

2. Professional Ethics

Truth, trust and communications skills

When God said that lying was a sin, he made an exception for doctors, and he gave them permission to lie as many times a day as they saw patients.

Dumas

When Dumas wrote the above, it was probably meant to be slightly ironic. However, it does reflect the historical notion that the extent to which patients are told the truth was a matter for the doctor to decide. The Hippocratic Oath is notably silent on the issue of telling patients the truth. In fact, Hippocrates advised the physician to 'calmly and adroitly conceal most things from their patients . . . turning his attention away from what is being done to him . . . revealing nothing of the patient's future or present condition'. So from ancient times until comparatively recently, lying to patients was not necessarily disapproved of, or even discouraged. Indeed 'to lie like a physician' used to be a compliment!

Current thought is completely different. The General Medical Council (GMC) states that doctors have a duty to be 'honest and trustworthy'. The Bristol Royal Inquiry made 37 recommendations on how a greater culture of respect and honesty could be fostered within the NHS.



Withholding the truth includes:

- Outright lies.
- Temporary deception.
- Not answering direct questions.
- Giving false hope.

Telling the truth

The concept of 'telling the truth' has two facets:

1. The 'telling' part, which deals with the *communication* of information.
- and

2. The 'truth' part, which holds that the information given has to be *true*.

From an ethical perspective, truthful information is important for a number of reasons:

- For reasons of autonomy; truthful information helps patients to decide how to proceed with treatment.
- Even if the information doesn't lead to a treatment decision, the patient may still wish to know information about their health, because their health is intricately linked with their sense of self.
- For reasons of trust, it is generally accepted that truth-telling promotes a sense of trust between both the doctor and their patient, and in general between doctors and the public at large.

So, it seems that in general, truth-telling is a necessary duty. However, is it an absolute one? Are there any circumstances in which it might be okay to lie to patients? What about not telling the *whole* truth? Is there a difference between avoiding answering a direct question, and telling a lie? The following scenarios illustrate the general principles at stake.

Scenario 1

A patient, Mrs X, is brought to A&E after being caught in a house fire. Mrs X's three children were also in the fire; two have died and it is not known whether the other will survive or not. Mrs X herself is in a critical condition. Mrs X asks you, the doctor treating her, how her children are.

You suspect that telling the truth will distress her so much that it may well lead to her death. Do you deceive her for a short period of time?

Here we have a conflict of ethical principles:

1. Respect for autonomy holds we should not lie to our patient.
2. Beneficence holds that lying may be crucial in saving the patient's life.

The conflict in principles is mirrored by a conflict in different ethical theories as well: utilitarianism would tell us to lie, Kantianism would oblige us to tell the truth. How can a compromise be reached?



Mrs X has asked a direct question and an ill-thought-out answer could be fatal to her. Ideally, we would like to be able to reassure Mrs X without lying to her. Deflecting her questions may be difficult. The bad news needs to be communicated to her, but is perhaps best done when her own medical condition is more stable.

It has been suggested that lying to patients is justified only 'if a person, acting rationally, were presented with the alternatives, he or she would always choose being lied to' (Gert & Culver 1979). The suggestion here is that when trying to promote autonomy, what is necessary is more than a simple presentation of potential options, because the way in which the options are presented may affect the ability of Mrs X to make an autonomous choice.

Scenario 2

Mr Y has a poor (but not terminal) prognosis due to cancer. You are treating Mr Y, and are about to tell him his diagnosis and prognosis.

Before you do so, his son, a local GP, who has guessed the diagnosis, urges you not to tell his father the truth. The son explains that his mother, Mr Y's wife, died a mere two months ago of a very aggressive cancer, and he fears that if his father knows the truth, he will 'give in' because the father thinks that any diagnosis of cancer is one without hope of recovery.

In this scenario, the deception is not a short-term one to allow recovery, but a permanent one. However, the conflict of principles is similar: autonomy vs. beneficence.

Weighing up the two sides of the equation is difficult because there are two ideas, or conceptions, about the nature of autonomy:

- One view is that autonomy is about *making decisions*: being in charge of one's own destiny.
- A different view is that autonomy is about making *certain types* of decision: specifically the types of decision that are consistent with a general life-plan or goal.

These differing conceptions of autonomy are developed further in the section on paternalism.

Telling the truth and the law

The legal implications of truth-telling mainly concern whether or not the consent given is valid. In order for consent to be valid, it must be *informed consent*. The law tends to consider whether doctors have fully disclosed risks inherent in treatment before obtaining consent.



There are different conceptions of autonomy:

- Long-term autonomy: value lies in promoting life-long goals that are consistent with deeply held and considered beliefs and values.
- Short-term autonomy: value lies in being able to make decisions about one's own health care – whether rationally based or capricious.

Your views on which conception of autonomy you consider to be more important may shape whether or not you believe that deceiving patients can ever be morally acceptable.

The important cases that dealt with disclosure of risk are:

1. *Chatterton v. Gerson* [1981] 1 All ER 257
2. *Sidaway v. Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] 1 All ER 643

In *Chatterton v. Gerson*, the courts looked at when doctors who didn't disclose risks would be guilty of trespass to the person. They said that:

... once the patient is informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is real, and the cause of the action on which to base a claim for failure to go into risks and implications is negligence, not trespass.

The key phrase from this judgement is that patients need to be informed '*in broad terms of the nature of the procedure*'. If this is done, then the charge of trespass, or battery, cannot be brought.

The courts also looked at when a non-disclosure of risks could lead to a charge of negligence. They said that a doctor:

... ought to warn what may happen by misfortune however well the operation is done, if there is a real risk of a misfortune inherent in the operation.

The key phrase here is that doctors 'ought to warn ... if there is a *real risk*'.

Who decides what constitutes a real risk was looked at in the *Sidaway* case. The outcome of this case was an endorsement of the *Bolam Test* (as discussed in Consent section). This test holds that in



questions of disclosure of risks, a doctor is only negligent if there is no reasonable body of medical practice that would have made the same choice. Effectively, this means that the medical profession itself sets the standards for disclosure of risk.

A popular rule of thumb is to disclose risks that are greater than 1%. BUT, if there is a grave risk (such as death or permanent disability), especially for minor procedure, then this 1% rule doesn't hold, and risks with a probability of less than 1% must also be disclosed. However, the doctor is duty-bound to answer any question truthfully. This is even more important if the procedure is a non-therapeutic one, or safer alternatives exist.

Other countries have developed different tests:

- Australia has a *prudent-patient* test: here a doctor must disclose those risks that a prudent patient would wish to know.
- Japan supports a *therapeutic privilege* where doctors don't need to disclose risks (or even a diagnosis) if they believe it isn't in the patient's best interests.



- To avoid a charge of trespass to the person, the doctor must inform the patient of the '*broad terms of the nature of the procedure*'.
- To avoid a charge of negligence, the doctor must inform the patient 'if there is a *real risk*' of harm.
- What constitutes a '*real risk*' is set by a degree of consensus within the medical profession.

- Testing for certain infectious diseases: these include the 'notifiable' diseases of cholera, plague, relapsing fever, smallpox and typhus.
- The patient is incapable of giving consent, for example in cases of mental disability (see p. 52) or a young child (see p. 49).



The components of a valid consent

- Being informed.
- Capacity.
- Voluntariness.
- Making a decision.

Informed consent (also see 'Telling the truth and the law')

The charge of battery can be brought against a doctor in the following situations:

1. Where no consent has been obtained.
2. When force is used.
3. When the treatment carried out is entirely different from the one specified.

Most charges are of negligence: for failure to warn the patient of risks. The courts determine which risks need to be mentioned to patients by using the *Bolam Test*. This test derives from the case of *Bolam v. Friern Hospital Management Committee* [1957] 1 WLR 582.

John Bolam was a psychiatric patient undergoing electro-convulsive therapy (ECT). He was not warned of a risk of fractures due to the convulsions, nor was he given muscle relaxants, or manually restrained. As a result of the ECT, he sustained bilateral fractures of the acetabula.

