General Medical Council

Regulating doctors
Ensuring good medical practice

Seeking patients' consent: The ethical considerations

November 1998

Contents

Guidance to doctors

Being registered with the General Medical Council gives you rights and privileges. In return, you must meet the standards of competence, care and conduct set by the GMC.

This booklet sets out the principles of good practice which all registered doctors are expected to follow when seeking patients' informed consent to investigations, treatment, screening or research. It enlarges on the general principles set out in paragraph 12 of Good Medical Practice (2006).

Introduction

1. Successful relationships between doctors and patients depend on trust. To establish that trust you must respect patients' autonomy - their right to decide whether or not to undergo any medical intervention even where a refusal may result in harm to themselves or in their own death1. Patients must be given sufficient information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care.

2. This right is protected in law, and you are expected to be aware of the legal principles set by relevant case law in this area2. Existing case law gives a guide to what can be considered minimum requirements of good practice in seeking informed consent from patients.

3. Effective communication is the key to enabling patients to make informed decisions. You must take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment. Open, helpful dialogue of this kind with patients leads to clarity of objectives and understanding, and strengthens the quality of the doctor/patient relationship. It provides an agreed framework within which the doctor can respond effectively to the individual needs of the patient. Additionally, patients who have been able to make properly informed decisions are more likely to co-operate fully with the agreed management of their conditions.

Consent to investigation and treatment

Providing sufficient information

4. Patients have a right to information about their condition and the treatment options available to them. The amount of information you give each patient will vary, according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the patient's own wishes. For example, patients may need more information to make an informed decision about a procedure which carries a high risk of failure or adverse side effects; or about an investigation for a condition which, if present, could have serious implications for the patient's employment, social or personal life 3.

5. The information which patients want or ought to know, before deciding whether to consent to treatment or an investigation, may include:

- details of the diagnosis, and prognosis, and the likely prognosis if the condition is left untreated;
- uncertainties about the diagnosis including options for further investigation prior to treatment;
- options for treatment or management of the condition, including the option not to treat;

- the purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief; how the patient should prepare for the procedure;and details of what the patient might experience during or after the procedure including common and serious side effects;
- for each option, explanations of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused by, or necessitated by, the treatment;
- advice about whether a proposed treatment is experimental;
- how and when the patient's condition and any side effects will be monitored or re-assessed;
- the name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team;
- whether doctors in training will be involved, and the extent to which students may be involved in an investigation or treatment;
- a reminder that patients can change their minds about a decision at any time;
- a reminder that patients have a right to seek a second opinion;
- where applicable, details of costs or charges which the patient may have to meet.

6. When providing information you must do your best to find out about patients' individual needs and priorities. For example, patients' beliefs, culture, occupation or other factors may have a bearing on the information they need in order to reach a decision. You should not make assumptions about patients' views, but discuss these matters with them, and ask them whether they have any concerns about the treatment or the risks it may involve. You should provide patients with appropriate information, which should include an explanation of any risks to which they may attach particular significance. Ask patients whether they have understood the information and whether they would like more before making a decision.

7. You must not exceed the scope of the authority given by a patient, except in an emergency[4]. Therefore, if you are the doctor providing treatment or undertaking an investigation, you must give the patient a clear explanation of the scope of consent being sought. This will apply particularly where:

- treatment will be provided in stages with the possibility of later adjustments;
- different doctors (or other health care workers) provide particular elements of an investigation or treatment (for example anaesthesia in surgery);
- a number of different investigations or treatments are involved;
- uncertainty about the diagnosis, or about the appropriate range of options for treatment, may be resolved only in the light of findings once investigation or treatment is underway, and when the patient may be unable to participate in decision making.

In such cases, you should explain how decisions would be made about whether or when to move from one stage or one form of treatment to another. There should be a clear agreement about whether the patient consents to all or only parts of the proposed plan of investigation or treatment, and whether further consent will have to be sought at a later stage.

8. You should raise with patients the possibility of additional problems coming to light during a procedure when the patient is unconscious or otherwise unable to make a decision. You should seek consent to treat any problems which you think may arise and ascertain whether there are any procedures to which the patient would object, or prefer to give further thought to before you proceed. You must abide by patients' decisions on these issues. If in exceptional circumstances you decide, while the patient is unconscious, to treat a condition which falls

outside the scope of the patient's consent, your decision may be challenged in the courts, or be the subject of a complaint to your employing authority or the GMC. You should therefore seek the views of an experienced colleague, wherever possible, before providing the treatment. And you must be prepared to explain and justify your decision. You must tell the patient what you have done and why, as soon as the patient is sufficiently recovered to understand.

