including verifying mental competence for execution, fitness for flogging or supervising judicial amputations or mutilations. In the BMA's view, doctors should not participate in such procedures. The Association believes that medical participation gives a spurious humanity and respectability to corporal punishment.

On the question of the artificial feeding of prisoners on hunger strike, the BMA supports the World Medical Association's Declaration of Tokyo, which states that when prisoners refuse nourishment and are considered by the doctor to be capable of forming an unimpaired judgement, they shall not be fed artificially. The Association recommends that prisoners be clearly informed in advance of the doctor's policy regarding resuscitation during hunger strike. A doctor who has any doubts about a prisoner's intention, or who is asked to treat an unconscious prisoner whose wishes the doctor cannot ascertain, must strive to do the best for that prisoner. This might involve resuscitating the prisoner and providing artificial feeding.[22]

Doctors in an increasing number of countries may also be asked to participate in operations to remove organs from prisoners following execution. Even though a form of prior consent is obtained from such prisoners, the BMA does not believe that this can be truly considered as valid and voluntary consent. It has condemned such practices.

1:4.3 *Members of the armed forces*

Members of the armed forces tacitly consent to give up some of the freedoms of civilian life in the interests of the unit as a whole. Confidentiality and the right to decline treatment are areas where servicemen and their families are likely to experience constraints or pressures. Although doctors in the armed forces have a duty to obey any lawful command, they also have the same ethical duties as other doctors to ensure that patient autonomy is not improperly compromised. This issue is discussed further in chapter 9 (section 9:9).

1:5 Treating without consent

As is mentioned in section 1:3 above, there are circumstances which justify treatment or diagnostic procedures even though the patient cannot consent.

It is sometimes argued that doctors should be able to carry out procedures they consider to be appropriate without specifically informing the patient, thus sparing the patient anxiety. As is stressed throughout this book, however, the BMA favours frankness between doctor and patient whenever possible. It considers that doctors should generally be prepared to discuss their uncertainty where appropriate. The Association does not consider it appropriate to carry out HIV-testing, for example, without patient consent.

1:5.1 *HIV-testing*

Ethically and legally, no treatment or diagnostic procedures should be undertaken without the valid consent of the competent patient. Some diagnostic procedures, particularly HIV-testing, have such profound implications for the patient that specific patient consent is deemed indispensable. Counselling is an essential prerequisite to HIV-testing.

The BMA is opposed to the compulsory testing of either patients or doctors.[23] It has long been committed to the view that testing must only take place with consent unless very exceptional circumstances justify other action. The General Medical Council has also firmly rejected HIV-testing without specific consent, save in the most exceptional circumstances. It requires doctors to be prepared to justify decisions to test in the absence of patient consent.

It is often suggested that wide testing should be encouraged in the population. Some evidence implies benefits for the HIV-infected individual in early establishment of HIV-status since, with treatment, the onset of AIDS might be delayed. Pre-test counselling should include mention of both the potential advantages and disadvantages of testing. The BMA supports the opportunity for all pregnant women to undergo screening for HIV-antibodies. When testing is routinely offered, it must still be accompanied by thorough counselling so patients can make an informed choice and have the time to discuss the matter with partners or people close to them, if they wish.

1:6 Refusal of treatment

Competent adult patients have a clear right to refuse treatment for reasons which are "rational, irrational or for no reason".[24] In such cases, the doctor should seek to explore the patient's motive for refusal and correct any misunderstanding, advise the patient of the increased risks of non-treatment and, if appropriate, other treatment options. No pressure should be brought to bear but the patient should be allowed time to consider the information.

Patients are sometimes asked to sign a declaration stating they have refused a particular treatment and that they accept responsibility for declining medical advice (see 1:2.3 above). The legal validity of such a document would partly depend on how much information had been given to the patient. It may prove an adequate legal defence if the doctor records in the patient's notes that testing or treatment has been refused. It may not be so, if the doctor has not given the patient sufficient information or help.