The judge defined the test of negligence to be: 'the standard of the ordinary skilled man exercising and professing to have that special skill'. Because other doctors testified that they would have treated Bolam in the same way that he was treated, that is, a '*reasonable body*' of medical practitioners would not have done anything differently, Bolam's doctor was found not guilty of negligence.

The Bolam Test originally applied to all aspects of treatment and diagnosis. It was applied to warning of risks by a subsequent case, that of *Sidaway v. Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] 1 All ER 643.

Informed consent and its elements

Treatment without consent can lead to the health-care practitioner being liable for trespass to the person, negligence or, in extreme cases, a criminal prosecution of assault or battery.

These legal provisions mean that patients can veto care. Treatment can only be forced upon patients in narrowly defined circumstances. Consent is not required when:

- The patient is unconscious and requires *emergency* treatment.



The standard of negligence was set out by the case of *Bolam v. Friern Hospital Management Committee* [1957] 1 WLR 582. It requires the standard of care not to fall below: 'the standard of the ordinary skilled man exercising and professing to have that special skill'. Effectively, this standard is set by the medical profession.

Guidelines for obtaining informed consent

The GMC has detailed 12 key pieces of information to give to patients in order to obtain informed consent:

1. Details of the diagnosis, and prognosis, and the likely prognosis if the condition is left untreated.
2. Uncertainties about the diagnosis including options for further investigation prior to treatment.
3. Options for treatment or management of the condition, including the option not to treat.
4. The purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief; how the patient should prepare for the procedure; and details of what the patient might experience during or after the procedure including common and serious side effects.
5. For each option, explanations of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks, and of any lifestyle changes that may be caused by, or necessitated by, the treatment.
6. Advice about whether a proposed treatment is experimental.
7. How and when the patient's condition and any side effects will be monitored or reassessed.
8. The name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team.
9. Whether doctors in training will be involved, and the extent to which students may be involved in an investigation or treatment.
10. A reminder that patients can change their mind about a decision at any time.
11. A reminder that patients have a right to seek a second opinion.
12. Where applicable, details of costs or charges which the patient may have to meet.

Remember: when presenting information to the patient, it must be at an appropriate level. Valid consent can only be given if the patient can understand the information. The following may help when presenting information:

1. Provide information in the patient's own language: this may involve the use of a professional interpreter or a member of the patient's family. Remember, however, the patient will have to consent to the use of this person. (This applies to spoken languages and sign-language.)
2. Use leaflets: these can be given to the patient to go away and read. They should be given an opportunity to ask any questions the leaflets may have raised. Ensure the leaflets are current.
3. Use diagrams: the patient may not know where her pancreas is; drawing even a simple diagram of where it is in relation to the rest of her organs, and of the position of a surgical scar, can be helpful.
4. Ask the patient if they would like a family member or friend to be present.
5. Ask if the patient would like to tape-record the consultation.
6. If the consultation involves breaking bad news, do it in a sensitive way. It may also be helpful to inform the patient of counselling services and/or patient support groups if appropriate.
7. Encourage input from other members of the health-care team. Patients may more readily understand information from nurses, simply because they may feel less nervous or less embarrassed around them.
8. Answer patients' questions directly, don't be evasive.
9. Allow plenty of time to understand the information given.

Capacity to consent (competence)

Capacity refers to the ability of an individual to make decisions with respect to their medical treatment. It is presumed, in the absence of evidence to the contrary, that adult patients are capable of giving consent.



The definition of capacity has been given by the High Court in the case *Re C (Adult: Refusal of Treatment)* [1994] 1 All ER 819.

C was an inpatient at Broadmoor Prison Hospital, diagnosed with paranoid schizophrenia. C believed he was an internationally renowned doctor. C developed gangrene on the toes of one foot. C's surgeon believed C should have a below-knee amputation, but C refused, believing it better to die with both feet than live with one. C's solicitor applied for an injunction to prevent amputation, which was granted, as the courts found that, notwithstanding his schizophrenia, C was capable.

The test used in this case to determine the capacity of C has become known as the *Re C Test*.

The *Re C Test* has three stages:

1. Can the patient take in and retain information?
2. Does the patient believe this information?
3. Can the patient weigh that information balancing risks and needs?

Remember: in adults, competence is a test for a minimal level of ability to use information given to weigh risks and benefits; it is *not* specific to the decision being made. In children, however, a patient's capacity may vary with the gravity of the decision involved. Different levels of competence are required for different procedures. A child may have the requisite capacity to agree to a broken wrist being plastered, but not to consent to treatment for leukaemia.

Where there is *fluctuating capacity* in an adult, capacity when the patient is at their most lucid should be determined. (This is different in children – see Chapter 3.)

Voluntary consent

For consent to be valid, it ought to be free from coercion. Whilst patients may take into account the advice of others – including medical staff, friends, family, police, prison authorities, employers and insurance companies – they must still feel that they are able to make an autonomous decision. Consent given under duress is invalid.

The courts have broadly backed this approach. They have found that consent may be invalidated if obtained fraudulently, by force or by undue influence (see *Re T* [1992] 3 WLR 782 below). Furthermore, if an adult patient refuses to give consent, the courts have held that no-one else is in a position to give proxy consent (see *F v. West Berkshire Health Authority* [1989] 2 All ER 545 below).

T [1992] 3 WLR 782, 4 All ER 649

T was pregnant and involved in a car accident. She went into premature labour and needed a caesarean section. Prior to the operation, T had a conversation with her mother. T's mother was a Jehovah's Witness, although T was not.

Subsequent to her conversation with her mother, T told hospital staff she did not want a blood transfusion. She had not indicated any concern about a transfusion earlier on.

The caesarean section was carried out without the need for a blood transfusion, although the baby was stillborn.

After the operation, T's condition deteriorated and she was admitted to ICU. It was decided that without a blood transfusion she would die.

The court of appeal decided:

- The refusal for a blood transfusion during a caesarean section might not apply to the new situation – by which point T was incapable of giving consent.
- That T had been unduly influenced by her mother's religious views, and this prevented her refusal being valid.

In this case, Lord Justice Staughton expressed a test for undue influence, saying:

In order for an apparent consent or refusal of consent to be less than a true consent or refusal, there must be such a degree of external influence as to persuade the patient to depart from her own wishes, to an extent that the law regards it as undue.

F v. West Berkshire Health Authority [1989] 2 All ER 545

F was a 36-year-old woman, with a mental age of 5. F was a long-term resident of a mental hospital, and had formed a sexual relationship with a male resident.

F's mother and doctors thought that F ought to be sterilized.

The courts stated that:

- For a patient of adult age, no-one could give proxy consent.
- In the case of an incompetent patient, doctors could only act *in the best interests* of their patient.
- The 'best interests' would be decided on whether the doctor acted *in accordance with a responsible and competent body of relevant professionals* – that is, in accordance with the *Bolam Test* (see section on informed consent).



What are a patient's 'best interests'? (see also 'Mental disorders and competence to consent')

How do doctors, or the courts, decide what an incompetent patient's best interests are? The courts themselves have not given a clear definition of 'best interests' (Fig. 2.1). However, the Draft Mental Incapacity Bill (2003) included the following points that should be considered:

- Whether the person is likely to have capacity in relation to the matter in question in the future.
- The need to permit and encourage the person to participate, or improve their ability to participate, as fully as possible in any act done for and any decision affecting that person.
- That person's past and present wishes, feelings and those factors that the person would consider if they were able to do so.
- The views of those caring for the person or interested in their welfare.
- The views of any person granted lasting power of attorney by the now incapacitated person.
- The views of any court appointed deputy for the incapacitated person.

Clinical dilemma

You are a clinical medical student. Your consultant asks you to do a per rectum examination on an anaesthetized patient in theatre. You don't know whether the patient has consented to a student doing this. What do you do? The key points to this dilemma are:

- Consent.
- Intimate examinations.

All examinations are in a sense 'intimate' because they involve a touching of the patient. Consent should be obtained for *all* examinations. However, some examinations involve a greater invasion of personal space and, therefore, can be seen to require a greater degree of rigour in obtaining consent. The fact that anaesthetized patients are temporarily unable to give consent does not mean that students can proceed with an intimate examination.

