Consent tool kit

BMA

Contents

About this tool kit

The purpose of this tool kit is to act as a prompt to doctors when they are seeking consent by providing answers to common questions raised by this process. The tool kit consists of a series of cards relating to specific areas of consent such as providing treatment to children; consent and research; and obtaining consent for teaching purposes. Separate cards have been produced identifying factors to be considered when assessing competence and determining 'best interests'. Each card is intended to stand alone, although there are some areas of overlap. Cards 1, 2 and 3 will be relevant to all doctors.

The tool kit is not intended to provide definitive guidance on all issues surrounding consent. Indeed, all cards refer to useful guidance, from bodies such as the GMC, the BMA and the medical defence bodies, that should be used in conjunction with the cards. In addition, many of the Royal Colleges produce specific advice for their members: Card 13 lists contact details for organisations from whom further advice can be obtained. The tool kit is designed to raise doctors' awareness about the ethical and legal principles that apply, to dispel some common misconceptions surrounding consent and to help doctors to obtain valid consent from their patients.

The tool kit is available on the BMA's website and NHS Trusts, medical schools and individual doctors may download and adapt it to suit their own requirements. There are no copyright restrictions on this tool kit – please feel free to make multiple copies.

The BMA would welcome feedback on the usefulness of the tool kit. If you have any comments please address them to:

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This is the fifth edition of the BMA's *Consent tool kit*. Information about developments since its publication may be obtained from the BMA's website or by contacting the BMA Medical Ethics Department.

CARD 1

Guidance on seeking informed consent

Publication	Abbreviation on other cards used
Research: The Role and Responsibilities of Doctors General Medical Council (2002)	'Research'
Consent: Patients and Doctors Making Decisions Together General Medical Council (2008)	'Consent'
0-18 Years: Guidance for all Doctors General Medical Council (2007)	'0-18 years'
Taking and Using Visual and Audio Images of Patients British Medical Association (2007)	'Recordings'
Reference Guide to Consent for Examination or Treatment Department of Health (2001)	'DoH'
Medical Treatment for Adults with Incapacity: Guidance on Medico-legal Issues in Scotland British Medical Association (2007)	'Scotland'
Consent, Rights and Choices in Health Care for Children and Young People British Medical Association (2001)	'Children'

The Impact of the Human Rights Act 1998 on Medical Decision Making British Medical Association (2007)	'HRA'
Assessment of Mental Capacity British Medical Association and The Law Society (3rd edition due in 2010)	'Capacity '
The Mental Capacity Act – Guidance for Health Professionals British Medical Association (2007)	'MCA'
Advance Decisions and Proxy Decision Making in Medical Treatment and Research	'Advance decisions'
British Medical Association (2007) Medical Ethics Today: The BMA's Handbook of Ethics and Law	'MET'
Consent to Treatment Medical Defence Union (2004)	'MDU'
Consent to Treatment Medical Protection Society (2002)	'MPS'
Good Clinical (Research) Practice International Conference on Harmonisation (1997)	'GCP'
Human Tissue Legislation British Medical Association (2006)	'HTL'

CARD 2

General information

1 When is it necessary to seek patient consent?

Patient consent is required on every occasion the doctor wishes to initiate an examination or treatment or any other intervention, except in emergencies or where the law prescribes otherwise (such as where compulsory treatment is authorised by mental health legislation). Consent may be explicit or implied. Explicit or express consent is when a person actively agrees, either orally or in writing. Consent can also be implied, signalled by the behaviour of an informed patient. Implied consent is not a lesser form of consent but it only has validity if the patient genuinely knows and understands what is being proposed. The provision of sufficient accurate information is an essential part of seeking consent. Acquiescence when a patient does not know what the intervention entails, or is unaware that he or she can refuse, is not 'consent'.

Consent is a process, not a one-off event, and it is important that there is continuing discussion to reflect the evolving nature of treatment.

2 Who should seek consent from a patient prior to an examination or treatment?

The BMA considers that the doctor who recommends that the patient should undergo the intervention should have responsibility for

providing an explanation to the patient and obtaining his or her consent. In a hospital setting this will normally be the senior clinician. In exceptional circumstances the task of reaffirming consent (see question 4) can be delegated to a doctor who is suitably trained and qualified, is sufficiently familiar with the procedure and possesses the appropriate communication skills.

The GMC makes it clear that the doctor who is providing the treatment or undertaking the investigation will be responsible for ensuring, before starting any treatment or intervention, that the patient has given valid consent. (See also Card 1 list: 'Consent'.)

3 Do certain examinations or procedures require written consent?

Generally there is no legal requirement to obtain written consent but in some cases it may be advisable. A consent form simply documents that some discussion about the procedure or investigation has taken place. The quality and clarity of the information given is the paramount consideration. Consent forms are evidence of a process, not the process itself. Any discussion, however, should be recorded in the patient's medical notes. (See also Card 1 list: 'Consent', 'DoH', 'MET', 'MDU', 'MPS'.)

