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Reference Guide to Consent for Examination or Treatment

Contents

Introduction

1. It is a general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation, or providing personal care, for a patient. This principle reflects the right of patients to determine what happens to their own bodies, and is a fundamental part of good practice. A health professional who does not respect this principle may be liable both to legal action by the patient and action by their professional body. Employing bodies may also be liable for the actions of their staff.

2. While there is no English statute setting out the general principles of consent, case law ("common law") has established that touching a patient without valid consent may constitute the civil or criminal offence of battery. Further, if health professionals fail to obtain proper consent and the patient subsequently suffers harm as a result of treatment, this may be a factor in a claim of negligence against the health professional involved. Poor handling of the consent process may also result in complaints from patients through the NHS complaints procedure or to professional bodies.

3. This booklet provides guidance on English law concerning consent to physical interventions on patients – from major surgery and the administration or prescription of drugs to assistance with dressing – and is relevant to all health care professionals (including students) who carry out interventions of this nature. Guidance is provided on the legal requirements for obtaining valid consent and on the situations where the law recognises exceptions to the common law requirement to obtain consent. References to the cases on which this guidance is based are given in Appendix C. It should be noted that this guidance is specific to consent for physical interventions on living patients, and the following areas are therefore not included:

   - participation in observational studies
   - the use of personal information
   - the use of organs or tissue after death (see below, paragraph 6)

4. Case law on consent has evolved significantly over the last decade. Further legal developments may occur after this guidance has been issued, and health professionals must remember their duty to keep themselves informed of legal developments which may have a bearing on their practice. Legal advice should always be sought if there is any doubt about the legal validity of a proposed intervention. While much of the case law refers specifically to doctors, the same principles will apply to other health professionals involved in examining or treating patients.

5. The *Human Rights Act 1998* came into force in October 2000, giving further effect in the UK to the rights enshrined in the European Convention on Human Rights. In future, courts will be expected to take into account the case law of the European Court of Human Rights in Strasbourg, as well as English case law. Although it is too early to predict how the *Human Rights Act* will affect English medical law, the guidance in this booklet is compatible with the existing case-law of the European Court of Human Rights. The main articles which are likely to be relevant in medical case law are Article 2 (protection of right to life), Article 3 (prohibition of torture, inhuman or degrading treatment or punishment), Article 5 (right to liberty and security), Article 8 (right to respect for private and family life), Article 9 (freedom of thought, conscience and religion), Article 12 (right to marry and found a family) and Article 14 (prohibition of discrimination in enjoyment of Convention rights).

6. The removal of organs or tissue from patients who have been declared dead, whether for diagnostic, therapeutic or research purposes, is governed by particular legislation, the *Human Tissue Act 1961*, whose terms currently focus on "lack of objection" rather than consent. The Government has indicated that it intends to amend the law in this area, to give increased emphasis to the wishes of the relatives of the deceased person.[1] Questions concerning the use of organs or tissue after death are beyond the scope of this Guidance.

7. The standards expected of health professionals by their regulatory bodies may at times be higher than the minimum required by the law. Although this Guidance focuses primarily on the legal position, it will also indicate where regulatory bodies have set out more stringent requirements. It should be noted that the legal requirements in negligence cases (see chapter 1 paragraph 5) have historically been based on the standards set by the professions for their members, and hence where standards required by professional bodies are rising, it is likely that the legal standards will rise accordingly.

[1] Department of Health, *The removal, retention and use of human organs and tissue from post-mortem examination: advice from the Chief Medical Officer*, 2001

1 Seeking Consent

Valid consent

1. For consent to be valid, it must be given voluntarily by an appropriately informed person (the patient or where relevant someone with parental responsibility for a patient under the age of 18[2]) who has the capacity to consent to the intervention in question. Acquiescence where the person does not know what the intervention entails is not "consent".

Does the patient have capacity?

2. For a person to have capacity, he or she must be able to comprehend and retain information material to the decision, especially as to the consequences of having or not having the intervention in question, and must be able to use and weigh this information in the decision–making process.

2.1 Thus, patients may have capacity to consent to some interventions but not to others. Adults are presumed to have capacity, but where any doubt exists the health professional should assess the capacity of the patient to take the decision in question. This assessment and the conclusions drawn from it should be recorded in the patient's notes. The British Medical Association has published advice on the assessment of capacity.[3]

2.2 A patient's capacity to understand may be temporarily affected by factors such as confusion, panic, shock, fatigue, pain or medication. However the existence of such factors should not be assumed automatically to render the patient incapable of consenting. Temporary incapacity is discussed further in chapter 2.

2.3 Capacity should not be confused with a health professional's assessment of the reasonableness of the patient's decision. The patient is entitled to make a decision which is based on their own religious belief or value system, even if it is perceived by others to be irrational, as long as the patient understands what is entailed in their decision. An irrational decision has been defined as one which is so outrageous in its defiance of logic or of accepted moral standards that no sensible person who had applied his or her mind to the question could have arrived at it.

2.4 However, if the decision which appears irrational is based on a misperception of reality, as opposed to an unusual value system – for example a patient who, despite the obvious evidence, denies that his foot is gangrenous, or a patient with anorexia nervosa who is unable to comprehend her failing physical condition – then the patient may not be able to comprehend and make use of the relevant information and hence may lack capacity to make the decision in question.

2.5 In practice patients also need to be able to communicate their decision. Care should be taken not to underestimate the ability of a patient to communicate, whatever their condition. Health professionals should take all steps which are reasonable in the circumstances to facilitate communication with the

[2] See chapter 3

[3] BMA and The Law Society, *Assessment of mental capacity: guidance for doctors and lawyers*, 1995

patient, using interpreters or communication aids as appropriate. The Department has issued guidance on reasonable steps which should be taken to communicate with patients with sensory disabilities.[4]

2.6 Care should also be taken not to underestimate the capacity of a patient with a learning disability to understand. Many people with learning disabilities have the capacity to consent if time is spent explaining to the individual the issues in simple language, using visual aids and signing if necessary.

2.7 Where appropriate, those who know the patient well, including their family, carers and staff from professional or voluntary support services, may be able to advise on the best ways to communicate with the person.

Is the consent given voluntarily?

3. To be valid, consent must be given voluntarily and freely, without pressure or undue influence being exerted on the patient either to accept or refuse treatment. Such pressure can come from partners or family members as well as health or care professionals. Professionals should be alert to this possibility and where appropriate should arrange to see the patient on their own to establish that the decision is truly that of the patient.

3.1 When patients are seen and treated in environments where involuntary detention may be an issue, such as prisons and mental hospitals, there is a potential for treatment offers to be perceived coercively, whether or not this is the case. Coercion invalidates consent and care must be taken to ensure that the patient makes a decision freely. Coercion should be distinguished from providing the patient with appropriate reassurance concerning their treatment, or pointing out the potential benefits of treatment for the patient's health. However, threats such as withdrawal of any privileges or loss of remission of sentence for refusing consent, or using such matters to induce consent, are not acceptable.

Has the patient received sufficient information?

4. To give valid consent the patient needs to understand in broad terms the nature and purpose of the procedure. Any misrepresentation of these elements will invalidate consent. Where relevant, information about anaesthesia should be given as well as information about the procedure itself.

4.1 Clear information is particularly important when students or trainees carry out procedures to further their own education. Where the procedure will further the patient's care – for example taking a blood sample for testing – then, assuming the student is appropriately trained in the procedure, the fact that it is carried out by a student does not alter the nature and purpose of the procedure. It is therefore not a legal requirement to tell the patient that the clinician is a student, although it would always be good practice to do so. In contrast, where a student proposes to conduct a physical examination which is not part of the patient's care, then it is essential to explain that the purpose of the examination is to further the student's training and to seek consent for that to take place.

5. Although informing patients of the nature and purpose of procedures enables valid consent to be given as far as any claim of battery is concerned, this is **not** sufficient to fulfil the legal duty of care to the patient. Failure to provide other relevant information may render the professional liable to an action for negligence if a patient subsequently suffers harm as a result of the treatment received.

