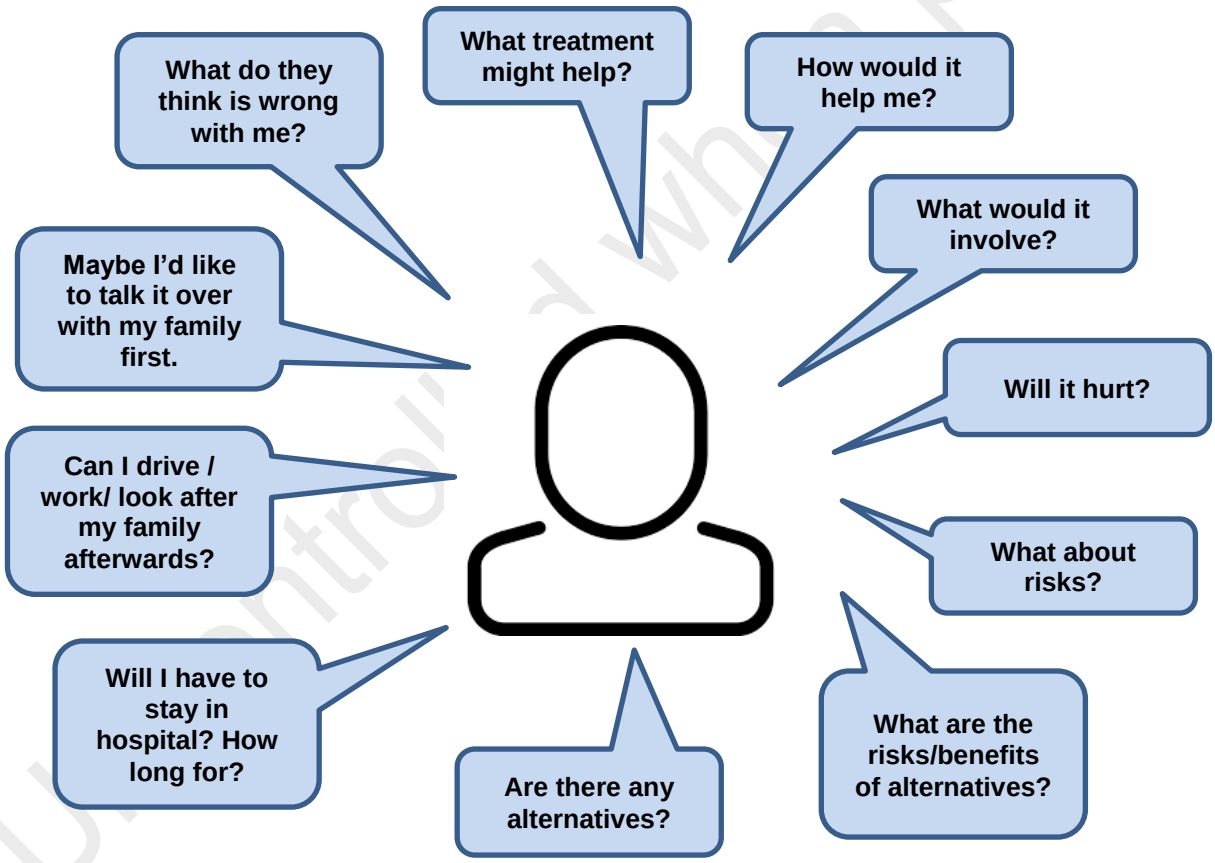
CONSENT FOR HEALTHCARE POLICY



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1. INTRODUCTION

Consent is integral to clinical interactions between healthcare staff and patients.
The principles pertaining to consent in this policy are relevant to all the health and care decisions that are made with patients about mental and physical health. This includes, but is not limited to, decisions about treatments, procedures, investigations, examinations and referrals, and applies whatever the method of communication, including remote consultations.

Patients have the right to make choices about their own lives and therefore healthcare staff have an ethical and legal responsibility to involve patients as much as possible in making decisions about their own health and care. No adult can give valid consent for another unless legally authorised to do so. The consent process should be a partnership based on openness, honesty, trust and good communication following the principles of shared decision making (SDM).

SDM means people are supported to:

- understand the care, treatment and support options available and the risks, benefits and consequences of those options
- make a decision about a preferred course of action, based on evidence-based, good quality information and their personal preferences.

It is, therefore, a process in which healthcare professionals and individuals work together to select tests, treatments, management or support packages, based on evidence and the individual's informed preferences.

For informed consent to be effective it is important two vital aspects are in place:

- The clinician must understand what matters to the patient – giving them the opportunity to share their needs, wishes and values, and listening to their priorities and concerns.
- The clinician must share information about the risks, harms and benefits of the different options, including not proceeding with the proposed treatment.

Regardless of age, race, sex, religion or disability, every patient has a right to self-determination under the European Convention on Human Rights incorporated into the Human Rights Act (1998) and the United Nations Convention on the Rights of a Child (UNCRC) (Incorporation) (Scotland) Bill. A patient also has a right to refuse treatment which is considered by the health professional to be in the patient's best interests.

NHS Lanarkshire recognises that patients have a fundamental legal and ethical right to:

- be given information about how we use and protect their information
- be given enough information in an understandable way with opportunity to ask questions* to allow an informed decision to be made and then
- give or withhold consent prior to any examination or treatment

*NHS Lanarkshire encourage the use of the 5 questions cards to encourage patients to ask about their treatment or procedure. The questions are:

- **NEED?** – Do I really need this test, treatment or medicine?
- **BENEFIT?** – What are the benefits to me?
- **RISK?** – Are there any risks or side effects?
- **CHANGE?** – How can I improve my condition or health?
- **IF I DON'T?** – What will happen if I don't do anything?

This initiative came from *'Realising Realistic Medicine: Chief Medical Officer for Scotland annual report 2015-2016'* and a copy of the '5 questions poster' is in appendix 2.

It is important to recognise that "consent" describes a **process** to be gone through with the patient - ensuring that patients understand the nature and purpose of a proposed treatment and having understood the options, agree to it. Consent is often wrongly equated with a patient's signature on a consent form. A signature on a form is evidence that the patient has given consent but is not proof of valid consent. If a patient is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature. More important is a detailed discussion with patients, clearly recorded in their notes.

The guidance in this policy is a good practice guide and summary of the main issues surrounding consent. It excludes situations such as obtaining consent for research and authorisation for post mortem examination. Steps should be taken to ensure access to up-to-date legal advice and to seek specific advice in any case of doubt. For further information relating to consent for research please follow this link; - http://www.hra-decisiontools.org.uk/consent/

The General Medical Council, the Nursing and Midwifery Council and the Royal College of Nursing have useful guidance documents on consent and decision making which will be listed in the references of this policy.

2. AIM, PURPOSE AND OUTCOMES

This policy aims to inform staff of NHS Lanarkshire of the principles of consent; to ensure that the ethical and legal principles relating to consent are adhered to in practice and to ensure that valid consent is obtained from patients prior to any treatment, investigation or examination.

This policy is also in keeping with national guidance that has been issued for health professionals in Scotland *"A Good Practice Guide in Consent for Health Professionals in NHS Scotland"*, the General Medical Council guidance "*Decision Making and consent*" and has its basis in Scots law and relevant Scottish and UK legislation.

It takes time to undertake the whole process of consent properly for every patient. Communication with the patient in a way they understand is central to "seeking consent". The patient and health professional need to come to an agreement on the best way forward, based on the patient's values and preferences and the health professional's clinical knowledge. Healthcare professionals must also give consideration to, for example, people's religious, cultural and other non-medical views that may influence the decisions they make about the overall management of their care.

The shifting emphasis from the language of 'consent' to that of 'patient involvement' and 'shared decision making' or supported decision making' reflects a move away from the traditional model of consent as a discrete requirement for invasive examinations or interventions. Shared decision-making means that patients should have a voice in all aspects of their healthcare, including decisions about medication and overall management of their conditions. NHS Lanarkshire supports this model with the use of 5 Question cards to prompt patients to discuss the options.

While informed consent for discrete interventions remains important, this aspect forms part of a broader requirement for healthcare professionals to support patients to make their own healthcare decisions.

The Supreme Court ruling in Montgomery (2015) endorsed a new test for consent which requires a health care professional to take into account an individual's circumstances and preferences when explaining a treatment, and to consider what risks this particular patient would be likely to attach significance to. The Montgomery ruling fundamentally changes the conversation between patients and healthcare professionals, empowering patients to take an active role in their healthcare.

3. SCOPE

3.1 Who is the Policy intended to Benefit or Affect?

The policy is intended to protect the rights of patients and ensure good clinical practice is followed to ensure shared decision making for healthcare interventions so patients will receive treatments and care of most benefit to them personally.

3.2 Who are the Stakeholders?

The principles of the policy apply to all healthcare staff who are interacting with patients however the main stakeholders are clinical health professionals who are responsible for proposing, planning and ensuring delivery of treatments and care.

3.3 Informed Consent pathway

1. NEED – Do I really need this treatment or test?
2. BENEFIT – what are the benefits to me?
3. RISK – Are there any risks or side effects?
4. CHANGE – How can I improve my condition or health?
5. IF I DON'T – What will happen if I don't do anything?