Some bodies, including the Royal Colleges and the GMC, recommend that written consent is obtained for certain types of procedure. Doctors should familiarise themselves with guidance relevant to their area of practice. The Department of Health

produces a series of model consent forms. These forms, and other information about consent, can be found on the Department of Health's website. There are separate forms and procedures for consent to post-mortem examination.

4 For how long is consent valid?

Consent should be perceived as a continuing process rather than a one-off decision. Where there has been a significant interval between the patient agreeing to a treatment option and its start, or if new information is available consent should be reaffirmed. In the intervening period, the patient may have changed his or her mind or there may have been clinical developments. It is therefore important that the patient is given continuing opportunities to ask further questions and to review the decision. (See also Card 1 list: 'Consent', 'MET', 'MDU', 'MPS', 'DoH'.)

5 Can patients withdraw consent during a procedure?

Patients can change their minds about a decision at any time, as long as they have the capacity to do so.

6 Can a competent patient refuse treatment?

Competent adult patients are entitled to refuse consent to treatment, (except where the law prescribes otherwise such as where compulsory treatment is authorised by mental health legislation), even when doing so may result in permanent physical injury or death. Therefore, for example, a Jehovah's Witness can refuse a blood transfusion even where this is essential for survival.

Where the consequences of refusal are grave, it is important that patients understand this, and also that, for clinical reasons, refusal may limit future treatment options (see also Card 1 list: 'Consent', 'DoH', 'MET', 'MDU', 'MPS'). Doctors must respect a refusal of treatment if the patient is an adult who is competent, properly informed and is not being coerced.

7 Are doctors obliged to follow an advance decision?

Yes, if it complies with certain legal criteria – see Card 9 on Advance Decisions.

CARD 3

Information provision

1 How much information should patients be given in order for the consent to be valid?

The amount of information doctors provide to each patient will vary according to factors such as the nature and severity of the condition, the complexity of the treatment, the risks associated with the treatment or procedure and the patient's own wishes. The GMC counsels doctors to take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment.

A careful balance needs to be struck between listening to what the patient wants and providing enough information in order that the patient's decisions are informed (see also question 2).

The GMC provides helpful guidance on the type of information doctors should provide, such as:

- the purpose of the investigation or treatment
- details and uncertainties of the diagnosis
- options for treatment including the option not to treat
- explanation of the likely benefits and probabilities of success for each option
- the risks such as known possible side effects, complications and adverse outcomes including where intervention or treatment may fail to improve a condition

- the name of the doctor who will have overall responsibility; and
- a reminder that the patient can change his or her mind at any time.

The GMC also reminds doctors:

- to try to ascertain the patient's individual needs and wishes
- not to exceed the scope of the authority given by the patient (except in an emergency where the patient's views are not known)
- to raise with patients the possibility of additional problems coming to light during the procedure and discuss possible action in this event.

Doctors should respond honestly to direct questions from patients and, as far as possible, answer questions as fully as patients wish (see also Card 1 list: 'Consent'). Failure to provide sufficient relevant information could be challenged in law, including under the Human Rights Act (see also Card 1 list: 'HRA'). Although the person carrying out the procedure is ultimately responsible for ensuring that the patient has sufficient information to give valid consent, other members of the health care team have an important role in the provision of information and answering questions. Good quality information leaflets that patients can take away with them can also be a useful way of improving information provision but these should not be seen as an alternative to discussion.

2 What should be done when a patient asks the doctor to make the decision on his or her behalf?

Doctors should explain to patients the importance of knowing the options open to them and what the treatment will involve. If patients still insist they do not want to know in detail about their condition and its treatment, the doctor must still provide basic information about the treatment before proceeding. (See also Card 1 list: 'Consent'.)

3 What should be done where a patient's relative asks the doctor to withhold information from the patient?

Where the patient is competent, doctors should take the lead from the patient. The GMC counsels doctors to seek the views of the patient in such cases. It also reminds doctors that they should not withhold relevant information unless they consider that disclosure of this information would cause the patient serious harm. Although distress could constitute 'harm' to the patient in some circumstances, this is not generally accepted as sufficient reason to withhold relevant information. Careful discussion will be needed if parents request that information is withheld from children. (See also Card 1 list: 'Consent', '0-18 years', 'Children'.)

4 If a patient gives consent for blood to be taken during an examination, is it necessary to specify what tests are to be performed?

Patients should be informed about the purpose of the tests and doctors should be prepared to respond to patients' questions. If doctors need to take blood to test for evidence of a serious communicable disease, patients should be properly informed of the nature and implications of being tested, including the relative advantages and disadvantages, and their specific consent should be obtained. (See also Card 12 on Serious Communicable Diseases, and Card 1 list: 'Consent', 'MET'.)

CARD 4

Emergency treatment

1 Does consent need to be sought for emergency treatment?

Yes, if the patient is competent.

