Policy Document

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University Hospitals of North Midlands NHS Trust

Consent to Treatment (incorporating Mental Capacity Act)

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V10	March 2021	Routine review

Statement on Trust Policies

The latest version of 'Statement on Trust Policies' applies to this policy and can be accessed here

CONTENTS **Page**

1. INTRODUCTION

Staff at the University Hospitals of North Midlands NHS Trust (UHNM) must adhere to the general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation, or providing personal care, for a person. This principle reflects the right of patients to determine what happens to their own bodies, and is a fundamental part of good practice. A healthcare professional (or other healthcare staff) who fails to respect this principle may be liable to both legal action by the patient and action by their professional body.

2. STATEMENT

The Trust is committed to ensuring compliance with English law concerning consent to physical interventions on patients – from major surgery to the administration or prescription of drugs to assistance with dressing.

3. SCOPE

This policy is relevant to all healthcare professionals (including students) who carry out interventions of any nature.

This policy covers obtaining consent from adults with capacity, children and the provisions of the Mental Capacity Act (2005) in respect of patients who do not have capacity to give consent.

This policy supports the Trust's compliance with the following national guidelines:
1. Care Quality Commission]
2. DH: Reference Guide to Consent for Examination or Treatment (second addition), July 2009
3. Human Tissue Act (2004) and associated Code of Practice: Consent
4. Mental Capacity Act (2005) and associated Code of Practice
5. Deprivation of Liberty Safeguards

An overview of the relevant case law and recent developments can be found at Appendix 2.

This policy should be cross referenced with the following Trust policies:
- HR53 Statutory Mandatory Training Policy
- HR50 Trust Policy for Performance and Development Review (HR50)
- HR17 Trust Policy for Induction Training (HR17)
- HR49 Learning and Education Policy (HR49)

4. DEFINITIONS

1. **'consent'** is a patient's agreement for a health professional to provide care and/or treatment. For consent to be valid, the patient must be competent to make the decision, have received sufficient information to make it and should not be acting under duress.

2. **'DOLS'** means Deprivation of Liberty Safeguards.

3. **'HTA'** means Human Tissue Authority.

4. **'HT Act'** means Human Tissue Act 2005.

5. **'MCA'** means Mental Capacity Act (2005).

6. **'material risk'** means a risk where, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the particular individual patient has attached significance to a risk.

7. **'risk'** is used throughout to refer to any adverse outcome, including those which some health professionals would describe as recognised complications.

Patients may indicate consent in the following ways:

- Non verbally, for example, by presenting their arm for their blood pressure to be taken
- Verbally, often for more minor procedures, such as cannulation or taking blood
- In writing, which is usually in the form of a written consent form.

5. ROLES AND RESPONSIBILITIES

The health professional undertaking the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being proposed. It is they who will be held responsible in law (and answerable to professional regulatory bodies) if this is challenged later.

Where verbal or implied consent is being sought at the point of the procedure being carried out, this will naturally be done by the healthcare worker at that time.

Delegated consent is not routinely undertaken within the Trust, except for those areas identified in the Appendix.

5.1 Role of the treating Consultant

It is generally accepted that the consent process for medical and surgical treatment is consultant led and that the treating consultant is often best placed to consent their patient for a particular procedure which they intend to carry out.

In the event that this responsibility is assigned to a junior (who should also be capable of carrying out the procedure), then the consultant still retains overall responsibility for ensuring that the patient is fully informed of the 'material risks'. The patient is required to understand the seriousness of the risk and the anticipated benefits of the proposed treatment and reasonable alternatives.

5.2 Role of all Healthcare Professionals

All healthcare professionals are responsible for:

- complying with the standards set out in the associated Practice Guidelines supporting this policy (appendix).
- using the standard consent forms, which should be available in all clinical areas
- clear, concise documentation within the handwritten medical notes, where appropriate
- providing access to interpreters where the patient does not speak English or has hearing difficulties (see Trust Policy C11)
- ensuring that any adverse events relating to the consent process are reported in accordance with Trust policy
- working within their own competence. A healthcare professional who feels that they are being pressurised to seek consent when they do not feel competent to do so should express their concern to their immediate clinical supervisor. If this does not result in appropriate action being taken they should contact the Medical Director.

5.3 Role of the Safeguarding Team

It is the role of the Safeguarding Team to provide support in the events where access to an Independent Mental Capacity Advocate is required.

5.4 Divisional Management Teams

The Divisional Senior Management Teams are responsible for ensuring that directorates clearly identify staff required to undertake Consent Training in line with the individual role. Divisional Management can use ESR BI Reporting to identify the number of staff who have completed training.

5.5 Divisional Governance and Quality Managers

The Divisional Governance and Quality Managers are responsible for reviewing adverse incidents in relation to the consent process and ensuring that appropriate action is taken. They should also ensure that any risks associated with the implementation of this policy are included in the Divisional Risk Register and are monitored via the Divisional Governance Quality and Safety meeting.

5.6 Quality, Safety & Compliance Department

The Quality, Safety & Compliance Department will be responsible for providing support to Divisions in investigating incidents and in provision of generic consent training via e learning package.

5.7 Legal Services Department

The Legal Services Department is responsible for providing legal advice in relation to consent and consent related matters and are available within office hours. In the event of an emergency, or the need for urgent advice, you should contact the Site Manager or Executive on-call.

The Legal Services Department will also support access to the provision of generic consent training when required.

6. IMPLEMENTATION

6.1 Documentation / Written Consent

For significant procedures it is essential for health professionals to document clearly, both a patient's agreement to the intervention and the discussions which led up to that agreement.

The healthcare professional is under a duty to take reasonable care to ensure that the patient is aware of any 'material risks' involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances, of a particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is, or should, reasonably be aware that the particular patient would be likely to attach significance to it.

Making a detailed record of the information provided to the patient about the risks involved in proposed treatment is crucial; this may include contemporaneous notes recorded in the medical records and/or a fully completed standard consent form. Any record should also make reference (by name and date issued) to patient information leaflets / literature.

6.2 Consent Forms

The standard consent form provides a space for healthcare professionals to provide information to patients and further space for them to sign, confirming that they have held the discussion with the patient. All consent forms should be completed comprehensively with the correct patient information.

Please see Appendix 1 for Trust an overview of Trust Consent Forms and when they should be used. Consent forms should be made available in all clinical areas.

7. EDUCATION/TRAINING AND PLAN OF IMPLEMENTATION

Training for clinicians involved in taking consent for treatment will be provided via e-learning system and any specific session following requests to Legal Services Department.

All training should be recorded within employee personal records on ESR. Reports on numbers of staff completing training will be provided by Quality, Safety & Compliance Department via ESR to Divisional Management Teams. The Divisional Management teams will follow up with individual services / individuals to improve compliance

8. MONITORING AND REVIEW ARRANGEMENTS

8.1 Monitoring Arrangements

Consent Audit will be undertaken as part of the Trust's Clinical Audit Plan and results presented to the Trust's Clinical Effectiveness Group and Quality & Safety Oversight Group to provide assurance that consent policy is being implemented and followed. Where actions are required to improve compliance these will be developed and monitored at the Clinical Effectiveness Group. Exception reports will be included in reports to Quality & Safety Oversight Group and Quality Governance Committee

Training reports will be provided via Quality, Safety & Compliance Department for Divisional Management Teams.

Divisional Management can use ESR BI Reporting to identify the number of staff who have completed training.

8.2 Review

The Quality Safety and Compliance Department, with the support of the Legal Services Department, is responsible for ensuring that this policy is reviewed 3 yearly or sooner in the event of updated legislation.

Appendix 1: Trust Consent Forms - When They Should Be Used

All consent forms should be available in appropriate clinical areas

No.	Title	When to Use
1.	**Patient agreement to investigation or treatment**	This form is for people who have the capacity to consent to treatment and therefore is largely unaffected by the MCA. **When not to use this form:** If the patient is 18 or over and lacks the capacity to give consent, you should use consent form 4.
2.	**Parent (or person who has parental responsibility) agreement to investigation or treatment for a child or young person**	This form should be used to document consent to a child's treatment, where that consent is being given by a person with parental responsibility for the child. The term 'parent' has been used in this form as shorthand for 'person with parental responsibility'. **When not to use this form**: Where children are legally competent to consent for themselves (see guidance notes), they may sign the standard 'adult' consent form (form 1). There is space on that form for a parent to countersign if a competent child wishes them to do so.
3.	**Parent (or person who has parental responsibility) / patient agreement to investigation or treatment (procedures where consciousness is not impaired)**	This form documents the patient's agreement (or that of a person with parental responsibility for the patient) to go ahead with the investigation or treatment you have proposed**. It is only designed for procedures where the patient is expected to remain alert throughout and where an anaesthetist is not involved in their care: for example for drug therapy where written consent is deemed appropriate.** **When not to use this form**: In other circumstances you should use either form 1 (for adults/competent children) or form 2 (parental consent for children/young people) as appropriate.
4.	**Form for adults who lack the capacity to consent to investigation or treatment**	This form should only be used where it would be usual to seek written consent but an adult patient (18 or over) lacks capacity to give or withhold consent to treatment. **When not to use this form**: If an adult **has** capacity to accept or refuse treatment, you should use the standard consent form and respect any refusal.
5.	**Consent to Post Mortem**	Post mortem.