[4] Department of Health circulars HSC 1999/093 and HSC 1999/156 (www.doh.gov.uk/publications/coinh.html)

5.1 The requirements of the legal duty to inform patients have been significantly developed in case law during the last decade. In 1985, the House of Lords decided in the *Sidaway*[5] case that the legal standard to be used when deciding whether adequate information had been given to a patient should be the same as that used when judging whether a doctor had been negligent in their treatment or care of a patient: a doctor would not be considered negligent if their practice conformed to that of a responsible body of medical opinion held by practitioners skilled in the field in question (known as the "Bolam test").[6] Whether the duty of care had been satisfied was therefore primarily a matter of medical opinion. However, *Sidaway* also stated that it was open to the courts to decide that information about a particular risk was so obviously necessary that it would be negligent not to provide it, even if a "responsible body" of medical opinion would not have done so.

5.2 Since *Sidaway*, judgements in a number of negligence cases (relating both to the provision of information and to the standard of treatment given) have shown that courts are willing to be critical of a "responsible body" of medical opinion. It is now clear that the courts will be the final arbiter of what constitutes responsible practice, although the standards set by the health professions for their members will still be influential.

5.3 In considering what information to provide, the health professional should try to ensure that the patient is able to make a balanced judgement on whether to give or withhold consent. Case law on this issue is evolving. It is therefore advisable to inform the patient of any "material" or "significant" risks in the proposed treatment, any alternatives to it, and the risks incurred by doing nothing. A recent Court of Appeal judgement stated that it will normally be the responsibility of the doctor to inform a patient of "a significant risk which would affect the judgement of a reasonable patient".[7]

5.4 The General Medical Council has gone further, stating in guidance that doctors should do their best to find out about patients' *individual* needs and priorities when providing information about treatment options. The guidance also emphasises that if the patient asks specific questions about the procedure and associated risks these should be answered truthfully.[8]

5.5 In the very rare event that the health professional believes that to follow the guidance in paragraphs 5.3 and 5.4 in full would have a deleterious effect on the patient's health, the GMC guidance states that this view, and the reasons for it, should be recorded in the patient's notes. When such concerns arise it is advisable to discuss the issue within the team caring for the patient. In an individual case the courts may accept such a justification but would examine it with great care. The mere fact that the patient might become upset by hearing the information, or might refuse treatment, is **not** sufficient to act as a justification.

5.6 Some patients may wish to know very little about the treatment which is being proposed. If information is offered and declined, it is good practice to record this fact in the notes. However, it is possible that patients' wishes may change over time, and it is important to provide opportunities for them to express this. The GMC guidance encourages doctors to explain to patients the importance of knowing the options open to them, and states that basic information should always be provided.

[5] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871

[6] *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118

[7] *Pearce v United Bristol Healthcare NHS Trust* (1999) 48 BMLR 118

[8] GMC, *Seeking patients' consent: the ethical considerations*, November 1998

Additional procedures

6. During an operation it may become evident that the patient could benefit from an additional procedure that was not within the scope of the original consent. If it would be unreasonable to delay the procedure until the patient regains consciousness (for example because there is a threat to the patient's life) it may be justified to perform the procedure on the grounds that it is in the patient's best interests. However, the procedure should not be performed merely because it is convenient. A hysterectomy should never be performed during an operation without explicit consent, unless it is necessary to do so to save life.

6.1 As noted in paragraph 19 below, if a patient has refused certain additional procedures before the anaesthetic (for example, specifying that a mastectomy should not be carried out after a frozen section biopsy result) this must be respected if the refusal is applicable to the circumstances. The GMC guidance states that it is good practice to seek the views of the patient on possible additional procedures when seeking consent to the original intervention.

Subsequent use of removed tissue

7. The legal status of tissue (including clinical samples such as blood samples) which has been removed from a patient during the course of a procedure is at present unclear. Tissue left over after routine pathological examination may have a range of potentially beneficial uses, for example in basic and applied research, in drug testing and in teaching. Further, excess human tissue from medical procedures, such as bone from hip replacements, may have therapeutic uses for others.

7.1 In the past, there seems to have been an assumption that such tissue has been "abandoned" by patients and that it may be freely used for any ethically acceptable purpose without the patient's consent being sought. This assumption is increasingly being challenged, on the basis that patients should be given the opportunity to give or refuse their consent for such use. The Chief Medical Officer has recommended that there should be a review of the existing law on the taking, storing and use of tissue, both before and after death, and the Government has accepted this recommendation.[9] Both the Royal College of Pathologists and the Medical Research Council are also currently undertaking work with the aim of ensuring that appropriate consent for tissue use is sought and is communicated to laboratory staff.

Consent to video recordings and clinical photography

8. Video recordings of treatment may be used both as a medical record or treatment aid in themselves, and as a tool for teaching, audit or research. The purpose and possible future use of the video must be clearly explained to the person, before their consent is sought for the recording to be made. If the video is to be used for teaching, audit or research, patients must be aware that they can refuse without their care being compromised and that when required or appropriate the video can be anonymised. As a matter of good practice, the same principles should be applied to clinical photography.

Who should seek consent?

9. The clinician providing the treatment or investigation is responsible for ensuring that the patient has given valid consent before treatment begins, although the consultant responsible for the patient's care will remain ultimately responsible for the quality of medical care provided. The GMC guidance states

[9] Department of Health, *The removal, retention and use of human organs and tissue from post-mortem examination: advice from the Chief Medical Officer*, 2001

that the task of seeking consent may be delegated to another health professional, as long as that professional is suitably trained and qualified. In particular, they must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved, in order to be able to provide any information the patient may require. Inappropriate delegation (for example where the clinician seeking consent has inadequate knowledge of the procedure) may mean that the "consent" obtained is not valid. Clinicians are responsible for knowing the limits of their own competence and should seek the advice of appropriate colleagues when necessary.

When should consent be sought?

10. The seeking and giving of consent is usually a process, rather than a one-off event. For major interventions, it is good practice where possible to seek the patient's consent to the proposed procedure well in advance, when there is time to respond to the patient's questions and provide adequate information (see above paragraphs 4-5). Clinicians should then check, before the procedure starts, that the patient still consents. If a patient is not asked to signify their consent until just before the procedure is due to start, at a time when they may be feeling particularly vulnerable, there may be real doubt as to its validity. In no circumstances should patients be given routine pre-operative medication before being asked for their consent to proceed with the treatment.

Form of consent

11. The validity of consent does not depend on the form in which it is given. Written consent merely serves as evidence of consent: if the elements of voluntariness, appropriate information and capacity have not been satisfied, a signature on a form will not make the consent valid.

11.1 Although completion of a consent form is in most cases not a legal requirement (exceptions include certain requirements of the *Mental Health Act 1983* and of the *Human Fertilisation and Embryology Act 1990*) the use of such forms is good practice where an intervention such as surgery is to be undertaken. Where there is any doubt about the patient's capacity, it is important, *before* the patient is asked to sign the form, to establish both that they have the capacity to consent to the intervention and that they have received enough information to enable valid consent to be given. Details of the assessment of capacity, and the conclusion reached, should be recorded in the case notes.

11.2 If the patient has capacity, but is illiterate, the patient may be able to make their mark on the form to indicate consent. It would be good practice for the mark to be witnessed by a person other than the clinician seeking consent, and for the fact that the patient has chosen to make their mark in this way to be recorded in the case notes. Similarly, if the patient has capacity, and wishes to give consent, but is physically unable to mark the form, this fact should be recorded in the notes. If consent has been validly given, the lack of a completed form is no bar to treatment.

12. Consent may be expressed verbally or non-verbally: an example of non-verbal consent would be where a patient, after receiving appropriate information, holds out an arm for their blood pressure to be taken. It is good practice to obtain written consent for any significant procedure such as a surgical operation or when the patient participates in a research project or a video recording (even if only minor procedures are involved).

Requirements concerning gametes

13. It is a legal requirement under the *Human Fertilisation and Embryology Act 1990* that consent to the storage and use of gametes must be given in writing after the person has received such relevant information as is proper and had an opportunity to receive counselling. Where these requirements are not satisfied, it is unlawful to store or use the person's gametes. Clinicians should ensure that written consent to storage exists before retrieving gametes.

