org.uk/](http://www.ncepod.org.uk/), including all published reports from 1987 onwards.

**Educational Lessons From CEPOD**

Many of the substandard practices identified could be put down to a lack of education or training in particular fields. These included:

- when and how to investigate
- when to give prophylaxis against infection and thromboembolism
- when to delay operation to resuscitate
- when not to operate
- when to call the consultant
- management of head injuries
- managing comorbid disease and the elderly
- keeping accurate records
- safe use of local anaesthetics
- local protocols for referral, handover and transfer
- organising effective audit or morbidity and mortality meetings

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**BOX 1.7 Key Elements of Criterion-Based or Indicator-Based Audit**

- Looks in a structured way at a small problematic aspect of care
- Criteria need to be agreed in advance by all clinicians involved
- Time is needed to plan and pilot the audit, discuss the results, implement change then reaudit after a period
- Whether criteria have been met must be reliably retrievable by nonmedical audit officers
- Recognition that there may be more than one valid way of achieving a solution
Research in Surgery

How Are Potentially Improved Methods Evaluated?

When new surgical techniques appear, they must be dispassionately evaluated and compared with existing practices, ideally by people with no vested interest. For a new technique to be introduced, it must be at least as good as existing methods or better in some way, for example, in achieving oncological clearance. New methods should be easily and quickly learnt—an operation that requires a learning curve of 500 patients is of little use to those 500. Methods need to be reasonably economical in equipment and in operating time and high-level hazards should be no greater than existing operations. While this may seem utopian, the greatest uncontrolled medical experiment of all, namely the introduction of laparoscopic cholecystectomy, was undoubtedly at the expense of a massive increase in common bile duct injuries. The proper view should be that the safety of the many outweighs the foibles of the few.

It was encouraging that laparoscopic hernia repair was not allowed to escape peer review in the same way, with multicentre trials comparing the existing standard of Lichtenstein open repair with the prospective standard of laparoscopic repair. Laparoscopic colorectal surgery has now been shown to give improved short-term outcomes with evidence of reduced pain, more rapid discharge from hospital and return to normal activities. However, recent multicentre noninferiority trials from Europe, the United States, Korea and Australasia have questioned long-term oncological outcomes. The response of the global surgical community to these data will be a watershed moment for the way clinical conduct is properly scrutinised, and research evidence is applied. Similar clinical scrutiny of outcomes applies to other new developments in surgery including robotic-assisted laparoscopic surgical techniques which are rapidly gaining popularity and wider-spread clinical use.

Design of Research and Experiments

All British health authorities have to establish an Ethics Committee charged with examining and sanctioning each research project before it is launched. They help ensure that all projects are ethical and can be justified and that the methodology is sound. Among medical members, these committees generally include lawyers, ethicists, statisticians and lay members.

Clinical Trials

Drug Trials

Once a potential drug has been identified, say from a likely plant molecule, a cell receptor that might be influenced or a modification of an old drug, it is tested for toxicity in animals and to see if it works. Then Phase I trials ‘first in man’ are performed on a few healthy young people. This is for toxicity, excretion rates and pathways, etc. If this works, Phase II trials in perhaps 200 people with the relevant illness are performed as ‘proof of concept’ to see if the drug is effective and to work out the dose. Many drugs fail at this point. Then Phase III trials are performed in hundreds or thousands of patients. These are randomised, blinded trials comparing the new drug against placebo or comparable treatments. More data on efficacy and safety is collected. Once successful trials are complete, the company applies for a licence to sell the drug. After it reaches market, the company and others usually conduct further trials and studies to look for unnoticed side-effects. However, trials do not tell the whole story: in the 1960s thalidomide, a very effective drug for morning sickness, had not been tested in pregnancy, and this led to many avoidable birth deformities in countries where it had been licensed.

Trial Design and Conduct

For a surgical trial, background work establishes the depth of current knowledge and the need for a trial. The hypothesis to be tested should be defined before designing the study and perhaps the need for a pilot study.

In general, prospective studies ensure that data are accrued chronologically and that patients are entered into the trial as they become available. However, it may take months (or even years) to recruit enough patients to make the data meaningful.