Consent: Policy in Practice

Overview of Relevant Law

1. The Human Tissue Act 2004

The Human tissue Act came fully into force on 1 September 2006. It sets out the legal framework for the storage and use of human tissue from the living and for the removal, storage and use of tissue and organs from the dead, including 'residual' tissue following clinical and diagnostic procedures. The Human Tissue Act makes consent a legal requirement for the removal, storage and use of tissue or organs and sets out whose consent is needed in which circumstances. The Act also established the Human Tissue Authority (HTA). The HTA is also responsible for approving the transplantation of organs from living donors and bone marrow and peripheral blood stem cells from adults who lack the capacity to consent and children who lack the competence to consent.

Further guidance on consent and codes of practice are available on the Human Tissue Authority website at http://www.hta.gov.uk/

The HTA Codes of Practice are available via the Trust Intranet.

2. The Mental Capacity Act 2005

The Mental Capacity Act (MCA) came fully into force on 1 October 2007 and sets out a statutory framework for making treatment decisions for people who lack the capacity to make such decisions, setting out who can make them and when. It sets out the legal requirements for assessing whether or not a person lacks the capacity to make a decision.

Where a person lacks the capacity to make a decision for themselves, a decision must be made in that persons best interests. The MCA introduced a duty to NHS bodies to instruct an independent mental capacity advocate (IMCA) in serious medical treatment decisions when a person who lacks the lacks the capacity to make a decision has no one who can speak for them, other than paid staff. The MCA also allows people to plan ahead for a time when they may not have the capacity to make their own decisions; it allows them to appoint a personal welfare attorney to make health and social care decisions, including medical treatment, on their behalf or to make an advanced decision to refuse medical treatment.

Further guidance is available in the Mental Capacity Act 2005 (2005) Code of Practice.

A **Practice Guide** on the Mental Capacity Act is also associated with this policy and can be found within the Practice Guideline at **Appendix 4**.

3. The Human Rights Act 1998

The Human Rights Act (HRA) came into force in October 2000, giving further effect in the UK to the rights enshrined in the European Convention on Human Rights (ECHR). All public authorities are required to act in accordance with the rights set out in the HRA, and all other statutes have to be interpreted by the courts so far as possible in accordance with those rights. The main articles that are likely to be relevant in medical case law are Article 2 (protection of the right to life), Article 3 (prohibition of torture and inhuman or degrading treatment or punishment), Article 5 (the right to liberty and security), Article 8 (the right to respect for private and family life), Article 9 (freedom of thought, conscience and religion), Article 12 (the right to marry and found a family) and Article 14 (prohibition of discrimination in the enjoyment of Convention rights).

Compliance with the HRA is largely reflected in existing good ethical practice, but all health practitioners should be aware of the HRA and ensure that they act in compliance with it. The British Medical

Association (BMA) has a handbook of ethics and law that gives advice on how the HRA relates to a range of relevant issues.

4. Case Law

The law on consent has recently gone through a significant change following the case of Montgomery v Lanarkshire Health Board [2015]. However, there are a number of legal cases that health professionals should be aware of:

Montgomery v Lanarkshire Health Board [2015] UK SC11
Nadine Montgomery suffered from diabetes and was not told of the risks of shoulder dystocia to her baby boy, who subsequently developed cerebral palsy. Although Nadine had repeatedly expressed concerns about giving birth naturally, her obstetrician said that she routinely chose not to explain the risk of shoulder dystocia to diabetic women, because the risk of serious injury to the baby was very small (0.1%) and that if she did explain it, *'then everyone would ask for a caesarean section'.*

The Supreme Court held that it would be a mistake to view patients as uninformed, incapable of understanding medical matters, or wholly dependent on information from doctors and ruled that it was for *patients* to decide whether the risks of treatment and alternative options had been adequately communicated. This takes the emphasis away from any medical paternalism.

The Montgomery ruling means that doctors/healthcare professionals will have to take "reasonable care to ensure that the patient is aware of any **material risks** involved in any recommended treatment and of any reasonable alternative or variant treatments

What counts as 'material risk'?
The Supreme Court rules that this is for the patient to decide. A "*responsible body of medical opinion*" has now been replaced by a "*reasonable person in the patient's position*".

The test of materiality therefore has two strands to it (1) those material risks that an objective person in the patient's position would consider relevant and (2) what the doctor would reasonably consider the patient would attach significance to.

It is insufficient to simply rely upon offering details of all of the *risks* of the actual proposed procedure, but all of the *options* available to that person must be discussed. In essence, the patient must be the one to choose the course of action, taking into account the doctor's recommendation.

The Court is uncompromising in its ruling and now expects "even those doctors who have less skill or inclination for communication, or who are more hurried, to pause and engage in the discussion".

Montgomery also outlines that reliance upon pre-printed information or 'demanding a signature' upon a consent form that lists a series of risks is insufficient to overcome breach of duty.
Please refer to **Practice Guide** at **Appendix 3** for more information.

Ms B v An NHS Hospital Trust [2002] 2 ALL ER 449
Following an illness, Ms B became tetraplegic and reliant on an artificial ventilator. She asked that the ventilator that was keeping her alive be switched off and claimed that the continued provision of artificial ventilation against her wishes was an unlawful trespass. The Court was asked to decide whether Ms B had the capacity to make the decision about whether the ventilator should be removed. The Court held that Ms B did have capacity to refuse treatment and she had therefore, been treated unlawfully.
Where a patient has the capacity to make decisions about treatment, they have the right to refuse treatment even when the consequences of such decisions could lead to their death. If a Doctor feels unable to carry out the wishes of the patient, their duty is to find another Doctor who will do so.

Glass v United Kingdom [2004]
The European Court of Human Rights held that a decision of health professionals to override the wishes of the mother of a seriously ill child gave rise to a breach of Article 8 of the European Convention of Human Rights. The court was critical of the fact that the courts were not involved at an earlier stage, and held that, in the event of a continued disagreement between parents and doctors about a child's

treatment, the courts should be consulted, and particularly before the matter reaches an emergency situation.

Chester v Afshar [2004]
The House of Lords judgement held that a failure to warn a patient of a risk of injury inherent in surgery, however small the probability of the risk occurring, denies the patient the change to make a fully informed decision. The judgement held that it is advisable that health practitioners give information about all significant possible adverse outcomes and make a record of the information given.

Burke v General Medical Council [2005]
The Court of Appeal held that the General Medical Council (GMC) guidance on withholding and withdrawing life prolonging treatment was lawful. A patient cannot demand a particular treatment, but health professionals must take into account a patient's wishes when making treatment decisions. Where a patient with capacity indicates his or her wish to be kept alive by the provision of Artificial Nutrition and Hydration (ANH), the doctor's duty of care will require the doctor to provide ANH for as long as such treatment continues to prolong life. Where life depends upon the continued provision of ANH, ANH will be clinically indicated. A health professional who deliberately brought that patients life to an end by withdrawing ANH would be in breach of their duty of care and guilty of murder. If the patient lacks capacity, all reasonable steps that are in the persons best interests should be taken to prolong their life. Although there is a strong presumption in favour of providing life sustaining treatment, there are circumstances when continuing or providing life sustaining treatment stops providing a benefit to a patient and is not clinically indicated.

This Practice Guide is one of a series of information sheets on consent and should be read in connection with Trust Policy C43.

Consent: Policy in Practice

Seeking Consent

Valid consent

For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question (this will be the patient or someone with parental responsibility for a patient under the age of 18, someone authorised to do so under a Lasting Power of Attorney (LPA) or someone who has the authority to make treatment decisions as a Court Appointed Deputy). Acquiescence where the person does not know what the intervention entails, is not 'consent'.

Does the person have capacity?

The Mental Capacity Act 2005 defines a person who lacks capacity as a person who is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain. It does not matter if the impairment or disturbance is permanent or temporary. A person lacks capacity if:

a. They have an impairment or disturbance (for example a disability, condition or trauma or the effect of drugs or alcohol) that affects the way their mind or brain works, ***and***
b. That impairment or disturbance means that they are unable to make a specific decision at the time it needs to be made.

An assessment of a person's capacity must be based on their ability to make a specific decision at the time it needs to be made, and not their ability to make decisions in general. A person is unable to make a decision if they cannot do one or more of the following things:

a. Understand the information given to them that is relevant to the decision;
b. Retain that information long enough to make the decision;
c. Use or weigh up the information as part of the decision making process;
d. Communicate their decision – this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

People may have capacity to consent to some interventions but not to others, or may have capacity at some times but not others. Under the MCA, a person must be assumed to have capacity unless it is established that they lack capacity. If there is any doubt, then the healthcare 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. Guidance on assessing capacity is given in Chapter 4 of the Mental Capacity Act (2005) Code of Practice and a **Practice Guide** is set out in **Appendix 4**.