13.1 Outside specialist infertility practice, these requirements may be relevant to health care professionals whose patients are about to undergo treatment which may render them sterile (such as chemotherapy or radiotherapy) where a patient may wish to have gametes, or ovarian or testicular tissue, stored prior to the procedure. Health professionals may also receive requests to remove gametes from a person unable to give consent. Further guidance is available from the Human Fertilisation and Embryology Authority.[10]

Additional legal requirements

14. Before a live transplant of an organ (as defined in the *Human Organ Transplants Act 1989*) can take place from one living person to another to whom the individual is not genetically related (as defined in the same Act) approval must first be sought from the Unrelated Live Transplant Regulatory Authority, from whom further information may be obtained.[11] Where the individuals are genetically related, this fact may need to be demonstrated and specialist advice should be sought.

14.1 The potential benefits of a live transplant for a sick relative may be such that a family member may feel under considerable emotional pressure to donate. As noted in paragraph 3 above, it is important to establish that the decision of the potential donor is truly their own. The position of child bone marrow donors is covered in more detail below (see chapter 3, paragraph 16).

Research and innovative treatment

15. The same legal principles apply when seeking consent from patients for research purposes as when seeking consent for investigations or treatment. However, in acknowledgement of the fact that research may not have direct benefits for the patients involved, the GMC states that "particular care" should be taken to ensure that possible research subjects have the fullest possible information about the proposed study and sufficient time to absorb it. Patients should never feel pressurised to take part, and advice must be given that they can withdraw from the research project at any time, without their care being affected. If patients are being offered the opportunity to participate in a clinical trial, they should have clear information on the nature of the trial.

15.1 If the treatment being offered is of an experimental nature, but not actually part of a research trial, this fact must be clearly explained to patients before their consent is sought, along with information about standard alternatives. It is good practice to give patients information about the evidence to date of the effectiveness of the new treatment, both at national/international level and in the practitioner's own experience, including information about known possible side-effects.

[10] Paxton House, 30 Artillery Lane, London E1 7LS. Tel: 020 7377 5077

[11] ULTRA Secretariat, Rm 421 Wellington House London SE1 8UG. Tel: 020 7972 4812; fax: 020 7972 4852

Duration of consent

16. When a patient gives valid consent to an intervention, in general that consent remains valid for an indefinite duration unless it is withdrawn by the patient. However, if new information becomes available regarding the proposed intervention (for example new evidence of risks or new treatment options) between the time when consent was sought and when the intervention is undertaken, the GMC guidance states that a doctor or member of the healthcare team should inform the patient and reconfirm their consent. In the light of paragraphs 4-5 above, the clinician should consider whether the new information should be drawn to the attention of the patient and the process of seeking consent repeated on the basis of this information. Similarly, if the patient's condition has changed significantly in the intervening time, it may be necessary to seek consent again, on the basis that the likely benefits and/or risks of the intervention may also have changed.

16.1 If consent has been obtained a significant time before undertaking the intervention, it is good practice to confirm that the person who has given consent (assuming he or she retains capacity) still wishes the intervention to proceed even if no new information needs to be provided or further questions answered. The position of patients who lack capacity is covered in chapter 2.

When consent is refused

17. If an adult with capacity makes a voluntary and appropriately informed decision to refuse treatment this decision **must** be respected, except in circumstances defined by the *Mental Health Act 1983* (see chapter 5). This is the case even where this may result in the death of the patient and/or the death of an unborn child, whatever the stage of the pregnancy. Refusal of treatment by those under the age of 18 is covered in chapter 3.

Withdrawal of consent

18. A patient with capacity is entitled to withdraw consent at any time, including during the performance of a procedure. Where a patient does object during treatment, it is good practice for the practitioner, if at all possible, to stop the procedure, establish the patient's concerns, and explain the consequences of not completing the procedure. At times an apparent objection may reflect a cry of pain rather than withdrawal of consent, and appropriate reassurance may enable the practitioner to continue with the patient's consent. If stopping the procedure at that point would genuinely put the life of the patient at risk, the practitioner may be entitled to continue until this risk no longer applies.

18.1 Assessing capacity during a procedure may be difficult and, as noted above, factors such as pain, panic and shock may diminish capacity to consent. The practitioner should try to establish whether at that time the patient has capacity to withdraw a previously given consent. If capacity is lacking, it may sometimes be justified to continue in the patient's best interests (see chapter 2), although this should not be used as an excuse to ignore distress.

Advance refusals of treatment

19. Patients may have a "living will" or "advance directive" specifying how they would like to be treated in the case of future incapacity. While professionals cannot be required by such directives to provide particular treatments (which might be inappropriate), case law is now clear that an advance refusal of treatment which is valid and applicable to subsequent circumstances in which the patient lacks capacity

is **legally binding**. An advance refusal is valid if made voluntarily by an appropriately informed person with capacity. Failure to respect such an advance refusal can result in legal action against the practitioner.

19.1 If there is doubt about the validity of an advance refusal a ruling should be sought from the court. It is not legally necessary for the refusal to be made in writing or formally witnessed, although such measures add evidentiary weight to the validity of the refusal. A health professional **may not** over-ride a valid and applicable advance refusal on the grounds of the professional's personal conscientious objection to such a refusal.

19.2 Although the issue has not yet come before a court, it has been suggested that as a matter of public policy individuals should not be able to refuse in advance measures which are essential to keep a patient comfortable.[12] This is sometimes referred to as "basic" or "essential" care, and includes keeping the patient warm and clean and free from distressing symptoms such as breathlessness, vomiting, and severe pain. However, some patients may prefer to tolerate some discomfort if this means they remain more alert and able to respond to family and friends.

19.3 However, although basic/essential care would include the offer of oral nutrition and hydration, it would **not** cover force feeding an individual or the use of artificial nutrition and hydration. The courts have recognised that a competent individual has the right to choose to go on a "hunger strike", although this may be qualified if the person has a mental disorder. Towards the end of such a period an individual is likely to lose capacity (become incompetent) and the courts have stated that if the individual has, whilst competent, expressed the desire to refuse food until death supervenes, the person cannot be force fed or fed artificially when incompetent. If the patient is refusing food as a result of mental disorder and is detained under the *Mental Health Act 1983*, different considerations may apply and more specialist guidance should be consulted.[13]

Self harm

20. Cases of self harm present a particular difficulty for health professionals. Where the patient is able to communicate, an assessment of their mental capacity should be made as a matter of urgency. If the patient is judged not to be competent, they may be treated on the basis of temporary incapacity (see paragraph 5 in chapter 2). Similarly, patients who have attempted suicide and are unconscious should be given emergency treatment if any doubt exists as to either their intentions or their capacity when they took the decision to attempt suicide.

20.1 However, as noted in paragraphs 17 and 19 above, competent patients **do** have the right to refuse life-sustaining treatment (other than treatment for mental disorder under the *Mental Health Act 1983*), both at the time it is offered and in the future. If a competent patient has harmed themselves and refuses treatment, a psychiatric assessment should be obtained. If the use of the *Mental Health Act 1983* is not appropriate, then their refusal must be respected. Similarly, if practitioners have good reason to believe that a patient genuinely intended to end their life and was competent when they took that decision, and are satisfied that the *Mental Health Act* is not applicable, then treatment should not be forced upon the patient although clearly attempts should be made to encourage him or her to accept help.

[12] British Medical Association, *Advance statements about medical treatment* (1995) BMA Publishing Group: London

[13] eg Mental Health Act Commission, *Guidance Note 3 – Guidance on the treatment of anorexia nervosa under the Mental Health Act 1983* (issued August 1997 and updated March 1999)

2 Adults Without Capacity

General principles

1. Under English law, no one is able to give consent to the examination or treatment of an adult unable to give consent for him or herself (an "incapable" adult). Therefore, parents, relatives or members of the healthcare team can **not** consent on behalf of such an adult. However, in certain circumstances, it will be lawful to carry out such examinations or treatment.

2. In general the refusal of an intervention made by a patient before their loss of capacity cannot be over-ridden if the refusal is valid and applicable to the situation (see advance refusals in chapter 1 paragraph 19). There are certain statutory exceptions to this principle, treatment for mental disorder under the *Mental Health Act 1983* being the main example, which are set out briefly in chapter 5.