4 THE CONSENT PROCESS

4.1 Conditions of Consent

"Consent" is a patient's agreement for a health professional to provide care and treatment. **Patients may indicate consent verbally, non-verbally, or in writing.** For the consent to be valid, the patient must:

- Have capacity to take the particular decision under discussion.
- Have received sufficient information on the need, benefit, risk and alternatives, including doing nothing, in order to take that decision.
- Not be acting under duress and without coercion, undue influence or deceit.

The patient only consents to what has been proposed being carried out. Additional or alternative procedures require further consent. The desire to spare a patient a second anaesthetic is not sufficient justification for dispensing with this rule.

When obtaining consent for any procedure patients should be advised of any foreseeable problems that could come to light when the patient is unconscious/sedated. This enables the doctor to obtain the patient's consent in advance for necessary treatment, including the transfusion of blood products, should the situation arise.
In the case of diagnostic procedures such as endoscopy or laparotomy, the doctor should discuss with the patient the possible operative procedures that may be required and seek the patient's consent for these should they be necessary.

The consent form should be completed to reflect these discussions and the key points of the discussion should be summarised in the appropriate section of the consent form and clinical record. The 5 Q card can support professionals in documenting their discussion summary. This discussion also provides the patient with the opportunity to identify procedures that the practitioner may **not** carry out without discussing the matter further with the patient - these should be documented on the consent form and in the clinical record.

Consent may **not** be required under the following special circumstances:

- In an emergency situation where treatment is **urgently** required in order to save life, or alleviate pain and/or suffering where the patient is unconscious and cannot indicate their wishes. In these circumstances, the intervention must be no more than the immediate situation requires. Depending on the emergency nature of the situation healthcare professionals should involve relatives/carers/civil partners where/when appropriate and check for an Advanced Directive or Anticipatory Care Plan that would indicate the proposed treatment was not wanted.
- Where there is statutory power requiring the examination of the patient. However, an explanation should be offered and the patient's co-operation should nevertheless be sought.

- In certain circumstances where a court decides that a specific treatment is in a child's best interest.

- Where treatment is authorised under part 16 of the Mental Health (Care and Treatment) Scotland Act 2003. (See section 8).

- Where treatment is authorised under part 5 of the Adults with Incapacity (Scotland) Act 2000. (See section 7). Where time allows, a certificate of incapacity should be completed.

Following treatment, appropriate records should be made stating what has been carried out and why. Where possible, the next-of-kin should be informed. Appendix 1 has a flow diagram of the process.

4.2 Who Obtains Consent?

It is normally the responsibility of the health professional who is providing treatment, carrying out an investigation or performing a surgical operation or other procedure to provide all the information necessary for the patient's understanding and to obtain consent. However, it is recognised that there are circumstances where this ideal is not practicable. Obtaining consent may be delegated to a person who:

- Is suitably trained and qualified in the proposed investigation or treatment OR
- Has sufficient knowledge of the proposed investigation or treatment (including understanding the risks involved)
- Acts in full accordance with both this policy statement, relevant guidance from professional regulatory bodies and professional codes of conduct.

Patients should be made aware that NHSL is a teaching hospital which means that procedures can be carried out by trainee professionals who are supervised by Consultants or other fully qualified professionals such as Advanced Nurse/AHP practitioners. If it is not the operator taking consent, it is important the patient understands this.

Additionally, there are situations in which it may be regarded as standard practice for one practitioner to refer a patient to a colleague to carry out a particular procedure or investigation or aspect of treatment, e.g. referral of a patient by a surgeon for anaesthesia or interventional radiology or procedures performed by advanced nurse or AHP practitioners. In these circumstances, the referring practitioner (in this case, the surgeon) should explain the general need for the proposed referral, possibly using information provided by the 'receiving' colleague and take consent on that basis.

It would be for the 'receiving' practitioner (in this case, the anaesthetist or radiologist or ANP) to provide any (further) 'specialist' information necessary to secure the patient's full understanding and valid consent.
It would be for the relevant specialist departments to decide standard practice as to those situations when further written consent was necessary.

Regardless of who has provided the information and obtained the consent, it remains the responsibility of the person performing the procedure to ensure that:

- The patient has been given sufficient time and information to make an informed decision.
- Any additional support or alternative forms of information patients may need about the procedure to reach an informed choice, has been made available to the patient.
- That the interpreting services are utilised if there are language barriers.
- All the other requirements of this policy have been met.

Any registered healthcare professional may obtain confirmation of consent previously given provided that the patient seeks no further information. If the patient wishes further discussion, this must be with the health professional providing treatment or their delegated deputy (as above).

Legislation for Ionising Radiation (IRMER regulations) states that prior to any procedure requiring radiation, sufficient information must be known about the patient to ensure the exposure is justified. The pregnancy status of the patient is always asked in female patients of reproductive potential before exposure. However, if a patient is unconscious when the radiographer is called to theatre, they are unable to ask the patient therefore the question must be asked before surgery. This should be done as part of the consent process and the pre-operative checklist. If there was an immediate risk to life the procedure would go ahead as an emergency.

4.3 Timing of Consent

This will depend on the degree of urgency of the procedure. In many cases, it will be appropriate for a health professional to initiate a procedure immediately after discussing it with the patient. In many such cases consent will be verbal and would be recorded in the clinical record as soon as possible. Where the proposed procedure carries significant risks, written consent should be sought.

Whilst there is no recognised absolute minimum period of time which should elapse between information provision, consent and procedure, it is appropriate for there to be sufficient time for the patient to reflect. This is particularly necessary where the information provided is complex and/or the risks are significant. In such cases, more than one session may be necessary to inform the patient adequately.

For elective surgery, consent should be obtained at an outpatient clinic at the time the patient is placed on the waiting list. The information the patient needs to make informed consent should be given at this time, thus allowing an opportunity for reflection by the patient and if necessary they may seek additional information or change their mind. The patient's agreement to undergo the treatment based on the information provided should then be recorded by the completion of the consent form.

In situations where patients are asked to consent to an elective procedure on the same day that it will be undertaken, they should have been provided with appropriate information in advance of their appointment/procedure to enable them to give informed consent to what is being proposed.

In the case of complex procedures requiring written consent, if a significant time has elapsed between consent and procedure, or similarly, if there has been significant change in the patient's condition, the existing consent form should be reviewed. It is good practice to confirm with the patient immediately prior to the procedure that they haven't had a "change of mind" and that there is continuing consent with an understanding what they have consented for. Although there is no expiry time for a consent form it is good practice to confirm with the patient that they still want to proceed if the consent was taken longer than 3 months before the procedure is performed.

For some procedures such as endoscopy, postal consent is sent to the patient in advance along with information regarding the procedure. This allows the patient time to consider the information before the appointment as there may not have been an opportunity for out-patient consultation. On admission the consent form is checked and the patient should be asked if they have any questions and provided with the opportunity to speak with the endoscopist regarding any questions if required. The endoscopist must satisfy themselves that the patient is aware of the procedure, risks associated with the procedure and will countersign the consent form that the patient has previously signed.

Key points:

- In an emergency consent may have to be directly before procedure.
- For elective cases time should be given between provision of information and procedure to allow time to reflect.
- Consent is best taken at outpatient clinics.
- If 3 months or longer has elapsed between consent and procedure it is good practice to confirm there is continuing consent.

5. THE PROVISION OF INFORMATION

The provision of information is central to the consent process. The presumption is that the patient wishes to be well informed about the risks and benefits of the various options. Where the patient makes it clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.
The type of information to be disclosed and discussed with the patient includes:

- The nature of patient's condition and proposed procedures, including degree of urgency.
- The various treatment options and their complexity (including the option of not to treat).
- The benefits to be reasonably expected of the procedure.
- The nature and probability of risks involved, including frequency, seriousness, permanence and consideration of the balance of risks and benefits.

- The individual circumstances and preferences of the patient (as in Montgomery case).
- The inability of the practitioner to predict results.
- The irreversibility of the procedure, if that is the case.
- The likely result of no treatment or procedure.
- The alternatives available, including their risks and benefits (this includes alternative treatments and alternative provision of the same treatment).
- Any additional procedures, including those which may become evident at a later stage.
- Any variance from generally accepted standards in clinical practice.
- The risks/benefits of radiation doses should be explained, where applicable, to all patients prior to exposure to ionising radiation as per NHSL's Employer Procedures.

Where there is no agreed definition of what constitutes a 'significant risk', practitioners must form their own view on what it is appropriate to tell patients, guided by professional bodies. In broad terms, a significant risk is one which is serious, but uncommon, or one which occurs frequently, even if it is not serious.

The term "risk" can refer to any adverse outcome, including those which some health professionals would describe as "side effects" or "complications". Although a practitioner may not need to tell the patient about every possible consequence of an intervention, a patient might reasonably take the view that a 'significant risk' is one that he/she would wish to take into account in deciding whether or not to consent to the proposed procedure. The practitioner is expected to take this into consideration.

Such significant risks include, but are not limited to, loss of life, loss of limb function, brain damage, paralysis, haemorrhage, allergic reactions, nerve injury, blood clots etc.
From a frequency point of view, a 1 in 100 risk is definitely significant – a 1 in 10,000 risk might be, particularly if the consequences are devastating. If a patient asks about a specific risk, e.g. death, a truthful answer must be provided.

Leaflets, recorded consultations and other materials (e.g. audio-visual, taped consultations), informing patients about their condition and the treatment being offered must be available to patients in a format and in a way they can interpret and understand well before proposed treatment. Any written patient information should follow NHS Lanarkshire's local and other national guidance standards.