Additional further guidance on how people should be helped to make their own decisions is given in chapter 3 of the Mental Capacity Act (2005) Code of Practice.

Is the consent given voluntarily?

To be valid, consent must be given voluntarily and freely, without pressure or undue influence being exerted on the person either to accept or refuse treatment. Such pressure can come from partners or family members, as well as healthcare practitioners. Practitioners should be alert to this possibility and where appropriate, should arrange to see the person on their own in order to establish that the decision is truly their own.

When people are seen and treated in environments where involuntary detention may be an issue, such as prisons and mental health 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 the person consents freely. Coercion should be distinguished from providing the person with

appropriate reassurance concerning their care or treatment, or pointing out the potential benefits of treatment for the persons health. However, threats such as withdrawal of any privileges, loss of remission of sentence for refusing consent or using such matters to induce consent may well invalidate the consent given, and are not acceptable.

Has the person received sufficient information?

To give valid consent, the person needs to understand the nature and purpose of the procedure. Any misrepresentation of these elements will invalidate consent. Where relevant, information about anaesthesia should be given alongside information about the procedure itself.

The legal requirement of the duty to inform patients continues to develop in case law and the recent decision on the case of Montgomery has significantly changed the legal position in relation to informed consent.

Duty to warn and advise (post Montgomery)

In considering what information to provide, the healthcare practitioner should try to ensure that the person is able to make an informed judgement on whether to give or withhold consent. Giving the leading judgement in the case of Montgomery v Lanarkshire Health Authority [2015], Lord Kerr said that an adult of sound mind is entitled to decide which, if any, of the *available treatments* to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. He opined that:

'The social and legal developments which we have mentioned point away from a model of the relationship between the doctor and the patient based on medical paternalism. They also point away from a model based on a view of the patient as being entirely dependent on information provided by the doctor. What they point towards is an approach to the law which, instead of treating patients as placing themselves in the hands of their doctors, treats them so far as possible as adults who are capable of understanding.'

The Supreme Court held that it would be a mistake to view patients as uninformed, incapable of understanding medical matters, or wholly dependent on information from doctors and ruled that it was for *patients* to decide whether the risks of treatment and alternative options had been adequately communicated. This takes the emphasis away from any medical paternalism.

The Montgomery ruling means that doctors/healthcare professionals will have to take reasonable care to ensure that the patient is aware of any **material risks** involved in any recommended treatment *and* of any **reasonable alternative or variant treatments**.

What counts as 'material' risks?

The Supreme Court ruled that this is for the patient to decide. A "*responsible body of medical opinion*" has now been replaced by a "*reasonable person in the patient's position*".
The test of materiality therefore has two strands to it:

a. Those material risks that an objective person in the patient's position would consider relevant, ***and***
b. What the doctor would reasonably consider the patient would attach significance to.

It is insufficient to simply rely upon offering details of all of the *risks* of the actual proposed procedure – instead, all of the *options* available to that person must also be discussed. In essence, the patient must be the one to choose the course of action, taking into account the doctor's recommendation.

The Court is uncompromising in its ruling and now expects "even those doctors who have less skill or inclination for communication, or who are more hurried, to pause and engage in the discussion".

Montgomery also outlines that reliance upon pre-printed information or 'demanding a signature' upon a consent form that lists a series of risks is insufficient to overcome breach of duty.

The Supreme Court also went on to make **three further key points**:

a. The assessment of whether a risk is material or not is no longer an issue of a percentage possibility of it arising. The significance of a given risk is likely to reflect factors in addition to

magnitude, such as the nature of the risk, the effect that it would have on the life of the patient if it were to occur, the importance to the patient of the benefits of desire to the treatment, the alternative treatments available, and the risks associated with those treatments. The assessment is therefore considered to be both fact sensitive and sensitive to the characteristics of the patient.

b. The doctor's 'advisory role' will involve dialogue, the aim of which will be to ensure that the patient understands the seriousness of the condition, the anticipated risks and benefits of the proposed treatment and any reasonable alternatives – thus be in a position to make an informed decision. That can only be achieved if the information provided is comprehensible. Providing a mass of technical information which the patient cannot reasonably be expected to understand will not therefore enable the patient to be properly informed. Similarly, a signature on a consent form will not achieve that.
c. The therapeutic exception - where the information would be seriously detrimental to the patient's health, or where the treatment is required in the circumstances of necessity, then information may be withheld. This position should not be abused and represents a limited exception to the general principle.

The GMC welcomed the Supreme Court judgement and further provides guidance on the type of information that patients may need to know before making a decision. The GMC recommends that doctors should do their best to find out about patients' individual needs and priorities when providing information about treatment options. It advises that discussions should focus on the patient's 'individual situation and risk to them' and sets out the importance of providing the information about the procedure and associated risks in a balanced way and checking that patients have understood the information given (see GMC – Consent: Patients and Doctors Making Decisions Together (2008)).

As per the therapeutic exception, some people may wish to know very little about the treatment that 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 individuals' wishes may change over time, and it is important to provide opportunities for them to express this. GMC and BMA guidance encourages doctors to explain to patients the importance of knowing the options open to them while respecting a person's wish not to know, and states that basic information should always be provided about what the treatment aims to achieve and what it will involve.

Who should take consent (including delegated consent)

The clinician providing the treatment or investigation is responsible for ensuring that the person has given valid consent before treatment begins. The GMC guidance states that the task of seeking consent may be delegated to another person, *as long as they are 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. The practitioner who eventually carries out the investigation or treatment must also be able to determine whether the person has the capacity to make the decision in question and what steps need to be taken if the person lacks the capacity to make that decision. 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.

Trust policy does not allow delegated consent apart from those exceptions to the general rule (see Appendix to C34)

When should consent be sought?

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 person's consent to the proposed procedure well in advance when there is time to respond to the person's questions and provide adequate information. Clinicians should then check, before the procedure is undertaken, that the person still consents.

If a person is not consented 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 a person be given routine pre-operative medication before being asked for their consent to proceed with the treatment.

Duration of consent

When a person gives valid consent to an intervention, in general that consent remains valid for an indefinite duration, unless it is withdrawn by the person. 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. The clinician should consider whether the new information should be drawn to the attention of the patient and the process of seeking consent should be 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.

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 that they retain capacity) still wishes the intervention to proceed, even if no new information needs to be provided or further questions answered.

Consent forms

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.

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 as amended by the Human Fertilisation and Embryology Act 2008) 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 person's capacity, it is important to establish both that they have the capacity and that they are aware of the material risks and alternative or variant treatments before the person is asked to sign the form. Details of the assessment of capacity, and the conclusion reached, should be recorded in the case notes.

If the person has capacity, but is unable to read or write, they 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 person has chosen to make their mark in this way to be recorded in the case notes. Similarly, if the person has capacity, and wishes to give consent, but is physically unable to mark the form, this fact should be recorded in the notes. Alternatively, the person can direct someone to sign the form on their behalf, but there is no legal requirement for them to do so. If consent has been given validly, the lack of a completed form is no bar to treatment, but a form can be important evidence of such consent.

Additional procedures

During an operation it may become evident that the person 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 person regains consciousness (for example because there is a threat to the person's life) it may be justified to perform the procedure on the grounds that it is in the person's best interests. However, the procedure should not be performed merely because it is convenient. For example, a hysterectomy should never be performed during an operation without explicit consent, unless it is necessary to do so to save life.

If a person 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), then this must be respected if the refusal is applicable to the circumstances. The GMC guidance states that, where anticipated, it is good practice to seek the views of the patient on possible additional procedures when seeking consent for the original intervention.

Subsequent use of removed tissue

The Human Tissue Act 2004 repeals and replaces the Human Tissue Act 1961, the Anatomy Act 1984

and the Human Organ Transplants Act 1989 as they relate to England and Wales. It also repeals and replaces the Human Tissue Act (Northern Ireland) 1962, the Human Organ Transplants (Northern Ireland) Order 1989 and the Anatomy (Northern Ireland) Order 1992.

The 2004 Act makes consent the fundamental principle underpinning the lawful retention and use of body parts, organs and tissue from the living or the deceased for specified health-related purposes and public display. It also covers the **removal** of such material from the deceased. It does not cover removal of such material from living patients – this continues to be dealt with under the common law and the Mental Capacity Act 2005.

The 2004 Act regulates removal, storage and use of human tissue. This is referred to in the Act as 'relevant material' and is defined as material that has come from a human body and consists of, or includes, human cells. Cell lines are excluded, as are hair and nail, from living people. Live gametes and embryos are excluded as they are already regulated under the Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology Act 2008.