3. A key principle concerning treatment of the incapable adult is that of the person's best interests. "Best interests" are not confined to best *medical* interests:[14] case law has established that other factors which may need to be taken into account include the patient's values and preferences when competent, their psychological health, well-being, quality of life, relationships with family or other carers, spiritual and religious welfare and their own financial interests. It is good practice for the healthcare team to involve those close to the patient in order to find out about the patient's values and preferences before loss of capacity, unless the patient has previously made clear that particular individuals should not be involved.

4. Where there is doubt about an individual's capacity or best interests, the High Court can give a ruling on these matters and on the lawfulness or unlawfulness of a proposed procedure. The duty officer of the Official Solicitor can advise on the appropriate procedure if necessary.[15] The court has given guidance on making applications to the court, which is reproduced at Appendix A. It is good practice to seek the views of the court prior to undertaking certain interventions, listed in paragraph 8 below, which arouse particular concern.

Temporary incapacity

5. An adult who usually has capacity may become temporarily incapable, for example whilst under a general anaesthetic or sedation, or after a road accident. Unless a valid advance refusal of treatment is applicable to the circumstances (see chapter 1 paragraph 19), the law permits interventions to be made which are necessary and no more than is reasonably required in the patient's best interests pending the recovery of capacity. This will include, but is not limited to, routine procedures such as washing and assistance with feeding. If a medical intervention is thought to be in the patient's best interests but can be delayed until the patient recovers capacity and can consent to (or refuse) the intervention, it must be delayed until that time.

[14] *Re MB* (1997) 38 BMLR 175

[15] The Official Solicitor can be contacted through the Urgent Court Business Officer out of office hours on 020 7947 6000. This should usually be done through the legal department of the NHS body involved.

Permanent or long-standing incapacity

6. Where the adult's incapacity is permanent or likely to be long-standing, it will be lawful to carry out any procedure which is in the "best interests" of the adult. The House of Lords has suggested that action taken "to preserve the life, health or well-being" of a patient will be in their best interests, and subsequent court judgements have emphasised that a patient's best interests go beyond their best medical interests, to include much wider welfare considerations (see paragraph 3 above). The principle of caring for patients in their best interests also covers such routine procedures as dressing, washing, putting to bed and assisting with the consumption of food and drink. Where treatment is given to an incapable adult on this basis, the standard consent form should not be signed by either relatives or healthcare professionals. It is good practice to note either in the records or in a "patient unable to consent" form why the treatment was believed to be in the patient's best interests.

6.1 Where the patient has never been competent, it is clearly impossible to determine their best interests by reference to earlier, competent, beliefs and values. In such cases, family and friends close to the patient will often be in the best position to advise health professionals on the patient's needs and preferences.

Fluctuating capacity

7. It is possible for capacity to fluctuate. In such cases, it is good practice to establish whilst the person has capacity their views about any clinical intervention that may be necessary during a period of incapacity and to record these views. The person may wish to make an advance refusal of certain types of treatment (see chapter 1 paragraph 19). If the person does not make any relevant advance refusal, the person's treatment when incapacitated should accord with the principles for treating the temporarily incapacitated (paragraph 5 above).

Referral to court

8. The courts have identified certain circumstances when referral should be made to them for a ruling on lawfulness before a procedure is undertaken. These are:

- sterilisation for contraceptive purposes
- donation of regenerative tissue such as bone marrow
- withdrawal of nutrition and hydration from a patient in a persistent vegetative state
- where there is doubt as to the patient's capacity or best interests.

8.1 It is unlikely that an adult without the capacity to consent would ever be considered as a donor of a solid organ, and even less likely that such a procedure would be in that adult's best interests. In the event that such an intervention was ever considered, referral should also be made to the court.

8.2 The courts have stated that neither sterilisation which is incidental to the management of detrimental effects of menstruation nor abortion need automatically be referred to Court, if there is no doubt that this is the most appropriate therapeutic response. However, these procedures can give rise to special concern about the best interests and rights of a person who lacks capacity. The need for such procedures occasionally arises in relation to women with a severe learning disability. It is good practice to involve a consultant in the psychiatry of learning disability, the multidisciplinary team, and the patient's family as part of the decision-making process, and to document their involvement. Less invasive or reversible

options should always be considered before permanent sterilisation. Where there is disagreement as to the patient's best interests, a reference to court may be appropriate.

8.3 It should be noted that the courts may extend the list of procedures concerning which court reference is good practice in the future.

8.4 Although some procedures may not require court approval, their appropriateness may give rise to concern. For example, some patients with learning disability may exhibit challenging behaviour, such as biting or self-injury. If such behaviour is severe, interventions such as applying a temporary soft splint to the teeth or using arm splints to prevent self-injury are exceptionally considered, within a wider therapeutic context. As with hysterectomies undertaken for menstrual management purposes, great care must be taken in determining the best interests of such patients as distinct from dealing with the needs of carers and others concerned with the individual's treatment.

Research

9. The lawfulness of medical research on adults or children who lack capacity has never been considered by an English court and therefore no definitive statement of the law can be made. General principles may provide some guidance. Ethically, any research project which is carried out on human beings should be approved by an independent research ethics committee. In the NHS this will be the Local Research Ethics Committee, and additionally where appropriate the Multi-Centre Research Ethics Committee. However, ethics committee approval does not absolve the clinicians carrying out the research from ethical or legal responsibility for their own actions.

9.1 Treatment for many conditions is imperfect, but new treatments are constantly being developed. In some cases, a competent patient will be offered the opportunity to enter into a clinical trial of two alternative therapies, on the basis that on the evidence available at the time the new therapy is at least as likely to benefit the patient as the standard therapy. Where children lack capacity to consent for themselves, parents may give consent for their child to be entered into a trial where the evidence is that the trial therapy may be at least as beneficial to the patient as the standard therapy. It is undesirable to carry out such research on adults without capacity if that research can equally well be carried out on those with capacity. However, where the standard treatment is non-existent or of very limited effectiveness, it may be in the best interests of an incapacitated adult to be entered into such a trial, unless there are reasons to believe that, when competent, the patient would not have wished to do so.

9.2 The position concerning research which does not have the potential immediately to benefit the person's health is a legally uncharted area. This type of research should never be undertaken on incapable patients if it is possible instead to carry out the research on persons capable of giving consent.

9.3 Although research has not been specifically considered, the courts have considered whether it would be legal to carry out a medical intervention with no therapeutic purpose on children lacking capacity. It was held that a person with parental responsibility can consent to an intervention which, although not in the best interests of that child, is not against the interests of such a child (the case in question concerned a blood test for non-therapeutic reasons). From this the idea has developed that research which is not of direct benefit to such children may be lawful (with consent from a person with parental responsibility) if it is **not against** the interests of the child and imposes no greater than minimal burden. The burden on the child must be assessed individually for each child: children's attitudes to blood tests and injections, for example, vary considerably.

9.4 Professional bodies such as the Medical Research Council and the Royal College of Physicians have suggested that it can, similarly, be ethical to perform research which involves minimal intervention on

incapable adults, if certain stringent conditions are met. The research must be approved by the relevant Research Ethics Committee, it must relate to the condition from which the incapable adult is suffering, and it must be demonstrated that the research is not against their interests.[16]

9.5 The alternative view is that such research would only be lawful if it was in the best interests of the adult, taking into account all the factors listed in paragraph 3 above. Only the courts can rule on this issue, and until there is such a ruling this type of research should be considered with caution.

[16] Medical Research Council, *The ethical conduct of research on the mentally incapacitated*, 1991 & The Royal College of Physicians of London, *Guidelines on the practice of ethics committees in medical research involving human subjects*, 3rd ed., 1996

3 Children and Young People

1. The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position for adults, in particular where treatment is being refused. In the following paragraphs the terms 'child' and 'young person' are used interchangeably.

Young people aged 16–17

2. By virtue of section 8 of the *Family Law Reform Act 1969*, people aged 16 or 17 are entitled to consent to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic. As for adults, consent will be valid only if it is given voluntarily by an appropriately informed patient capable of consenting to the particular intervention. However, unlike adults, the refusal of a competent person aged 16-17 may in certain circumstances be over-ridden by either a person with parental responsibility or a court (see below paragraphs 8-8.5).