2 Can treatment be provided in an emergency situation where the patient is unable to give consent?

In an emergency, where consent cannot be obtained, doctors should provide medical treatment that is in the patient's best interests and is immediately necessary to save life or avoid significant deterioration in the patient's health. If, however, the patient is an adult and there is clear evidence of a valid advance refusal of a particular treatment (such as a refusal of blood by a Jehovah's Witness) that treatment should not be given. If a patient has appointed a welfare attorney, or there is a court-appointed deputy or guardian this person where practicable must be consulted about treatment decisions. (See also Cards 6 Adults Who Lack Capacity, 8 on Assessing Best Interests and 9 on Advance Decisions and Card 1 list: '0-18 years', 'Scotland', 'MCA', 'Advance decisions', 'Consent' 'DoH', 'MET', 'MDU', 'MPS'.)

3 Can treatment be provided to a child in an emergency situation where there is nobody available to give consent?

Where the patient is under 18 years old in England, Wales and Northern Ireland and under 16 in Scotland and is unable to consent, either because of

lack of capacity or because of illness, anyone with parental responsibility can provide consent (see Card 7 on Children and Young People and Card 1 list: 'Children'). If, however, treatment is required urgently and nobody with parental responsibility is available, doctors can proceed with treatment that is in the young person's best interests (see also Card 8 on Determining 'Best Interests' and Card 1 list: '0-18 years', 'Children').

4 What action can be taken where a patient is unconscious and an unexpected finding is made during the course of a procedure that requires urgent attention?

When obtaining consent for any procedure, doctors should advise the patient of any foreseeable problems that could come to light while the patient is unconscious. This enables the doctor to obtain the patient's consent in advance for necessary treatment should the situation arise. The GMC warns doctors that where they treat outside patient consent their actions may be challenged. Where treatment which has not been discussed with the patient is required as a matter of urgency and it is not possible to wait until the patient has regained consciousness, the guidance contained in question 2 will apply. (See also Card 1 list: 'Consent'.)

CARD 5

Assessment of competence

1 Are adults presumed to be competent to give consent?

Yes. All people aged 16 and over are presumed, in law, to have the capacity to consent to treatment unless there is evidence to the contrary. A patient who is suffering from a mental disorder or impairment does not, necessarily, lack the competence to consent to treatment. Equally, patients who would otherwise be competent may be temporarily incapable of giving valid consent due to factors such as fatigue, drunkenness, shock, fear, severe pain or sedation. The fact that an individual has made a decision that appears to others to be irrational or unjustified should not be taken as evidence that the individual lacks the mental capacity to make that decision. If, however, the decision is clearly contrary to previously expressed wishes, or is based on a misperception of reality, this may be indicative of a lack of capacity and further investigation will be required. (See also Card 1 list: 'Consent', 'Capacity', 'MCA', 'DoH', 'MET', 'MDU', 'MPS'.)

2 Are children and young people presumed to be competent to give consent?

No. There is no presumption of competence for people under 16 and those under this age must demonstrate their competence by meeting certain standards set by the Courts. In England, Wales and Northern Ireland, the central test is whether the

young person has sufficient understanding and intelligence to understand fully what is proposed. In Scotland, a young person is considered competent to make treatment decisions if he or she is capable of understanding the nature and possible consequences of the procedure or treatment. (See also Card 7 on Children and Young People and Card 1 list: '0-18 years', 'Children'.)

3 What factors should be taken into account when assessing competence to consent to treatment?

The assessment of a patient's capacity to make a decision about medical treatment is a matter for clinical judgement guided by professional practice and subject to legal requirements. To demonstrate capacity individuals should be able to:

- understand (with the use of communication aids, if appropriate) in simple language what the medical treatment is, its purpose and nature and why it is being proposed
- understand its principal benefits, risks and alternatives
- understand in broad terms what will be the consequences of not receiving the proposed treatment
- retain the information for long enough to use it and weigh it in the balance in order to arrive at a decision
- communicate the decision (by any means).

In order for the consent to be valid the patient must be able to make a free choice (ie free from pressure). (For other aspects of competence and for practical guidance, see Card 1 list: 'Consent', '0-18 years', 'Children', 'Capacity' 'MCA'.)

CARD 6

Adults who lack capacity

1 Where a patient lacks capacity to consent to treatment, can consent be sought from the relatives?

In England and Wales, the Mental Capacity Act allows people over 18 years of age, who have capacity, to make a Lasting Power of Attorney appointing a welfare attorney to make health and personal welfare decisions on their behalf once capacity is lost. The Court of Protection may also appoint a deputy to make these decisions. Neither welfare attorneys or deputies can demand treatment which is clinically inappropriate. Where there is no welfare attorney or deputy the doctor may treat a patient who lacks capacity, without consent, providing the treatment is necessary and in the patient's best interests. The Act also requires doctors to take into account, so far as is reasonable and practicable, the views of the patient's primary carer (see also Card 1 list: 'Capacity,' 'MCA').