In some cases, refusal of the treatment recommended by the doctor may indicate that the doctor-patient relationship has broken down and the patient may require a transfer to another doctor. If this is not the case, the

BRITISH MEDICAL ASSOCIATION – MEDICAL ETHICS TODAY – ITS PHILOSOPHY AND PRACTICE – 1993

litigation has begun.[57] If asked by a court to disclose information in breach of confidentiality, the doctor should explain why such disclosure should not be made. It may, for example, reveal sensitive information about third parties unconnected with the action. The court may take this into consideration and hear evidence in camera, but if the judge or magistrate orders the doctor to answer questions, the doctor must do so or be held in contempt of court. A former Master of the Rolls, Lord Denning, summarised the situation, thus:

> "Take the clergyman, the banker or the medical man. None of these is entitled to refuse to answer when directed to by a judge. Let me not be mistaken. The judge will respect the confidences which each member of these honourable professions receives in the course of it, and will not direct him to answer unless not only is it relevant but also it is a proper and, indeed, necessary question in the course of justice to be put and answered. A judge is the person entrusted, on behalf of the community, to weigh these conflicting interests - to weigh on the one hand the respect due to confidence in the profession and on the other hand, the ultimate interest of the community to justice being done".[58]

2:4.4 *A duty to society*

It may be considered an offence to conceal information about a serious crime and doctors have little problem in judging whether to co-operate with police or other authorities when information clearly concerns lives being put at risk. There are some legal arguments, which appear persuasive, that doctors may have a positive duty to disclose in such circumstances. It has been suggested, for example, that a doctor who knew that a patient was driving incompetently but failed to take any action, might be liable in damages for negligence to anyone harmed by the patient on the road.[59] Some legal experts have considered such a scenario improbable although the BMA was informed of a civil action on precisely this issue in 1992. The Association, however, would hesitate ever to tell doctors that they had a "duty" to breach confidentiality in any particular circumstance. Ultimately, this must be a matter for the doctor's clinical decision, since it is the doctor who must defend it if called upon to do so.

It is argued that when some foreseeable harm is in view, people who have a special relationship either with the dangerous person or potential victim(s) have a duty to take some action to avoid it. The doctor-patient relationship is a special one in this sense. The full extent of the doctor's duty, and legal liability if the doctor fails to act, is unclear. In one case,[60] the appeal court ruled that, although there is a public interest in maintaining confidentiality, this is rightly overridden by the need to protect the public against a real risk of danger. Even when the risk of danger is indisputable, the doctor must ensure that information is only

given to an appropriate person and not disclosed indiscriminately. It follows that doctors may be justified in disclosing information about patients who are dangerous drivers to the medical officers of the Driver and Vehicle Licensing Authority but not to the Sunday newspapers. Fitness to drive is discussed in more detail in 2:4.4.2 below.

The decision about disclosure is most problematic when the degree of risk is ill-defined or not immediate. Some doctors, for example, refuse to disclose information to the police about past activity by paedophiles if the patient is undergoing active or residential treatment, on the grounds that no individual is actually at risk. Issues concerning disclosure without consent are a matter for clinical judgement and doctors must be prepared to defend whichever decision they make.

2:4.4.1 *HIV infection*

An increasing preoccupation as regards confidentiality concerns HIV infection. Fear associated with its fatal prognosis, together with its connotations of drug addiction and homosexual orientation, despite the fact that sufferers increasingly defy such facile labelling, leads to considerable stigmatisation. In addition, HIV-positive patients are vulnerable to practical disadvantages in numerous ways which leads them to particular anxiety about the confidentiality of their status.

Some see HIV as a flashpoint, where public and private interests clash. It is sometimes said that the individual's interest in privacy may be superseded by a public interest in protecting health workers or patients and others who might be at risk to exposure to body fluids. This is not an argument which the BMA supports. Public debate on the issues occurred in 1988 when health authority employees sought to divulge to the media information about two practising doctors who were being treated for AIDS. The court did not accept that disclosure was in the public interest since it might deter others from seeking treatment. The judge maintained that "in the long run, preservation of confidentiality is the only way of securing public health; otherwise doctors will be discredited as a source of education".[61]

HIV infection also gives rise to dilemmas concerning the sharing of such information between doctors. It is usual to infer that in cases where necessary medical information is exchanged between doctors responsible for the patient's care the original consent covers this transaction. In respect of HIV infection, patients sometimes prohibit the passing on of such information to other doctors. Some doctors have consequently been accused of being over-protective of confidentiality by respecting the patient's instruction. Clearly, such restrictions are likely to hinder the provision of optimum treatment to the patients, who must be made aware of that fact. Nevertheless, the competent patient must retain the right to make such decisions even if they entail therapeutic disadvantages.