2.1 Section 8 of the *Family Law Reform Act* applies only to the young person's own treatment. It does not apply to an intervention which is not potentially of direct health benefit to the young person, such as blood donation or non-therapeutic research on the causes of a disorder. However, a young person may be able to consent to such an intervention under the standard of Gillick competence, considered below.

3. In order to establish whether a young person aged 16 or 17 has the requisite capacity to consent to the proposed intervention, the same criteria as for adults should be used (see paragraph 2 of chapter 1).

4. If the requirements for valid consent are met, it is not legally necessary to obtain consent from a person with parental responsibility for the young person in addition to that of the young person. It is, however, good practice to involve the young person's family in the decision-making process, unless the young person specifically wishes to exclude them.

Children under 16 – the concept of "*Gillick* competence"

5. Following the case of *Gillick*,[17] the courts have held that children who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent to that intervention. This is sometimes described as being "*Gillick* competent" and may apply to consent for treatment, research or tissue donation. As the understanding required for different interventions will vary considerably, a child under 16 may therefore have the capacity to consent to some interventions but not others. As with adults, assumptions that a child with a learning disability may not be able to understand the issues should never be made automatically (see chapter 1, paragraph 2.6).

5.1 The concept of *Gillick* competence is said to reflect the child's increasing development to maturity. In some cases, for example because of a mental disorder, a child's mental state may fluctuate significantly so that on some occasions the child appears *Gillick* competent in respect of a particular decision and on other occasions does not. In cases such as these, careful consideration should be given to whether the child is truly *Gillick* competent at any time to take this decision.

[17] *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112

6. If the child is *Gillick* competent and is able to give voluntary consent after receiving appropriate information, that consent will be valid and additional consent by a person with parental responsibility will not be required. However where the decision will have on-going implications, such as long-term use of contraception, it is good practice to encourage the child to inform his or her parents unless it would clearly not be in the child's best interests to do so.

The requirement of voluntariness

7. Although a child or young person may have the capacity to give consent, valid consent must be given voluntarily. This requirement must be considered carefully. Children and young people may be subject to undue influence by their parents, other carers, or a potential sexual partner, and it is important to establish that the decision is that of the individual him or herself.

Child or young person with capacity refusing treatment

8. Where a young person of 16 or 17 who could consent to treatment in accordance with section 8 of the *Family Law Reform Act*, or a child under 16 but Gillick competent, refuses treatment, such a refusal can be over-ruled either by a person with parental responsibility for the child or by the court. If more than one person has parental responsibility for the young person, consent by any one such person is sufficient, irrespective of the refusal of any other individual.

8.1 This power to over-rule must be exercised on the basis that the welfare of the child/young person is paramount. As with the concept of best interests, "welfare" does not just mean physical health. The psychological effect of having the decision over-ruled must also be considered. While no definitive guidance has been given as to when it is appropriate to over-rule a competent young person's refusal, it has been suggested that it should be restricted to occasions where the child is at risk of suffering "grave and irreversible mental or physical harm".

8.2 The outcome of such decisions may have a serious impact on the individual concerned. Examples might include a young person with capacity refusing an abortion or further chemotherapy for cancer in the knowledge of a poor prognosis. When a person with parental responsibility wishes to over-rule such decisions, consideration should be given to applying to the court for a ruling prior to undertaking the intervention. Such applications can be made at short notice if necessary.

8.3 For parents to be in a position to over-rule a competent child's refusal, they must inevitably be provided with sufficient information about their child's condition, which the child may not be willing for them to receive. While this will constitute a breach of confidence on the part of the clinician treating the child, this may be justifiable where it is in the child's best interests. Such a justification may only apply where the child is at serious risk as a result of their refusal of treatment.

8.4 Refusal by a competent child and all persons with parental responsibility for the child can be over-ruled by the court if the welfare of the child so requires.

8.5 A life threatening emergency may arise when consultation with either a person with parental responsibility or the court is impossible, or the persons with parental responsibility refuse consent despite such emergency treatment appearing to be in the best interests of the child. In such cases the courts have stated that doubt should be resolved in favour of the preservation of life and it will be acceptable to undertake treatment to preserve life or prevent serious damage to health.

Child or young person without capacity

9. Where a child lacks capacity to consent, consent can be given on their behalf by any one person with parental responsibility or by the court. As is the case where patients are giving consent for themselves, those giving consent on behalf of child patients must have the capacity to consent to the intervention in question, be acting voluntarily, and be appropriately informed. The power to consent must be exercised according to the "welfare principle": that the child's "welfare" or "best interests" must be paramount. Even where a child lacks capacity to consent on their own behalf, it is good practice to involve the child as much as possible in the decision-making process.

9.1 Where necessary the courts can, as with competent children, over-rule a refusal by a person with parental responsibility. It is recommended that certain important decisions, such as sterilisation for contraceptive purposes, should be referred to the courts for guidance, even if those with parental responsibility consent to the operation going ahead.

10. The *Children Act 1989* sets out persons who may have parental responsibility. These include:

- the child's parents if married to each other at the time of conception or birth;
- the child's mother, but not father if they were not so married unless the father has acquired parental responsibility via a court order or a parental responsibility agreement or the couple subsequently marry;
- the child's legally appointed guardian;[18]
- a person in whose favour the court has made a residence order concerning the child;
- a Local Authority designated in a care order in respect of the child;
- a Local Authority or other authorised person who holds an emergency protection order in respect of the child.

Section 2(9) of the *Children Act 1989* states that a person who has parental responsibility for a child "may arrange for some or all of it to be met by one or more persons acting on his behalf". Such a person might choose to do this, for example, if a childminder or the staff of a boarding school have regular care of their child. As only a person exercising parental responsibility can give valid consent, in the event of any doubt specific enquiry should be made. Foster parents do not automatically have parental responsibility.

11. Consent given by one person with parental responsibility is valid, even if another person with parental responsibility withholds consent. However, the courts have stated that a "small group of important decisions" should not be taken by one person with parental responsibility against the wishes of another, citing in particular non-therapeutic male circumcision.[19] Where persons with parental responsibility disagree as to whether non-therapeutic procedures are in the child's best interests, it is advisable to refer the decision to the courts. It is possible that major experimental treatment, where opinion is divided as to the benefits it may bring the child, might also fall into this category of important decisions, although such a case has not yet been considered in the English courts.

[18] Under section 5 of the *Children Act 1989*, courts may appoint a guardian for a child who has no parent with parental responsibility. Parents with parental responsibility may also appoint a guardian in the event of their own death.

[19] Female circumcision is always prohibited, under the *Prohibition of Female Circumcision Act 1985*

12. In order to consent on behalf of a child, the person with parental responsibility must themselves have capacity. Where the mother of a child is herself under 16, she will only be able to give valid consent for her child's treatment if she herself is Gillick competent (see paragraphs 5-6 above). Whether or not she has capacity may vary, depending on the seriousness of the decision to be taken.

13. Where a child is a ward of court, no important step may be taken in the life of the ward without the prior consent of the court. This is likely to include more significant medical interventions but not treatment for minor injuries or common diseases of childhood.

14. In an emergency, it is justifiable to treat a child who lacks capacity without the consent of a person with parental responsibility, if it is impossible to obtain consent in time and if the treatment is vital to the survival or health of the child. The Department of Health will be issuing guidance to health professionals in 2001 which will include coverage of situations where parents refuse consent to examination, and abuse or neglect is suspected.

Research

15. The legal position concerning research on patients unable to consent is discussed in chapter 2 paragraphs 9 – 9.5. Where children lack capacity to consent for themselves, parents may give consent for their child to be entered into a trial where the evidence is that the trial therapy may be at least as beneficial to the patient as the standard therapy. It may also be compatible with the welfare principle for a person with parental responsibility to give consent to a research intervention which is not strictly in the best interests of the child, but is not against the interests of the child. Such an intervention must involve only minimal burden to the child.

Using children lacking capacity as bone marrow donors

16. Donation of bone marrow can be painful and carries some significant risks. It is not a minimal intervention. Children lacking capacity have on some occasions provided bone marrow to assist in the treatment of a sibling. To have such a transplant may clearly be in the best interests of the sibling. However, in relation to medical interventions it is not acceptable for the needs of one sibling to be balanced against the needs of another. The legal test is whether donating bone marrow is in the best interests of the healthy child.