The only time that doctors (or medical students) can perform an examination on an anaesthetized patient that has not been consented to is when such an examination would be in the best interests of the

Fig. 2.1 A summary of consent (see p. 49 for consent in children).

A summary of consent				
Age Group	Who can consent to treatment		Who can refuse treatment	
>18 years	<i>Patients</i>	Yes	<i>Patients</i>	Yes
	<i>Parents</i>	No	<i>Parents</i>	No
	<i>Courts</i>	No – unless patient is incompetent, then courts can decide what is in the patient's <i>best interests</i>	<i>Courts</i>	Yes
	<i>Doctors</i>	No – unless patient is incompetent, then doctors can treat in the patient's <i>best interests</i> . If the doctors are unclear as to what a patient's best interests are, they can refer the decision to the courts	<i>Doctors</i>	Yes – doctors retain the right not to treat patients if they believe this is in the best interests of the patient or they have a conscientious objection (in which case they should refer to another doctor). Doctors must treat in emergencies (if in the patient's best interests)



patient. Examination by a student is most often simply for the educational benefit to that student. The doctor will perform the same examination in order to make a diagnosis. Therefore, the examination by the student will rarely be in the best interests of the patient.

If a student examines an anaesthetized patient without having first got consent, then they are liable to a charge of assault. The doctor supervising the student will also be liable to a charge of assault. Best practice in this kind of scenario would involve:

- Seeing the patient prior to surgery and obtaining consent to perform any examination.
- Informing the patient that the examination is for your education.
- Informing the patient that the examination will be repeated by the doctor.
- Informing the patient that you will be supervised by the doctor whilst performing the examination.
- Informing the patient that they can refuse to be examined by students and that this refusal will not affect their medical care.



Intimate examinations

These include examinations of the:

- Breasts.
- Groin.
- Rectum.
- Vagina.
- Male genitalia.

Paternalism in medicine

Paternalism refers to those practices and actions when 'those in positions of authority refuse to act according to people's wishes, or they restrict people's freedom, or in other ways attempt to influence their behaviour, allegedly in the recipients' own best interest' (Häyry 1998).

Medical paternalism occurs when a doctor makes a decision that he/she believes is in his/her patient's best interest but that is contrary to the wishes of a competent patient.

Remember: the notion of beneficence (doing good) involves acting so as to serve the patient's best interests. Beneficence may slide into paternalism where a doctor believes he/she is 'doing good' and

acts against the immediate wishes of the patient, or indeed without even consulting the patient.

The notion of autonomy began to gain prevalence only in the 1950s and 1960s. The traditional doctor–patient relationship was one based on the idea of the doctor furthering patient interests. It was assumed that it was in the patient's interest – indeed it was the patient's role – to be cured by the doctor. Furthermore, it was assumed that this required the patient to entrust their care to the doctor entirely.

Over the last few decades there has been a shift in attitudes where doctors are seen as being in a partnership with their patients and other health-care professionals – all working together.

The arguments *for* paternalism:

1. Doctors have a duty to act in the patient's best interests, even if the patient doesn't know what her best interests are.
2. Patients are incapable of making medical decisions because they are too technical.
3. By 'shouldering the burden' of difficult decisions, doctors are able to maximize utility.

The arguments *against* paternalism:

1. Patients are better placed than their doctors in deciding what is in their own interests. Whilst doctors may be able to make better 'medical' decisions, they are not necessarily able to make better 'moral' decisions.
2. Technical explanations can be explained to patients – given time and appropriate communication skills.
3. From a practical point of view it is difficult to show that this is true. It is plausible that total welfare may be increased by certain paternalistic actions but it is hard to prove. Once again the patient is better placed to decide what level of information they wish to be provided with.

Clinical dilemma

Paternalism: what happens when the patient doesn't want to know the diagnosis? Key points would include:

- Autonomy.
- The right not to know.
- Withholding of information.

What should happen if a patient expresses a desire not to know their diagnosis, or details of treatment? This sort of scenario may occur in a number of different settings: patients may not wish to confront a diagnosis of cancer, HIV, or genetic disease.



Scenario

Jane is 63 years of age, and is found to have an abnormality on a mammogram. Both Jane's mother and sister died of breast cancer. Jane says to her doctor: 'Please don't tell me if it's cancer, I don't want to know. Just do what you have to do.'

What to do when a patient doesn't want to know their diagnosis is a genuine moral dilemma, because it complicates our idea of autonomy. How can a patient make an autonomous decision not to know information about their health status, when that knowledge is necessary to make autonomous decisions? Can a patient give informed consent to surgery if they don't know that the proposed operation is to remove a tumour? How can an oncologist discuss options such as radiotherapy, as opposed to chemotherapy, if the patient doesn't want to know they have cancer? How in fact can the patient remain in ignorance at all if to be treated they need to go to the oncology department for that treatment?

The ethical issues in this scenario revolve around whether autonomy and a right to self-determination confer a right not to know, or a right to remain in ignorance.

Remember: if the patient asks not to be informed about their own health status, and for the doctor to go ahead and 'do what they think is best', then strictly speaking, the doctor is *not* acting paternalistically. Paternalism involves acting contrary to the patient's wishes.

The alleged 'right not to know' is somewhat problematic. It can be argued that to be meaningful a 'right to know' implies that right can be waived, so there is a complementary 'right not to know'. Others have argued that 'a *right* not to know' is too strong a term to use (remember in Chapter 1, rights were described as 'insistent normative demands', which can 'trump' other forms of moral argument) and the debate ought to be framed in terms of freedoms. So, patients may be 'free not to know', but this freedom should be weighed against the interests and concerns of others, such as the doctor's right not to make those decisions that properly belong to the patient. Of course, this does not mean that unwanted information *must* be forced upon the patient, merely that the doctor is under no obligation not to withhold the diagnosis. So:

- It remains controversial as to whether autonomy confers a right not to know.
- It is not paternalistic to withhold information if the patient has chosen to remain in ignorance about their condition.

- If you are asked to withhold information by your patient, doing so may be morally *permissible*, but not necessarily morally *compulsory*.

Confidentiality

Whatever, in connection with my professional practice . . . I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret.

Hippocratic Oath ~425 BC

Confidentiality has, since the time of Hippocrates, played an important role in maintaining the doctor–patient relationship. A modern version of the Hippocratic Oath is found in the Geneva Declaration, which states: 'I will respect the secrets which are confided in me, even after the patient has died.' Both the public and members of the medical profession recognize that without confidentiality health care will inevitably suffer.

The GMC asserts that a duty of confidentiality arises from a combination of:

- Patient's rights: 'Patients have a right to expect that information about them will be held in confidence by their doctors.'
- and
- Consequentialist reasoning: 'Confidentiality is central to trust between doctors and patients. Without assurances about confidentiality, patients may be reluctant to give doctors the information they need in order to provide good care.'

The right to confidentiality derives ultimately from a right to autonomy. Part of self-determination is deciding who knows what about oneself. Medical consultations consist in a disclosure of information to a health-care professional. The purpose of such information is to treat the patient – it has not been given for any other reason. That information in a sense 'belongs' to the person who disclosed it and ought not to be broadcast to third parties without specific consent. If a health-care professional does not treat patients as autonomous, she is not treating them as equals – in the sense of being rational beings in control of their own lives. The importance of privacy, and by extension confidentiality, is that it forms an intimate part of who we are. Without privacy our very identities would be radically different.

The practice of keeping medical information confidential can also be supported by, or derived



from, consequentialist reasoning. Justice Clark gave the following reasons for maintaining medical confidentiality in an important American case (see discussion of *Tarasoff v. Regents of the University of California*, 17 Cal. 3d 425 in Chapter 3):

1. *Deterrence from treatment* – without the assurance of confidentiality, ‘those requiring treatment will be deterred from seeking assistance’.
2. *Full disclosure* – the ‘guarantee of confidentiality is essential in eliciting the full disclosure necessary for effective treatment’.
3. *Successful treatment* – confidentiality is an integral part of procuring a successful treatment – trust between patient and physician or therapist is essential.