The practitioner should make a record of the information provided for each patient, including the key points of any discussions that are held, on the appropriate section of the clinical record or on the consent form. It is important to document discussion of the merits and burdens of alternative treatment options, including doing nothing. The patient must be explicitly informed if the recommended treatment is at variance from generally accepted standard treatments.

The clinician should record the date/issue number of written information provided as there can be significant differences between different versions.

Where possible and dependant on individual circumstances/needs, information may need to be provided in alternative languages or via interpreters.

Additional interpreting services support must also be arranged for people with sensory impairment such as Deaf or Deafblind or for people with learning disabilities or literacy problems. Further information on accessing interpreting support is available from the link below.
http://firstport2/staff-support/interpreting/default.aspx

Information must also be provided in a clear and concise format using plain English and avoiding jargon wherever necessary. Further information on communication supports and the format of the information should follow the guidance set out in the Board's **Accessible Information Translation Policy.**
https://www.nhslanarkshire.scot.nhs.uk/download/accessible-information-translation-policy/

Leaflets, recorded consultations and other materials (e.g. audio-visual, taped consultations), informing patients about their condition and the treatment being offered must be available to patients in a format and in a way they can interpret and understand well before proposed treatment. Any written patient information should follow NHS Lanarkshire's **Written Information Policy** and other national guidance standards. If you need further help on the design of leaflets for patients, please contact the patient information team at patientinformation@lanarkshire.scot.nhs.uk

Patient information leaflets on consent to treatment (Adult & Child)
https://www.nhsinform.scot/publications/consent-its-your-decision-leaflet **for downloadable copies.**

It should be noted that evidence of good communication with patients is far more important than the completion of a consent form. Patients should be given a continuing opportunity to raise questions. Staff should also be familiar with how to access sources of Interpreting, Advocacy and other support agencies should additional assistance be required by patients, to enable good communication. Some people will find it helpful to have someone accompany them to appointments to assist with discussions and considering options.
If the patient does not have someone but would like this support, an advocacy service can be contacted at the following websites:

- South Lanarkshire Council
- **http://www.southlanarkshire.gov.uk/info/200225/protecting_vulnerable_people/966/independent_advocacy**

- North Lanarkshire Council
  Advocacy | North Lanarkshire Council

6. RECORD KEEPING

6.1 Evidence of discussion

It is essential for health professionals to record clearly both a patient's agreement to the intervention and the discussions that led up to that agreement including the nature of information provided, specific requests by the patient and details of the scope of the consent given. This will be done either using a consent form or through documenting in the patient's case record if they have given verbal consent.
It is not usually necessary to record a patient's consent to routine and low-risk procedures, such as providing personal care or taking a blood sample as person centred plans of care should be developed with the patient involved in agreeing goals and outcomes. However, if the consent may be disputed later, or if the procedure is of particular concern to the patient it would be helpful to do so.

6.2 Written Consent

Patients can indicate their informed consent either orally or in writing. For routine procedures such as venepuncture, physical examination or the following of simple instructions, the patient's willingness to comply following explanation of what is required and why it is required, usually provides adequate indication of consent. However, in some cases the nature of the risks to which the patient might be exposed makes it important that a written record is available of the patient's consent and other wishes in relation to the proposed investigation and treatment. This helps to ensure later understanding between the health professional, the patient and anyone else involved in carrying out the procedure or providing care.

Where it is not an emergency situation and where the patient has the capacity to give consent, this policy requires that practitioners **must** get express **written consent** for:

- any procedure that is complex, or involves significant risks or side effects.
- any procedure to be carried out under general anaesthesia, sedation or utilising nerve blockage or regional anaesthesia beyond that provided topically or by simple infiltration (written consent not required for the anaesthesia, just the procedure that requires it).
- any procedure to be undertaken in theatres/endoscopy units
- any procedure which could be considered new, novel or experimental (treatment involving research requires a specific form approved by a Research Ethics Committee)
- any procedure where providing clinical care is not the primary purpose of the investigation or examination such as photography and/or video/audio recording
- any situation where there are implications for 'third parties' e.g. relatives and insurance companies in relation to genetic studies or HIV testing

It should be noted that some statutes require written consent to be obtained before a procedure can be carried out. Examples of this are treatments under Part 16 of the Mental Health (Care and Treatment) (Scotland) Act 2003, where the patient is capable of consenting to treatment and the Human Fertilisation and Embryology Act 1990, which deals with certain fertility treatments.

If the patient is unable to write (for whatever reason), and has full capacity the health professional should document on the consent form the patient has authorised treatment and sign this alongside a witness signature.

6.3 Consent Forms

The consent form documents the patient's agreement to go ahead with the treatment the clinician has proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed.

Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a check-list of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed.

In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

There is a standard NHS Lanarkshire **standard consent form** (Appendix 3) and specific forms for particular procedures including consent for photography and video-recording/digital imaging.

Consent forms in current use will be regularly reviewed to ensure that these comply with current good practice and this Policy therefore it is important that the current version of the form is used.

Procedure specific consent forms can be developed for high volume procedures with the intention of standardising information regarding risks of treatment and maximising the time spent with the patient. This form must be in accordance with the clinical records policy which discusses the principles of record design and development and be formally approved by the Clinical Records Steering Group.

There is no requirement for separate written consent for anaesthesia. Where an anaesthetist is involved in a patient's care, it is their responsibility to seek consent for anaesthesia, having discussed the anaesthetic techniques to be used and associated risks. Patients should be provided with appropriate information about anaesthesia. Key points of the discussion with the patient should be documented on the anaesthetic form/patients clinical record.

A signature, (or patient identification mark for patients with literacy problems) on a form is *evidence* that the patient has given consent but is not *proof* of valid consent. Consent does not equate with a signature (or mark); it is not a binding contract and the patient may, if they wish, withdraw consent at any time.

All writing on consent forms by healthcare professionals must be:

- Legible
- Unambiguous
- Contain no abbreviations
- Signed & dated by patient and health professional.

Consent forms should be audited on a regular basis to ensure they conform to agreed standards.

Completed consent forms will be kept with the patient's case record. Any changes made to a form, made after the patient has signed, will be initialled and dated by both patient and health professional.

If an error is detected on the consent form before the patient has been given any sedative pre-medication or anaesthetic medication, then the practitioner performing the treatment/operation must be informed and the form should be changed or rewritten to ensure the correct details (if the procedure or the site is incorrect the form should be re-written). The patient is given an explanation of the error and is asked to confirm a changed form or sign the new form.

If an error is detected after a sedative pre-medication or general anaesthetic is given, the practitioner performing the treatment/operation must be informed and there should be a discussion involving the other relevant healthcare professional such as Anaesthetist, nursing staff, Operating Department Practitioners and AHPs.

A decision on whether to proceed is taken primarily by the operator who has responsibility for the procedure and should consider the following factors in discussion with the team involved:

- What is the nature of the error – is it a minor documentation error or is there confusion regarding the understanding of the patient and what is about to be performed?
- Can it be established that patient agreement has been achieved but the form not completed?
- Can it be established if the patient's judgement is affected by the sedation?
- What is the urgency of the procedure and the risk related to delay / cancel?
- Is there enough relevant information to be sure that the correct procedure will be performed in line with the patient's wishes e.g.
    - medical notes
    - out-patient letters info
    - x-ray / scan results / images
    - familiarity with patient
    - site marking

If it is decided to proceed, the operator should take responsibility to change the details written on the consent form and should sign and date any alterations.

Other staff present should record in the clinical record that the form had been incorrect, the operator was informed and a decision to continue following review of information has been made.

It may be decided to wait until sedative has worn off before confirming patient agreement. Each case must be considered individually as a dynamic risk assessment is required for decision making. The operator should seek agreement from the team involved as to how to proceed. Ultimately the operator has the authority and responsibility for ensuring adequate consent.

Any concerns should be recorded and all errors detected in consent process reported as clinical incidents.

Pre-operative marking has a significant role in promoting correct site surgery. All operations in which there is a possibility of mistaking the correct location of surgery will follow a procedure to ensure the correct site is identified and marked. This includes the specific side e.g. right knee or the specific anatomical location e.g. index finger right hand.

All patients requiring surgery or a procedure requiring written consent should have a valid consent form which includes in the operation description the side / site of the procedure written out in full. The only exception would be for critically ill patients where patient agreement is not possible and a delay maybe life threatening.

Patient's health records must be available when completing the consent form and when marking the site.

Consent forms are also required from patients for the use of unlicensed medicines. The form required for this can be found here.

7. CAPACITY AND ADULTS WITH INCAPACITY

7.1 Capacity

It is presumed in the law in Scotland that all adult patients (aged 16 or over) have the capacity to give consent to treatment unless there is evidence to the contrary. Patients have the capacity to give consent if they are capable of understanding and retaining information in respect of the treatment proposed, are capable of believing the information and have an ability to weigh up and decide based upon that information. That is, the patient is able to:

- understand in simple language what the medical treatment is, its purpose and nature and why it is being proposed
- understand its principle benefits, risks and alternatives
- understand in broad terms what will be the consequences of not receiving the proposed treatment
- retain the information long enough to make an effective decision, and
- make a free choice

For capable adults, only the patient may provide consent. Whilst it is good practice to keep relatives, carers etc., appropriately informed (with the patient's consent), only the patient may give or refuse consent. In most cases, discussions with those close to the patient will take place with the patient's knowledge and consent. But if someone close to the patient wants to discuss their concerns about the patient's health without involving the patient, you should not refuse to listen to their views or concerns on the grounds of confidentiality. The information they give you might be helpful in your care of the patient. *(MWC 2018)*

Mental disorder does not necessarily make a patient incapable of giving or refusing consent. Capacity to consent should be assessed in relation to the particular patient, at the particular time, as regards the particular treatment proposed. Temporary factors can remove or reduce

capacity, e.g. altered consciousness, confusion, shock, fatigue, pain, drugs. However, a practitioner would need to be satisfied that such factors were operating to such a degree that the ability to decide was absent before concluding that a patient lacked capacity.