In Scotland, the Adults with Incapacity (Scotland) Act allows people over 16 years of age to appoint a welfare attorney who has the power to give consent to medical treatment when the patient loses capacity. The Court of Session may also appoint a welfare guardian on behalf of an incapacitated adult. Neither welfare attorneys or guardians can demand treatment which is judged to be against the patient's interests. Where there is no proxy decision maker, doctors have a general

authority to treat a patient who is incapable of giving consent to the treatment in question. The Act also requires doctors to take account, so far as is reasonable and practicable, the views of the patient's nearest relative and his or her primary carer. (See also Card 1 list: 'Scotland'.)

In Northern Ireland, no person can give consent to medical treatment on behalf of another adult. As the law currently stands, doctors may treat a patient who lacks capacity, without consent, providing the treatment is necessary and in the patient's best interests (see Card 8 on Determining 'Best Interests'). Even where the views of people who are close to the patient have no legal status in terms of actual decision making, it is good practice for the health care team to consult with them in assessing the patient's best interests. This may also be a requirement of the Human Rights Act. Any such enquiries should, however, be mindful of the duty of confidentiality owed to the patient (see also Card 1 list: 'HRA').

For information about assessing competence see Card 5.

2 Where a patient lacks capacity to consent to treatment and has no relatives or friends who should be consulted?

In England and Wales the Mental Capacity Act requires an independent mental capacity advocate (IMCA) to be consulted about all decisions about 'serious medical treatment' or place of residence where patients lack capacity and have nobody appropriate to speak on their behalf (see also

Card 1 list: 'Capacity', 'MCA'). There is no such obligation in Scotland and Northern Ireland.

3 Can treatment be provided to a patient without seeking consent if he or she is detained under mental health legislation?

Mental health legislation permits doctors to treat a patient compulsorily for a mental disorder, although it is still good practice to explain the treatment to be provided and, wherever possible, to seek the patient's agreement. The legislation does not provide the doctor with authority to proceed where the treatment is for a condition unrelated to the mental disorder. In those circumstances, the patient's competence should be assessed and, if he or she is deemed to lack decision-making capacity, the doctor should act in the patient's best interests. (See also Card 8 on Determining 'Best Interests', Card 5 on Assessment of Competence and Card 1 list: 'Capacity', 'MCA', 'Consent', 'DoH', 'MDU', 'MPS'.)

4 Can a patient who lacks capacity be sterilised if the health care team and relatives agree it is necessary?

The sterilisation of a minor or a mentally incompetent adult will, in virtually all cases, require the prior approval of a court. Unless sterilisation is a necessary consequence of a procedure carried out for therapeutic purposes, such as treatment for cancer, doctors are advised to seek legal advice. (See also Card 5 on Assessment of Competence and Card 1 list: 'Capacity', 'MCA', '0-18 years', 'Children'.)

CARD 7

Children and young people

1 Who can consent to treatment where the patient is under 18?

A young person of any age can give valid consent to treatment or examination provided he or she is considered to be competent to make the decision. At the age of 16 there is a presumption that the patient is competent to give valid consent. Up to the age of 18 in England, Wales and Northern Ireland and up to the age of 16 in Scotland, where the person lacks capacity, a person or local authority with parental responsibility can give consent on behalf of the patient. In some circumstances, the courts will give consent to treatment and/ or examination. (See also Card 5 on Assessment of Competence and Card 1 list: '0-18 years', 'Children', 'Consent', 'DoH', 'MET', 'MDU', 'MPS'.)

2 Who has parental responsibility?

Not all parents have parental responsibility.
In relation to children born after 1 December 2003 (England and Wales), 15 April 2002 (Northern Ireland) and 4 May 2006 (Scotland), both of a child's biological parents have parental responsibility if they are registered on a child's birth certificate.
In relation to children born before these dates, both of a child's biological parents will only automatically acquire parental responsibility if they were married at the time of the child's conception or at some time thereafter. If the parents have never been married, only the mother automatically has parental

responsibility, but the father may acquire that status by order or agreement. Neither parent loses parental responsibility on divorce. Parents who do not have parental responsibility nonetheless play an essential role in determining best interests and may have a right, under the Human Rights Act, to participate in the decision-making process (see Card 1 list: '0-18 years', 'Children', 'HRA'). In some circumstances people other than parents may acquire parental responsibility, for example by the appointment of a guardian or on the order of a court. If there is any doubt about whether the person giving consent is legally entitled to do so, legal advice should be sought.

3 When is a minor competent to give valid consent?

There is no presumption of competence for those under the age of 16 and those under this age must demonstrate their competence. A young person under 16 can consent to treatment provided he or she is competent to understand the nature, purpose and possible consequences of the treatment proposed (see also Card 5 on Assessment of Competence and Card 1 list: '0-18 years', 'Children', 'Consent', 'DoH', 'MET', 'MDU', 'MPS'). Parental involvement should be encouraged, particularly for important or life-changing decisions, but a competent young person's request for confidentiality should be respected.