Confidentiality

When thinking about or discussing confidentiality, it is helpful to think in terms of three categories:

1. *A theoretical basis* for confidentiality – such as the right to privacy and the consequential benefits of maintaining such a system.
2. *Professional regulation*, which can include a system of oaths (e.g. the Hippocratic Oath) or guidelines from the Royal Colleges or the ‘Duties of a Doctor’ as laid down by the GMC.
3. *Legal regulation*, which asserts where a common law duty to maintain confidentiality exists and when it can be broken (e.g. Prevention of Terrorism Act 1989).

When can confidential information be disclosed?

The GMC has outlined that confidential information about a patient can be disclosed:

- With the patient’s consent (or the consent of a person properly authorized to act on the patient’s behalf, e.g. the parent of a young child).
- Within teams:

- in order to provide best care possible
- patient should be informed so as to understand why and when information may be shared between team members
- when disclosure is required for a procedure that has been agreed to, *explicit* consent would not be required, for example giving relevant clinical information to the radiologist when sending a patient for an X-ray
- in an emergency if a patient is unable to give consent, but disclosure would be in the patient’s best interests

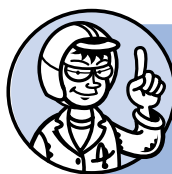
It must be noted, however, that:

- if a patient does not wish you to share particular information with team members, you must respect those wishes
- it is the responsibility of *all* members of the team to ensure that other team members understand and observe confidentiality.
- To employers and insurance companies only with the patient’s *written* consent. The purpose of the consultation (if on behalf of a third party) should be made clear from the outset.
- For the purpose of education, audit or research:
 - inform patient of the purpose of disclosure and that the person given access to the records will be under a duty of confidentiality, and seek their consent
 - as far as possible anonymize the data
 - keep the disclosures to the minimum necessary
 - where research projects are using identifying information, and it is not practicable to inform patients, then this needs to be brought to the attention of a research ethics committee
 - express consent should be obtained before publishing case histories and photos (many journals now require written consent from the patient).
- In the patient’s best interest:
 - if a patient is unable to give consent owing to immaturity, illness or mental incapacity; however the patient should as far as possible be informed of your intention
 - if a patient is a victim of neglect, physical or sexual abuse *and* unable to give valid consent, *and* you believe disclosure will prevent further harm, you should disclose information to the *appropriate* responsible person or statutory agency.
- In the interests of others:
 - if not doing so will lead to a risk of serious harm or death (e.g. contact tracing in HIV); however,



you should inform the patient of your intention to make the disclosure

- if a colleague, who is also a patient, is placing patients at risk
- if disclosure is required for the prevention or detection of a serious crime.
- When it is required by statute or the courts:
 - for example there is requirement by statute to give information under the Public Health (Infectious Diseases) Regulations SI 1988/1546 about certain 'notifiable' diseases [Remember that HIV is *not* a notifiable disease]
 - if ordered to disclose by a judge or the coroner
 - doctors are allowed to object to disclosure if an attempt is made to obtain information about those not involved in a particular proceeding or if irrelevant details are requested.
- After a patient's death:
 - the obligation of confidentiality in general persists after the patient's death
 - there are some instances when disclosure is appropriate. For example, in order to assist a coroner, as part of National Confidential enquiries or other clinical audits, on death certificates, or to obtain information relating to public health surveillance.
- To the Driver and Vehicle Licensing Agency (DVLA):
 - the DVLA is responsible for deciding if a person is medically unfit to drive
 - if a patient has a condition that impairs their ability to drive, you should explain to them that they have a legal duty to inform the DVLA
 - if the patient cannot understand this advice, for example owing to dementia, you should inform the DVLA
 - if patients refuse to accept your diagnosis, you should advise them to seek a second opinion and refrain from driving until that time
 - if a patient continues to drive when they are not fit to do so, you should make every effort to persuade them to stop; this can include telling their next of kin
 - if they cannot be persuaded, you should inform the medical advisor at the DVLA. Inform the patient that this is your intention and write to confirm that a disclosure has been made.



- Although the GMC Guidelines are not legally binding, they are relied upon in court so have a 'quasi-legal' status.
- There exists a key principle that confidentiality *ought* to be maintained, so if doctors make a disclosure, they must be prepared to justify why they did so.

person . . . in circumstances where he has notice, or is held to have agreed, that the information is confidential'. Such a duty is held to apply to doctors.

In addition, the Data Protection Act 1998 provides a statutory duty to maintain the confidentiality of medical records.

The Health and Social Care Act 2001 deals with the regulation of patient information. It allows the Secretary of State to make provision for the disclosure of information in the interests of improving patient care or in the public interest. In particular this allows for the disclosure of patient records to the patient or a prescribed individual on behalf of the patient.

However, there are a number of exceptions to the common law duty of confidentiality (Fig. 2.2). These include:

1. Disclosure in court, for example when a doctor is brought to give evidence on the extent or cause of an injury.
2. If the police request access to records in accordance with the Police and Criminal Evidence Act 1984.
3. 'Notifiable' disease must be reported to the authorities in accordance with the Public Health (Infectious Diseases) Regulations 1988 (SI1988, No. 1546). These include, amongst others, cholera, meningitis, anthrax, diphtheria, measles, mumps, rubella, and tuberculosis (neither HIV nor AIDS is a notifiable disease).
4. In accordance with the Prevention of Terrorism (Temporary Provisions) Act 1989.
5. The Children Act 1989 holds that information pertaining to child abuse must be given if requested by the local authority – it does not oblige doctors to report suspected abuse, although both the GMC and the BMA advise reporting.

Legal regulation of confidentiality

This duty of confidentiality in common law arises where 'information comes to the knowledge of a



Guidance on when doctors should or should not breach confidentiality

When doctors should not breach confidentiality:

For amusement or in conversation

To prevent a minor crime – this would probably include most instances of burglary and property-related crime

To prevent minor harm to someone else

Doctors working in a genitourinary clinic should not provide information to a third party that might identify a patient examined or treated for any sexually transmitted disease (with a few exceptions mentioned below)

To insurers, employers or any other third party without the patient's consent – preferably written

When doctors should breach confidentiality:

Notifiable diseases

Termination of pregnancy

Births

Deaths

To the police on request, e.g. name and address of driver who has committed an offence

Search warrant signed by a judge

Under court orders

When doctors have discretion:

Sharing information with the rest of the health-care team

Patients who continue to drive, but are not medically fit to do so (GMC advises disclosure)

When a third party is at significant risk

The detection or prevention of serious crime

Source: adapted from Hope T, Salvulescu J, Hendrick J 2003 *Medical Ethics and Law: the core curriculum*. Edinburgh: Churchill Livingstone

Fig. 2.2 Guidance on when doctors should or should not breach confidentiality.

Patients' access to health-care records

This is governed by the Data Protection Act 1998. It applies to both computer records and paper records. It outlines eight principles of the act that ensure that:

- Information is processed fairly and lawfully.
- Information is obtained for specified and lawful purposes.
- Information is adequate, relevant and not excessive in relation to the purpose for which obtained.
- Information is accurate and, where necessary, kept up to date.
- Information is not kept for longer than necessary.
- Information is not used in ways contrary to the rights of the data subject (the patient in medical records).

- Appropriate measures are taken to prevent unauthorized disclosure of information.
- Information is not transferred to areas that cannot provide the above assurances.

The Data Protection Act 1998 gives the patient a certain number of rights with respect to their medical records. These include:

- *The right to be informed* about what information is being held, and why.
- *The right of access to personal data*. Patients have a right to a copy of their medical records. They also have the right to have this information communicated to them in a way they can understand it. However, in order to obtain this information, the patient must make a written



request, and may be required to pay a fee (not exceeding a maximum).

- *The right to correct information that is inaccurate.* If a patient feels that the information about them is misleading, they can ask for it to be changed.
- *The right to seek damages as a result of misleading information.*

Clinical dilemma

An HIV-positive patient demands you tell no-one else of his diagnosis, including others of the health-care team. Key points would include:

- Confidentiality.
- Preventing risk to third parties.

What makes HIV/AIDS different from other diseases is that there is still no cure for the disease, that patients can live apparently unaffected for a long period of time (but still be infective) and that there is a degree of stigma associated with the disease.