The Human Tissue Act 2004 lists the purposes for which consent is required in Schedule 1, and they are referred to as 'scheduled purposes'. The consent required under the Act is called 'appropriate consent', which means consent from the appropriate person, as identified in the Act. Where there has been a failure to obtain or misuse of consent, penalties of up to three years imprisonment or a fine, or both, are provided for in the Act.

Full details on the requirements of the Human Tissue Act 2004 and the HTA's codes of practice are on the HTA's website at www.hta.gov.uk. These should be consulted to ensure compliance.

All HTA Codes of Practice are also available via the Clinical Governance section of the Trust Intranet.

Requirements concerning gametes

It is a legal requirement under the Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology Act 2008 that consent must be obtained in writing before a person's gametes can be used for the treatment of others, or to create an embryo *in vitro*. Consent in writing is also required for the storage of gametes. Information and an opportunity to receive counselling must be provided before the consent is given. Where these requirements are not satisfied, it is unlawful to store or use the person's gametes for these purposes. Clinicians should ensure that written consent to storage exists before retrieving gametes.

Outside specialist infertility practice, these requirements may be relevant to health practitioners whose patients are about to undergo treatment that might 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. Healthcare practitioners may also receive requests to remove gametes from a person who is unable to give consent.

Requirements for living donation

The HTA is responsible for the regulation, through a system of approvals, of the donation from living people of solid organs, bone marrow and peripheral blood stem cells for transplantation into others. Information on the legal requirements and how to proceed is available from the HTA.

Research and innovative treatment

The same legal principles apply when seeking consent from a person for research purposes as when seeking consent for investigations or treatment. GMC guidance advises that patients 'should be told how the proposed treatment differs from the usual methods, why it is being offered, and if there are any additional risks or uncertainties'. Clinical trials are covered by the Medicines for Human Use (Clinical Trial Regulations) 2004.

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 a person with capacity before their consent is sought, along with information about standard alternatives. It is good practice to give the patient information about the evidence, to date, of the effectiveness of the new treatment, both at national/international levels and in the practitioner's own experience, including information about known possible side-effects.

Where the person is an adult who lacks capacity or a child, then the experimental treatment cannot be given, unless it would be in their best interests. In the case of *Simms v Simms*, the court found that where a responsible body of relevant professional opinion supported innovative treatment, that treatment should meet the 'Bolam' test. Where there is no alternative treatment available and the disease is progressive and fatal, it will be reasonable to consider experimental treatment with unknown benefits and risks but without significant risks of increased suffering to the patient, and where there is some chance of benefit to the patient. In this case, the court held that the treatment was in the best interests of both a child and an adult lacking capacity.

Consent to Visual and Audio Recordings

Consent should be obtained for any visual or audio recording, including photographs or other visual images. The purpose and possible future use of the recording must be clearly explained to the person before their consent is sought for the recording to be made. If it is to be used for teaching, audit or research, people must be aware that they can refuse without patient care being compromised and that when required, or appropriate, it can be anonymised. GMC guidance gives more detailed advice, including situations when permission is not required and about obtaining consent to use recordings as part of the assessment or treatment of patients and for training or research.

See Trust policy.

When consent is refused

If an adult with capacity makes a voluntary and appropriately informed decision to refuse treatment (whether contemporaneously or in advance), this decision **must** be respected, except in certain circumstances as defined by the Mental Health Act 1983 (see chapter 5). This is the case even where this may result in the death of the person (and/or the death of an unborn child, whatever the stage of the pregnancy).

Withdrawal of consent

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

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 person has capacity to withdraw a previously given consent. If capacity is lacking, it may sometimes be justified to continue in the person's best interests, but this should not be used as an excuse to ignore distress.

Advance decisions to refuse treatment

A person may have made an advance decision to refuse particular treatment in anticipation of future incapacity (sometimes previously referred to as a 'living will' or 'advance directive').

A valid and applicable advance decision to refuse treatment has the same force as a contemporaneous decision to refuse treatment. This is a well-established rule of common law, and the Mental Capacity Act 2005 now puts advance decisions on a statutory basis.

The Mental Capacity Act sets out the requirements for a valid and applicable advanced decision. In summary these are:

a. the person must be 18 or over;
b. the person must have the capacity to make such a decision;
c. the person must make clear which treatments they are refusing;
d. if the advance decision refuses life-sustaining treatment, it must be in writing (it can be written by someone else or recorded in healthcare notes), it must be signed and witnessed and it must state

clearly that the decision applies even if life is at risk;

e. a person with capacity can withdraw their advance decision at any time.

Healthcare professionals *must* follow an advance decision if it is valid and applicable, even if it may result in the person's death. If they do not, they could face criminal prosecution or civil liability.

A further **Practice Guide** is set out in **Appendix 4**.

Self-Harm

Cases of self-harm present a particular difficulty for healthcare professionals. Where the person is able to communicate, an assessment of their mental capacity should be made as matter of urgency. If the person is judged not to have capacity, then they may be treated on the basis of temporary incapacity. 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.

Patients with capacity 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 an in the future. Making a decision which, if followed, may result in death does not necessarily mean that a person is, or feels, suicidal. Nor does it necessarily mean that the person lacks the capacity to make the decision now or in advance. If the person is clearly suicidal, this may raise questions about their capacity to make the decision. If a patient with capacity has harmed themselves, a prompt psychological assessment of their needs should be offered. However, if the person refuses treatment and 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, had capacity when they took the decision, and are satisfied that the Mental Health Act is not applicable, then treatment should not be forced upon the person, although clearly attempts should of course be made to encourage them to seek/accept help.

This Practice Guide is one of a series of information sheets on consent and should be read in connection with Trust Policy C43.

Consent: Policy in Practice

Adults Without Capacity

General principles

The Mental Capacity Act (MCA) 2005 came fully into force in October 2007 and applies in England and Wales to everyone who works in health and social care and is involved in the care, treatment or support of people over 16 years of age who may lack capacity to make decisions for themselves. It is largely based on previous common law and creates a single, coherent framework for decision-making, including decisions about treatment. This chapter summarises the main provisions of the MCA.

The MCA provides healthcare professionals with protection from civil and criminal legal liability for acts or decisions made in the best interests of the person who lacks capacity. The Act makes it clear that when determining what is in a person's best interests a healthcare professional must not make assumptions about someone's best interests merely on the basis of the person's age or appearance, condition or any aspect of their behaviour.

Under English law, no one is able to give consent to the examination or treatment of an adult who lacks the capacity to give consent themselves unless they have been authorised to do so under a Lasting Power of Attorney or they have the authority to make treatment decisions as a Court appointed Deputy. Therefore, in most cases, parents, relatives or members of the healthcare team cannot consent on behalf of such an adult. However, the MCA sets out the circumstances in which it will be lawful to carry out such examinations or treatment.

In general, the refusal to an intervention made by a person when they had capacity cannot be overridden if the advance decision is valid and applicable to the situation. There are certain statutory exceptions to this principle, including treatment for mental disorder under the Mental Health Act 1983, which are set out briefly in the **Practice Guide** at **Appendix 8**.

Does the person have capacity?

The Mental Capacity Act 2005 defines a person who lacks capacity as a person who is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain. It does not matter if the impairment or disturbance is permanent or temporary. A person lacks capacity if:

a. They have an impairment or disturbance (for example a disability, condition or trauma or the effect of drugs or alcohol) that affects the way their mind or brain works, ***and***
b. That impairment or disturbance means that they are unable to make a specific decision at the time it needs to be made.

c. An assessment of a person's capacity must be based on their ability to make a specific decision at the time it needs to be made, and not their ability to make decisions in general. A person is unable to make a decision if they cannot do one or more of the following things:
   - Understand the information given to them that is relevant to the decision;
   - Retain that information long enough to make the decision;
   - Use or weigh up the information as part of the decision making process;
   - Communicate their decision – this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

People may have capacity to consent to some interventions but not to others, or may have capacity at some times but not others. Under the MCA, a person must be assumed to have capacity unless it is established that they lack capacity. If there is any doubt, then the healthcare 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. Guidance on assessing capacity is given in Chapter 4 of the Mental Capacity Act (2005) Code of Practice and a **Practice Guide** is set out in **Appendix 4**.

Additional further guidance on how people should be helped to make their own decisions is given in chapter 3 of the MCA (2005) Code of Practice.

Best Interests checklist – refer to Appendix 5

Section 4 of the MCA requires that a healthcare professional **must** consider all of the relevant circumstances relating to the decision in question. These are described as factors that the healthcare professional is aware of and which are reasonable to take into account.