4 Can a competent minor refuse treatment?

In England, Wales and Northern Ireland, refusal of treatment by competent young people under the age of 18 is not necessarily binding upon doctors

since the courts have ruled that consent from people with parental responsibility, or a court, still allows doctors to provide treatment. Where a competent young person refuses treatment, the harm caused by violating a young person's choice must be balanced against the harm caused by failing to treat. In these cases the courts have said that children and young people have a right to consent to what is being proposed, but not to refuse it if this would put their health in serious jeopardy. In Scotland, it is likely that neither parents nor the courts are entitled to override a competent young patient's decision, although this matter cannot be considered settled. If a competent young person refuses treatment, it would be advisable to seek legal advice and it may be necessary to take the matter to court. (See also Card 1 list: '0-18 years', 'Children', 'Consent', 'DoH', 'MET', 'MDU', 'MPS'.)

5 Where a minor lacks capacity is it necessary to obtain the consent of both parents?

Anyone with parental responsibility can consent to treatment on behalf of a minor who lacks capacity. Where the proposed intervention is controversial, agreement between parents is desirable. If this cannot be achieved, ethical and legal advice should be sought. The courts have held that there is a small group of controversial procedures, such as male infant circumcision for non-medical reasons, which should only be carried out with the consent of both parents or the approval of a court.

CARD 8

Determining 'best interests'

1 What factors should be taken into account when considering what is in a patient's best interests?

A number of factors should be addressed including:

- the patient's own wishes and values (where these can be ascertained), including any advance decision
- clinical judgement about the effectiveness of the proposed treatment, particularly in relation to other options
- where there is more than one option, which option is less restrictive of the patient's future choices
- the likelihood and extent of any degree of improvement in the patient's condition if treatment is provided
- the views of the parents, if the patient is a child
- the views of people close to the patient, especially close relatives, partners, carers, welfare attorneys, court-appointed deputies or guardians about what the patient is likely to see as beneficial; and
- any knowledge of the patient's religious, cultural and other non-medical views that might have an impact on the patient's wishes.

(See also Card 1 list: 'Consent', 'DoH', '0-18 years', 'Children', 'Capacity', 'Scotland', 'MCA', 'MET', 'MDU', 'MPS'.)

CARD 9

Advance decisions

1 What is an advance decision?

People who understand the implications of their choices can state in advance how they wish to be treated if they suffer loss of capacity. An advance decision (sometimes known as a living will) can be of two main types:

- a statement authorising or requesting specific procedures
- a clear instruction refusing some or all medical procedures (also called an advance directive).

2 What form should an advance decision take?

An advance decision can be a written document, a witnessed oral statement, a signed printed card, a smart card or a note of a particular discussion recorded in the patient's file. In England and Wales, the decision should comply with the provisions of the Mental Capacity Act if it is to be legally binding.

3 Who can make an advance decision?

Any person can make an advance decision including an individual under the age of 18, although advance decisions will only be legally binding in certain circumstances (see below).

4 Are advance decisions legally binding?

Advance refusals of treatment have long been legally binding under common law. Advance requests or authorisations have not had the same binding status but should be taken into account in assessing best interests. Following the Burke case in 2005, it is accepted that there is a duty to take reasonable steps to keep the patient alive (eg by provision of artificial nutrition and hydration) where that is the patient's known wish.

In England and Wales, advance decisions are covered by the Mental Capacity Act. Patients who are aged 18 or over who have capacity may make an advance refusal of treatment orally or in writing which will apply if they lose capacity. To be valid and legally binding the advance decision must be specific about the treatment that is being refused and the circumstances in which the refusal will apply. Where the patient's advance decision relates to a refusal of life-prolonging treatment this must be recorded in writing and witnessed. The patient must acknowledge in the written decision that they intend to refuse treatment even though this puts their life at risk. (See also Card 1 list: 'Capacity', 'MCA', 'Advance decisions'.)

In Scotland and Northern Ireland, advance decisions are not covered by statute but it is likely they are covered by common law. An advance refusal of treatment is likely to be binding in Scotland and Northern Ireland if the patient was an adult at the time the decision was made (16 years old in Scotland and 18 in Northern Ireland). The patient

must have had capacity at the time the decision was made and the circumstances that have arisen must be those that were envisaged by the patient. (See also Card 1 list: 'Capacity', 'Scotland', 'Advance decisions'.)

Advance decisions can be overruled if the individual is being treated compulsorily under mental health legislation. However, a valid and applicable advance refusal of treatment for conditions that are not covered by the compulsory powers of the legislation will be binding.

In the case of young people under the age of 18, advance decisions should be taken into account and accommodated, if possible, but do not necessarily have the same status as those of adults. (See also Card 7 on Children and Young People and Card 1 list: 'Advance decisions', '0-18 years', 'Children').