In addition, capacity in any person may vary with:

- Time
- The adult's mood
- Influence of drugs or alcohol
- Distractions
- Time allowed to consider and decide their response
- Level of familiarity with surroundings
- The way information is presented
- The presence of infection or other physical complaints.

7.2 Adults with Incapacity

The "Adults with Incapacity (Scotland) Act 2000" provides a framework for decisions to be made on behalf of incapable adults. Part 5 of the Act, which came into effect in July 2002, and was updated in January 2008, relates to medical treatment and provides authority for a healthcare professional who has primary responsibility to treat an incapable adult on the issuing of a Certificate of Incapacity (section 47).

The aim of the Act is to protect the rights and interests of adults who are incapable of managing their own affairs.

A Code of Practice has been published for persons authorised to carry out medical treatment or research under Part 5 of the Act. For treatment of adults with incapacity, the more detailed guidance contained in this Code of Practice **must** be used in conjunction with this policy on consent. There is a flow chart for guidance in the pad of medical treatment certificates (Appendix 4).

Incapacity is not an "all or nothing" concept - it is to be judged in relation to particular decisions. A person may be legally capable of some decisions and actions and not capable of others.

For the purposes of the Act "incapable" means incapable by reasons of mental disorder, or inability to communicate* because of physical disability and in relation to a particular matter is incapable of at least one of the following:

- Acting; or
- Making decisions; or
- Communicating decisions; or
- Understanding decisions; or
- Retaining memory of decisions

* The Act clearly states that a person shall not fall within the definition of incapacity if the lack can be made good by human or mechanical aids to communication. So any practitioner assessing capacity must make every effort to utilise appropriate specialists; such as Speech & Language Therapists or Psychologists or communication aids to overcome perceived

barriers to Communication (There is a Caring and Consent leaflet on the NHS Inform website https://www.nhsinform.scot/care-support-and-rights/health-rights/consent/consent-when-using-the-nhs website – about information on consent for carers of people who come under the Adults with Incapacity Act.)

Lack of decision-making capacity as regards healthcare treatment is verified by an assessment of the adult and that assessment follows the principles described in the Act.

The Mental Welfare Commission for Scotland provides guidance on the issue of memory in the Good Practice Guide: The Adults with Incapacity Act in general hospitals [9]. Their stated view is that (p2) "...*the person must be able to retain information for long enough to make a decision. We believe he/she must:*

- *remember the decision; and/ or*
- *make the same decision consistently given the same information; and/or*
- *agree with a record of that decision*

When assessing capacity, it is unlikely that a decision can be reached instantaneously. It will be important to talk to other health care professionals, relatives and carers before making a decision. It may be necessary to utilise the skills of speech and language therapists, interpreter or signer to help with communication.

7.3 Provisions of the Act

The Act provides a general authority to treat patients with incapacity. Medical treatment is defined in the Act to include:

"Any procedure or treatment designed to safeguard or promote physical or mental health"

All decisions made on behalf of an adult with incapacity must be in accordance with the General Principles of the Act. These are that decisions must:

- **Benefit the adult**
  The authorising doctor must be satisfied that the intervention will benefit the adult and that such a benefit cannot reasonably be achieved without the intervention.

- **Minimum intervention**
  The intervention should be the least restrictive option in relation to the freedom of the adult, consistent with the purpose of the intervention.

- **Encourage the adult to exercise residual capacity**

- **Take account of the adult's wishes**
  It is compulsory to take account of the present and past wishes and feelings of the adult if these can be ascertained. This includes ascertaining their wishes by any means of communication.
  It will be necessary also to consider the individual's right to confidentiality and any previously expressed wishes about disclosure of information.

- **Consultation with relevant others**
  In determining if an intervention is to be made, and if so, what intervention is to be made, account should be taken, if it is reasonable and practicable to do so, of the views of:

- The nearest relative and primary carer of the adult (this may not always be the same person)
- Any person whom a sheriff has directed should be consulted
- Any other person appearing to have an interest in the welfare of the adult or the intervention proposed where these views have been made known to the person responsible
- Any guardian, continuing attorney, welfare attorney or other proxy of the adult who has powers relating to the proposed intervention

The Act requires that even where a proxy has been appointed a certificate under section 47(1) should be completed (Appendix 5).

A proxy may be a guardian, a welfare attorney or a person authorised under an intervention order. It will be desirable for any proxy to make himself or herself known during the admission process of a patient into hospital and produce the appropriate paperwork outlining the powers and a registration certificate from the Office of the Public Guardian. If the existence of a proxy with powers to consent to treatment on behalf of the adult is suspected but not known, it would be good practice for the medical practitioner to check with the adult's close relatives.

A public register held by the Office of the Public Guardian can be accessed in exceptional circumstances over the telephone by a Doctor or Social Worker if a patient is waiting for treatment. In all other cases a request can be made to the office, and on payment of a fee the register can be searched and information provided via link http://www.publicguardianscotland.gov.uk/general/contact-us .

The local authority social work department may also have this information. The details of any proxy with welfare powers appointed prior to the Act will be unknown to the Public Guardian. Proxy decision-makers **cannot** consent to certain irreversible or hazardous treatments regulated under section 48(2) of the Act. However, their views should be taken into account when considering treatment for the adult.

Section 50 of the Act envisages that a proxy with welfare powers should be given the opportunity to consent to the proposed medical treatment wherever reasonable and practicable. Situations may arise where even after discussion proxy decision-makers will not always agree with the medical treatment proposed by the doctor in charge of the case. Others close to the adult may also disagree with the doctor, and indeed with the decision of the proxy. Section 50 of the Act sets out a procedure for resolving such disagreements.

The Adults with Incapacity Act contains additional safeguards for patients. Section 47 of the Adults with Incapacity Act cannot be used where Part 16 of the Mental Health (Care and Treatment) (Scotland) Act 2003 applies, and there are additional criteria which must be satisfied before electro-convulsive therapy, sterilisation (including any medical treatment likely to lead to sterilisation as an unavoidable result), termination of pregnancy or implantation of hormones or drug treatment to reduce sexual drive can be carried out. Detailed guidance is provided in the Adults with Incapacity (Scotland) Act 2000, Part 5 of the Code of Practice.

7.4 Certificate of Incapacity

The medical practitioner primarily responsible for the medical treatment of the adult issues the certificate of incapacity. If the consultant is not present and it is important to avoid delay in treatment, the medical practitioner primarily responsible will be the doctor who is in attendance and to whom it is delegated to give treatment in the absence of the consultant. This should be a fully registered medical practitioner competent in the terms of the intervention proposed and with an understanding of the provisions of the Act.

The Smoking, Health & Social Care (Scotland) Act 2005 has amended the persons who can assess capacity and issue certificates of incapacity authorising treatment to now include certain people, as prescribed by regulation, such as dentists, nurses and ophthalmic opticians who have undergone further training. They may complete a certificate for treatment within their own specialty.

Under subsection 47(5) (as amended), the certificate of incapacity has to be in a prescribed form and must specify the period during which the authority remains valid, being a period which:

- The person who issues the certificate for the medical treatment of the adult considers appropriate to the condition or circumstances of the adult; but
- Does not exceed one year; unless the Adults with Incapacity (Conditions and Circumstances Applicable to the Three Year Medical Treatment Certificates) (Scotland) Regulations 2007 (as outlined below) are met.

The maximum duration of 3 years is dependent on the nature of the illness from which the patient is suffering particularly where the level of incapacity may vary or recovery may be anticipated. A certificate of 3 years would only be appropriate where, in the view of the practitioner who issues the certificate, a patient was suffering from at least one of the following conditions:

- Severe or profound learning disability, or
- Severe dementia, or
- Severe neurological disorder,

which causes the adult to lack capacity in respect of decisions about medical treatment as defined in Section 47 of the Act (as amended) and which is unlikely to improve and for which no curative treatment is available.

It is good clinical practice however to review the capacity of the patient on a regular basis and where a treatment plan exists, could be reviewed annually. Where a practitioner would normally review and seek fresh agreement from a competent patient that may well be the appropriate point at which to review and re-certify in relation to a patient, the same principle should apply.

To demonstrate that the practitioner has fulfilled the requirements of section 47(3) of the Act (as amended), it is good practice to record such instructions, approval or agreement in the patient's medical record.

Four matters must be considered before completing the certificate of incapacity:

1. The practitioner issuing the certificate must have in contemplation some treatment, whether acute or continuing. A medical practitioner primarily responsible for the medical treatment of the adult may issue a certificate in respect of any medical treatment, whereas any other healthcare professional authorised to issue a certificate may only do so for the kind of treatment for which they are responsible.

2. The practitioner must be satisfied that the adult is incapable in relation to a decision about the treatment in question.

3. If the person issuing the certificate is aware of the existence of a proxy with welfare powers, that person should, where it is reasonable and practicable to do so, obtain the consent of that proxy.