The ethical thinking behind maintaining confidentiality and not disclosing includes:

- The right to privacy, based on a respect for autonomy.
- The fact that the erosion of confidence in the medical consultation will lead to worse consequences (for example fewer people with HIV seeking treatment).

Factors that might persuade us in this case to break confidentiality would include:

- Not disclosing the patient's HIV status to others (including the patient's partner and potentially other health-care professionals) would mean their being unaware of an increased risk of infection.
- Not telling other members of the health-care team (e.g. the GP) may lead to the provision of inappropriate treatment.

In practice, a reasonable course of action would start with explaining to the patient why you think it is necessary that the health-care team knows about his HIV status. The patient should also be informed that all health-care staff (and students) are under a duty of confidentiality, and in particular, a GP is not well placed to manage the patient's condition unless she is informed about the patient's HIV status. However, with regards to informing a GP, if the patient continues to refuse a disclosure, his wishes in general ought to be respected. Rarely, for example if the patient is violent or severely mentally disturbed,

disclosure to the GP without consent may be appropriate.

What then of disclosing information to the patient's partner? One way of thinking about what to do is to try and weigh up relative benefits and harms caused by disclosure and by non-disclosure. The harm of disclosure is the breach of confidentiality and resultant loss of privacy of the patient. The benefits are the potential avoidance of a serious life-threatening risk to the patient's partner. It seems reasonably uncontroversial that preventing a loss of life is better than preventing a loss of privacy. Some people have argued that doctors have a duty of care only toward patients (not their partners) and as such do not need to look out for the interests of such individuals. This view is not generally accepted.

The GMC advises that you should disclose information in order to protect a person from risk of death or serious harm. However, you must not disclose information to relatives or others who have not been, and are not, at risk of infection. The approach of the courts has been to consider the public interest in maintaining confidentiality (confidentiality encourages patients to seek treatment) against the public interest in disclosure (protection of people at risk).



Confidentiality and HIV

- In general, difficulties that arise around the issue of confidentiality and HIV can be addressed by open and honest discussion with the patient.
- If after counselling, a patient refuses that their GP be informed about their HIV status, then this wish should be respected – unless the doctor is judged to be at risk of infection.
- If after counselling, a patient refuses to inform their partner (who may have been, or is continuing to be exposed to infection), it is not improper to inform the partner against the wishes of the patient. However, the patient must be told of the intention to inform.



Common problems in medical practice

Public expectations of the medical profession have noticeably changed since the advent of the NHS. The attitude of 'doctor knows best' has waned: a sociological change mirrored in ethics by a move from paternalism to the autonomy-based approaches of today. In 1991, the Patient's Charter set out the standards that patients had a right to expect from the NHS. These were presented as ten patient's rights, which included minimum waiting times, levels of information to be provided, the right to treatment on the basis of need rather than ability to pay and so on. The Patient's Charter has subsequently been updated. Further changes have been imposed upon hospitals; over 100 targets (on cleanliness, waiting times, and numbers of procedures and so on) are imposed by central government.

These changes, along with an increasingly litigious and rights-conscious society, have contributed to a more consumerist approach to patients. Indeed, the Patient's Charter refers to patients as 'care consumers'. Much debate has focused on whether the strengthening of patients' rights has helped or hindered the provision of care based on clinical need. It has undoubtedly, however, led to an increased scrutiny of how the medical profession and the provision of care are regulated.

Professional regulation

The Royal College of Physicians came into being in the 16th century. They were the first body to be responsible for examinations and registration of doctors. The British Medical Association (BMA) was established in 1832. The BMA's main function is to protect the interests of its members; it is a trade union for doctors. However, it was the BMA that lobbied for the creation of the GMC. This was established by an Act of Parliament (the Medical Registration Act 1858). The GMC is the governing body of the medical profession. The functions of the GMC are broadly:

- To set professional standards.
- To ensure that those allowed to practise medicine (registered medical practitioners) are fit to do so.
- A supervision of standards of education – the GMC sets out a syllabus for medical schools to follow.
- The enforcement of professional discipline – the ultimate sanction is to 'strike a doctor off the register' either temporarily or permanently.

The GMC sets out guidelines called *Duties of a Doctor* on what it deems to be good practice (Fig. 2.3). These guidelines are important because they represent the opinion of a respected body of medical professionals. For this reason the guidelines are often relied upon in court, and a doctor who has not followed guidelines will be expected to justify why he hasn't.

The NHS complaints procedure

The current NHS complaints procedure was instituted in 1996 by the NHS Executive. It was titled: '*Complaints, Listening . . . Acting . . . Improving: Guidance on Implementation of the NHS Complaints Procedure*'. The aims of this complaints procedure are to provide a simple, responsive way of tackling complaints, with the goal of improving the level of service provided by the NHS. In essence it proposes three tiers of response to complaints. The complaints procedure is an alternative to legal action. If a patient expresses the desire to take a health authority to court, the complaints procedure is stopped.

Most complaints should be dealt with at a local level. This would involve the person about whom the complaint was made responding either in writing or in person to the complainant. Hospital trusts provide a lay conciliator to facilitate such meetings. The idea is that with honest and open communication, the complainant and the person complained about can see each other's points of view, and resolution to the satisfaction of both parties can be achieved.

If a complainant is not satisfied by attempts at local resolution, he/she can request an independent review of the complaint. All Trusts will have a complaints convenor who will decide whether to set up an independent review panel or return the complaint to the local level. There is no automatic right to independent review, and the complainant must state a case for why local resolution has been unsatisfactory.

An independent review panel consists of three lay members advised by clinical specialists. The function of the panel is to investigate the complaint and make a report setting out its conclusions, with appropriate comments and suggestions. It cannot suggest that any person should be subject to disciplinary action or referred to any of the professional regulatory bodies.

The report is sent to the chief executive of the trust, who must then write to the complainant informing them of any action that is being taken as a result of the panel's deliberations and the right of the



The GMC's *Duties of a Doctor*

The GMC produces a number of booklets including the following:

Good Medical Practice

This starts with the principle that:

All patients are entitled to good standards of practice and care from their doctors. Essential elements of this are professional competence; good relationships with patients and colleagues; and observance of professional ethical obligations

It also covers what good standards of practice and care entail, as well as recommendations about how to make medical decisions, how to keep up to date, maintaining trust with patients and colleagues, how to deal with complaints, professional probity and what to do if doctors believe their own health is putting patients at risk

Seeking Patients' Consent: the Ethical Considerations

This starts with:

Successful relationships between doctors and patients depend on trust. To establish that trust you must respect patients' autonomy – their right to decide whether or not to undergo any medical intervention even where a refusal may result in harm to themselves or in their own death

It outlines the necessity of providing sufficient information, responding to questions, where information can be withheld and how to present information to patients

Confidentiality: Protecting and Providing Information

This starts with:

Patients have a right to expect that information about them will be held in confidence by their doctors

Confidentiality is discussed earlier on in this chapter

Serious Communicable Diseases

This starts with the reminder that:

All patients are entitled to good standards of practice and care from their doctors, regardless of the nature of their disease or condition

The booklet gives guidance on how to obtain consent to testing for diseases such as HIV, tuberculosis and hepatitis B and C. It also deals with how to respond to needlestick injuries, research, and disclosure to others

Available as booklets from the GMC or online at www.gmc-uk.org

Other booklets cover research, withholding and withdrawing life-prolonging treatments, management in health care and the new doctor.

Fig. 2.3 The GMC's *Duties of a Doctor*.

complainant to take their grievance to the ombudsman if they remain dissatisfied. It is up to the chief executive to decide whether or not to refer the cases to a professional body (e.g. the GMC) or initiate their own disciplinary procedures.

The ombudsman (or health service commissioner) is a civil servant, independent of the NHS, who is responsible for reporting to parliament about the running of the NHS. It is up to the ombudsman whether or not to further investigate any complaints. It is within his power to ask health-care professionals involved in complaints to appear before a parliamentary select committee in order to give their account of the subject of the complaint. This complaints procedure provides no avenue for the

complainant to be compensated. In order to do this the complainant needs to use the civil justice system, as outlined in Chapter 1.