16.1 It may be extremely difficult for a person with parental responsibility who has one dying child to take a dispassionate view of the best interests of that child's healthy sibling. Factors to be taken into account in a best interests assessment are described in chapter 2 paragraph 3. Health professionals may also find it difficult to assess the needs of the children independently. However, without such dispassionate assessment the treatment may not be lawful.

16.2 The Council of Europe's Convention on Human Rights and Biomedicine requires that authorisation for organ or tissue removal from a person not able to consent (whether adult or child) must be approved by a 'competent body'. States have discretion in how they implement this requirement. Although the UK has not yet signed the Convention, best practice requires some form of independent scrutiny of the healthy child's best interests. Examples might include use of an assessor who is independent of the team responsible for the sick child, or consideration of the case by a hospital clinical ethics committee or other multidisciplinary board convened for the purpose. If there is any doubt about the healthy child's best interests, a ruling from the court should be sought before undertaking the intervention.

4 Withdrawing and Withholding Life-prolonging Treatment

General principles

1. The same legal principles apply to withdrawing and withholding life-prolonging treatment as apply to any other medical intervention. However, the gravity and sensitivity of these decisions are such that the assessment of capacity and of best interests are particularly important. Sometimes decisions will need to be made immediately – for example whether it is appropriate to attempt resuscitation after severe trauma.[20] When more time is available and the patient is an adult or child without capacity, all those concerned with the care of the patient – relatives, partners, friends, carers and the multidisciplinary team – can potentially make a contribution to the assessment. The discussions and the basis for decisions should be recorded in the notes.

2. Legally, the use of artificial nutrition and hydration (ANH) constitutes medical treatment. Thus the legal principles which apply to the use of ANH are the same as those which apply to all other medical treatments such as medication or ventilation. The courts have confirmed that the current case-law in this area is compatible with the *Human Rights Act 1998*.

3. There is an important distinction between withdrawing or withholding treatment which is of no clinical benefit to the patient or is not in the patient's best interests, and taking a deliberate action to end the patient's life. A deliberate action which is intended to cause death is unlawful. Equally, there is no lawful justification for continuing treatment which is not in an incompetent patient's best interests.

Adults and children with capacity

4. Except in circumstances governed by the *Mental Health Act 1983*, if an adult with the capacity to make the decision refuses treatment, or requests that it be withdrawn, practitioners **must** comply with the patient's decision.

5. However, if a child with capacity makes such a request or refusal, this may be over-ridden, as noted in chapter 3, by either a person with parental responsibility or by the courts, if this is believed to be necessary for the welfare of the child. Moreover, the courts consider that to take a decision which may result in the individual's death requires a very high level of understanding, so that many young people who would have the capacity to take other decisions about their medical care would lack the capacity to make such a grave decision.

5.1 Refusal of treatment by a child with capacity must always be taken very seriously, even though legally it is possible to over-ride their objections. It is not a legal requirement to continue a child's life-prolonging treatment in all circumstances. For example, where the child is suffering an illness where the likelihood of survival even with treatment is poor, and treatment will pose a significant burden to the child, it may not be in the best interests of the child to continue treatment.

[20] See circular HSC 2000/28 for further guidance on resuscitation decisions.

Adults and children lacking capacity

6. If a child lacks capacity it is still good practice to involve the child as far as is possible and appropriate in the decision. The decision to withdraw or withhold life-prolonging treatment must be founded on the welfare of the child. If there is disagreement between those with parental responsibility for the child and the clinical team concerning the appropriate course of action, a ruling should be sought from the court.

7. If an adult lacks capacity, and has not made an advance refusal of treatment which is valid and applicable to the circumstances, the decision must be based on the best interests of the adult, again involving the patient as far as this is possible.

7.1 The British Medical Association has suggested that extra safeguards should be followed before a decision to withhold or withdraw ANH is made: that a senior clinician not otherwise involved in the patient's care should formally review the case; that details of cases where ANH has been withdrawn should later be made available for clinical audit; and, where the patient is in PVS or a state closely resembling PVS, that legal advice should be sought. Further, the courts have stated that it is good practice for court approval to be sought before ANH is withdrawn from patients in PVS.

Brain stem death

8. "Best interests" is a concept which only applies to the living. The courts in England have recognised what were originally referred to as the "brain death criteria" as part of the law for the purposes of diagnosing death. The criteria are more accurately described as "brain stem death criteria". Updated guidance on the diagnosis of brain stem death is available.[21]

8.1 When the diagnosis of brain stem death has been confirmed, all clinical interventions can be withdrawn. If, subject to the requirements of the *Human Tissue Act 1961*, the deceased person will become an organ donor, medical interventions to facilitate donation, such as maintaining electrolyte balance, may be continued.

8.2 If a patient is expected to die shortly but brain stem death has not been established, the Department of Health has issued guidance based on legal advice that artificial ventilation with the sole aim of preserving organ function is unlawful.[22] Its purpose is not to benefit the patient and may run the risk of causing serious harm. It is therefore not in the best interests of the patient.

[21] HSC 1998/35: *A code of practice for the diagnosis of brain stem death*

[22] HSG(94)41: *Identification of potential donors of organs for transplantation*

5 Other Exceptions to the Principles

1. Certain statutes set out specific exceptions to the principles noted in the previous chapters. These are briefly noted below. Those concerned with the operation of such statutes should consult more detailed guidance.

2. Part IV of the *Mental Health Act 1983* sets out circumstances in which patients detained under the Act may be treated without consent for their mental disorder. It has no application to treatment for physical disorders unrelated to the mental disorder, which remains subject to the common law principles described in previous chapters. Chapters 15 and 16 of the *Mental Health Act Code of Practice* offer guidance on consent and medical treatment in this context.[23]

2.1 Neither the existence of mental disorder nor the fact of detention under the 1983 Act should give rise to an assumption of incapacity. The patient's capacity must be assessed in every case in relation to the particular decision being made. The capacity of a person with mental disorder may fluctuate.

2.2 Significant reforms to the 1983 Act have been described in the White Paper, *Reforming the Mental Health Act*, published in December 2000.[24] However, these reforms should not affect the principle that treatment for physical disorders, unrelated to the mental disorder for which the patient is receiving compulsory treatment, does not come within the scope of mental health legislation.

3. The *Public Health (Control of Disease) Act 1984* provides that, on an order made by a magistrate, persons suffering from certain notifiable infectious diseases can be medically examined, removed to, and detained in a hospital without their consent. Although the Act has a power for regulations to be made concerning the treatment of such persons without their consent, such regulations have not been made and thus the treatment of such persons must be based on the common law principles previously described.

4. Section 47 of the *National Assistance Act 1948* provides for the removal to suitable premises of persons in need of care and attention without their consent. Such persons must either be suffering from grave chronic disease or be aged, infirm or physically incapacitated and living in insanitary conditions. In either case, they must be unable to devote to themselves (and are not receiving from others) proper care and attention. The Act does not give a power to treat such persons without their consent and therefore their treatment is dependent on common law principles.

[23] Department of Health and Welsh Office, *Code of Practice: Mental Health Act 1983* (1999) The Stationery Office: London

[24] Department of Health and Home Office, *Reforming the Mental Health Act*, Cm 5016-I (2000) The Stationery Office: London

Appendix A: Principles to be followed regarding applications to the court when the patient's capacity to consent is in doubt

Extract from the Court of Appeal's decision in St. George's Healthcare NHS Trust v S:[25]

"The case highlighted some major problems which could arise for hospital authorities when a pregnant woman presented at hospital, the possible need for Caesarean surgery was diagnosed, and there was serious doubt about the patient's capacity to accept or decline treatment. To avoid any recurrence of the unsatisfactory events recorded in this judgement, and after consultations with the President of the Family Division and the Official Solicitor, and in the light of the written submissions from Mr Havers and Mr Gordon, we shall attempt to repeat and expand the advice given in *Re MB [1997] 2 FCR 541, 38 BMLR 175*. This advice also applies to any cases involving capacity when surgical or invasive treatment may be needed by a patient, whether female or male. References to 'she' and 'her' should be read accordingly. It also extends, where relevant, to medical practitioners and health professionals generally as well as to hospital authorities.