4. The proposal for treatment must be consistent with the general principles laid down in section 1 of the Act.

It would be unreasonable, impractical and unnecessary to issue a separate certificate of incapacity for every health care intervention in some people. *For example, an adult with dementia in a nursing home may have multiple physical and mental health care needs in addition to a requirement for fundamental procedures to ensure nutrition, hydration, elimination, etc.* On the other hand, a single certificate of incapacity is entirely appropriate when an adult requires a single procedure such as an operation.

The Act specifies, under section 47(2)(as amended), that "the person who by virtue of subsection (1) has issued a certificate for the purposes of that subsection shall have . . . authority to do what is reasonable in the circumstances, in relation to the medical treatment, to safeguard or promote the physical or mental health of the adult". This would cover not only the operation but also post-operative medical care and pain relief. It is therefore clear that the certificate of incapacity, as designed, will provide an effective and workable means for managing single healthcare interventions but requires careful completion for a person who needs multiple interventions. A possible way to complete the certificate would be by reference to a treatment plan.

If after issuing a certificate, the medical practitioner responsible for the treatment of the adult is of the opinion that the condition or circumstances of the adult has changed, the medical practitioner may:

- revoke the certificate
- issue a new certificate specifying a period not exceeding one year or if, in the opinion of that person, the Adults with Incapacity (Conditions and Circumstances Applicable to the Three Year Medical Treatment Certificates) (Scotland) Regulations 2017, are met, three years.

7.5 Treatment Plan

For adults requiring multiple or complex healthcare interventions, it is recommended that a treatment plan similar to that suggested at Annex 5 of guidance of The Code of Practice (see Appendix 6) may be drawn up.

The treatment plan could outline the healthcare interventions that can be foreseen over the time specified in the certificate of incapacity and may be attached to the certificate of incapacity and held in the adult's case record.

The practitioner could write in the line *following "incapable within the meaning of the Adults with Incapacity (Scotland) Act (the 2000 Act) in relation to a decision about the following medical treatment"* the phrase "See attached treatment plan". The treatment plan could contain a list of interventions along with a judgement from the practitioner regarding the adult's capacity to consent to those interventions.

The exact content of the treatment plan will be negotiable. The practitioner should follow the general principles of the Act in formulating a plan and seeking the views of other relevant people. The practitioner must strike a balance between a plan that is too broad and therefore at odds with the principles of the Act, and one that is too narrow and might need to be changed on a frequent basis to the detriment of the adult's general health. A plan which is not broad enough is no less inconsistent with the Act's principles and purpose than one which is unnecessarily broad.

8. MENTAL HEALTH CARE AND TREATMENT (SCOTLAND) ACT 2003

Where a patient, who is subject to compulsory powers due to mental disorder, requires treatment for that mental disorder, the treatment is regulated by Part 16 of the Mental Health (Care and Treatment) (Scotland) Act 2003. Informal patients, i.e. *those not subject to any form of compulsory power*, will have the same rights as any other capable adult to give or refuse consent to any proposed treatment intervention.

'Mental disorder' is defined as one or more of the following categories:

- Mental illness
- Learning disability
- Personality disorder

The Mental Health Care and Treatment (Scotland) Act 2003 provisions only cover treatment for mental disorder; any patient not capable of giving or refusing consent to treatment offered for a physical disorder would be covered by the Adults with Incapacity (Scotland) Act 2000, which is described in section 7.
Part 16 of the 2003 Act provides a general authority to treat individuals where they are subject to an order that authorises treatment under that part of the Act.
Patients subject to compulsory powers have additional rights and safeguards under Part 16 of the Act in relation to specified treatments these are:

- Treatments over a period of time
- ECT and other treatments
- Neurosurgery

For these treatments:

Consent must be provided in writing by the patient **or**;
Where a patient has capacity and refuses to consent or if the patient lacks capacity to consent, a second opinion for the proposed treatment must be given by a **Designated Medical Practitioner** appointed by the **Mental Welfare Commission before treatment can commence.**

For further detail please consult the code of practice here.

9. CHILDREN AND YOUNG PEOPLE

This sections provides a summary of the main points in reference to children and young people with a more detailed policy available in appendix 7.

9.1 Age and Capacity

Under Scottish Law, young people **aged 16 or over** have the same right to consent or refuse as adults and for the purpose of consent should be treated as adults.

The Age of Legal Capacity (Scotland) Act 1991 allows children and young persons **under 16 years** to consent (or refuse to consent) on the same basis as adults "provided they are capable of understanding the nature and possible consequences of the procedure or treatment".

This is a matter of clinical judgment and will depend on several things including the age of the patient; the maturity of the patient; the complexity of the proposed intervention; its likely outcome and the risks associated with it.

Further, a parent or legal guardian may only consent to healthcare and treatment if the child is not capable of doing so on his or her own behalf. In practice, a parent or guardian usually accompanies children and it will be for the practitioner to assess the capacity of the child to consent and ask the appropriate person to sign the consent form.
A full note should be made of the factors taken in to account by the doctor in making his/her assessment of the child's capacity to give valid consent. The appropriate section of the consent form should be signed. The obligation to provide appropriate information remains unaltered regardless of who signs the form. A note is not required in situations where a child gives verbal consent for a minor procedure.

When the child has independently sought advice, efforts should be made to encourage the child that his or her parents should be involved in the healthcare shared decision-making process, except in circumstances where it is not in the child's best interest to do so. Where a child is treated without parental knowledge, a note should be made of the factors taken into account by the doctor in making his/her assessment of the child's capacity to give valid consent.

If a child's capacity to consent is unclear, the healthcare practitioner attending the child may wish to involve an independent health professional (e.g. a clinical psychologist) but the medical practitioner will ultimately have the responsibility of deciding the child's competency.

Even where children are not able to give valid consent for themselves, it is very important to involve them as much as possible in decisions about their own health. Even very young children will have opinions about their healthcare and methods appropriate to their age and understanding should be used to enable these views to be taken into account.
Parents will often be unsure about how much information they want their child to have (particularly when a young child is seriously ill) and this will need to be discussed sensitively with them.

Shared decision-making with older children will often be a matter of negotiation between the child, those with parental responsibility and healthcare professionals: children should never feel that decisions are being made over their heads.

9.2 Children refusing consent

If a child or young person is able to understand the nature, purpose and possible consequences of the proposed treatment/investigation, as well as the consequences of non-treatment, the child can refuse to give consent. It should be borne in mind that:

- at age 16 a young person has the same right to refuse as adults
- under age 16 children/young people may have the capacity to decide, depending on their ability to understand what is involved
- the best interests of the child or young person should not be compromised by their refusal to consent to a procedure or treatment
- if a competent child/young person refuses treatment, those with parental responsibilities cannot authorise procedures. Legal advice may be helpful in how to deal with such cases.

9.3 Emergency Situations

In an emergency, where:

- the child or young person either lacks capacity or is too ill to consent *and* where there is no-one with parental responsibility present
- the treatment is in the best interests of the child to prevent death or permanent damage.

Life-saving treatment can be carried out immediately. The treatment given must be no more than the immediate situation requires (HDL(2006)34). The practitioner should then seek legal advice as soon as possible.

Where consent is required in an emergency, the doctor may proceed with either verbal consent or no consent if it is in the best interest of the child. Where written consent is possible this should be obtained.

9.4 Consenting of behalf of a child who lacks capacity

Subject to any Court order restricting parental rights those who can give consent on behalf of an incapable child include:

- The mother whether married to the father or not.
- The child's natural father, if married to the mother, at any time from conception or subsequently.
- The child's natural father, even if divorced from the mother.
- An unmarried father whose name is on the child's birth certificate, registered on or after 04 May 2006, has full parental responsibility and rights as though married to the mother.
- An unmarried father who has entered and registered a formal Parental Responsibilities and Parental Rights Agreement with the mother.
- A legal guardian nominated in writing by a parent before the parent's death. This appointment comes into effect automatically on the death of the parent.
- A person holding a Residence Order in relation to the child, or any other court order giving them the right to consent on the child's behalf.
- A person aged 16 or over who has care or control, unless it is within their knowledge that a parent would refuse consent.

10. REFUSAL AND WITHDRAWAL OF CONSENT

10.1 Refusal of Consent

Competent adult patients are entitled to refuse treatment, even when it is clinically believed that this would clearly benefit their health. A patient's refusal to consent, with the reason for refusal, must be fully documented in the case note. It is also important to explain the consequences of not proceeding and to document this in the case record.

Where a patient has refused a particular intervention, practitioners must ensure that they continue to provide any other appropriate care to which the patient has consented. Practitioners should also ensure that the patient realises that they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they should be advised accordingly.

If a patient provides consent to a particular procedure but refuses certain aspects of the intervention, the practitioner must explain to the patient the possible consequences of their partial refusal. If the practitioner genuinely believes that the procedure cannot be safely carried out under the patients stipulated conditions, he/she is not obliged to perform it. The practitioner must, however, continue to provide any other appropriate care.

10.2 Advanced Directives

Healthcare professionals should take into account Advance Statements, which is a document composed when the patient has sufficient decision-making capacity.
Advance Statements describe how patients would like to be treated should they lack decision-making capacity at some future time. The BMA guidance states that "an unambiguous and informed advance refusal is as valid as a contemporaneous decision" (BMA, 1995).