Dealing with uncertainty and conflict

Medicine has been described as the least accurate of the sciences. The inaccuracy means that sometimes



NHS complaints procedure

- Level 1 – Local resolution
- Level 2 – Independent review
- Level 3 – Ombudsman



treatment is not successful or outcomes are less than hoped for by doctors and patients. Evidence-based medicine (EBM) is the approved approach to dealing with those questions where uncertainty exists. This is dealt with in Chapter 9.

However, what should the doctor 'at the coalface' do when unsure of the way forward? One response has been to practise what has become known as 'defensive medicine'. This is to do the investigations and treatment that will ensure the least chance of being sued, rather than ensuring the best outcome for the patient.

Clinical mistakes and whistle-blowing

Mistakes happen in all workplaces; however, given that medicine does literally deal with matters of life and death, the results of mistakes may be considerably more grave than those made in other walks of life. The Bristol Royal Infirmary Inquiry addressed the question of how to learn from mistakes. This inquiry identified a 'culture of blame and stigma' within the NHS. How then should students and doctors react when they realize they have made a mistake? How should they react if they become aware that one of their colleagues is making mistakes?

If you make a mistake, a reasonable course of action may be to:

- Inform a senior colleague.
- Apologize to the patient and explain why the mistake was made – also explain the consequences of the mistake. The patient may wish to speak to a more senior doctor, and depending on the gravity of the mistake this may be appropriate.
- Inform the patient of the mistake and what steps are being taken to rectify it.
- It is difficult to ethically justify *not* telling the patient that a mistake has been made.

If you believe that a colleague is unfit to practise medicine you could:

- Consider whether or not patients are at risk – your primary concern is the safety of patients.
- If you feel able to, you could approach your colleague directly and voice your concerns. You may be able to reach an agreement whereby your colleague takes time off work and seeks professional help.
- If you are uncomfortable approaching your colleague directly, or your colleague denies there is

a problem, you should voice your concerns to an appropriate person from the employing authority, for example the medical director, or your colleague's educational supervisor. If the concern is about a medical problem such as drug/alcohol addiction, psychiatric illness or a serious infectious disease, you may wish to speak to a consultant occupational doctor (see below).

- You may wish to discuss your options with your defence organization or the GMC.

The Public Interest Disclosure Act 1998, which is sometimes called the 'Whistle-Blowing Act', is designed to protect from victimization and dismissal those employees who report their concerns about the performance of colleagues (to the appropriate authorities).

Occupational health

What then are the sorts of problems that would lead to health-care professionals requiring help from an occupational-health department? The GMC is not completely specific, rather it talks about any condition that leads to a colleague 'placing patients at risk as a result of illness or another medical condition'. One envisages that this could include the following:

- Serious communicable diseases: particularly HIV, tuberculosis, hepatitis B and C. The GMC recommends that if you believe a medical colleague has a serious communicable disease and is continuing to practise *in a way which places patients at risk*, you must inform an appropriate person in the health-care worker's employing authority, such as an occupational health physician. Of course, doctors with disease are allowed to continue to practise; however, they may be restricted in the invasive procedures they perform.
- Psychiatric disorders, including depression (that hinders the ability of the doctor to properly care for her patients), personality disorders and psychotic disorders.
- Alcohol and drug addiction.



It is important to determine whether or not patients are at risk because of the behaviour or illness of the health professional.



Ethics in medical research

A brief history of guidelines and abuse in medical research

~425 BC

The Hippocratic Oath, whilst making no mention of research, does have a clause advocating doing only that which benefits patients: 'Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption.'

1900

Ironically, one of the first codes of conduct was a directive from the Prussian Minister of Religious, Educational and Medical Affairs. According to this directive medical experimentation could be conducted only on competent adults who had consented after a proper explanation of the adverse consequences that might result. This was in force during the Third Reich, but flouted.

1932–70

The US Public Health Service undertook an experiment to study the progression of syphilis. This took place in Tuskegee where up to 400 black men with syphilis were studied. They were denied effective treatment (penicillin) even after it became available.

1940–45

'Medical experiments' were carried out in Nazi Germany under the direction of Dr Josef Mengele. Human subjects were treated like, or indeed worse than, animals in medical research.

1947

World Medical Association (WMA) issued the *Declaration of Geneva* – basically an updated version of the Hippocratic Oath. This includes the phrase: '*The health of my patient will be my first consideration.*'

1949

The Nuremberg Court specified ten points – known as the '*Nuremberg Code*' – as a result of the case *United States v. Brandt*. (Brandt was Hitler's personal physician – although the case also heard 19 other Third Reich doctors and three biomedical scientists; and the trial was conducted under US military patronage.) The ten points included:

1. An *absolute* need for *voluntary* consent.
2. A justification in terms of potential 'fruitful results'.
3. Proper design and previous animal experiments.
4. The avoidance of 'unnecessary physical and mental suffering and injury'.
5. The conduct of the experiment by 'scientifically qualified persons'.
6. The termination of the experiment if it becomes clear that harm will result or if the human subject wishes to bring it to an end.

1954

WMA adopted a Code for Research and Experimentation that allowed proxy consent; effectively a weakening of the position of the Nuremberg Code.

1964

Declaration of Helsinki (updated 1975, 1983, 1989, 1996, and 2000) allowed for some experimentation on human subjects including the very young, the unconscious, and those who lack legal capacity such as the mentally ill. More popular with the medical profession as the Nuremberg Code is more restrictive.

1968

Informal research ethics committees established in the UK after a report by the Royal College of Physicians; these are non-statutory bodies composed of members drawn predominantly from the health professions (although there are some lay members) to consider proposals for clinical trials.

1984 and 1990

Principal guidelines covering research in UK issued by the Royal College of Physicians require that experimentation be subject to ethical review prior to being carried out. The guidelines make a number of recommendations about the review process:

Where the administration of effective treatment is important for the future well-being of the patient, it is ethical for a controlled trial to be undertaken only if, at the outset, the investigator does not know whether the trial treatment is more effective or less effective than the standard treatment with which it is to be compared (or than no treatment at all in the case of a placebo controlled study) – *Author's note: this is the position of equipoise* (see below).

7.99



Withholding effective treatment for a short time . . . can sometimes be acceptable . . . patient consent is necessary and the patient may agree that he need not know precisely when this will take place

7.100

. . . If a patient expresses a strong preference for a particular treatment, he is probably ineligible as a participant

7.103

. . . randomization of treatment without the consent of the patient is unethical

7.105

1991

Department of Health issues guidelines (HSG(91)5) to local research ethics committees.

1997

Department of Health issues guidelines (HSG(97)23) to establish multi-centre research ethics committees.

2000

Declaration of Helsinki revised.

2001

Governance arrangements for NHS research ethics committees. This document provided a framework for the process of review of the ethics of all proposals for research in the NHS and social care.

2001

International Conference on Harmonization – Guidelines for Good Clinical Practice. This sets out an international ethical and scientific standard for research on human subjects. It is consistent with the principles of the Declaration of Helsinki and it aims to provide a unified standard for the European Union, Japan and the USA.

2001

EU Directive 2001/20/EC published.
This directive governs research on human subjects in the EU.

The ethical issues at stake in medical research

Given the starting point that there isn't complete knowledge about how diseases progress and how best to treat them, medical research of some sort is necessary. The benefits of research include reducing future human suffering and contributing to the sum

of human knowledge. However, previous abuses, under the auspices of medical research, require us to remain vigilant in order that the rights of the individual are not ignored. Thus, there exists a tension between reducing future suffering and the rights of the individual.

Medical research in the UK is subject to ethical review by a research ethics committee. In 1991, The Department of Health required that every health district set up a local research ethics committee to scrutinize the ethical justification for local medical research. These committees require a multi-disciplinary approach and commonly consist of lay members, clinicians, and often a philosopher/theologian and/or a statistician/scientist. What then do these committees look for in research proposals? How do they weigh potential public benefit against potential harm to individuals?