It is sometimes predicted that doctors will be confronted by mounting dilemmas about patients who refuse to disclose their HIV status to their sexual partners or, in the case of drug abusers, to people who share needles with the patient. How much this reflects a genuine problem is difficult to ascertain, although at least one case, sensationalised by the media in 1992, of a young man who apparently knowingly risked infecting several women, indicates that the problem is not a theoretical one for doctors. Such cases, however, appear to be exceptional. If the patient understands the implications of behaviour which endangers others but refuses to modify it or to share information with sexual partners, so depriving them of the opportunity to make an informed choice, there is a strong case for the doctor breaching confidentiality after warning the patient of this intention. Doctors must first seek to persuade the patient to either discontinue all behaviour which puts others at risk, to disclose the information voluntarily or to consent to the doctor so doing. The doctor may be considered to have a duty in very exceptional circumstances to disclose information to a particular individual or to a responsible authority, capable of restraining the patient's behaviour. Magistrates have powers under the Public Health (Infectious Diseases) Regulations 1985 to order compulsory treatment and examination of people who have, or are suspected of having AIDS or to be HIV-positive, if such individuals pose a real risk to others. Doctors would need to think very carefully about the genuineness of the risk. These powers appear to have been invoked only once in the case of a patient with AIDS.[62]

As stated previously, the BMA does not seek to lay down "blanket" rulings in such situations and recognises that there may be scope for negotiation with patients which allows them to make the disclosure at their own pace, without exposing others to risk. However, if the patient does not admit to such behaviour the doctor is faced with the difficult problem of assessing the extent of the risk of the patient infecting someone else. It is to be hoped there will be few such cases that cannot be resolved by education and counselling. Doctors must bear in mind that they may have to justify the decisions they take: where there is any doubt, advice should be sought in confidence from professional bodies.

2:4.4.2 Fitness to drive

Much attention has been paid to assessing medical fitness to drive, particularly in relation to assessment of patients with diabetes, epilepsy, defective eyesight or cardiac conditions. In 1992 some avoidable fatalities were drawn to the BMA's attention by coroners who sought specific ethical advice about doctors' duties in relation to patients who are dangerous drivers. In this and all other cases of dangerous behaviour, the BMA emphasises that the principal onus to take action must fall on the individual who knowingly puts others at risk. Doctors, however, have a

duty to inform patients that they should not drive when, in the doctor's opinion, it would be dangerous to do so. If there is disagreement or uncertainty as to the extent of the patient's impairment, doctors should draw to patients' attention the importance of obtaining an objective view from a driving examiner. Individuals with suspected impairment can obtain independent evaluation of their driving skills at specialised driving assessment centres.

Having informed the patient of the danger of driving, doctors must actively encourage the patient to inform the licensing authorities and must indicate that they will do so themselves if the patient continues to drive. This may require further follow-up. Doctors should ask patients to return after considering the matter and inform them of the action they have taken. Patients should be aware that withdrawal of licence is not necessarily automatic, since options exist for a second medical opinion and an independent assessment of driving competence. In exceptional circumstances doctors may consider breaching confidentiality in the public interest, if they deem this appropriate. A separate question concerns the liability of doctors who fail to take action to protect members of the public. As noted above this is not, as yet, clear in law.