In considering the relevant circumstances, the Act rules that the healthcare professionals **must** take the following steps:

- Consider whether the person is likely to regain capacity and if so whether the decision can wait;

- Involve the person as fully as possible in the decision that is being made on their behalf;

- As far as possible, consider:
    - the person's past and present wishes and feelings (in particular if they have been written down)
    - any beliefs and values (e.g. religious, cultural or moral) that would be likely to influence the decision in question, and any other relevant factors, and
    - the other factors that the person would be likely to consider if they were able to do so;

- As far as possible, consult other people if it is appropriate to do so and take into account their views as to what would be in the best interests of the person lacking capacity, especially:
    - anyone previously named by the person lacking capacity as someone to be consulted
    - anyone engaging in caring for or interested in the person's welfare
    - any attorney appointed under a Lasting Power of Attorney (see paragraphs 14–16)
    - any deputy appointed by the Court of Protection to make decisions for the person (see paragraphs 17–20).

- For decisions about serious medical treatment, where there is no one appropriate other than paid staff, healthcare professionals have to instruct an IMCA (see paragraphs 21–23);

- If the decision concerns the provision or withdrawal of life-sustaining treatment, the person making the best interests decision must not be motivated by a desire to bring about the person's death.

The MCA (2005) Code of Practice makes it clear that the steps set out in the Act should form the starting point for considering all the relevant circumstances of each case, and often other factors will be important. Further guidance on interpreting best interests is provided in chapter 5 of the Code of Practice.

Healthcare professionals should demonstrate in their record-keeping that the decision has been based on all available evidence and has taken into account any conflicting views. What is in a person's best interests may well change over time. This means that even where similar actions need to be taken repeatedly in connection with the person's care or treatment, the person's best interests should be reviewed regularly.
In cases of serious doubt or dispute about an individual's mental capacity or best interests, an application can be made to the Court of Protection for a ruling. The duty officer of the Official Solicitor can advise on the appropriate procedure if necessary. See also chapter 8 of the Mental Capacity Act (2005) Code of Practice for further information.

Detailed guidance is provided in the Code of Practice, which has statutory force. The Act imposes a duty on health professionals (and other healthcare staff) to have regard to the Code of Practice.

Duration of lack of capacity

The provisions of the MCA apply to acts or decisions made on behalf of an adult who lacks capacity – whether the lack of capacity is likely to be temporary or permanent. It is possible for capacity to fluctuate. In such cases, it is good practice to establish, while the person has capacity, their views about any clinical intervention that may be necessary during a period of anticipated incapacity, and to record these views. The person may wish to make an advance decision to refuse treatment or a statement of their preferences and wishes. If the person does not make a relevant advance decision, decisions about that person's treatment if they lack capacity must be made in accordance with the MCA. This would include considering whether the person is likely to regain capacity and, if so, whether the decision can wait, as well as the statutory principle that all practical steps must be taken to enable the person to make their own decision.

Statements of preferences and wishes

A healthcare professional must take all statements of a person's preferences and wishes into consideration as part of a best interests assessment. Written statements which request specific treatments made by a person before losing capacity should be given the same consideration as those made by people who currently have capacity to make treatment decisions. However, a healthcare professional would not have to follow a written request if they thought that the specific treatment would be clinically unnecessary or not appropriate for the person's condition, and therefore not in the person's best interests. If the decision is different to a written statement, a healthcare professional should keep a record of this and be prepared to justify the decision if challenged. There is an important legal distinction between a written statement expressing treatment preferences, which a healthcare professional must take into account when making a best interests decision, and a valid and applicable advance decision to refuse treatment. Healthcare professionals cannot ignore a written statement that is a valid and applicable advance decision to refuse treatment.

Lasting Power of Attorney

The MCA enables a person (aged 18 or over) to appoint an attorney to make health and welfare decisions if they should lack the capacity to make such decisions in the future. Under a personal welfare LPA, the attorney (if they have the authority to do so) can make decisions that are as valid as those made by the person themselves. The LPA must be made in the form, and meet the criteria, set out in the regulations, and it must be registered with the Office of the Public Guardian before it can be used.

The LPA may specify limits to the attorney's authority, and the LPA must specify whether or not the attorney has the authority to make decisions about life-sustaining treatment. Healthcare practitioners directly involved in the care or treatment of a person who lacks capacity should not agree to act as that person's attorney other than in exceptional circumstances (for example if they are the only close relative of the person). If the person lacks capacity and has created a personal welfare LPA, the attorney will have the authority to make decisions and consent to or refuse treatment as set out in the LPA. Healthcare practitioners should read the LPA if it is available, in order to understand the extent of the attorney's power.

The attorney must follow the statutory principles under the MCA and make decisions in the best interests of the person lacking capacity. If the decision is about life-sustaining treatment, the attorney must not be motivated by a desire to bring about the person's death. Attorneys also have a legal duty to have regard to the guidance in the MCA (2005) Code of Practice. If there is a dispute that cannot be resolved, e.g. between the attorney and a doctor, it may have to be referred to the Court of Protection.

More information about LPAs is given in chapter 7 of the Code of Practice.

Court Appointed Deputies

If a person lacks capacity to make a decision relating to their personal welfare, then the Court of Protection can make an order making a decision on their behalf. Alternatively, the Court of Protection can appoint a deputy to make decisions on behalf of the person who lacks capacity. The MCA makes it clear that in such situations it is preferable for the Court of Protection to make the decision if at all possible, and that if a deputy is appointed, then their powers should be limited in scope to what is absolutely necessary.

The court must ensure that any deputy appointed has the necessary skills and abilities and is prepared to take on the duty and responsibility of the role. Both the court and any deputy must follow the statutory principles of the Act and make decisions in the person's best interests.

Deputies for personal welfare decisions will only be required in the most difficult cases, where important and necessary actions cannot be carried out without the court's authority or where there is no other way of settling the matter in the best interests of the person who lacks capacity. For example, a deputy could be appointed to make on-going decisions, having consulted all relevant parties. This could be useful where there is a history of family disputes.

If a deputy has been appointed to make treatment decisions on behalf of a person who lacks capacity then it is the deputy rather than the healthcare professional who makes the treatment decision. A deputy cannot go against a decision of an attorney under an LPA made before the person lacks capacity. Deputies must follow the MCA statutory principles and must make decisions in the person's best interests.

A deputy cannot refuse consent to the provision of life-sustaining treatment. More information about the powers of the Court of Protection and the role of deputies is given in chapter 8 of the Code of Practice.

Independent Mental Capacity Advocates (IMCA)

The MCA introduced a duty on NHS bodies to instruct an IMCA in serious medical treatment decisions when a person who lacks capacity to make a decision has no one who can speak for them, other than paid staff. In matters that meet the definition of serious medical treatment, IMCAs are only able to represent and support people whose treatment is arranged by the NHS. They have the right to information about an individual and can see relevant healthcare records.

The duties of an IMCA are to:

a. support the person who lacks capacity and represent their views and interests to the decision-maker;
b. obtain and evaluate information, both through interviewing the person and through examining relevant records and documents;
c. obtain the views of professionals providing treatment for the person who lacks capacity;
d. identify alternative courses of action;
e. obtain a further medical opinion, if required;
f. prepare a report (that the decision-maker must consider).

IMCAs are not decision makers for the person who lacks capacity. They are there to support and represent that person and to ensure that decision making is done appropriately and in accordance with the MCA. More information is given at www.dh.gov.uk/imca and in chapter 10 of the Mental Capacity Act (2005) Code of Practice.

If an IMCA is required, please contact the Safeguarding Team.

Consent Forms

When a decision has been made to treat an individual in their bests interests, the consent form should not be signed unless the person signing has a LPA (for health and welfare) that authorises them to make the decision in question, or they are a Court appointed deputy with similar authority.

It is good practice to make a note in the medical records of any discussions that have taken place and the rationale for any decisions made in the best interests of the patient.

Consent form 4 should be used for any significant procedures that are to be undertaken.

Referral to Court

The MCA established the Court of Protection to deal with decision-making for adults (and children in a few cases) who may lack the capacity to make specific decisions for themselves.

The Court of Protection deals with serious decisions affecting personal welfare matters, including healthcare, which were previously dealt with by the High Court. In cases of serious dispute, where there is no other way of finding a solution or when the authority of the Court is needed in order to make a particular decision or take a particular action, the Court can be asked to make a declaration that proposed treatment is lawful.

The courts have identified certain circumstances when referral must be made for a ruling on the lawfulness of a procedure being undertaken. These are:

a. Decisions about the proposed withholding or withdrawal of ANH from patients in a permanent vegetative state or minimally conscious state;

b. Cases involving organ, bone marrow or peripheral blood stem cell donation by an adult who lacks the capacity to consent;

c. Cases involving the proposed non-therapeutic sterilisation of a person who lacks the capacity to consent to this (e.g. for contraceptive purposes);

d. All other cases where there is a doubt or dispute about whether a particular treatment will be in a person's best interests.

Other cases likely to be referred to the court include those involving ethical dilemmas in untested areas (such as innovative treatments for variant CJD), or where there are otherwise irresolvable conflicts between healthcare staff, or between staff and family members. More information about the powers of the Court of Protection and the cases that should be referred to the court is given in the Mental Capacity Act (2005) Code of Practice and in a Court of Protection Practice Direction.