These are a duly witnessed written statement provided by the patient or a witnessed verbal statement which is recorded in the patient's case record. An advance refusal of consent is legally binding providing that the patient is an adult who had decision-making capacity when the Advance Statement was made. The statement must be clearly applicable to the treatment option proposed and the patient's present circumstances and there must be no reason to believe that the patient has changed their mind (BMA, 2001).

Similarly, clinical staff should take into account the provisions outlined in an anticipatory care plan. While not legally binding, the preferences documented in such plans should influence clinical decision making, particularly so in regard to treatment escalation / limitation decisions when a patient is approaching the end of life.

10.3 Special Circumstances

If a patient refuses blood or blood products on religious or other grounds this must be clearly documented on the consent form and in the clinical record. A Jehovah's Witness will use an Advance Decision document.

A woman has a right to refuse a caesarean section even when it might benefit her foetus. All Obstetric practitioners must be familiar with and abide by guidance from the Royal College of Obstetricians & Gynaecologists on this topic.

When a parent refuses consent to urgent or life-saving treatment for a child lacking capacity, and the Consultant has a written supporting opinion from a medical colleague (usually another Consultant, not their own junior) that the patient's life is in danger if the treatment is withheld, but the Consultant does not wish to proceed without consent, consent may be obtained from a Court of Session judge, if time permits.
When patients are detained under the statutory powers of the Mental Health (Care and Treatment) (Scotland) Act 2003, practitioners must ensure that they know the conditions and safeguards needed for providing treatment and care without consent.

10.4 Withdrawal of Consent

Patients can change their minds about a decision at any time, as long as they have the capacity to do so. It is important to determine if possible what their concerns are and to explain the consequences of not proceeding and to document this in the case record. However, if they are competent and decide to withdraw consent their wishes must be respected.

11. CLINICAL PHOTOGRAPHY AND VIDEO RECORDINGS

The generic consent form should only be used for photography and video where the recordings are implicit to the procedure (such as endoscopy, laparoscopic images or retinal screening). Recordings consented in this way form part of the patient health record; if there is no possibility that the patient might be recognised, they can also be used within the clinical setting for education or research purposes.

In all other circumstances, a specific consent to photography form should be used: this provides more detailed information on the levels of consent available to the patient. It should be noted that express consent must be sought for any form of publication.

For further information, please refer to the NHS Lanarkshire *Recordings (Photography and Video) for Clinical and Service Use Policy.*
https://www.nhslanarkshire.scot.nhs.uk/download/recordings-photography-and-video-for-clinical-and-service-use-policy/?wpdmdl=4702&ind=1548934238574

12. QUALITY IMPROVEMENT – Monitoring and Review

Healthcare professionals have a responsibility to monitor and review their clinical practice. Consideration should be given to auditing the compliance with this policy by:

- Auditing health professional's understanding of consent processes and requirements.
- Auditing health records to ensure appropriate recording on consent forms and within the clinical record.
- Auditing patient experience to determine if the process met their expectations.

Other methods of monitoring include and adverse events, complaint, claims or ombudsman reports where consent is cited as an issue.

13. EQUALITY AND DIVERSITY IMPACT ASSESSMENT

This policy meets NHS Lanarkshire's EQIA (tick box) ✓

14. REFERENCES AND FURTHER GUIDANCE

A Good Practice Guide on Consent for Health Professionals in NHS Scotland
Scottish Executive Health Department, June 2006

Adults with Incapacity (Scotland) Act 2000: guide to assessing capacity
https://www.gov.scot/publications/adults-incapacity-scotland-act-2000-communication-assessing-capacity-guide-social-work-health-care-staff/documents/

Adults with Incapacity (Scotland) Act 2000: Code of Practice for Persons Authorised to Carry Out Medical Treatment or Research Under Part 5 of the Act (2nd Edition)
The Scottish Government, January 2008

Age of Legal Capacity (Scotland) Act 1991

British Medical Association (2013) Key guidance on consent issues

Consent: Patients and Doctors Making Decisions Together 2008 General Medical Council
http://www.gmc-uk.org/static/documents/content/Consent_-_English_1015.pdf

General Medical Council, Mental Capacity Decision support tool (2016)

General Medical Council, Confidentiality: good practice in handling patient information (updated 2018)
https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/confidentiality

HCPC Standards of conduct, performance and ethics (2016)
https://www.hcpc-uk.org/standards/standards-of-conduct-performance-and-ethics/

Making and Using Visual and Audio Recordings of Patients, General Medical Council, May 2011
http://www.gmc-uk.org/guidance/ethical_guidance/making_audiovisual.asp

Mental Health (Care and Treatment) (Scotland) Act 2003 Code of Practice.
https://www.gov.scot/publications/mental-health-care-treatment-scotland-act-2003-code-practice-volume-1/pages/11/

Mental Welfare Commission Good Practice: Carers and Confidentiality.
2018_update_carers___confidentiality_final_draft_16_oct_2018.pdf (mwcscot.org.uk)

National Education for Scotland (NES) Think Capacity, Think Consent Learning Module 2013

Obtaining Valid Consent: Clinical Governance Advice no.6 Royal College of Obstetricians and Gynaecologists (2015)
https://www.rcog.org.uk/globalassets/documents/guidelines/clinical-governance-advice/cga6.pdf

Realising Realistic Medicine: Chief Medical Officer for Scotland annual report 2015-2016
https://www.gov.scot/publications/chief-medical-officer-scotland-annual-report-2015-16-realising-realistic-9781786526731/

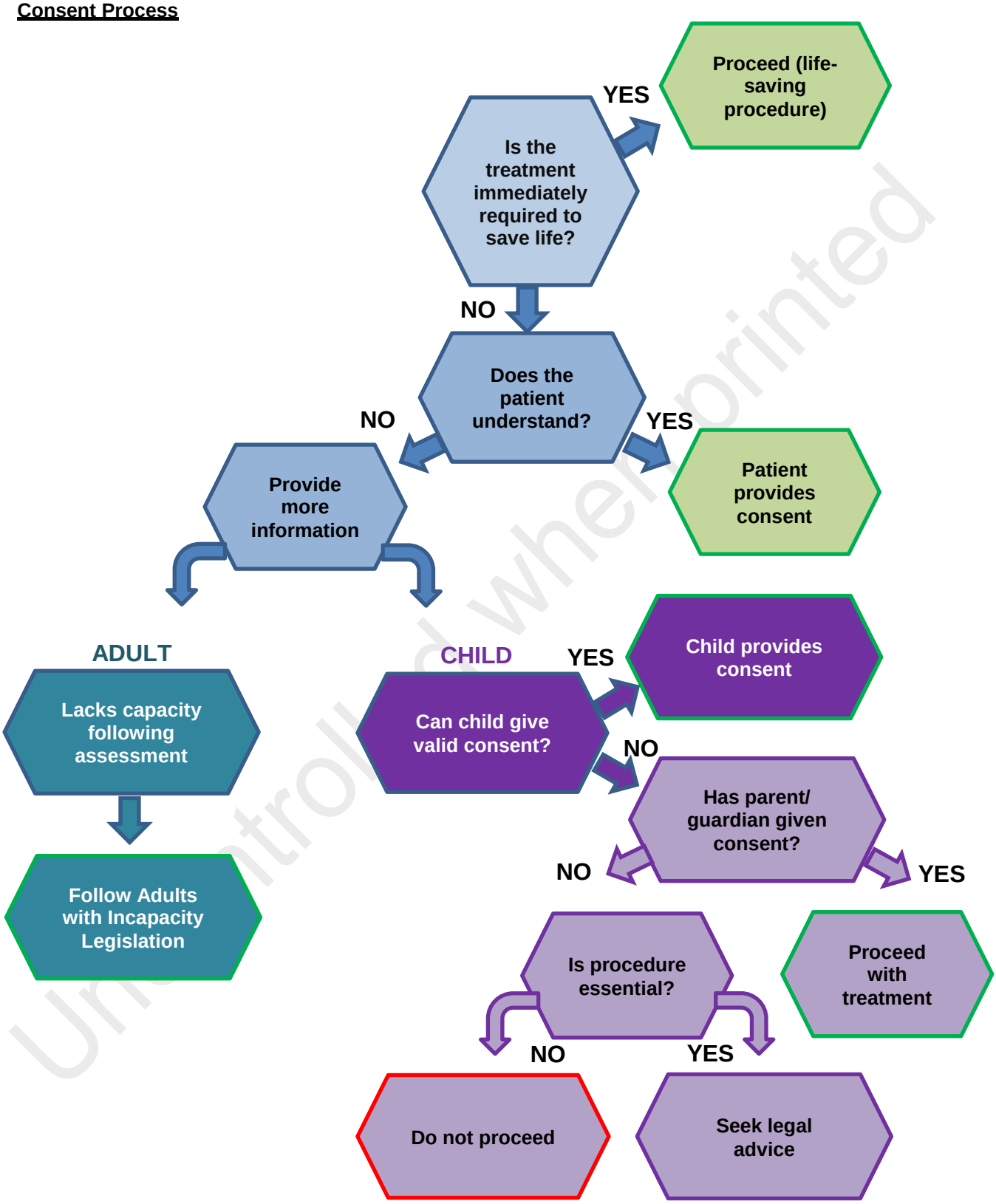
RCN Guidance - Principles of consent (2017)
https://www.rcn.org.uk/professional-development/publications/PUB-006047

The Code: Professional Standards of Practice and Behaviour Nurses and Midwives
Nursing & midwifery Council, 2015
https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf

United Nations Convention on the Rights of a Child (Incorporation) (Scotland) Bill
https://www.gov.scot/publications/implementing-united-nations-convention-rights-child-introductory-guidance/pages/5/

APPENDIX 1.