Elderly drivers are a group which might be expected to represent an increasing risk to other road-users for health reasons and yet there are no standard procedures for assessing their competence. The DVLC does not request a driver to undergo a medical examination unless it has received a report questioning that driver's ability. It requires drivers over the age of 70 to indicate that they consider themselves fit to drive but there is no requirement that this statement be supported by a medical opinion. Problems of failing vision and cataracts in elderly drivers might be thought to be obvious hazards about which eye specialists would counsel patients. In practice, this does not seem to be the case and the Association considers it necessary to draw this matter to the attention of such eye specialists.

Furthermore, many patients with dementia continue to drive despite significant deterioration in ability. This raises problems about defining the onset of dementia. Whilst the Association considers it would be entirely inappropriate to expect doctors accurately to judge a person's competence to drive in the absence of any clear medical condition, it feels they should take the opportunity to raise the question with patients if it seems appropriate. Clearly, doctors may be placed in an invidious position since they do not have the advantage of seeing the person actually drive, but in some cases the patient's incompetence to drive because of a medical condition would be patently obvious.

Doctors have a duty to raise the issue of ability to drive when they know that a patient suffers from a visual impairment or medical condition which makes driving hazardous. Some assume that such a duty applies only to

seems to have been more theoretical than practical". The daughter died on the day after the transplantation of the tumour into her mother and the mother died a year later of diffuse melanoma that metastasised from a small piece of the transplanted tumour.

In 1967, in England, Pappworth published his influential study, Human Guinea Pigs,[244] which laid the groundwork for the establishment of regional committees to supervise research. It was hoped that by subjecting each research project to the scrutiny of these committees blatantly unethical practices would be eliminated. Unfortunately, the efficacy of the review system has often been questioned. A notable example of its ineffectiveness was provided in 1981 when an elderly widow died from the effects of an experimental drug used in a trial which had the approval of eleven ethics committees. Her death was caused by bone marrow depression induced by the drug. The patient had been included, without her knowledge, in a randomised controlled clinical trial of the new drug. At her inquest, attention was drawn to the fact that patients could be subjected to a risky procedure without their knowledge or consent. The chairman of one of the committees which had approved the trial argued that the patient's consent to surgery for cancer extended to related, albeit experimental, treatment and that seeking informed consent would involve "unacceptable psychological trauma". The Lancet strongly condemned the study procedure, stating:

> "The fluoroucil trial, involving a portal catheter and a toxic drug, should - on the criteria of both variance from standard procedure and degree of risk - have had special consent... If the patient is not capable of understanding the basic plan of management, he or she should not be included in the trial. No one pretends that these matters are easy for doctor or patient, but it is important that the clinical research exercise remains a partnership built on trust".

Such trust depends upon the observing of high ethical standards which give due prominence to the duties owed to research subjects (see 8:8 below).

8:4.3 *Achieving good standards*

It is not difficult to understand the apprehensions of patients regarding research. Society and the profession must concentrate on building an ethical framework which permits research activities to progress, while at the same time maintaining the public's confidence that individual autonomy is respected. Various measures have been set in train to achieve this. The Department of Health has, for example, commissioned specific training materials for members of local research ethics committees. The King's Fund report[245] draws attention to the confusion experienced by some committees about their role and has given detailed recommendations on both the work of LRECs, and on measures to facilitate good ethical practice.

The various guidelines (mentioned in 8:12 below) also set high standards but do not have the force of law. Nevertheless, influential research bodies have made considerable efforts to promote good practice. The Association of the British Pharmaceutical Industry (ABPI) has, for example, voluntarily adopted as policy the European Commission's principles of Good Clinical (Research) Practice in advance of this being mandated by an EC Directive. (These principles are discussed further in 8:8 below.)

Efforts have also been made to eliminate fraud in research. Until recently only one case of clinical research fraud appeared to have been reported, although many in the field believed that some of the data supplied by UK clinical investigators was fraudulent.[246] Common-sense principles for the detection of fraud have been set down by the ABPI, which recommends that any investigator found to have submitted fraudulent data be referred to the General Medical Council or prosecuted for the criminal offence of fraud. The BMA also emphasises that fraud is totally unacceptable and supports such measures to detect and eliminate it.