Responding to questions

9. You must respond honestly to any questions the patient raises and, as far as possible, answer as fully as the patient wishes. In some cases, a patient may ask about other treatments that are unproven or ineffective. Some patients may want to know whether any of the risks or benefits of treatment are affected by the choice of institution or doctor providing the care. You must answer such questions as fully, accurately and objectively as possible.

Withholding information

10. You should not withhold information necessary for decision making unless you judge that disclosure of some relevant information would cause the patient serious harm. In this context serious harm does not mean the patient would become upset, or decide to refuse treatment.

11. No-one may make decisions on behalf of a competent adult. If patients ask you to withhold information and make decisions on their behalf, or nominate a relative or third party to make decisions for them, you should explain the importance of them knowing the options open to them, and what the treatment they may receive will involve. If they insist they do not want to know in detail about their condition and its treatment, you should still provide basic information about the treatment. If a relative asks you to withhold information, you must seek the views of the patient. Again, you should not withhold relevant information unless you judge that this would cause the patient serious harm.

12. In any case where you withhold relevant information from the patient you must record this, and the reason for doing so, in the patient's medical records and you must be prepared to explain and justify your decision.

Presenting information to patients

13. Obtaining informed consent cannot be an isolated event. It involves a continuing dialogue between you and your patients which keeps them abreast of changes in their condition and the treatment or investigation you propose. Whenever possible, you should discuss treatment options at a time when the patient is best able to understand and retain the information. To be sure that your patient understands, you should give clear explanations and give the patient time to ask questions. In particular, you should:

- use up-to-date written material, visual and other aids to explain complex aspects of the investigation, diagnosis or treatment where appropriate and/or practicable;
- make arrangements, wherever possible, to meet particular language and communication needs, for example through translations, independent interpreters, signers, or the patient's representative;
- where appropriate, discuss with patients the possibility of bringing a relative or friend, or making a tape recording of the consultation;
- explain the probabilities of success, or the risk of failure of, or harm associated with options for treatment, using accurate data;

- ensure that information which patients may find distressing is given to them in a considerate way. Provide patients with information about counselling services and patient support groups, where appropriate;
- allow patients sufficient time to reflect, before and after making a decision, especially where the information is complex or the severity of the risks is great. Where patients have difficulty understanding information, or there is a lot of information to absorb, it may be appropriate to provide it in manageable amounts, with appropriate written or other back-up material, over a period of time, or to repeat it;
- involve nursing or other members of the health care team in discussions with the patient, where appropriate. They may have valuable knowledge of the patient's background or particular concerns, for example in identifying what risks the patient should be told about;
- ensure that, where treatment is not to start until some time after consent has been obtained, the patient is given a clear route for reviewing their decision with the person providing the treatment.

Who obtains consent

14. If you are the doctor providing treatment or undertaking an investigation, it is your responsibility to discuss it with the patient and obtain consent, as you will have a comprehensive understanding of the procedure or treatment, how it is carried out, and the risks attached to it. Where this is not practicable, you may delegate these tasks provided you ensure that the person to whom you delegate:

- is suitably trained and qualified;
- has sufficient knowledge of the proposed investigation or treatment, and understandsthe risks involved;
- acts in accordance with the guidance in this booklet.

You will remain responsible for ensuring that, before you start any treatment, the patient has been given sufficient time and information to make an informed decision, and has given consent to the procedure or investigation.

Ensuring voluntary decision making

15. It is for the patient, not the doctor, to determine what is in the patient's own best interests. Nonetheless, you may wish to recommend a treatment or a course of action to patients, but you must not put pressure on patients to accept your advice. In discussions with patients, you should:

- give a balanced view of the options;
- explain the need for informed consent.

You must declare any potential conflicts of interest, for example where you or your organisation benefit financially from use of a particular drug or treatment, or treatment at a particular institution.

16. Pressure may be put on patients by employers, insurance companies or others to undergo particular tests or accept treatment. You should do your best to ensure that patients have considered the options and reached their own decision. You should take appropriate action if you believe patients are being offered inappropriate or unlawful financial or other rewards.

17. Patients who are detained by the police or immigration services, or are in prison, and those detained under the provisions of any mental health legislation may be particularly vulnerable. Where such patients have a right to decline treatment you should do your best to ensure that they know this, and are able to exercise this right.

Emergencies

18. In an emergency, where consent cannot be obtained, you may provide medical treatment to anyone who needs it, provided the treatment is limited to what is immediately necessary to save life or avoid significant deterioration in the patient's health. However, you must still respect the terms of any valid advance refusal which you know about, or is drawn to your attention. You should tell the patient what has been done, and why, as soon as the patient is sufficiently recovered to understand.