The guidelines depend on basic legal principles, which we summarise.

i) They have no application where the patient is competent to accept or refuse treatment. In principle a patient may remain competent notwithstanding detention under the Mental Health Act.

ii) If the patient is competent and refuses consent to the treatment, an application to the High Court for a declaration would be pointless. In this situation the advice given to the patient should be recorded. For their own protection hospital authorities should seek unequivocal assurances from the patient (to be recorded in writing) that the refusal represents an informed decision: that is that she understands the nature of and reasons for the proposed treatment, and the risks and likely prognosis involved in the decision to refuse or accept it. If the patient is unwilling to sign a written indication of this refusal, this too should be noted in writing. Such a written indication is merely a record for evidential purposes. It should not be confused with or regarded as a disclaimer.

iii) If the patient is incapable of giving or refusing consent, either in the long term or temporarily (eg. due to unconsciousness), the patient must be cared for according to the authority's judgement of the patient's best interests. Where the patient has given an advance directive, before becoming incapable, treatment and care should normally be subject to the advance directive. However, if there is reason to doubt the reliability of the advance directive (eg. it may sensibly be thought not to apply to the circumstances which have arisen), then an application for a declaration may be made.

[25] *St George's Healthcare NHS Trust v S* [1998] 3 All ER 673

Concern over capacity

iv) The authority should identify as soon as possible whether there is concern about a patient's competence to consent to or refuse treatment.

v) If the capacity of the patient is seriously in doubt it should be assessed as a matter of priority. In many such cases the patient's general practitioner or other responsible doctor may be sufficiently qualified to make the necessary assessment, but in serious or complex cases involving difficult issues about the future health and well-being or even the life of the patient, the issue of capacity should be examined by an independent psychiatrist, ideally one approved under s12(2) of the Mental Health Act. If following this assessment there remains a serious doubt about the patient's competence, and the seriousness or complexity of the issues in the particular case may require the involvement of the court, the psychiatrist should further consider whether the patient is incapable by reason of mental disorder of managing her property or affairs. If so the patient may be unable to instruct a solicitor and will require a guardian *ad litem* in any court proceedings.

The authority should seek legal advice as quickly as possible. If a declaration is to be sought, the patient's solicitors should be informed immediately and if practicable they should have a proper opportunity to take instructions and apply for legal aid where necessary. Potential witnesses for the authority should be made aware of the criteria laid down in *Re MB* and this case, together with any guidance issued by the Department of Health, and the British Medical Association.

vi) If the patient is unable to instruct solicitors, or is believed to be incapable of doing so, the authority or its legal advisers must notify the Official Solicitor and invite him to act as guardian *ad litem*. If the Official Solicitor agrees he will no doubt wish, if possible, to arrange for the patient to be interviewed to ascertain her wishes and to explore the reasons for any refusal of treatment. The Official Solicitor can be contacted through the Urgent Court Business Officer out of office hours on 020 7947 6000.

The hearing

vii) The hearing before the judge should be *inter partes*. As the order made in her absence will not be binding on the patient unless she is represented either by a guardian *ad litem* (if incapable of giving instructions) or (if capable) by counsel or solicitor, a declaration granted *ex parte* is of no assistance to the authority. Although the Official Solicitor will not act for a patient if she is capable of instructing a solicitor, the court may in any event call on the Official Solicitor (who has considerable expertise in these matters) to assist as an *amicus curiae*.

viii) It is axiomatic that the judge must be provided with accurate and all the relevant information. This should include the reasons for the proposed treatment, the risks involved in the proposed treatment, and in not proceeding with it, whether any alternative treatment exists, and the reason, if ascertainable, why the patient is refusing the proposed treatment. The judge will need sufficient information to reach an informed conclusion about the patient's capacity, and, where it arises, the issue of best interest.

ix) The precise terms of any order should be recorded and approved by the judge before its terms are transmitted to the authority. The patient should be accurately informed of the precise terms.

x) Applicants for emergency orders from the High Court made without first issuing and serving the relevant applications and evidence in support have a duty to comply with the procedural requirements (and pay the court fees) as soon as possible after the urgency hearing.

Conclusion

There may be occasions when, assuming a serious question arises about the competence of the patient, the situation facing the authority may be so urgent and the consequences so desperate that it is impracticable to attempt to comply with these guidelines. The guidelines should be approached for what they are, that is guidelines. Where delay may itself cause serious damage to the patient's health or put her life at risk then formulaic compliance with these guidelines would be inappropriate."

Appendix B: Further Reading

Alderson, P & Montgomery J, *Health care choices: making decisions with children* (1996) IPPR: London.

Association of Anaesthetists of Great Britain and Ireland, *Information and consent for anaesthesia* (1999) Association of Anaesthetists of Great Britain and Ireland: London. (www.aagbi.org)

British Medical Association, *Advance statements about medical treatment* (1995) BMA Publishing Group: London. (www.bma.org.uk)

British Medical Association, *Consent, rights and choices in health care for children and young people* (2001) BMJ Books: London. (www.bmjpg.com/consent)

British Medical Association, Royal College of Nursing and Resuscitation Council (UK), *Decisions relating to cardiopulmonary resuscitation* (2001) BMA: London. (web.bma.org.uk/cpr)

British Medical Association, *The impact of the Human Rights Act 1998 on medical decision-making* (2000) BMA: London. (www.bma.org.uk)

British Medical Association, *Withdrawing and withholding life prolonging treatment: guidance for decision making*, 2nd edition (2000) BMJ Books: London. (www.bmjpg.com/withwith/ww.htm)

Department of Health and Welsh Office, *Code of Practice: Mental Health Act 1983* (1999) The Stationery Office: London. (www.doh.gov.uk/mhact1983.htm)

Department of Health, current edition of *Immunisation against infectious diseases*, The Stationery Office: London (contains chapter on consent for immunisation).

Department of Health, HSC 1998/35: *A code of practice for the diagnosis of brain stem death*, and attached booklet *A code of practice for the diagnosis of brain stem death including guidelines for the identification and management of potential organ and tissue donors.* (www.doh.gov.uk/publications/coinh.html, circular only)

Department of Health, *Working together to safeguard children: a guide to inter-agency working to safeguard and promote the welfare of children* (1999) The Stationery Office: London.

Department of Health, *The removal, retention and use of human organs and tissue from post-mortem examination: advice from the Chief Medical Officer* (2001) The Stationery Office: London. (www.doh.gov.uk/orgretentionadvice)

General Dental Council, *Maintaining standards: guidance to dentists on professional and personal conduct* (May 2000) GDC: London.

General Medical Council, *Seeking patients' consent: the ethical considerations* (1998) GMC: London. (www.gmc-uk.org)

GMC guidance, *Making and using visual and audio recordings of patients* (1997) GMC: London. (www.gmc-uk.org)

Keywood, K et al, *Best practice? Health care decision making by, with and for adults with learning disabilities* (1999) National Development Team: Manchester.

Royal College of Pathologists, *Guidelines for the retention of tissues and organs at post-mortem examination* (2000) Royal College of Pathologists: London. (www.rcpath.org)

Royal College of Physicians of London, *Guidelines on the practice of ethics committees in medical research involving human subjects*, 3rd edition (1996) Royal College of Physicians: London.

Royal College of Surgeons of England, *Good surgical practice* (2000) Royal College of Surgeons of England: London. (www.rcseng.ac.uk/publications/list.asp?menu=publications)

Senate of Surgery of Great Britain and Ireland, *The surgeon's duty of care* (1997) Senate of Surgery of Great Britain and Ireland: London.

United Kingdom Central Council for Nursing, Midwifery and Health Visiting, *Code of professional conduct* (1992) UKCC: London. (www.ukcc.org.uk/cms/content/Publications/)

United Kingdom Central Council for Nursing, Midwifery and Health Visiting, *Guidelines for professional practice* (1996) UKCC: London. (www.ukcc.org.uk/cms/content/Publications/)

United Kingdom Central Council for Nursing, Midwifery and Health Visiting, *Guidelines for mental health and learning disabilities nursing* (1998) UKCC: London. (www.ukcc.org.uk/cms/content/Publications/)

United Kingdom Central Council for Nursing, Midwifery and Health Visiting, *Midwives Rules and Code of Practice* (1998) UKCC: London. (www.ukcc.org.uk/cms/content/Publications/)

In addition to the codes of practice of the regulatory bodies cited above, the professional bodies of each of the allied health professions publish codes of conduct which include requirements on seeking consent. These codes of conduct are normally congruent with the 'statements regarding infamous conduct' which regulate all the professions covered by the Council for Professions Supplementary to Medicine.