All recognise that particularly vulnerable groups require special consideration when research is proposed but there is still disagreement about whether and how members of such groups should be included in research. We consider below (8:8) the involvement of minors, the mentally handicapped, psychiatric patients and prisoners in research projects.

8:5 Innovative treatment

Although in the past fears have been expressed about the lack of review or limitation of innovative treatments, nowadays, local research ethics committees are usually asked to approve innovations but may be faced with requests to approve activities which have far wider implications than a merely local application. Examples of this type of activity have included the transplantation of fetal tissue for treatment of Parkinson's disease, intubation of moribund patients for the purposes of organ transplantation and the transplantation of animal organs into human beings. Many would say that such important issues should be aired in public and fear that there may be inherent risks in relying solely on local committee approval. Anecdotal examples can be found of innovative techniques being approved by committees whose membership includes individuals who might be personally interested in promoting the project.

The BMA supports the elaboration of public policy on such issues through debate in a public forum which includes both experts and non-experts.

8:6 Consent

Research brings the risk of causing harm, in the practical sense of possibly damaging or disadvantaging a patient, and of doing wrong, in the

moral sense of ignoring the autonomy of that individual. People are wronged if they are deprived of choice or their values are transgressed on the assumption that the best clinical outcome is necessarily what is best for them. The possibility of harm cannot be entirely eliminated from research but by insisting that patients have adequate information and choice about participation, we minimise the possibility of wronging them.

8:6.1 *Background to the emphasis on voluntary consent*

Following World War II information came out about the atrocities, conducted in the name of scientific experimentation, in concentration camps. This led to serious international concern about the use of non-consenting subjects and has lent a very emotive undertow to the discussion about research, particularly in Europe. Since the Nuremberg Trials, the issue of consent and the amount of information required to make such consent valid, has received more attention than any other ethical issue in biomedical research involving human subjects. The Nuremberg Code and WMA Declaration of Helsinki[247] arose from this concern.

8:6.1.1 The Nuremberg Code[248]

Rule 1 of the Nuremberg Code states:

> "the person involved should have the legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration and purpose of the experiment; the methods and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment".

Most people will strongly refute the existence of even the ghost of a connection between the criminal acts of wartime and present-day research and see no analogy between the two. Nevertheless, this is clearly not an issue for complacency. As a 1991 Lancet editorial indicated:

> "Like other self-evident truths, the need for informed consent has not been universally recognised, even after the Nuremberg judges stated it so plainly. The columns of the Lancet bear witness to research by fraud and research verging on common assault in which patients participated in pure research disguised as clinical investigation or treatment".[249]

It is important, therefore, to reiterate the general principles which govern the seeking of valid consent to research.

8:6.2 *General principles*

Fundamental principles of consent are discussed in chapter 1 where it is seen that the BMA generally lays great emphasis on valid patient consent, freely given after the patient has received as full an explanation as the doctor thinks appropriate, giving due regard to the individual needs of the patient and the Bolam principle (see chapter 1, section 1:2.4). The researcher should inform the subject about potential benefits and risks of the procedure, why it is proposed and the significance in terms of advancing knowledge and the researcher's own stake (if any) in proposing the procedure. Where patients are offered choices, they need information about the alternatives to the treatment recommended by their doctor. When a clinical study is proposed patients need to know about the advantages and shortcomings of conventional treatments as well as the options in the trial. In any situation, the more risky or invasive the procedure, the greater attention must be paid to the patient's understanding of it and consent to it.

There are problems with applying such a view to randomised trials, which are sometimes seen as very stressful. Such trials, by their impersonal nature, take no account of the therapeutic effect of the patient having confidence in the doctor's advice. Given the clinical uncertainty which justifies the trial and the fact that some treatment options may only be available as part of the trial, there is often little meaningful freedom of choice for patients about participation. In any situation, however, treatment decisions are not dictated by clinical reasons alone and patients may have preferences for one treatment rather than another, for personal reasons. Clearly, patients who have such preferences should not participate in any study where their treatment will be randomised. This is discussed further in 8:7.3 below.