Retrospective analyses of previously recorded data are open to criticism because of the lack of an appropriate control group and the difficulty of extracting complete data from case notes. Despite flaws, a retrospective study may show the need for a prospective study, give some idea of the likely results and allow the trial design to be streamlined.

Longitudinal studies examine the effects of therapy on a predetermined population or epidemiological changes in a population. Cross-sectional studies take a ‘snap shot’ at a particular time and place; these are most commonly used to monitor the incidence and location of diseases and treatment.

For most trials, computer randomisation removes the natural tendency for bias to affect results and is particularly relevant when comparing new treatments with tried and tested techniques. This is often ‘blinded’ such that neither the patient (single blind), or neither the patient nor the investigator (double blind), knows which arm an individual has been allocated to. Any therapeutic effect of placebos is maximised if patients are unaware of the nature of their treatment. The double-blind technique attempts to eliminate personal preferences of the doctor for a particular treatment. To study the effects of a treatment in a particular environment, like must be compared with like and a case control study used. Matching of individuals for characteristics, such as weight, sex, age and disease severity allow comparisons to be made when looking for small differences between groups.

Once the study design has been established, an achievable cohort size must be identified which has sufficient power to show differences between treatments and organise data collection, storage and analysis. After that, it is necessary to establish inclusion and exclusion criteria, the population size and characteristics to be studied and then to determine how the data will be analysed and presented statistically.

Specialised personnel, equipment and training must be funded. Worthwhile research is expensive and should not be undertaken simply for the sake of the CV.

Patient Safety

Dealing With an Adverse Event

• Apologise to the patient for the failure as soon as the error is recognised.
• Report to your consultant and other responsible people.
• Take steps to correct the error and make sure you see the patient often.
• If an official complaint is made, patient letters are usually sent to the patient advice and liaison service then to the department managers.
• If asked to comment, provide full and honest detail.
• If legal action is threatened, contact your medical insurance society.
• Adverse outcomes should be discussed at local meetings to seek system problems.

Introduction

‘First do no harm’, an aphorism attributed to Thomas Sydenham, an English physician in the mid-1600s, is sound advice for surgeons too. All surgical treatments should be thought of in terms of their potential harm as well as benefit.

Some hazards are intrinsic to the surgical procedure or disease and are unavoidable. Other hazards are avoidable, and systems need to be designed to assist. Furthermore, the surgeon’s prime responsibility is to the patient so, for example, prioritising an operation should be based on need not on financial or managerial grounds, although surgeons have responsibilities to balance demands as far as possible.

To Err is Human is an influential report published by the US Institute of Medicine in 1999 that is well worth reading. It called for a national effort to make health care safer. The recent impetus given to Human Factors training by governments, surgical regulatory bodies and commissioners is a welcome move to protect both patients and surgeons. Human factors are, in short, all the things that make us unpredictable individuals. The scope of Human Factors is broad and includes team working, communication, risk management, situational awareness and self-management (stress and fatigue).

General Hazards

The two most common sources of error leading to patient harm are communication failures and drug prescribing errors. Some 26% of 100 consecutive cases referred to the Medical Protection Society resulted from communication failure. There need to be explicit systems for dealing with risky situations, for example, informing seniors about sick patients, handing over properly to staff coming on duty, knowing who to call about patients that have ‘gone off’ during unsocial hours. This applies especially to anyone not familiar with the patient’s current state, particularly locums, who are unlikely to be familiar with how things work locally.

Drug prescribing is fraught with dangers: illegible prescription, wrong drug, wrong dose, unexpected drug interactions or failure to elicit a history of allergy or idiosyncrasy. Electronic prescribing systems with built-in warnings of interactions help, but so does the regular presence of a ward pharmacist.

Theatre Safety

The period between a patient entering the operating department and leaving the recovery unit is potentially hazardous for both the patient and the staff (Boxes 1.8 and 1.9). A fully conscious patient has automatic defence mechanisms to avoid injury but when anaesthetised or recovering, relies on the care of trained staff.