1. *The position of equipoise*: In order to carry out medical research, you must be in a position of equipoise – this means that it isn't *known* whether the experimental treatment is any more effective than current treatments. You should have reason to believe that it is, for example it has been demonstrated to be more effective in animal studies, but have no actual evidence. This means there is a responsibility to ensure that the research proposed hasn't already been carried out.
2. *A clear purpose*: You must establish a need for doing the proposed experiment – it is important not only that there is a position of equipoise before the experiment, but that when the experiment is completed, the results will in some way be important. If the experiment is not scientifically valid, then it is unlikely that it will be ethically justifiable.
3. *The principle of least harm*: You should ensure that the experiment's design allows only the minimal amount of harm to befall the individual. This usually means that experiments should compare a new treatment against the current standard treatment, rather than against a placebo. You must demonstrate that the potential benefits are greater than the potential risks of the treatment.
4. *Consent*: Before commencing research, the participants should give their fully informed consent to take part. You must inform patients of the potential risks and benefits, and, if appropriate, whether or not they will randomly



be allocated to a treatment or control group. Patients should be informed that they can refuse to participate – and their refusal will not affect their level of care. Patients should also be aware that they can withdraw from the experiment at any time – and that their withdrawal will not affect their subsequent level of care. Valid consent needs to be informed, voluntary and from a competent patient (see p. 15).

5. *The difference between therapeutic and non-therapeutic research:* Therapeutic research involves giving patients an experimental treatment in order to see how effective it is. Non-therapeutic research involves giving a treatment to healthy individuals. That is, therapeutic research has potential benefits for the patient, whereas non-therapeutic research does not. Many people believe that non-therapeutic research should involve lower levels of risk – because there is little area for benefit. This distinction has been dropped from the 2000 Helsinki Revision, but still has legal force with respect to children and those decisions to include individuals in a trial in their *best interests*.

The philosophical approach one uses can determine whether or not certain risks are acceptable (Figs 2.4 & 2.5).

Research on vulnerable groups

In ethical terms, a vulnerable group is any group that lacks the ability to make informed choices about themselves. Thus, vulnerable individuals include

children, the incapacitated, the mentally ill and groups that may be easily exploited (for example prisoners or those in the third world).

Research in children

The basic problem posed by children is that they are not always able to give valid consent. They may be competent to make some decisions, but not others (p. 49). Children over 16 are able to consent to medical treatment and possibly therapeutic research. Children under 16 *may* be sufficiently competent to give such consent as well. However, if a child is incompetent, consent to participate in research should be obtained from an individual with parental responsibility. Furthermore, the risks of the research must be sufficiently low to say that participating in the research is still in the best interests of the child. Whether or not a child can take part in non-therapeutic research is contentious. However, if the research involves something relatively low-risk, for example taking a blood sample, then it may be ethically defensible to allow such research (assuming the other criteria above were met). If at all possible, it would be better to seek the child's assent to the procedure, even if fully informed consent cannot be obtained.

Research in incapacitated adults and adults with mental disabilities

Research in this group has some parallels with that in children, but unlike the situation with children, in UK law, no-one can consent on behalf of adults. All treatment, which includes being entered for a trial, is

A comparison of three different ethical approaches to research					
	High-risk research where participants are <i>not</i> fully informed	High-risk research where participants are fully informed	Low-risk research where participants are <i>not</i> fully informed	Low-risk research where participants are fully informed	Poor-quality research: low risks but patients are fully informed
Libertarian (rights based)	No	Yes	No	Yes	Yes
Paternalistic (duty based)	No	No	Yes	Yes	?No
Utilitarian (consequentialist)	?No	Yes	Yes	Yes	No

Source: adapted from Hope T, Salvulescu J, Hendrick J 2003 Medical Ethics and Law: the core curriculum. Edinburgh: Churchill Livingstone

Fig. 2.4 A comparison of three different ethical approaches to research.



Fig. 2.5 Phases of clinical trials.

Phases of clinical trials
<p>Phase One:</p> <p>Study of pharmacokinetics and pharmacodynamics</p> <p>Aim to confirm safe dosages for patients</p> <p>Use <i>healthy</i> volunteers</p> <p>Placebo comparisons common</p> <p>Small numbers of participants (order of tens)</p>
<p>Phase Two:</p> <p>Aim to demonstrate efficacy of new agent</p> <p>Use <i>real patients</i> with the disease for which the new agent is intended</p> <p>Comparison with established agent or placebo</p> <p>Larger numbers of participants (order of hundreds)</p>
<p>Phase Three:</p> <p>Aim to demonstrate superiority of new agent</p> <p>Use <i>real patients</i> often in <i>double blind</i> trials</p> <p>Comparison between new agent, existing therapy and if possible placebo</p> <p>Very large numbers of participants required (order of thousands)</p> <p>Results used as basis for request for licensing</p>
<p>Phase Four:</p> <p>Conducted after agent is licensed</p> <p>Aim to determine long-term efficacy and safety</p> <p>Way of refining optimal doses and identifying categories of patients who do not respond to treatment</p> <p>Variable number of participants</p>
<p>Source: adapted from Schwartz L, Preece PE, Hendry RA 2002 Medical Ethics: A case-based approach. Edinburgh: Saunders, p. 193</p>

made on the basis of the patient's best interests. However, it is hard to justify proceeding with experimental treatment on incapacitated adults (for example stroke victims) without consulting relatives first, simply because this shows a willingness to communicate and a desire to find out what the patient's wishes would have been if they were able to express them.

Animal research

The ethics of animal research are not clear cut. There exists a range of animals used in research and it is not obvious that standards appropriate for treating mice are necessarily the same as the standards we think ought to exist for experiments on primates. Furthermore, there exist good and bad experiments; some with the potential to provide significant benefits to mankind and some that won't. As a result, it tends to be a bit simplistic to either say that animal experiments should be allowed or that they shouldn't. Rather more

debate is centred on what sort of potential benefit justifies experimenting on animals.

A useful list of points to consider when deciding whether a particular experiment justifies the use of animals might be as follows:

1. Is the experiment well designed, and will it produce significant results?
2. Could the experiment be done without using laboratory animals?
3. Will animal suffering be maximally alleviated, for example if the experiment involves new surgical techniques, will the animals used be given anaesthetic and analgesic agents as well as agents for muscle paralysis?
4. When using primates for research, consider the following question 'Is this the sort of research we would be happy doing to humans with a mental capacity that is equivalent to that of the animals being used? If not, why are we happy to do it on primates but not the mentally ill?'



A Select Committee on Animals in Scientific Procedures reported in 2002 that:

- It is morally acceptable for human beings to use other animals for research, but it is morally wrong to cause them unnecessary or avoidable suffering.
- There is a continued need for animal experiments both in applied research and in research aimed purely at extending knowledge.
- There is scope for the pursuit of the three Rs of animal research.



The three Rs of animal research:
Replacement of conscious, living animals by non-sentient alternatives

Reduction in the number of animals needed to obtain information of a given amount and precision

Refinement of procedures so as to produce the minimal amount or severity of suffering experienced by those animals which have to be used.

Why is resource allocation necessary?

The usual answer to this question is that resources (money, doctors and other health professionals, equipment and so on) are not infinite, thus scarcity becomes inevitable. With scarcity comes a need to decide who receives treatment and who does not.

Remember: whilst resources are not infinite, they are not finite either – they are indefinite. Any budget can be traded off other budgets – priorities can be reassessed – so if this year the budget for the NHS is £130 billion, it could be increased next year if people are happy to pay higher rates of tax. Demand for a service is not inevitably infinite – rather ‘the amount demanded of a free service is determined at the point where customers see no additional benefits to be gained from additional recourse to the service in question’. This can be at quite modest levels (Harris 2001).

Having said this, it is generally accepted that some decisions have to be made with regard to the allocation of resources. If this is the case, what are the grounds upon which rationing decisions could be made? The following are some suggestions regarding the grounds upon which we could choose between claimants:

- Increase in *quantity* of life as a result of treatment.
- Increase in *quality* of life as a result of treatment.
- *Prognosis* – treat those with the best *chance* of a successful outcome.
- Past *contribution* or future (expected) *contribution* to society – who has paid the most taxes? Or will do in the future?
- *Personal responsibility* – should smokers and alcoholics have equal access to health care as people without such harmful habits? What about skiers and people injured whilst quad biking? What about risky professions, such as firemen?
- *Moral character* and fault – de-prioritize treatment for those seen to be at fault, such as drunken drivers in accidents?
- *Triage* – immediate treatment will help? Can wait but need treatment? No point treating?