As previously mentioned, the BMA supports the general tenets of the Helsinki Declaration. An exception is made in the Declaration of Helsinki to an absolute requirement for patient consent in therapeutic trials but the researcher must justify to the ethical committee the reasons why patient consent should not be sought.

The Department of Health advises that written consent should be required for all research, except where the most trivial of procedures is concerned, and that in cases of therapeutic research, patient consent should be recorded in the patient's medical records.

8:6.3 *Information and information sheets*

8:6.3.1 Informed consent

It is necessary to examine what type of information is needed in order to obtain valid consent. Informed consent is an American rather than a British preoccupation but even so, it is often said that this is a fashionable shibboleth to which the medical and legal professions pay lip-service while neglecting other ethical values. In the context of cancer research in particular, some feel that the requirement to explain fully the limits of medical knowledge undermines patient confidence and may retard the validation of new and possibly more effective treatments by making patients reluctant to participate in trials. Therefore some doctors feel that the duty of beneficence obliges them to conceal uncertainty. The BMA believes that doctors should be frank with patients when there is uncertainty about the merits of various treatments.

Research subjects must be told that they are free to withdraw without explanation or hindrance at any stage of the procedure and, if a patient, with no detriment to their treatment. Patients must know not only the details and risks of the treatment(s) proposed in the trial but also the alternatives open to them if they do not choose to participate in the study. Since much routine research, particularly in general practice, is undertaken at the behest of the pharmaceutical industry, it is important that patients have an accurate perception of their contribution and are not given a false impression of the nature of the study.

8:6.3.2 Full information

In general terms, we talk about giving patients full information and doctors often ask the Association for guidance about what that means. It is clearly impossible for a health professional to convey to the patient a summary of all available information. The Helsinki Declaration requires that every subject "must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail". What is adequate information, will clearly vary with the requirements of the individual patient, the complexity of the procedures proposed and the capacity of the researcher to get across that information. As previously mentioned, patients also need information about the advantages and disadvantages of the alternatives, including those of the conventional treatment and no treatment.

Talk of the duty to provide full information or full disclosure of risks does not advance our understanding of what doctors must tell research subjects. In some cases, one risk may give rise to a host of sub-risks of varying likelihood and one possible outcome of treatment may give rise to a legion of other events, whose statistical predictability is subject to almost infinite variability. It would be entirely inappropriate to say that doctors

should draw the line at mentioning a risk which is one in a hundred or a thousand or one in ten thousand. Common sense must prevail and what is adequate will be interpreted in different ways by different people. What is certain, is that sufficient time must be taken and sufficient skill used, to establish beyond doubt that the research subject understands what is being proposed and freely consents to it.

8:6.3.3 Information sheets

Information sheets are sometimes used as a way of providing research subjects with detail. The BMA supports this practice of providing documentary material but emphasises that written information should be in addition to, not in place of, the opportunity for the individual to pose questions. The King's Fund report[250] sets out criteria for good information sheets. They should deal straightforwardly with the patient, and with the nature of the research, making it clear that the best treatment is not known since if it were, the research would be unjustifiable. It should be made clear that the patient can withdraw and any risk involved by being in the study, however minimal, should be clearly spelled out. The report also maintains that information sheets should mention financial aspects of the project, noting, however, that while some LRECs consider patients might feel pressured to participate if aware that this would attract funding, others feel that patients should be in a position to question the money-making aspect of their participation.

In the United States, patients are often provided with very substantial background documentation, covering not only the possible risks and side-effects relating to the present trial but containing also frank discussion of the sometimes poor results obtained by the conventional alternatives. Some[251] have pointed out the terminology and legal precision of these documents indicate a greater interest in protecting the researcher from a potential lawsuit than empowering the patient. In our view, the aim should be to inform the patient in as much detail as the averagely prudent person might be expected to require and such documents must be combined with the opportunity for further questioning.

Other forms of conveying information to the public, such as books and videos have been proposed and many would welcome further educative work in this area.