All operating theatres have safety protocols, with patients’ identities, nature and type of operation, allergies, etc., being repeatedly checked—but errors still occur. The WHO has developed a well-tested tool for minimising errors using a simple three-stage checklist for each case: before induction of anaesthesia (with at least nurse and anaesthetist), before the skin incision (with nurse, anaesthetist and surgeon) and before the patient leaves the operating room (with nurse, anaesthetist and surgeon). This is now used extensively around the world; see Box 1.8 and http://www.who.int/patientsafety/safesurgery/en/
Anaesthetic incidents can be substantially reduced by good anaesthetist training, by having trained anaesthetic assistant staff so that more than one pair of hands is available, by standardised patient monitoring including pulse oximetry, and by ‘preflight’ checking of anaesthetic equipment. Professional recovery nurses and equipment further increase safety.

Surgical Mishaps
Surgical mishaps in the operating theatre range from dramatic uncontrolled haemorrhage to the harder to define inadequate surgery leading to complications, slow recovery or avoidable recurrence of cancer. Surgeons have long had clear evidence of poor results of surgical treatment and at last, improvements are occurring with audit, specialisation, national audit databases, training and continuing medical education after specialist accreditation. Governments eager to save money sometimes mandate excessively short training and this is likely to impair outcomes and, in the end, do more damage and cost more.

Injuries and Hazards of Moving and Positioning Patients
*Damage to the cervical spine* may occur if the unsupported head is allowed to fall backwards or sideways in unconscious patients, particularly those with rheumatoid arthritis of the cervical spine.

*Falls to the floor* usually occur only if several things go wrong simultaneously.

*Damage to upper limbs* can occur during transfer and positioning, and lower limb damage can occur when placing diseased hips into flexed abduction.

*Traction* on infusion lines, tubes and catheters can cause tissue injury or interfere with monitoring or intravenous therapy, or both.

*Drains and catheters* are at similar risk. *Chest drains* require special attention as detachment allows air to enter the pleural cavity causing pneumothorax. *Acute compartment syndrome* is a rare complication of patients placed in lithotomy position for prolonged periods. It is good practice to monitor the leg elevation time and ensure the legs are lowered at set intervals during a long operation.

Peripheral Nerve Injuries
Peripheral nerve injuries after anaesthesia are probably caused by nerve ischaemia and can occur after as little as 30 minutes in an adverse position. Examples include ulnar nerve compression at the elbow, facial nerve damage from face mask pressure, radial nerve injury from a post clamped to the operating table. The brachial plexus is vulnerable to traction. If the arm is to be placed at right angles, the hand should be *pronated* and the patient’s head turned towards the arm.

Eye Injuries
Irritant fluids such as antiseptics, sprays or gastric acid may be spilled on the cornea causing chemical injury. The eyelids are usually taped gently shut during operation to prevent direct trauma and drying which causes damage after 10 minutes.

Direct Pressure Effects
Under anaesthesia, the weight of parts of the body may cause pressure necrosis of skin over the occiput, sacrum and heels. The heels of patients with lower limb ischaemia are particularly at risk.

Pressure on calves on the operating table may cause DVT by compression of veins, trauma to the vein wall and stagnation of blood. Elevation by pads under the ankle, graduated compression stockings and pneumatic compression devices all reduce the risk.

Burns
Burns on the operating table are often caused by faulty positioning. Diathermy burns occur if the patient comes into contact with bare metal of the operating table. Other diathermy burns result from poor earth plate contact.

Hypothermia
Unintentional hypothermia is a danger to children and to adults undergoing prolonged surgical procedures and is largely avoidable. Reduced core temperature causes changes in drug metabolism, impaired coagulation and an increase in tissue oxygen requirement during the postoperative period and consequent acidosis. This has been shown to predispose to serious postoperative complications. Maintaining normothermia is a mainstay of enhanced recovery protocols. Trauma patients are particularly vulnerable as are patients undergoing laparoscopy for prolonged periods. Efforts to maintain normothermia with foil blankets, warmed fluids, warm air blankets and insufflation of warmed, humidified carbon dioxide are simple, but effective measures for minimising hypothermia and its associated complications.

Infection Risks
These are dealt with in Chapter 3.

Hazards During Immediate Postoperative Recovery
Twenty percent of all deaths and serious neurological damage caused by anaesthesia are believed to occur in the recovery room, and full monitoring and observation needs to be continued in the recovery area.

Radiation Hazards
In the United Kingdom, all healthcare workers who use or prescribe X-irradiation (X-ray) undergo mandatory radiation protection training courses to learn the risks and safeguards needed.