In the rest of this section a number of alternative theoretical foundations for deciding how to allocate scarce resources will be analysed.

Quality adjusted life years

The quality adjusted life years (QALY) theory is an approach to cost-effectiveness and is a *utilitarian* theory (see also p. 78). It attempts to bring two

Ethics in resource allocation

Resource allocation within the NHS is one of the most intractable ethical problems. No health service in the world is able to provide the best available treatment for every single patient that could benefit from it. The NHS, in attempting to provide a ‘cradle to the grave’ service, largely without a private sector input, is more stretched than most.

Broadly speaking there are two levels of resource allocation:

1. Micro-allocation: decisions about treatment between patients.
2. Macro-allocation: decisions over the share of a society’s total resources which are devoted to health, and the division of the health-care budget between possible uses (Harris 2001).

Doctors tend to be concerned with decisions of micro-allocation, i.e. deciding which patients get which treatments. Health Authorities and the Government make decisions regarding macro-allocation.



considerations into a single framework when assessing the cost-effectiveness of health-care interventions:

1. Quality of life
and
2. Quantity of life.

These two criteria are used because both are thought to be central to the purpose of health care. Medicine is not seen simply as a method of saving lives (increasing *life years*); part of its role is to alleviate suffering, that is improve *quality*. QALYs combine both criteria in a single measurement.

This theory was developed by Williams, who wrote:

The essence of a QALY is that it takes a year of health life expectancy to be worth 1, but regards a year of unhealthy life expectancy as worth less than 1. Its precise value is lower the worse the quality of life of the unhealthy person (which is what the 'quality adjusted' bit is all about).

(Williams 1985)

This theory allows health-care interventions to be scored according to how many QALYs they result in. When this is considered along with the cost of an intervention, health interventions can be considered in terms of *cost per QALY*. This allows cost-effective analysis to take place. Without such a system, it can be hard to compare widely divergent medical treatments.

QALYs allow two sorts of decisions to be made when choosing health care. These are:

1. To determine which therapy is given to an individual patient: this is effectively a decision made according to the rules of evidence-based medicine.
2. To determine which patients receive treatment at all: a cost-effective analysis.

Like utilitarianism, QALYs are popular because they tap into two main moral intuitions. First, that we *ought* to promote *well-being* as measured: the 'quality' part, and, second, that we *ought* to *maximize* the amount of well-being: the 'quantity'.

Objections to quality adjusted life years

Two of the major problems with QALYs are:

1. QALYs are arguably *unjust*.
2. QALYs are arguably *difficult to calculate practically*.

The argument from justice claims that QALYs are systematically biased against certain sections of the population and that this means they are an unfair

basis upon which to allocate resources. Those groups which aren't favoured by the QALY system include the disabled, the chronically ill and the elderly. This bias is illustrated by considering the following case.

Imagine Tom, Dick and Harry are in a car crash. Tom is 20 years old with no previous disabilities. Dick is also 20 years old and is blind. Harry is 40 and was previously well. The car crash results in all three sustaining similar injuries, for example a fractured pelvis. They all arrive at A&E at the same time, but the hospital has enough resources (for example orthopaedic surgeons or blood) for only one patient.

Assuming that all three patients could be returned to the same level of health they had before the accident, the QALY system would oblige the hospital to treat Tom over the other two. The reasons for this are that Tom will live longer than Harry (assuming both have an average life-span), therefore, even though both can be returned to perfect health, treating Tom will lead to a greater number of QALYs being accrued. (Assuming the average life expectancy to be 75, treating Tom will lead to 55 QALYs versus 35 QALYs for Harry.) Whilst many people think that we should treat children in preference to the very old, it becomes less clear whether we should treat 20 year olds instead of 40 year olds, or 30 year olds instead of 35 year olds.

Tom will also be treated in preference to Dick, although both have the same life expectancy. Because Dick already has a disability, treating his fractured pelvis will not restore him to *perfect* health. Each year of life after treatment will be worth less than 1 on the QALY scale – so his total expected QALY score will be less than 55. John Harris has called this problem 'double jeopardy' (Harris 1995); not only does Dick have the misfortune to be blind, but this disability can also, under the QALY system, adversely affect the priority assigned to him in receiving treatment for an unrelated injury.

The problem of *calculating* QALYs is a more practical difficulty. For example, how can we compare the quality of life of being blind as against that of being paralysed? The answer tends to depend both on how the question is asked and which groups of individuals answer the question. Disabled groups tend to rate their quality of life much higher than do non-disabled groups.

Rawls' theory of justice

John Rawls utilizes a hypothetical device he calls the '*veil of ignorance*' – this is part of an explanatory model to explain an ideal social contract – for Rawls



this is the type of contract it would be rational to choose if we had been given the chance. Unlike the QALY theory, the supreme goal in Rawls' theory of justice is not maximization of welfare as such, but treating those who have the greatest need for treatment. This theory emphasizes fairness rather than absolute welfare.

Rawls supposes:

- Humans are rational.

and

- Humans are self-interested.

Thus, in order to further fairness (justice), steps must be taken to avoid selfish interest in the original position (from which the social contract is made) as follows:

1. If people are self-interested, they will seek advantages at the expense of others whenever they can.

BUT

2. If people did not know how to advantage themselves, they would not 'rationally' try to advantage themselves.

HENCE

3. The veil of ignorance disguises salient information that they could use to advantage themselves.

THEREFORE

4. If we can suppose what the social contract would have been, had it been designed from behind a veil of ignorance, it would be just (i.e. fair).

AND

5. If we could be sure of this, it would also be fair to hold people to this in the real world.

Working under this model, Rawls produced two important principles:

1. People would choose to have an equal right to the most extensive basic liberties compatible with everyone having those liberties: that is, there would be **MAXIMUM FREEDOM**.
2. Because people are rationally self-interested, they will adopt a **MAXIMIN POLICY** (i.e. a worst-case scenario). As people don't know where they will be in society, they will accept the prudence of making the situation of those on the



- Why is telling the truth important?
- Name a principle that would lead to truth-telling and one that would lead to non-disclosure of information.
- What legal cases have set precedents in the disclosure of risk?
- Who decides what constitutes a *real* risk?
- What is paternalism? What are three arguments for it and three against it?
- What are the problems with asserting there is a '*right not to know*' information?
- What is necessary for *informed consent*?
- What is the *Re C Test* used for?
- What is the *Bolam Test* used for?
- How should doctors act in cases where the patient is incompetent?
- When can confidential information be disclosed?
- Which statutes grant patients access to their health records?
- What is the role of the General Medical Council?
- Outline five ethical issues at stake in medical research.
- What is the difference between micro-allocation and macro-allocation?
- Outline three problems with QALYs.
- What is the *veil of ignorance*?



lowest rung as good as possible (MAXimum welfare for the MINimally well off).

References

- Gert B, Culver C 1979 The justification of paternalism. *Ethics* 2(199–210): 204
- Harris J 1995 Double jeopardy and the veil of ignorance – a reply. *Journal of Medical Ethics* 21: 151–7
- Harris J 2001 Micro-allocation: deciding between patients. In: Singer PA (ed.) *Companion to Bioethics*. Oxford: Blackwell Publishers

- Häyry H 1998 Paternalism. In: Chadwick R (ed.) *Encyclopedia of Applied Ethics*, Vol. 3. London: Academic Press
- Williams A 1985 The value of QALYs. *Health and Social Service Journal* (Centre 8 Supplement) pp. 3–5

Further reading

- General Medical Council 2000 *Confidentiality: Protecting and Providing Information*. London: General Medical Council
- Rawls J 1972 *A Theory of Justice*. Oxford: Oxford University Press
- Singer PA (ed.) 2001 *Companion to Bioethics*. Oxford: Blackwell Publishers