8:6.4 *Voluntariness*

Reference to consent is often prefixed by qualifiers such as "real" or "informed". We have discussed what might be understood by informed consent but have greater difficulty in envisaging how "real consent" can be obtained. All acknowledge that such consent is highly desirable but there is considerable scepticism amongst patients and doctors about whether it can be obtained. The balance of power in the doctor-patient relationship

and the vulnerability of patients ensures that patients are influenced by doctors' choices. Indeed, many commentators draw attention to the fact that patients may submissively agree because they wish to please the medical team, to appear co-operative and to be "good patients" or because they have not initially understood fully their options, including the option to say "no". It is important that patients should be helped to feel comfortable about saying "no" when they feel this is the right choice for them. Such problems do not apply only to research but to treatment in general, but may be more acute in the case of research.

8:6.4.1 Pressure

Pressure on patients to participate may be unintended and not perceived as such by the researcher seeking to explain how the study is in the interests of society and future patients. Nevertheless, patients sometimes report that they are left feeling guilty or uncaring if they refuse. Certainly patients should know the reason for the research and its likely future benefits but care must be taken to avoid the impression of direct or indirect pressure to participate.

It is often suggested that the patient's consent should be witnessed or that a person other than the researcher should seek patient consent in order to ensure that no pressure is brought to bear. It is generally envisaged that this role be undertaken by nurses but it is sometimes argued that this simply extends the chain of implicit pressure so that nurses feel obliged to cajole patients on behalf of the doctor. The BMA rejects this argument and sees the independence of nurses as a valuable asset in ensuring that pressure is avoided. It is inappropriate for anyone, including a nurse, to be asked to approach patients about consent unless that person has been trained to do so.

8:6.4.2 Healthy volunteers

In the context of research on healthy volunteers, medical students and others may be pressured by financial considerations or hopes of advancement. Members of the armed forces may also have little option but to agree. In practice, healthy volunteers are often recruited from the researcher's own students or nursing staff. The risk of pressure has led many to believe that the use of medical students and junior staff from the researcher's own department should be discouraged and that stronger guidelines should be brought in to achieve this. The risks and safeguards for healthy volunteers are discussed further in 8:8 below on vulnerable subjects.

8:6.5 *A trusting relationship*

Despite the role of medical students and nurses, the vast majority of research subjects are lay people. Since the 1960s, a heightened awareness

of both civil and consumer rights have firmly and rightly brought in the lay person as partners in decision-making, both as informed subjects and as members of ethics committees. Attitudes about the doctor-patient relationship have changed dramatically over the past 30 years. Patients rightly expect both information and support. The fact that this is not easy for either side is frequently evident but it must remain the goal. A patient's perspective is described by Faulder:[252]

> "Doctors do not like to confess their own doubts and worries; indeed they regard such revelations as a sign of weakness, a threat to the patient's morale and a major offence against the canon of trust in the patient-doctor relationship. But who has established this canon of trust? And why is it that the trust is almost uniquely discussed in terms of the patient's confidence in the doctor? Seldom do we hear about doctors trusting their patients... Trust between two people, if it is to mean anything, must be reciprocal."

This involves health professionals trusting that patients will voluntarily support research if they do not feel suspicious about being entered for trials without their knowledge. Veracity, we believe, is an essential element throughout medicine but particularly so in the difficult area of experimentation. The problems associated with telling patients the truth - that of undermining patient morale and confidence, or of introducing difficult decisions at a vulnerable time, are often laboured but evidence suggests that uninformed patients may also be alarmed, anxious and subject to considerable stress, precisely because they are being kept in the dark.

8:7 Randomised controlled trials (RCTs)

8:7.1 *Background*

At the beginning of this century, controlled clinical trials began to be accepted as a proper method of scientific evaluation. Randomisation was introduced into medical research by Sir Austin Bradford Hill in 1946 with the trial of the antibiotic streptomycin for treatment of tuberculosis. In the early 1970s Dr Archibald Cochrane contributed greatly to the spread of RCTs, seeing them not only as a way of evaluating new treatments but also as an important method for testing traditional procedures seen by some as illogical or outdated.