Establishing capacity to make decisions

19. You must work on the presumption that every adult has the capacity to decide whether to consent to, or refuse, proposed medical intervention, unless it is shown that they cannot understand information presented in a clear way5. If a patient's choice appears irrational, or does not accord with your view of what is in the patient's best interests, that is not evidence in itself that the patient lacks competence. In such circumstances it may be appropriate to review with the patient whether all reasonable steps have been taken to identify and meet their information needs (see paragraphs 5-17). Where you need to assess a patient's capacity to make a decision, you should consult the guidance issued by professional bodies6.

Fluctuating capacity

20. Where patients have difficulty retaining information, or are only intermittently competent to make a decision, you should provide any assistance they might need to reach an informed decision. You should record any decision made while the patients were competent, including the key elements of the consultation. You should review any decision made whilst they were competent, at appropriate intervals before treatment starts, to establish that their views are consistently held and can be relied on.

Mentally incapacitated patients

21. No-one can give or withhold consent to treatment on behalf of a mentally incapacitated patient7. You must first assess the patient's capacity to make an informed decision about the treatment. If patients lack capacity to decide, provided they comply, you may carry out an investigation or treatment, which may include treatment for any mental disorder8, that you judge to be in their best interests. However, if they do not comply, you may compulsorily treat them for any mental disorder only within the safeguards laid down by the Mental Health Act 19839, and any physical disorder arising from that mental disorder, in line with the guidance in the Code of Practice of the Mental Health Commission10. You should seek the courts' approval for any non-therapeutic or controversial treatments which are not directed at their mental disorder.

Advance statements

22. If you are treating a patient who has lost capacity to consent to or refuse treatment, for example through onset or progress of a mental disorder or other disability, you should try to

find out whether the patient has previously indicated preferences in an advance statement ('advance directives' or 'living wills'). You must respect any refusal of treatment given when the patient was competent, provided the decision in the advance statement is clearly applicable to the present circumstances, and there is no reason to believe that the patient has changed his/her mind. Where an advance statement of this kind is not available, the patient's known wishes should be taken into account - see paragraph 25 on the 'best interests' principle.

Children

23. You must assess a child's capacity to decide whether to consent to or refuse proposed investigation or treatment before you provide it. In general, a competent child will be able to understand the nature, purpose and possible consequences of the proposed investigation or treatment, as well as the consequences of non-treatment. Your assessment must take account of the relevant laws or legal precedents in this area11. You should bear in mind that:

- at age 16 a young person can be treated as an adult and can be presumed to have capacity to decide;
- under age 16 children may have capacity to decide, depending on their ability to understand what is involved12;
- where a competent child refuses treatment, a person with parental responsibility or the court may authorise investigation or treatment which is in the child's best interests. The position is different in Scotland, where those with parental responsibility cannot authorise procedures a competent child has refused. Legal advice may be helpful on how to deal with such cases.

24. Where a child under 16 years old is not competent to give or withhold their informed consent, a person with parental responsibility may authorise investigations or treatment which are in the child's best interests13. This person may also refuse any intervention, where they consider that refusal to be in the child's best interests, but you are not bound by such a refusal and may seek a ruling from the court. In an emergency where you consider that it is in the child's best interests to proceed, you may treat the child, provided it is limited to that treatment which is reasonably required in that emergency.

'Best interests' principle

25. In deciding what options may be reasonably considered as being in the best interests of a patient who lacks capacity to decide, you should take into account:

- options for treatment or investigation which are clinically indicated;
- any evidence of the patient's previously expressed preferences, including an advance statement;
- your own and the health care team's knowledge of the patient's background, such as cultural, religious, or employment considerations;
- views about the patient's preferences given by a third party who may have other knowledge of the patient, for example the patient's partner, family, carer, tutor-dative (Scotland), or a person with parental responsibility;
- which option least restricts the patient's future choices, where more than one option (including non-treatment) seems reasonable in the patient's best interest.

Applying to the court

26. Where a patient's capacity to consent is in doubt, or where differences of opinion about his or her best interests cannot be resolved satisfactorily, you should consult more

experienced colleagues and, where appropriate, seek legal advice on whether it is necessary to apply to the court for a ruling. You should seek the court's approval where a patient lacks capacity to consent to a medical intervention which is non-therapeutic or controversial, for example contraceptive sterilisation, organ donation, withdrawal of life support from a patient in a persistent vegetative state. Where you decide to apply to a court you should, as soon as possible, inform the patient and his or her representative of your decision and of his or her right to be represented at the hearing.