The courts have stated that neither sterilisation which is incidental to the management of the 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 as part of the decision-making process a consultant in the psychiatry of learning disability, the multidisciplinary team and the patient's family, 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.
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 who are concerned with the individual's treatment.

Advice should be sought from the Trust Legal Services Department when an application to the Court of Protection is being considered.

Research

The MCA sets out a legal framework for involving people who lack the capacity to consent to taking part in research. Anyone setting up, or carrying out, such research will need to make sure that the research complies with the provisions set out in the Act and will need to follow the guidance given in chapter 11 of the Mental Capacity Act (2005) Code of Practice. The Act does not include clinical trials, which are covered by the Medicines for Human Use (Clinical Trial Regulations) 2004.

The Act requires that a family member, or unpaid carer, must be consulted about any proposal and agree that the person who lacks capacity can be part of the research. If such a person cannot be identified, then the researcher must nominate a person who is independent of the research project to provide advice on the participation of the person who lacks capacity in the research. The person consulted should be asked for advice about whether the person who lacks capacity should participate

in the research project and what, in their opinion, the person's wishes and feelings about taking part would be likely to be if they had capacity.

The patient's past or present wishes, feelings and values are most important in deciding whether they should take part in research or not. If the person without capacity shows any sign that they are not happy to be involved in the research, then the research should not be allowed to continue.

Mental Capacity Assessment &
Best Interests Decision-Making Protocol

NHS
University Hospitals of North Midlands
NHS Trust

Anyone undertaking an assessment using this form should be familiar with the Mental Capacity Act and Deprivation of Liberty Safeguards Code of Practice. This may be accessed on the Trust Intranet.

Name of person completing this form:			
Date of completion of assessment:		**Time:**	

Patient Details: Please complete the fields below or insert patient label	
Patient name:	
Unit number:	
Date of Birth:	
Address:	

The Decision Maker:			
Name:			
Job title:		**Signature:**	
Telephone:			

What is the nature of the decision required (medical treatment or intervention proposed)?

People who have planned ahead:			
	Circle		**Signature**
Is there a lasting power of attorney?	**Y**	**N**	
a) Financial	**Y**	**N**	
b) Health & Welfare	**Y**	**N**	
Is there a relevant Advance Decision?	**Y**	**N**	
If you have answered **'yes'** to any of the above, and these are relevant to the care or treatment proposed, this will override any decision made by the 'decision maker'.			

PART 1: Mental Capacity Assessment (2-stage test)
Note: all the determinations below are specific to this decision.

For a person to lack capacity to make a decision, the Mental Capacity Act states that their impairment or disturbance must affect their ability to make the specific decision they need to. **The patient must be given all practical and appropriate support to help them make the decision for themselves. Stage 2 can only apply if all practical and appropriate support has failed.**

Stage 1: Is there an impairment of, or disturbance in, the functioning of the persons mind or brain (permanent or temporary)?	**Y**	**N**	*Comments:*
Stage 2: Does the impairment or disturbance make the person unable to make the decision, or is it likely to interfere with their ability to do so?	**Y**	**N**	*Comments:*
Consider the following points:			
1. Can the person understand the information relevant to the decision?	**Y**	**N**	*Comments:*
2. Can they retain that information long enough to make the decision?	**Y**	**N**	*Comments:*
3. Can they use or weigh that information as part of the process of making the decision?	**Y**	**N**	*Comments:*
4. Can they communicate their decision, by any means available to them?	**Y**	**N**	*Comments:*
5. Can the treatment or procedure be delayed because the person is likely to regain capacity in the future?	**Y**	**N**	*Comments:*

If your consideration of the above has resulted in a conclusion that the patient lacks the capacity to consent to the proposed treatment, you may proceed if you, and other relevant individuals believe it to be in the patients best interests. The best interests assessment at the next section of this form may assist you in making this decision.

Please use the space below to provide any additional details you may have about your assessment of capacity (i.e. what steps have you taken to assist the person to make or be involved in the decision – e.g. visual aids etc.):

PART 2a: Best Interests Assessment

You must be able to assert that you have followed the Best Interests Principle of the Mental Capacity Act:

The Mental Capacity Act places a duty on the decision maker to consult other people close to a person who lacks capacity, on decisions affecting the person and what might be in the persons best interests. The decision maker should take into account the views of other people, including:

- Anyone the person has previously named as someone they want to be consulted
- Anyone involved in caring for the person
- Anyone interested in their welfare (family, carers, other close relatives, or an advocate already working with the person)
- An attorney, appointed by the person under a Lasting Power of Attorney
- A deputy appointed for that person by the Court of Protection

Contact details of these individuals and their views should be recorded at section 2b of this form.

If there is no-one to speak to about the persons best interests, in some circumstances the person might quality for an Independent Mental Capacity Advocate (IMCA). An IMCA can be instructed if necessary by contacting the Site Manager.

The Mental Capacity Act confirms that the best interests principle applies to any act done, or any decision made, on behalf of someone where there is reasonable belief that the person lacks capacity. This covers day to day informal decisions and actions.

Please consider the following:

Best Interests Indicator:	Circle		Rationale
Have you avoided making assumptions based on the persons age, appearance or behavior?	**Y**	**N**	
Have you considered all of the relevant circumstances?	**Y**	**N**	
Have you considered whether the person is likely to regain capacity and whether the decision can be delayed?	**Y**	**N**	
Have you involved the person as fully as possible?	**Y**	**N**	
Have you considered your motivation (or perceived motivation) in withdrawing life sustaining treatment? Are you satisfied that you have no conflict of interest and have you checked their perceptions with other professionals and interested others?	**Y**	**N**	
Have you considered the persons past and present wishes inasmuch as they are known to you?	**Y**	**N**	
Have you considered any beliefs and values (religious, cultural or moral) which would be likely to influence the decision?	**Y**	**N**	
Have you consulted all relevant people? Please ensure that their details are recorded in section 2b of this form.	**Y**	**N**	
Is there a less restrictive option available?	**Y**	**N**	

Having considered the above, please document your decision as to how you will proceed, confirming your reasons why this is in the best interests of the patient:

PART 2b: Contact Details for the ‘Best Interests’ Assessment Consultation Group	
IMCA (if relevant):	
Date Instructed:	
Requested by:	
Name of IMCA:	
Telephone:	

Details of person consulted with:		
Name:		*Their views*:
Role:		
Telephone:		
Details of person consulted with:		
Name:		*Their views*:
Role:		
Telephone:		
Details of person consulted with:		
Name:		*Their views*:
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Role:		
Telephone:		
Details of person consulted with:		
Name:		*Their views*:
Role:		
Telephone:		

This Practice Guide is one of a series of information sheets on consent and should be read in connection with Trust Policy C43.

Consent: Policy in Practice

Children and Young People

The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position for adults.

For the purposes of this guidance 'children' refers to those aged below 16 and 'young people' refers to those aged 16–17.

Young People (aged 16 – 17)

By virtue of section 8 of the Family Law Reform Act 1969, people aged 16 or 17 are presumed to be capable of consenting to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic. As for adults, consent will only valid if it is given voluntarily by an appropriately informed young person capable of consenting to the particular intervention.

However, unlike adults, the refusal of a competent person aged 16–17 may in certain circumstances be overridden by either a person with parental responsibility or a court (see below).

Section 8 of the Family Law Reform Act 1969 applies only to the young person's own treatment. It does not apply to an intervention that is not 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 'Fraser Rules' competence, considered below.

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. If a young person lacks capacity to consent because of an impairment of, or a disturbance in the functioning of the mind or brain then the Mental Capacity Act 2005 will apply in the same way as it does to those who are 18 and over (see Practice Guide at Appendix 4).

If the young person unable to make the decision for some other reason (ie because they are overwhelmed by the implications of the decision) then the MCA will not apply to them and the legality of any treatment should be assessed under common law principles.

It may be unclear whether a young person lacks capacity within the meaning of the MCA. In such circumstances, it would be prudent to seek a declaration from the court. More information on how the Act applies to young people is given in chapter 12 of the Mental Capacity Act (2005) Code of Practice.

If the young person is capable of giving valid consent then it is not legally necessary to obtain consent from a person with parental responsibility in addition to the consent of the young person. It is, however, good practice to involve the young person's family in the decision-making process if the young person consents to their information being shared.

Children under 16 (the concept of Fraser Rules competence)

In the case of *Gillick*, the court 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 or 'Fraser Rules' competent. A child under 16 may be Fraser Rules competent to consent to medical treatment, research, donation or any other activity that requires their consent.

The concept of Fraser Rules competence is said to reflect a child's increasing development to maturity. The understanding required for different interventions will vary considerably. Thus a child under 16 may have the capacity to consent to some interventions but not to others. The child's capacity to consent should be assessed carefully in relation to each decision that needs to be made.