8:7.2 *Randomisation and the double-blind technique*

Despite their wide use, RCTs remain the most fiercely argued aspect of research and much has been written on the subject. Within the medical profession, there are those who maintain that RCTs are the only effective way to validate treatment options and that it is unethical to subject

considers that it would be incorrect for doctors to pre-empt patient choice and to assume it is necessarily contrary to the patient's interest to provide information. The decision about whether to authorise disclosure must ultimately rest with the patient. Again, patients should be encouraged to exercise their right of access to the report before it is submitted, if it might be detrimental to their interests.

Often patients only give consent for the release of information to their employer or to an insurance company because if it is withheld the employer or insurer will draw adverse conclusions.

The general view is that it is not for the doctor to enquire into the motives or constraints that underlie a consent freely given in full knowledge of the implications. Therefore provided the statutory requirements relating to consent for insurance or employment medical reports have been complied with, the doctor ought to accept the consent given.

There is another point of view which, although a minority point, deserves acknowledgement both because it is carefully argued and also because some of the medical advisers to the trade union movement have urged it upon their trade unions. This view argues that the purpose of confidentiality is to secure a free flow of information between doctor and patient and that this flow is inhibited just as much by the fear that the patient may be placed under constraints requiring consent to disclosure as by the fear of unauthorised disclosure.

Accordingly it is argued that those who seek medical information about an individual should primarily obtain it through an examining doctor relationship and that consent to the release of information given in a therapeutic relationship is only an acceptable alternative where the patient has chosen that option, having had the genuine alternative of being examined by a doctor with whom no previous therapeutic relationship has existed.

9:3.2 *HIV-testing*

Questions are sometimes raised about the inclusion of HIV-testing in pre-employment medical examinations, and discriminatory practices arising against applicants who either decline to be tested or test positive. The BMA is, in principle, opposed to coercive measures being applied to people to oblige them to accept any form of treatment, particularly measures which do not bring benefit to the individual but which might, on the contrary, be extremely disadvantageous. It also condemns employment discrimination based solely on an applicant's HIV status. This practice cannot be justified by reference to the risk of transmission (although the GMC recognises that HIV-positive individuals employed in some areas of the health care sector may represent a hypothetical risk to patients). Nor is it necessarily the case that HIV-positive workers will be incapable of carrying out their jobs solely by reason of their HIV status.

With the exception of sexual, racial and, in Northern Ireland, religious discrimination, the law does not provide a remedy to an individual refused employment on the basis of some discriminatory views of the employer. Employers can therefore refuse to employ applicants who refuse to submit to tests such as that for HIV.

In all circumstances, doctors who carry out HIV-testing have an ethical duty to provide pre-test counselling and to recognise that the applicant may also require post-test counselling, for which arrangements must be made. Further discussion of such testing is included in chapter 1 (section 1:5.1).

9:3.3 *Genetic screening for employment purposes*

As genetic predispositions to disease are increasingly identified it is expected that employers may wish to introduce screening of employees and prospective employees in order to identify those most at risk of developing adverse reactions to hazards in the workplace. Such screening, if implemented with appropriate safeguards, can have benefits for both employers and employees alike. For this to be so, the screening must be optional and should be offered to inform employees about the health risks they may run if they are employed in particular types of work. If an employee is found to have an increased susceptibility to certain occupational illnesses the decision whether or not to accept the risk should be left to that individual. The purpose of the test should not be to exclude people from employment who are considered by the company to be an economic risk, or to avoid the implementation of safer working conditions or practices which would be of benefit to all employees. Furthermore, employees or prospective employees must have the right to refuse genetic screening without prejudice to their employment prospects.

Because of the sensitive nature of genetic information and the possibility that employers might interpret wrongly the significance of such information, the use of genetic screening in the workplace should move forward only very slowly and guidelines or legislation may be required to bring appropriate control to this area.[280]

9:4 Occupational health physicians

9:4.1 *Objectives*

Occupational medicine deals with the effects of work on health and the implications of the employee's health on his or her performance and that of others in the workforce.

The objectives of an occupational health service can be summarised in five points:

- to promote and maintain the health and safety of employees;
- to provide immediate treatment for the sick and injured;