Forms of consent

27. To determine whether patients have given informed consent to any proposed investigation or treatment, you must consider how well they have understood the details and implications of what is proposed, and not simply the form in which their consent has been expressed or recorded.

Express consent

28. Patients can indicate their informed consent either orally or in writing. In some cases, the nature of the risks to which the patient might be exposed make it important that a written record is available of the patient's consent and other wishes in relation to the proposed investigation and treatment. This helps to ensure later understanding between you, the patient, and anyone else involved in carrying out the procedure or providing care. Except in an emergency, where the patient has capacity to give consent you should obtain written consent in cases where:

- the treatment or procedure is complex, or involves significant risks and/or side effects;
- providing clinical care is not the primary purpose of the investigation or examination;
- there may be significant consequences for the patient's employment, social or personal life;
- the treatment is part of a research programme.

29. You must use the patient's case notes and/or a consent form to detail the key elements of the discussion with the patient, including the nature of information provided, specific requests by the patient, details of the scope of the consent given.

Statutory requirements

30. Some statutes require written consent to be obtained for particular treatments (for example some fertility treatments). You must follow the law in these areas.

Implied consent

31. You should be careful about relying on a patient's apparent compliance with a procedure as a form of consent. For example, the fact that a patient lies down on an examination couch does not in itself indicate that the patient has understood what you propose to do and why.

Reviewing consent

32. A signed consent form is not sufficient evidence that a patient has given, or still gives, informed consent to the proposed treatment in all its aspects. You, or a member of the team, must review the patient's decision close to the time of treatment, and especially where:

- significant time has elapsed between obtaining consent and the start of treatment;
- there have been material changes in the patient's condition, or in any aspects of the proposed treatment plan, which might invalidate the patient's existing consent;
- new, potentially relevant information has become available, for example about the risks of the treatment, or about other treatment options.

Consent to screening

33. Screening (which may involve testing) healthy or asymptomatic people to detect genetic predispositions or early signs of debilitating or life threatening conditions can be an important tool in providing effective care. But the uncertainties involved in screening may be great, for example the risk of false positive or false negative results. Some findings may potentially have serious medical, social or financial consequences not only for the individuals, but for their relatives. In some cases the fact of having been screened may itself have serious implications.

34. You must ensure that anyone considering whether to consent to screening can make a properly informed decision. As far as possible, you should ensure that screening would not be contrary to the individual's interest. You must pay particular attention to ensuring that the information the person wants or ought to have is identified and provided. You should be careful to explain clearly:

- the purpose of the screening;
- the likelihood of positive/negative findings and possibility of false positive/negative results;
- the uncertainties and risks attached to the screening process;
- any significant medical, social or financial implications of screening for the particular condition or predisposition;
- follow up plans, including availability of counselling and support services.

If you are considering the possibility of screening children, or adults who are not able to decide for themselves, you should refer to the guidance at paragraphs 19-25. In appropriate cases, you should take account of the guidance issued by bodies such as the Advisory Committee on Genetic Testing 14.

Consent to research

35. Research involving clinical trials of drugs or treatments, and research into the causes of, or possible treatment for, a particular condition, is important in increasing doctors' ability to provide effective care for present and future patients. The benefits of the research may, however, be uncertain and may not be experienced by the person participating in the research. In addition, the risk involved for research participants may be difficult to identify or to assess in advance. If you carry out or participate in research involving patients or volunteers, it is particularly important that you ensure:

- as far as you are able, that the research is not contrary to the individual's interests;
- that participants understand that it is research and that the results are not predictable.

36. You must take particular care to be sure that anyone you ask to consider taking part in research is given the fullest possible information, presented in terms and a form that they can understand. This must include any information about possible benefits and risks; evidence that a research ethics committee has given approval; and advice that they can withdraw at any time. You should ensure that participants have the opportunity to read and consider the research information leaflet. You must allow them sufficient time to reflect on the implications of participating in the study. You must not put pressure on anyone to take part in research. You must obtain the person's consent in writing. Before starting any research you must always obtain approval from a properly constituted research ethics committee.

37. You should seek further advice where your research will involve adults who are not able to make decisions for themselves, or children. You should be aware that in these cases the legal position is complex or unclear, and there is currently no general consensus on how to balance the possible risks and benefits to such vulnerable individuals against the public interest in conducting research. (A number of public consultation exercises are under way.) You should consult the guidance issued by bodies such as the Medical Research Council and the medical royal colleges16 to keep up to date. You should also seek advice from the relevant research ethics committee where appropriate.