5 Are all advance refusals of treatment legally binding?

An advance refusal is legally binding providing that the patient is an adult, the patient was competent and properly informed when reaching the decision, it is clearly applicable to the present circumstances and there is no reason to believe that the patient has changed his or her mind. If an advance decision does not meet these criterion but appears to set out a clear indication of the patient's wishes, it will not be legally binding but should be taken into consideration in determining the patient's best interests.

In England and Wales, an advance decision is superseded if the patient subsequently gives

someone lasting power of attorney to make that decision. If doubt exists about what the patient intended, the Court of Protection in England and Wales, the High Court in Northern Ireland and the Court of Session in Scotland can clarify the situation. In the meantime, the law supports a presumption in favour of providing clinically appropriate treatment, but where the situation that has arisen is clearly that which was envisaged by the patient, treatment should not be provided contrary to a valid advance refusal. (See Card 8 on 'Determining Best Interests' and Card 1 List: 'Scotland', 'Capacity', 'MCA', 'Advance decisions'.)

CARD 10

Research

1 Is separate consent required for research procedures?

Yes. Doctors must take care to ensure that patients asked to consider taking part in research are given the fullest possible information presented in terms and a form that they can understand. Patients must be aware that they are being asked to participate in a research project and that the results are not predictable. Adequate time must be given for reflection prior to the patient giving consent. Where patients do not wish to receive full information about the research, this may affect the doctor's decision to involve them. (See also Card 1 list: 'Research', 'Consent', 'DoH', 'MET', 'MDU', 'MPS', 'GCP'.)

The storage and use of identifiable human tissue removed from living individuals and the storage and use of identifiable and anonymised human tissue removed after death for research requires consent from the donor, a person with parental responsibility, a 'qualifying relative' or 'nearest relative'. Consent should be documented. Consent is not required for the storage and use of material from living individuals for research where the material has been anonymised, such that the person carrying out the research does not know the identity of the donor, and the research has been approved by a research ethics committee unless this is a requirement of the research ethics committee. (See also Card 1 list: 'HTL').

2 What information should be provided?

Information should preferably be provided in writing and should include: the purpose of the research; the probability of random allocation to treatment; information about trial-related procedures, particularly invasive procedures; arrangements for covering expenses of patients and compensation in the event of trial-related injury. Information should also be provided about confidentiality and the possibility of access to confidential notes by third parties such as regulatory authorities, auditors or ethics committees. Patients must also be aware that they can withdraw at any time without penalty. All written information should be approved in advance by a research ethics committee. (See also Card 1 list: 'GCP'.)

3 Is there a relevant distinction between 'therapeutic' and 'non therapeutic' research?

Research is often divided into two categories of 'therapeutic' and 'non-therapeutic' although this distinction is increasingly challenged. All research that involves particularly vulnerable people (such as children or incompetent adults) must have special safeguards. Whether or not the participant is likely to benefit personally (so-called 'therapeutic research') is one of a number of relevant factors for research ethics committees to consider.

4 Can patients who lack capacity participate in research?

In England, Wales and Scotland it is lawful under the relevant mental capacity legislation to involve adults who lack capacity in research provided it is related to the condition from which they are suffering. The research must be approved by a research ethics committee and it must not be possible to conduct the research involving individuals who retain capacity to consent. Where the research is 'therapeutic' the risks must not be excessive in relation to the anticipated benefits. Where the research is 'non-therapeutic' the risk to the individual must be negligible and any intrusion kept to a minimum.

In Northern Ireland, such research is not covered by statute but it is the generally accepted view that it is lawful under the common law provided it is 'therapeutic' in nature. Advice should, however, be sought from the appropriate research ethics committee. (See also Card 1 list: 'Capacity', 'Scotland', 'MCA'.)

5 Can research take place in an emergency situation where the patient is unable to give consent?

Yes, if the research has approval by a research ethics committee. In December 2006, an amendment to the UK's Medicines for Human Use (Clinical Trials) Regulations 2004 came into force to allow unconscious patients to be enrolled in clinical trials of pharmaceutical products without prior consent in emergency situations.

6 Can a competent minor give consent to participate in 'therapeutic' research?

Current guidance emphasises that, even where the minor is competent to make this decision for him or herself, it would be inadvisable to proceed without the approval of someone with parental responsibility. Researchers should seek the views of the appropriate research ethics committee. (See also Card 1 list: '0-18 years', 'Children', 'Capacity'.)

7 Can children who lack capacity to consent participate in 'non-therapeutic' research?

There is general agreement that participation by immature minors in 'non-therapeutic' research is not necessarily unethical provided that: the research carries no more than minimal risk; it does not entail any suffering for the child; parental agreement is obtained; there is approval from an appropriate research ethics committee; and the child does not appear to object. Nonetheless, researchers should be aware that the law is unclear and therefore legal advice should be sought. (See also Card 1 list: '0-18 years', 'Children', 'Capacity'.)