Consent Process



APPENDIX 2


5 QUESTIONS
to ask at your appointment before you get any test, treatment or medicine.
NEED? 1
Do I really need this test, treatment or medicine?
BENEFIT? 2
What are the benefits to me?
RISK? 3
Are there any risks or side effects?
CHANGE? 4
How can I improve my condition or health?
IF I DON'T? 5
What will happen if I don't do anything?
Please ask at reception for a card
NHS Lanarkshire

APPENDIX 3

CHI no .....
First name ..... DOB ...../...../.....
Last name ..... Sex: ☐ M ☐ F
Address .....
.....
.....
or attach addressograph label here

Hospital/Site: .....
Clinic/Ward: .....

Patient Agreement to Investigation or Treatment
Consent Form

Special requirements: (e.g. other language, other communication method)

Statement of Health Professional (to be completed by health professional with appropriate knowledge of proposed procedure as specified in consent policy)

Describe proposed operation, investigation or other treatment.
Where appropriate specify site or side (write in full).

Specific risks/complications
Please detail any specific risk/complications related to the procedure that were discussed. Please reference any information leaflets the patient has been given on the procedure that includes risk and complications.

- ☐ I have discussed the intended benefits of the treatment advised and risks of any available alternative treatments (including no treatment).
- ☐ I have discussed the side effects of the treatment advised, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.
- ☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments, etc.) and location.
- ☐ I have explained to the patient that he/she has the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.
- ☐ I have discussed concerns of particular importance to the patient in regard to treatment.

CAT295

Completed by: (PRINT NAME)	**Job Title:**
Signature:	**Date:** ...../...../..... **Time:** ..... : .....

NMAHP.SCONSF.19_28008.L

Pub. date: Feb. 2020 | Review date: Feb. 2025 | Issue No: 01

NHS Lanarkshire

CHI no .....
First name ..... DOB ...../...../.....
Last name ..... Sex: ☐ M ☐ F
Address .....
.....
.....
or attach addressograph label here

Statement to be Completed by Patient or Parent/Guardian*
(*parental responsibility for a minor without capacity)

You should read this form and the notes below carefully. If there is anything you do not understand, ask the health professional for an explanation. If the information is correct and you understand the procedure, you should sign the form. You have the right to change your mind at any time, including after you have signed this form.

I understand:

- The procedure, important risks and appropriate alternatives, which have been explained to me by the health professional named on this form.
- Who will be performing the procedure on the day.
- That any procedure in addition to that named on this form will only be carried out if it is necessary and is reasonable in the circumstances, in relation to the medical treatment proposed, to safeguard or promote physical or mental health.
- That examination for the purpose of teaching will not be undertaken without my consent.

I have been told about additional procedures which may become necessary during my treatment. I have listed below **any procedures which I do NOT wish to be carried out without further discussion.**

I agree: (tick as applicable)

☐ To the administration of an anaesthetic or to sedation if required.
☐ To the procedure named on this form.
☐ To photographic images and video recordings being held in records, and made available for teaching, audit and ethically-approved research purposes, to improve the quality of patient care.
☐ To the emergency administration of blood or blood products.

Patient Refusal for Blood Products

Please sign here if you decline to consent to the emergency administration of blood or blood products, **even if this results in death**.

Signature: (Patient or Parent/Guardian)	**Date:** ...../...../.....
Signature: (Health Professional)	**Date:** ...../...../.....

A witness or intepreter should sign below if the patient is unable to sign/speak English but has indicated his/her consent. Young people/children may also like a parent to sign here (see consent policy).

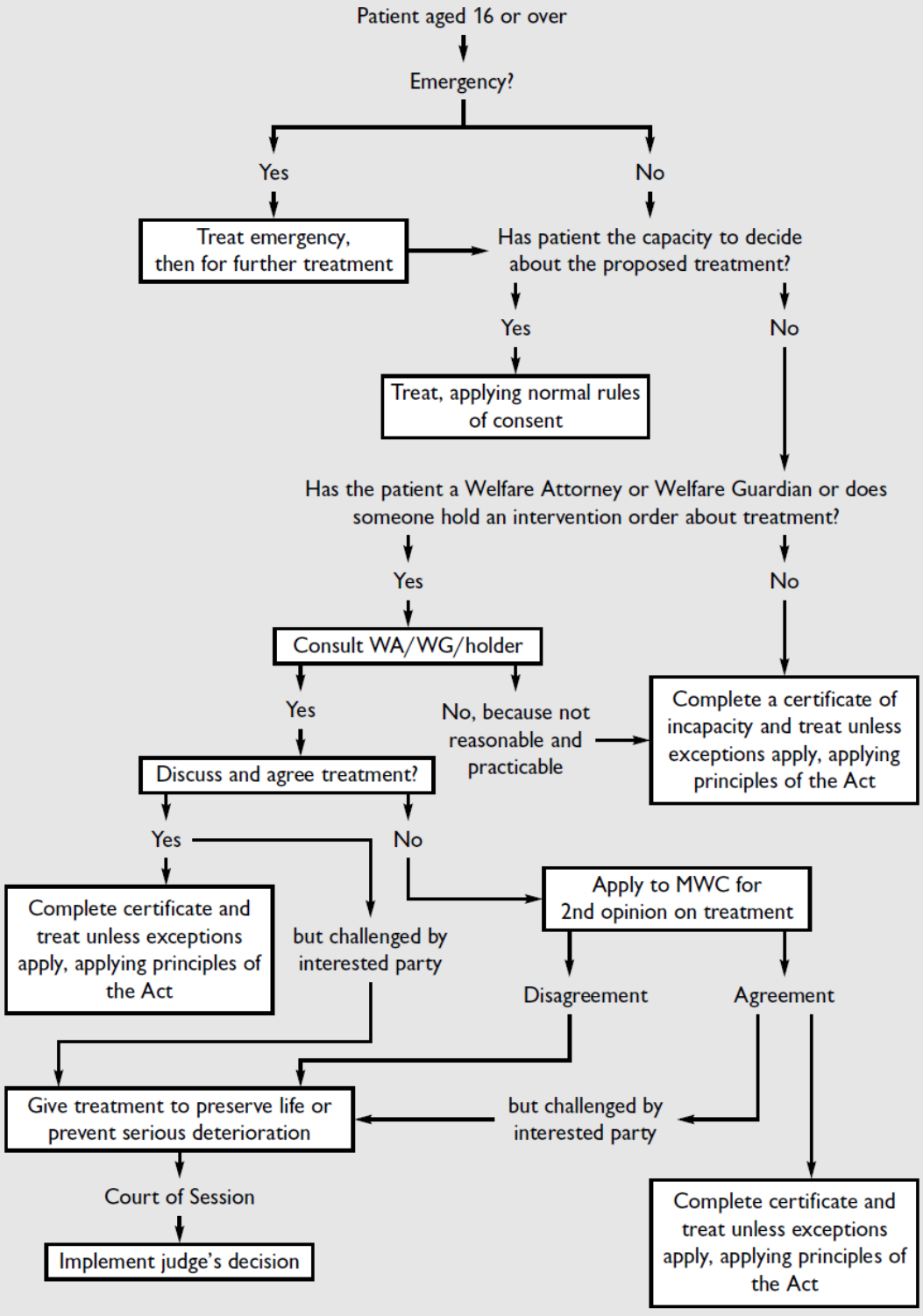
Signature:	
Name: (PRINT)	**Date:** ...../...../.....

Patient or Parent/Guardian* Agreement to Treatment

Signature:	
Name: (PRINT)	**Date:** ...../...../.....

APPENDIX 4

ADULTS WITH INCAPACITY (SCOTLAND) ACT 2000
PART 5 – MEDICAL TREATMENT – FLOWCHART



APPENDIX 5

ADULTS WITH INCAPACITY
(SCOTLAND) ACT 2000

Certificate of Incapacity under Section 47 of the Adults with Incapacity (Scotland) Act 2000

I _____ (name)

of _____ (address)

*am the medical practitioner primarily responsible for the medical treatment of; or

*am a person who is *a dental practitioner/an ophthalmic optician/a registered nurse and who satisfies such requirements as are prescribed by the Adults with Incapacity (Requirements for Signing Medical Treatment Certificates) (Scotland) Regulations 2007 and who is primarily responsible for treatment of the kind in question of:

_____ (name)

of _____ (address) D D M M Y Y (date of birth)

for whom the *guardian/welfare attorney/person appointed by intervention order/nearest relative/carer

is _____

I have examined the patient named above on D D M M Y Y (date). I am of the opinion that *he/she is incapable within the meaning of the Adults with Incapacity (Scotland) Act 2000 ("the 2000 Act") in relation to a decision about the following medical treatment:

_____

because of (nature of incapacity) _____

_____

_____

This incapacity is likely to continue for _____ months.