Footnotes

1 This right to decide applies equally to pregnant women as to other patients, and includes the right to refuse treatment where the treatment is intended to benefit the unborn child. See St George's Healthcare NHS Trust v S [1998] Fam Law 526 and 662, and MB (an adult: medical treatment) [1997] 2 FCR 541,CA

2 Advice can be obtained from medical defence bodies such as the Medical Defence Union, Medical Protection Society, the Medical and Dental Defence Union of Scotland, or professional associations such as the BMA., or your employing organisation.

3 Our booklet 'Serious Communicable Diseases' gives specific guidance on seeking consent to testing for conditions like HIV, Hepatitis B and C.

4 Guidance on treating patients in emergencies is included in paragraph 18.

5 A patient will be competent if he or she can: comprehend information, it having been presented to them in a clear way; believe it; and retain it long enough to weigh it up and make a decision. From Re C (Adult: Refusal of Medical Treatment) [1994] 1 All ER 819. But seek legal advice, in case of doubt.

6 For example the BMA/Law Society publication, "Assessment of Mental Capacity: Guidance for Doctors and Lawyers" available from the BMA.

7 Except in Scotland where a 'tutor-dative' with appropriate authority may make medical decisions on behalf of the patient. Seek legal advice, in case of doubt.

8 Legal advice should be obtained in case of doubt. A relevant precedent is the case of Regina v Bournewood Community and Mental Health NHS Trust ex parte L [1998] 3 All ER, 289 HL.

9 And similar legislation in Scotland and Northern Ireland

10 Code of Practice Dec 1998 Pursuant to S118 of the Mental Health Act 1983

11 You should consult your medical defence body or professional association for up to date advice. Appendix A lists some of the relevant key legislation.

12 Age of Legal Capacity (Scotland) Act 1991 (Section 2.4); Gillick v West Norfolk and Wisbech AHA ALL ER [1985], 3 ALL ER 402

13 This also applies to young people between 16 and 18 years old, except in Scotland.

14 ACGT can be contacted at: ACGT Secretariat, Department of Health, Room 401, Wellington House, 133-135 Waterloo Road, London, SE1 8UG. Telephone: 020 7972 4017

15 Consult your medical defence body, a professional association such as the BMA, or your employing organisation.

16 Appendix B gives an indicative list of published guidance. The GMC plans to publish further guidance on research.

APPENDIX A

Children and Consent to Treatment and Testing: Some Key Legislation

England & Wales

- Family Law Reform Act 1969
- Gillick *v* West Norfolk and Wisbech AHA [1985], 3 AER 402
- Children Act 1989

Scotland

- Age of Legal Capacity (Scotland) Act 1991
- Children Act (Scotland) 1995, Section 6, Part 1.

Northern Ireland

- Age of Majority Act 1969, Section 4.

APPENDIX B

Other Guidance on Research: Indicative List of Relevant Publications

'Good Medical Practice', paragraphs 55-56. The General Medical Council, 178-202 Great Portland Street, London, W1W 5JE. 1998.

'The Ethical Conduct of Research on Children'. MRC Ethics Series. The Medical Research Council, 20 Park Crescent, London, W1N 4AL. 1991 and 1993.

'Responsibility in Investigations on Human Participants and Materials and on Personal Information'. MRC Ethics Series. The Medical Research Council. 1992.

'The Ethical Conduct of Research on the Mentally Incapacitated'. MRC Ethics series. The Medical Research Council. 1991 and 1993.

'Research Involving Patients'. The Royal College of Physicians of London, 11 St Andrew's Place, London, NW1 4LE. January 1990.

'Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects'. Second Edition. The Royal College of Physicians of London, 11 St Andrew's Place, London, NW1 4LE. January 1990.

'Local Research Ethics Committees' (HSG(91)5). Department of Health, Richmond House, 79 Whitehall, London, SW1A 2NS. 1991.

'Multi-Centre Research Committees' (HSG(97)23). Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS. 1997.

'ABPI Guidance Note. Patient Information and Consents for Clinical Trials'. Association of British Pharmaceutical Industry, 12 Whitehall, London, SW1A 2DY. May 1997.

'International Ethical Guidelines for Biomedical Research Involving Human Subjects'. Council for International Organisations of Medical Sciences (CIOMS), c/o World Health Organisation, Avenue Appia, 1211 Geneva 27, Switzerland.

'Charter for Ethical Research in Maternity Care.'1997. National Childbirth Trust, Alexandra House, Oldham Terrace, Acton, London W3 6NH.

'Human Tissue: Ethical and Legal Issues 'Nuffield Council on Bioethics, 28 Bedord Square, London WC1B 3EG April 1995.