In some cases (ie because of a mental disorder) a child's mental state may fluctuate significantly, so that on some occasions the child appears competent in respect of a particular decision and on other occasions does not. In cases such as these, careful consideration should be given as to whether the child is truly competent at the time that they need to take a relevant decision.

Where advice or treatment relates to contraception, or the child's sexual or reproductive health, the healthcare professional should try to persuade the child to inform his or her parent(s), or allow the medical professional to do so. If the child cannot be persuaded, advice and/or treatment should still be given if the healthcare professional considers that the child is very likely to begin or continue to have sexual intercourse with or without advice or treatment, and that unless they receive the advice or treatment then the child's physical or mental health is likely to suffer.

If the child seeks advice or treatment in relation to abortion and cannot be persuaded to inform her parent(s), every effort should be made to help the child find another adult (such as another family member or a specialist youth worker) to provide support to the child.

The requirement of voluntariness

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

Children or young person with capacity refusing treatment

Where a young person of 16 or 17 who could consent to treatment in accordance with section 8 of the Family Law Reform Act 1969, or a child under 16 but Gillick competent, refuses treatment, it is possible that such a refusal could be overruled if it would in all probability lead to the death of the child/young person or to severe permanent injury.

In the case of *Re W (a minor) (medical treatment),* the court stated that it has jurisdiction to override a refusal of a child/young person, at least where they seek to refuse treatment in circumstances that will, in all probability, lead to the death of the child/young person or to severe permanent injury; or where there is a serious and imminent risk that the child/young person will suffer grave and irreversible mental or physical harm.

The courts have, in the past, also found that parents can consent to their competent child being treated even where the child/young person is refusing treatment. However, there is no post-Human Rights Act 1998 authority for this proposition, and it would therefore be prudent to obtain a court declaration or decision if faced with a competent child or young person who is refusing to consent to treatment, to determine whether it is lawful to treat the child.

Where the treatment involved is for mental disorder, consideration should be given to using mental health legislation.

The changes made to section 131 of the Mental Health Act 1983 by section 43 of the Mental Health Act 2007 mean that when a young person of 16 or 17 has capacity (as defined in the Mental Capacity Act 2005) and does not consent to admission for treatment for mental disorder (either because they are overwhelmed, do not want to consent or refuse to consent), they cannot then be admitted informally on the basis of the consent of a person with parental responsibility (see chapter 36 of the Code of Practice to the Mental Health Act 1983, as amended 2008).

A life-threatening emergency may arise when consultation with either a person with parental responsibility or the court is impossible, or the person with parental responsibility refuses 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 lacking capacity

Where a child under the age of 16 lacks capacity to consent (i.e. is not Gillick competent), consent can be given on their behalf by any one person with parental responsibility (if the matter is within the 'zone of parental control') 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.

Where necessary, the courts can overrule 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.

The European Court of Human Rights judgment in a case where doctors treated a child contrary to his mother's wishes, without a court order (*Glass v United Kingdom*), made clear that the failure to refer such cases to the court is not only a breach of professional guidance but also potentially a breach of the European Convention on Human Rights. In situations where there is continuing disagreement or conflict between those with parental responsibility and doctors, and where the child is not competent to provide consent, the court should be involved to clarify whether a proposed treatment, or withholding of treatment, is in the child's best interests. Parental refusal can only be overridden in an emergency.

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

- the child's mother
- the child's father, if he was married to the mother at the time of birth
- unmarried fathers, who can acquire parental responsibility in several different ways:
    - For children born before 1 December 2003, unmarried fathers will have parental responsibility if they:
        a. marry the mother of their child or obtain a parental responsibility order from the court
        b. register a parental responsibility agreement with the court or by an application to court
    - For children born after 1 December 2003, unmarried fathers will have parental responsibility if they:
        a. register the child's birth jointly with the mother at the time of birth
        b. re-register the birth if they are the natural father
        c. marry the mother of their child or obtain a parental responsibility order from the court
        d. register with the court for parental responsibility
- the child's legally appointed guardian
- 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 or her behalf'. Such a person might choose to do this, for example, if a child-minder 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 then specific enquiry should be made. Foster parents do not automatically have parental responsibility.

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 and immunisation. Where persons with parental responsibility disagree as to whether these 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.

Where there is doubt about whether a parent is acting in the interest of the child or young person, then the healthcare practitioner would be unwise to rely on the parent's consent, for example if a child alleges abuse and the parent supports psychiatric treatment for the child. The Government's guidance *Working Together to Safeguard Children* covers situations involving parental consent where abuse or neglect is suspected.

In order to consent on behalf of a child, the person with parental responsibility must themselves have capacity. Where the person with parental responsibility for a child is themself under 18, they will only be able to give valid consent for the child's treatment if they themselves are Gillick competent (see paragraphs 6–11 above). Whether or not they have capacity may vary, depending on the seriousness of the decision to be taken.

Where a child is a ward of court, no important step may be taken in the life of the child 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.

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.

Research

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 that is not strictly in the best interests of the child, but is not against the interests of the child either. Such an intervention must involve only minimal burden to the child.

Decisions about experimental treatment must be made in the child's best interests (see reference guide C43a, paragraph 40).

Using children as bone marrow donors

This is covered by the Human Tissue Authority's Code of Practice on donation of allogeneic bone marrow and peripheral blood stem cells for transplantation, and healthcare professionals should consult this for detailed information on the legal requirements and how to proceed.

This Practice Guide is one of a series of information sheets on consent and should be read in connection with Trust Policy C43.

Consent: Policy in Practice

Withdrawing & Withholding Life-sustaining Treatment

General principles

The law does not require a consent form to be completed when withdrawing or withholding life-sustaining treatment. However, it is imperative that doctors must document any discussions regarding this clearly in the medical record, in particular any discussions with relevant family, friends, carers or other representative(s).

Under these circumstances, it is important that a second consultant opinion is sought in such cases and that this is also recorded in the medical record.

A healthcare professional's legal duty is to care for a patient and to take reasonable steps to prolong their life. Although there is a strong presumption in favour of providing life-sustaining treatment, there are circumstances when continuing or providing life-sustaining treatment stops providing a benefit to a patient and is not clinically indicated. There is no legal distinction between withdrawing and withholding life-sustaining treatment. A person with capacity may decide either contemporaneously or by a valid and applicable advance decision that they have reached a stage where they no longer wish treatment to continue. If a person lacks capacity, this decision must be taken in their best interests and in a way that reflects their wishes (if these are known).

The legal principles around consent are the same for all medical interventions, including decisions to withdraw or withhold life-sustaining treatment, but the issues surrounding seriously ill or dying patients are necessarily more grave and sensitive. Persons with the capacity to do so can make such decisions for themselves. If the person is an adult who lacks capacity to make such decisions then the provisions of the Mental Capacity Act 2005 will apply to these, as to other decisions. When making a best-interests decision in relation to life-sustaining treatment, healthcare professionals should be aware that the Mental Capacity Act requires that the healthcare professional must not be motivated by a desire to bring about the person's death.

Sometimes decisions will need to be made immediately – for example whether it is appropriate to attempt resuscitation after severe trauma. In an emergency situation, where there is doubt as to the appropriateness of treatment, there should be a presumption in favour of providing life-sustaining treatment. 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.

Legally, the use of artificial nutrition and hydration (ANH) constitutes medical treatment. Thus the legal principles that apply to the use of ANH are the same as those that apply to all other medical treatments, such as medication or ventilation. Decisions about the proposed withholding or withdrawal of ANH from a patient in a permanent vegetative state should be referred to court (see reference guide C43b, paragraph 26). The courts have confirmed that the current case law in this area is compatible with the Human Rights Act 1998.

There is an important distinction between withdrawing or withholding treatment that 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 that is intended to cause death is unlawful. Although there is a strong presumption in favour of providing life-sustaining treatment, there are circumstances when continuing or providing life-sustaining treatment stops providing a benefit to a patient and is not clinically indicated. Healthcare professionals should discuss the situation with a patient with capacity and agree

if and when the patient no longer wishes treatment to continue. If the patient lacks capacity, this decision must be taken in their best interests and in a way that reflects their wishes, beliefs and values (if these are known). Suitable care should be provided to ensure that both the comfort and dignity of the patient are maintained.

Adults and children with capacity

Except in circumstances governed by the Mental Health Act 1983, if an adult with the capacity to make the decision refuses life-sustaining treatment, or requests that it be withdrawn, practitioners **must** comply with the person's decision, even if it may result in the person's death. If a refusal is ignored, they will be treating the person unlawfully.

The case of *Burke v GMC* established that an adult patient with capacity does not have the legal right to demand treatment that is not clinically indicated. Where a patient with capacity indicates his or her wish to be kept alive by the provision of ANH, the doctor's duty of care will require them to provide ANH while such treatment continues to prolong life. A patient cannot demand that a healthcare professional do something unlawful such as assisting them to commit suicide.