CARD 11

Teaching

1 Is it necessary to seek the patient's consent for students or other observers to be present at a consultation?

Yes. The doctor carrying out the consultation should explain to the patient that an observer would like to sit in on the consultation, who that person is and why he or she wishes to observe. Patients should feel able to refuse consent to the presence of students or other observers during their consultation and/or examination. They should be reassured that their decision will, in no way, affect their treatment. Wherever possible, patients should be given the option of considering this request prior to the arrival of the observers.

2 Is it necessary to seek consent prior to a patient being questioned and examined by students for teaching purposes?

Teaching hospitals should draw up detailed protocols about the extent to which students will be present during, and involved with, treatment. Patients should be made aware of this in advance and, where students will be directly involved with providing treatment, specific consent should be sought.

3 Is specific consent required to teach additional practical procedures on a patient who has been anaesthetised?

Yes. A patient who is anaesthetised has the same right to give and withhold consent as any other patient. Before any anaesthetic is given, the specific consent of the patient should be obtained to additional practical procedures being carried out solely for teaching purposes.

4 Is it necessary to seek consent from patients for the use of visual and audio recordings of procedures made for teaching purposes?

Yes. It is necessary to seek the consent of the patient prior to a recording being made and for its subsequent use for teaching purposes. In relation to adults lacking capacity the law is untested. In the BMA's view it is difficult to see how such a decision could be in the individual's best interests. Legal advice should be sought on a case-by-case basis for the use of identifiable recordings for reasons other than treatment and research. If the recording is of a child unable to give consent him or herself, consent should be sought from someone with parental responsibility and consent to its continued use should be sought from the child him or herself when he or she is sufficiently mature to make a decision. Patients may vary or withdraw their consent to the use of visual and audio recordings in teaching at any time. If consent is withdrawn, the recording should be erased. (See also Card 1 list: 'Recordings', '0-18 years', 'Children', 'Capacity', 'Scotland', 'MCA'.)

5 What type of consent is required for the use of human tissue for educational purposes?

The storage and use of human tissue removed after death for educational purposes requires consent from the donor, a person with parental responsibility, 'a qualifying relative', or 'nearest relative'. Consent should be documented. Consent is not required for the storage and use of material from living individuals for teaching purposes provided it is anonymised. (See also Card 1 List: 'HTL'.)

CARD 12

Serious communicable diseases

1 Is patient consent required prior to testing for serious communicable diseases in all cases?

Doctors must obtain consent from patients before testing for serious communicable diseases including HIV except in the rare circumstances addressed in the questions below.

2 What information should be provided to the patient?

Doctors must make sure that the patient is given appropriate information about the implications of the test, including the advantages and disadvantages, and wherever possible allow the patient appropriate time to consider and discuss them. (See also Card 1 list: 'Consent', 'MET'.)

3 Where a child cannot give or withhold consent, can consent be sought from a person with parental responsibility?

Yes, if testing is in the child's best interests. If a parent refuses consent to testing, and the doctor believes that person's judgement to be distorted, for example because he or she may be the cause of the child's infection, the doctor must decide whether the medical interests of the child override the wishes of those with parental responsibility. Legal advice should be sought if testing is medically necessary, but parental consent is refused. The GMC also advises doctors to consult with an experienced

colleague. (See also Card 1 list: 'Consent', 'MET', '0-18 years', 'Children'.)

4 What should be done when a health care worker has suffered a needlestick injury or other occupational exposure to blood or body fluids?

If the patient is competent, consent should be sought to test the patient or an existing sample for HIV or other serious communicable disease. Where the patient is unable to consent or refuses to do so, an existing sample may only be tested for HIV or other serious communicable disease if the test is in the best interests of the patient. This may change and up-to-date information can be obtained from the BMA. (See also Card 1 list: 'Consent', 'MET', 'HTL'.)

5 Are there any circumstances when an unconscious patient can be tested for serious communicable diseases?

The GMC indicates that doctors may test unconscious patients for serious communicable diseases including HIV without their prior consent, where testing would be in their immediate clinical interests, for example to help in making a diagnosis. Where a health care worker has suffered a needlestick injury or other exposure to blood or body fluids, consent for the test should be sought once the patient has regained full consciousness. Where a patient does not regain consciousness it is unlikely that it would be lawful to test an existing sample for HIV or other serious communicable disease. (See also Card list 1: 'Consent', 'MET', 'HTL'.)

6 Can a deceased patient be tested for HIV where a health care worker has suffered a needlestick injury or other occupational exposure to blood or body fluids?

The GMC advises that testing of deceased patients for serious communicable diseases should be done only when it is likely to be relevant to the cause of death and a post-mortem examination has been authorised or ordered. If this is not the case, the GMC states that testing should not be done routinely simply to protect health workers. In any instance where there are grounds for believing that a serious communicable disease is present, the GMC advises doctors to assume that the body is infectious and take precautions accordingly. (See also Card 1 list: 'Consent', 'MET'.)

Patients in whom death has been confirmed as brain stem dead may be assessed as suitable organ donors. It should be explained to the relatives or people close to the patient that assessment includes testing for certain infections, including HIV. (See also Card 1 list: 'HTL'.)