Appendix C: Legal References

References to the main cases and professional guidance from which the principles set out in this guidance are derived are given below, by paragraph number.

Chapter 1

1. *Re F (mental patient: sterilisation)* [1990] 2 AC 1
2. *Re MB (an adult: medical treatment)* (1997) 38 BMLR 175; *Re T (adult: refusal of treatment)* [1993] Fam 95
3. *Re T (adult: refusal of treatment)* [1993] Fam 95
4. *Chatterton v Gerson* [1981] 1 All ER 257; *Appleton v Garrett* (1995) 34 BMLR 23
5. *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871; *Smith v Tunbridge Wells HA* (1994) 5 Med LR 334; *Bolitho v City & Hackney HA* [1997] 4 All ER 771; *Pearce v United Bristol Healthcare NHS Trust* (1999) 48 BMLR 118
6. This issue has never been directly addressed in English case law, but academic commentators suggest that English courts would be likely to follow the Canadian cases of *Marshall v Curry* [1994] 3 DLR 260 & *Murray v McMurchy* [1949] 2 DLR 442; *Re T (adult: refusal of treatment)* [1993] Fam 95 (regarding advance refusals)
7. No English cases as yet
8. GMC guidance, *Making and using visual and audio recordings of patients*, September 1997
9. *Re F (mental patient: sterilisation)* [1990] 2 AC 1; General Medical Council, *Seeking patients' consent: the ethical considerations*, November 1998; UKCC, *Code of professional conduct*, June 1992
10. *Re MB (an adult: medical treatment)* (1997) 38 BMLR 175 highlights temporary factors such as fear which may affect a patient's capacity to consent and advocates identifying 'potential problems' (in that case a patient's fear of needles) as far in advance as possible.
11. *Chatterton v Gerson* [1981] 1 All ER 257
12. No direct English cases, but a well-established principle, based on the Massachusetts case of *O'Brien v Cunard SS Co* (1891) 28 NE 266 (Mass Sup Jud Ct)
13. Schedule 3 of the *Human Fertilisation and Embryology Act 1990*
14. Section 2 of the *Human Organ Transplants Act 1989*
15. *Chatterton v Gerson* [1981] 1 All ER 257; General Medical Council, *Seeking patients' consent: the ethical considerations*, November 1998, paragraphs 35-36
16. General Medical Council, *Seeking patients' consent: the ethical considerations*, November 1998, paragraph 32
17. *Re C (adult: refusal of medical treatment)* [1994] 1 All ER 819; *Re MB (an adult: medical treatment)* (1997) 38 BMLR 175; *St George's Healthcare NHS Trust v S* [1998] 3 All ER 673

18. No direct English case law, but Canadian Supreme Court judgement *Ciarlariello v Schacter* (1993) 100 DLR (4th) 609

19. *Re T (adult: refusal of treatment)* [1993] Fam 95*; Re C (adult: refusal of medical treatment)* [1994] 1 All ER 819; *Re MB (an adult: medical treatment)* (1997) 38 BMLR 175; *St George's Healthcare NHS Trust v S* [1998] 3 All ER 673; *Secretary of State for the Home Department v Robb* [1995] 1 All ER 677 (on refusal of food)

20. *Re T (adult: refusal of treatment)* [1993] Fam 95; *B v Croydon District HA* [1995] Fam 133

Chapter 2

1. *Re F (mental patient: sterilisation)* [1990] 2 AC 1

2. *Re T (adult: refusal of treatment)* [1993] Fam 95

3. *Re MB (an adult: medical treatment)* (1997) 38 BMLR 175 (best interests not restricted to best medical interests); Kennedy and Grubb, eds, *Principles of Medical Law* (1998), pp 247-252, draws together numerous cases in which 'best interests' have been discussed by the courts in the clinical context.

4. *St George's Healthcare NHS Trust v S* [1998] 3 All ER 673

5. *Re F (mental patient: sterilisation)* [1990] 2 AC 1

6. *Re F (mental patient: sterilisation)* [1990] 2 AC 1

7. *Re F (mental patient: sterilisation)* [1990] 2 AC 1

8. *Re F (mental patient: sterilisation)* [1990] 2 AC 1 (sterilisation for contraceptive purposes); *Re Y (mental patient: bone marrow donation)* [1997] Fam 110 (donation of regenerative tissue); *Airedale NHS Trust v Bland* [1993] AC 789 (withdrawal of artificial nutrition and hydration); *St George's Healthcare NHS Trust v S* [1998] 3 All ER 673 (where doubt as to patient's capacity); *Re SG (a patient)* (1990) 6 BMLR 95 (abortion); *F v F* (1991) 7 BMLR 135 (hysterectomy for serious menorrhagia declared lawful); *Re S (adult patient: sterilisation)* [2000] 3 WLR 1288 (hysterectomy for menorrhagia declared unlawful)

9. No directly relevant English cases as yet, but *S v S, W v Official Solicitor* [1972] AC 24 ruled that a blood test to establish paternity was "not against the interests" of a child.

Chapter 3

1. The *Children Act 1989; Gillick v West Norfolk and Wisbech AHA* [1986] AC 112; *Re R (a minor) (wardship: consent to treatment)* [1992] Fam 11; *Re W (a minor) (medical treatment)* [1992] 4 All ER 627

2. Section 8 of the *Family Law Reform Act 1969*

3. Section 8 of the *Family Law Reform Act 1969*

4. Section 8 of the *Family Law Reform Act 1969*

5. *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112; *Re R (a minor) (wardship: consent to treatment)* [1992] Fam 11

6. *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112

7. *Re T (adult: refusal of treatment)* [1993] Fam 95; *Re S (a minor) (consent to medical treatment)* [1994] 2 FLR 1065

8. *Re W (a minor) (medical treatment)* [1992] 4 All ER 627; *Re C (a minor) (evidence: confidential information)* (1991) 7 BMLR 138; *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112 (resolving doubts in favour of saving life)

9. Sections 1 and 3 of the *Children Act 1989*; *Re B (a minor) (wardship: sterilisation)* [1988] AC 199; *Re E (a minor) (medical treatment)* (1991) 7 BMLR 117

10. Sections 2, 4, 5, 12, 33 and 44 of the *Children Act 1989*

11. Section 2(7) of the *Children Act 1989*; *Re J (child's religious upbringing and circumcision)* (1999) 52 BMLR 82

12. *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112

13. *Re D (a minor) (wardship: sterilisation)* [1976] Fam 185

14. *Gillick v West Norfolk and Wisbech AHA* [1986] AC 112

15. No directly relevant English cases as yet, but *S v S, W v Official Solicitor* [1972] AC 24 ruled that a blood test to establish paternity was "not against the interests" of a child.

16. No English cases yet involving children but *Re Y (mental patient: bone marrow donation)* [1997] Fam 110 sets out the "best interests" approach for incompetent adults; Council of Europe, *Convention on Human Rights and Biomedicine*, Article 20(2)(iv).

Chapter 4

1. *Airedale NHS Trust v Bland* [1993] AC 789

2. *Airedale NHS Trust v Bland* [1993] AC 789*; NHS Trust A v Mrs. M : NHS Trust B v Mrs H* [2001] 1 All ER 801

3. *Airedale NHS Trust v Bland* [1993] AC 789

4. *Re C (adult: refusal of medical treatment)* [1994] 1 All ER 819; *Re MB (an adult: medical treatment)* (1997) 38 BMLR 175; *St George's Healthcare NHS Trust v S* [1998] 3 All ER 673

5. *Re W (a minor) (medical treatment)* [1992] 4 All ER 627

6. *R v Portsmouth Hospitals NHS Trust ex parte Glass* (1999) 50 BMLR 269

7. *Airedale NHS Trust v Bland* [1993] AC 789

8. *Re A (a minor)* [1992] 3 Med LR 303

This guidance has been prepared with the assistance of the Good Practice in Consent Advisory Group, whose membership is listed below.

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