If a child with capacity makes such a request or refusal it is possible that such a refusal could be overruled if it would in all probability lead to the death of the child or to severe permanent injury (see reference guide C43c, paragraph 13). 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.

Refusal of treatment by a child with capacity must always be taken very seriously, even though legally it is possible to override their objections. It is not a legal requirement to continue a child's life-sustaining treatment in all circumstances. For example, where the child is suffering an illness where the likelihood of survival even with treatment is extremely 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.

Adults and children lacking capacity

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-sustaining treatment must be made in the best interests of the child. The best interests of a child in the context of the withholding of medical treatment should be interpreted more broadly than medical interests, and should include emotional and other factors. There is a strong presumption in favour of preserving life, but not where treatment would be futile, and there is no obligation on healthcare professionals to give treatment that would be futile. 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 as early as possible. This requirement was emphasised in the *Glass* judgment (see reference guide C43c, paragraph 21).

A person with parental responsibility for a child or young person is legally entitled to give or withhold consent to treatment. A person with parental responsibility cannot demand a particular treatment to be continued where the burdens of the treatment clearly outweigh the benefits for the child. If agreement cannot be reached between the parent(s) and the healthcare professionals, a court should be asked to make a declaration about whether the provision of life-sustaining treatment would benefit the child. In exceptional cases, the court has been willing to authorise the withdrawal of life-sustaining treatment against the parents' wishes. However, the views of the parents are given great weight by the courts and are usually determinative unless they conflict with the child's best interests.
If an adult lacks capacity, and has not made a valid and applicable advance decision to refuse life-sustaining treatment, the provisions of the Mental Capacity Act will apply and the decision must be based on the best interests of the adult, again involving the person as far as this is possible.

As with all decisions made under the Mental Capacity Act, before deciding to withdraw or withhold life-sustaining treatment, the healthcare professional must consider the range of treatment options available in order to work out what would be in the person's best interests. All of the factors set out in the Mental Capacity Act (2005) Code of Practice should be considered, and in particular the healthcare professional should consider any statements that the person has previously made about

their wishes and feelings about life-sustaining treatment. Healthcare professionals should also refer to relevant professional guidance when making decisions regarding life-sustaining treatment.

Where a patient had indicated, while they had capacity, his or her wish to be kept alive by the provision of ANH, the doctor's duty of care will require the doctors to provide ANH while such treatment continues to prolong life. Where life depends upon the continued provision of ANH, ANH will be clinically indicated. If the patient lacks capacity, all reasonable steps that are in the person's best interests should be taken to prolong their life. Although there is a strong presumption in favour of providing life-sustaining treatment, there are circumstances when continuing or providing life-sustaining treatment stops providing a benefit to a patient and is not clinically indicated.

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Consent: Policy in Practice

Other Exceptions to the Principles

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.

The Mental Health Act

Part 4 of the Mental Health Act 1983 ('the 1983 Act') sets out circumstances in which persons liable to be detained under the Act may be treated without consent for their mental disorder. The 1983 Act 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, even where the person concerned is detained under the Act. The Mental Health Act Code of Practice offers guidance on consent and medical treatment in this context.

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

Significant amendments to the 1983 Act have been made by the Mental Health Act 2007.The 1983 Act will continue to provide legal authority, within certain limits and subject to certain safeguards, to treat detained patients for mental disorder without consent. Except in emergencies, however, it will no longer be permissible to use the 1983 Act to administer electro-convulsive therapy (ECT) to a patient who has capacity to consent to it, but who does not. Additionally, if a person made an advanced decision when they had capacity, saying that they never wished to receive ECT and the hospital knows about this, then the treatment cannot be given. The only exception would be in an emergency if it was immediately necessary to save a patient's life or to prevent a serious deterioration of the patient's condition.
In addition, except in emergencies it will not be permissible to administer ECT as a treatment for mental disorder in any circumstances to any child or young person under the age 18 (whether or not they are otherwise subject to the 1983 Act) unless it has been independently approved in accordance with the 1983 Act. Further guidance is given in the Mental Health Act Code of Practice.

There will also be a new procedure by which certain patients discharged from detention under the 1983 Act can be made subject to community treatment orders (CTOs), making them liable to recall to hospital for further treatment if necessary. While patients are subject to CTOs they may only be treated for mental disorder in accordance with the 1983 Act. Unless they have been recalled to hospital, it will not be permissible to treat such patients without their consent if they have the capacity to consent to the treatment in question but do not do so. Treatment for mental disorder of patients subject to CTOs who lack capacity to consent will be permitted, subject to the rules set out in the new Part 4A of the 1983 Act.

It will remain the case that no-one (whether or not detained under the 1983 Act) may be given neurosurgery for mental disorder ('psychosurgery') or have hormones surgically implanted in order to reduce male sex drive, unless they consent to the procedure and it has been independently approved in accordance with section 57 of the 1983 Act.

None of these changes will 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.

The Public Health (Control of Disease) Act 1984

Provided that, on an order made by a magistrate, persons suffering from certain notifiable infectious diseases could be medically examined, removed to and detained in a hospital without their consent. A magistrate when ordering the detention of a person in a hospital could not order that a person undergo medical treatment. The treatment of such persons must be based on the common law principles previously described. The 1984 Act is now amended by the Health and Social Care Act 2008. Under part 2A there is express provision prohibiting regulations under new sections 45B or 45C from legislating for the administering of medical treatment by force. Nor will there be power for a magistrate to order compulsory treatment under new section 45G, which gives powers to magistrates to make orders in relation to persons who pose a threat to the health of others.

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Consent: Policy in Practice

Jehovah's Witness Patients

Guidelines for the Surgical Management of Jehovah's Witness Patients

Jehovah's Witnesses have absolutely refused the transfusion of blood and primary blood components ever since these techniques became universally available. The giving of a transfusion to a Jehovah's Witness without consent is regarded as a gross physical violation.

Jehovah's Witnesses are usually well informed regarding their right to determine their own treatment. The clinician should be open to a discussion with the Hospital Liaison Committee if the patient, or those with parental responsibility for the patient, wishes them to do so. Doctors should discuss with the patient the medical consequences of non-transfusion in the management of their condition. Views held by each Jehovah's Witness patient should be discussed, as certain forms of transfusion may be acceptable.

It is unlawful to administer whole blood or blood products to a patient who refuses it. Its administration could lead to criminal and/or civil proceedings. Jehovah's Witnesses refuse whole blood and its primary components (i.e. red cells, white cells, platelets and plasma). Individual Jehovah's Witnesses make their own personal decisions about "fractions" of any of these components, such as clotting factors, for example it is unlawful to administer blood and primary blood components to a patient who refuses it. Its administration could lead to criminal and/or civil proceedings.

In the management of trauma, Jehovah's Witness status may not be known but most Jehovah's Witnesses carry a signed "advance directive card" absolutely refusing blood and releasing clinicians from liability.

If the patient can give an informed rational opinion or an advance directive exists, this should be acted upon. If not, the judgement of the doctor should take precedence over relatives or associates of the patient.

Before surgery, a full and frank discussion needs to take place between the surgeon and the patient and/or the person with parental responsibility. The rules of subsequent management must be established and discussed in the presence of witnesses. The agreement reached must be recorded in the patient's hospital record and must be signed by the doctor, patient and witness.

Restricted consent should be reviewed with the patient/person with parental responsibility, if the situation changes e.g. the patient's condition deteriorates and blood transfusion may become potentially life-saving whereas, when restricted consent was given, the need for transfusion seemed remote.

The following committee should be seen as the first point of contact in a medical emergency involving one of Jehovah's Witnesses:

Hospital Liaison Committee for Jehovah's Witnesses

The Management of Children of Jehovah's Witnesses

The well-being of the child is paramount. If after consultation with the person with parental responsibility, blood and primary blood products are refused, the clinician may seek to use the law to protect the child's interest. Frank discussion must take place between the person who has parental responsibility, the surgeon and the anaesthetist regarding the child's care.

If after consultation with the person who has parental responsibility, consent for treatment is refused, referral can be made to the High Court for a Specific Issue Order under the Children Act 1989.

Where consent is withheld, the Executive Director of Nursing and Operations and/or Medical Director should be informed of the decisions made. In the absence of the Executive Director of Nursing and Operations or Medical Director another Executive Director of the Trust should be contacted. The Divisional General Manager on-call should be contacted out of hours.

A “Specific Issue Order” (in England and Wales) may be applied for to provide legal sanction for special action. Advice about obtaining the Order can be sought from the Legal Services Department. The person with parental responsibility should be kept informed at all stages.

If a child needs blood and primary blood products in an emergency despite the surgeon’s best efforts to control haemorrhage, it should be given. To allow a child to die when blood may have saved his/her life could incur criminal prosecution.

The High Court is the most appropriate forum to achieve a fair hearing when conflict arises between religious, medical and ethical opinions.

List of contacts:

[redacted]