CARD 13

Useful names and addresses

British Medical Association
Medical Ethics Department, BMA House,
Tavistock Square, London WC1H 9JP.
Tel: 020 7383 6286,
Fax: 020 7383 6233,
Web: www.bma.org.uk/ethics

Department of Health
Wellington House, 133-55 Waterloo Road,
London SE1 8UG.
Tel: 020 7972 2000,
Web: www.dh.gov.uk

Department of Health, Social Services and Public Safety (Northern Ireland),
Castle Buildings, Stormont, Belfast BT4 3SJ.
Tel: 028 90520500
Web: www.dhsspsni.gov.uk

Faculty of Pharmaceutical Medicine,
1 St Andrew's Place, Regent's Park,
London NW1 4LB.
Tel: 020 7224 0343
Fax: 020 7224 5381,
Web: www.fpm.org.uk

General Medical Council,
Regent's Place, 350 Euston Road, London NW1 3JN.
Tel: 0845 357 8001
Web: www.gmc-uk.org

Health Professions Council, Park House,
184 Kennington Park Road, London SE11 4BU.
Tel: 020 7582 0866
Fax: 020 7820 9684
Web: www.hpc-uk.org

Medical and Dental Defence Union
of Scotland
Mackintosh House, 120 Blythswood Street,
Glasgow G2 4EA
Tel: 0845 275 2034
Fax: 0141 228 1208
Web: www.mddus.com

Medical Defence Union
230 Blackfriars Road, London SE1 8PG.
Tel: 020 7202 1500
Fax: 020 7202 1666
Web: www.the-mdu.com

Medical Foundation for AIDS and
Sexual Health
BMA House, Tavistock Square, London WC1H 9JP.
Tel: 020 7383 6345
Fax: 0870 442 1792
Web: www.medfash.org.uk

Medical Protection Society
33 Cavendish Square, London W1G 0PS.
Tel: 0845 605 4000
Fax: 020 7399 1301
Web: www.medicalprotection.org.uk

Nursing and Midwifery Council
23 Portland Place, London W1B 1PZ.
Tel: 020 7333 9333
Web: www.nmc-uk.org

Royal College of General Practitioners
14 Princes Gate, Hyde Park, London SW7 1PU.
Tel: 0845 456 4041
Fax: 020 7225 3047
Web: www.rcgp.org.uk

Royal College of Nursing
20 Cavendish Square, London W1M 0AB.
Tel: 020 7409 3333
Web: www.rcn.org.uk

Royal College of Obstetricians and Gynaecologists
27 Sussex Place, London NW1 4RG.
Tel: 020 7772 6200
Fax: 020 7723 0575
Web: www.rcog.org.uk

Royal College of Ophthalmologists
17 Cornwall Terrace, London NW1 4QW.
Tel: 020 7935 0702
Fax: 020 7935 9838
Web: www.rcophth.ac.uk

Royal College of Paediatrics and Child Health
5-11 Theobalds Road, London WC1X 8SH.
Tel: 020 7092 6000
Fax: 020 7092 6001
Web: www.rcpch.ac.uk

Royal College of Pathologists
2 Carlton House Terrace, London SW1Y 5AF.
Tel: 020 7451 6700
Fax: 020 7451 6701
Web: www.rcpath.org

Royal College of Physicians
11 St Andrew's Place, London NW1 4LE.
Tel: 020 7935 1174
Fax: 020 7487 5218
Web: www.rcplondon.ac.uk

Royal College of Physicians and
Surgeons of Glasgow
232-42 St Vincent Street, Glasgow G2 5RJ.
Tel: 0141 221 6072
Fax: 0141 221 1804
Web: www.rcpsglasg.ac.uk

Royal College of Physicians of Edinburgh
9 Queen Street, Edinburgh EH2 1JQ.
Tel: 0131 225 7324
Fax: 0131 220 3939
Web: www.rcpe.ac.uk

Royal College of Psychiatrists
17 Belgrave Square, London SW1X 8PG.
Tel: 020 7235 2351
Fax: 020 7245 1231
Web: www.rcpsych.ac.uk

Royal College of Radiologists
38 Portland Place, London W1B 1JQ.
Tel: 020 7636 4432
Fax: 020 7323 3100
Web: www.rcr.ac.uk

Royal College of Surgeons of Edinburgh
Nicolson Street, Edinburgh EH8 9DW.
Tel: 0131 527 1600
Fax: 0131 557 6406
Web: www.rcsed.ac.uk

Royal College of Surgeons of England
35-43 Lincoln's Inn Fields, London WC2A 3PN.
Tel: 020 7405 3474
Fax: 020 7831 9438
Web: www.rcseng.ac.uk

Scottish Executive Health Department
St Andrew's House, Regent Road,
Edinburgh EH1 3DG.
Tel: 0131 556 8400
Fax: 0131 244 2162
Web: www.scotland.gov.uk