*I therefore consider it appropriate for the authority conferred by section 47(2) of the 2000 Act to subsist from:

D D M M Y Y (date of examination) until D D M M Y Y, being a period which does not exceed one year from the *date of the examination on which this certificate is based/date of revocation of the certificate issued previously by me; or

*I am of the opinion that (a) *he/she is suffering from *a severe or profound learning disability/dementia/a severe neurological disorder; and (b) *what he/she is suffering from is unlikely to improve within the meaning of the Adults with Incapacity (Conditions and Circumstances Applicable to Three Year Medical Certificates) (Scotland) Regulations 2007/ Y Y and therefore consider it appropriate for the authority conferred by section 47(2) of the 2000 Act to subsist until:

D D M M Y Y being a period which does not exceed three years from the *date of the examination on which this certificate is based/date of revocation of the certificate issued previously by me.

The authority conferred by section 47(2) of the 2000 Act shall subsist for the period specified above or until such earlier date as this certificate is revoked.

In assessing the capacity of the patient, I have observed the principles set out in section 1 of the 2000 Act.

Signed _____ Date D D M M Y Y

*delete as appropriate

APPENDIX 6

Treatment plan for patients

receiving ongoing treatment under the terms of Part 5 of the Adults with Incapacity (Scotland) Act 2000.

Name of patient…… Date of birth……/……/……

Address……

……

I have examined the patient named above on……/……/……(Date) and consider that he/she needs to undergo procedures to safeguard or promote physical or mental health in relation to the treatment plan below. I have assessed his/her capacity to consent to treatment in relation to each area of intervention.

Disorder/intervention (See note A)	**Capacity** C = capable I = incapable
1. Fundamental healthcare procedures (see note B)	

I have consulted the following people over this treatment plan and over the patient's capacity (see note C):

Name……Designation……
Address……

Name……Designation……
Address……

Signed……..

APPENDIX 7: Children & Young People Guidance

Introduction

Children have the right to say what they think should happen, when adults are making decisions that affect them, and to have their opinions taken into account.

(Article 12 UN Convention on the Rights of the Child)

The process of consenting children or young people (those aged 12 years or more) for healthcare assessment, care or treatment is different to the process for adults. The fundamental difference is set in legislation, The Age of Legal Capacity (Scotland) Act, 1991 (Section 2(4)), which states that:

"A person under the age of 16 years shall have legal capacity to consent on his own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending him, he is capable of understanding the nature and possible consequences of the procedure or treatment."

In practice, this means that a child or young person under the age of 16 years may have the legal capacity to consent (or refuse), to any surgical, medical or dental treatment where, in the opinion of a qualified health care professional attending the child or young person, they are capable of understanding the proposed procedure or treatment and possible outcomes which could arise.

Information provision

Information about the proposed procedure or treatment must be given in appropriate terms which the child or young person understands e.g. the words for a 14yr old differ from those for an adult or from those for a 9yr old. Use of complex language or jargon may result in poor understanding, misunderstanding or in increased fear and anxiety.

There are different ways of passing on information including orally, in age- appropriate writing, storyboards, videos (no one way suits all) and the use of paediatric preadmission programmes.

The information should include the benefits and significant risks of the proposed treatment and any relevant alternatives including not having the intervention.

All questions must be answered truthfully and if a question cannot be answered the clinician should involve a colleague who knows and then listen when the issues are discussed with the family.

Voluntariness

Consent must be given voluntarily, without pressure, deceit or undue influence from family, health professionals or others. Once a decision is made it is still possible for the child or young person or the parent, whoever consented, to change their mind.

Verbal or written consent
With verbal or non-verbal/implied consent (e.g. holding out an arm for an injection), there is a need to be explicit about the consent process. Written consent is not required unless the procedure involves sedation or unless there is a legal requirement for written consent.

It is important that the health professional and the patient/parent understand what has been agreed and also that there is documentation in the patient case notes that verbal information has been provided and what the outcome of the discussion is.
Written consent will only be required when procedures are complex, pose risk or requiring a general, regional anaesthetic or sedation are being proposed. In addition, written consent must be obtained as required by the NHSL Recordings (Photography and Video) for Clinical and Service Use Policy. It is good practice to record consent discussions even where there is no requirement for written consent

Who can give consent
Under Scottish Law, young people aged 16 and over have the same right to consent or refuse as adults

Children and young people under 16 are able to give their own consent if the qualified health care professional considers the patient capable of understanding the nature and possible consequences of the procedure or treatment, according to the Age of Legal Capacity (Scotland) Act, 1991. Where a child or young person does give their own consent, it is appropriate to discuss the details with the parent (see Section 2.6 below for definition) or the person with parental responsibility, providing confidentiality is not breached. It is good practice, although not required in legislation, for both the child or young person and parent to sign a consent form.

Responsibility for signing a consent form cannot be passed on by a competent child to a parent. If a competent child consents verbally but refuses to sign the consent form this should be fully documented noting that the verbal consent has been given and the reasons why the consent form has not been signed. The procedure can go ahead. In cases like this the parents should not consent on the patient's behalf; although it is good practice to involve the parent, their written consent is not legally applicable in these cases

Where a child or young person lacks capacity, consent should normally be obtained from a person with parental rights and responsibilities.

There are occasions where the person with parental responsibility and rights is not available. If the procedure cannot be deferred until the parent is available, the Children (Scotland) Act 1995 (Section 5) gives a person, who has care or control of the child but no parental responsibility or rights in relation to that child, the power to do what is reasonable in all circumstances to safeguard the child's health, development and welfare. This could include a step-parent, relative or child-minder but excludes teachers and others with control of a child in school. This person may consent to any surgical, medical or dental treatment or procedure where the child cannot give his/her own consent and it is not within the knowledge of the person that a parent would refuse. (HDL[2006]34).

Where the mother of the patient is under 16 years old, she may have the capacity to consent for her child. It is however good practice to involve the person with parental responsibility for the mother under 16 years (often the patient's grandmother) in the information provision and consent process.

Capacity or competency (to consent)

Judging capacity or competency depends on:

- Clinical judgement
- The maturity of the patient
- The complexity of the proposed intervention
- Its likely outcome
- The risks associated with it.

If the child or young person is not capable of understanding the nature of the intervention and its consequences the parent or legal carer should be asked for their consent to proceed.

Competence decisions can only be made by senior staff. If a child's capacity to consent is unclear, the medical practitioner attending the child may wish to involve an independent health professional (e.g. a paediatric clinical psychologist) but he/she will ultimately have the responsibility of deciding the child's competency. If the child's or family's capacity to consent is complicated by family or psychiatric problems, then discussion with a child or adolescent psychiatrist may be useful.

Legal definition of 'parent' (*if unclear seek advice from senior colleagues*):

- The mother whether married to the father or not.
- The child's natural father, if married to the mother, at any time from conception or subsequently.
- The child's natural father, even if divorced from the mother.
- An unmarried father whose name is on the child's birth certificate, registered on or after 04 May 2006, has full parental responsibility and rights as though married to the mother**.
- An unmarried father who has entered and registered a formal Parental Responsibilities and Parental Rights Agreement with the mother.
- A legal guardian nominated in writing by a parent before the parent's death. This appointment comes into effect automatically on the death of the parent.
- A person holding a Residence Order in relation to the child, or any other court order giving them the right to consent on the child's behalf.
- A person aged 16 or over who has care or control, unless it is within their knowledge that a parent would refuse consent.

** This bullet point has been added as a result of the Family Law (Scotland) Act.

When to obtain consent (elective situations)

In the elective situation, the health care professional carrying out the procedure or treatment should go through the consent procedure with the parents and child or young person.

Where consent is obtained at the outpatient clinic for surgery, and it is supported by written information, it would be wise and consistent with good practice to ensure continued understanding on admission to hospital. A member of the medical team should review the consent close to the surgery, especially where:

- significant time has elapsed between obtaining consent and the date of surgery
- there have been material changes in the patient's condition, or any aspects of proposed surgery
- new information has become available about surgical options
- the parents and child do not appear to understand clearly the procedure to be undertaken.

It is good practice to check with the parent(s) and patient that they know what procedure is to be undertaken and they still give valid consent at the time of admission. Details should be explained at a level appropriate for the maturity of the child.

Emergency situations

In an emergency, where:

- the child or young person either lacks capacity or is too ill to consent *and* where there is no-one with parental responsibility present
- the treatment is in the best interests of the child to prevent death or permanent damage.

Lifesaving treatment can be carried out immediately. The treatment given must be no more than the immediate situation requires (HDL(2006)34). The practitioner should then seek legal advice as soon as possible.

Where consent is required in an emergency, the doctor may proceed with either verbal consent or no consent if it is in the best interest of the child. Where written consent is possible this should be obtained.

Best Interests

An assessment of 'best interests' will include, but is not limited to, what is clinically indicated in a particular case. Other factors include:

- the views of the child or young person, so far as these are ascertainable, including any previously expressed preferences
- The views of parents and others close to the child or young person
- The child's or parents' cultural, religious or other beliefs and values
- The views of other health care professionals involved in providing care to the child or young person
- Which choice, where there is more than one, will least restrict the child or young person's future options
- This list is not exhaustive and any other relevant information should be considered.

Who should obtain consent

The person obtaining consent must be properly qualified to do so. The appropriate level of seniority will therefore depend on the complexity of the procedure and any likely

consequences. In many cases, especially complex ones, a medical consultant will obtain consent.

However, where a doctor obtaining the consent is more junior, he/she should be deemed by him or herself and by the consultant to be competent to do so and should be sufficiently familiar with the procedure and possible side effects to enable this to be done competently.

The consultant is not legally bound him/herself to carry out the procedure, despite having obtained consent in outpatients. This possibility should be explained by the doctor while obtaining the original consent and where possible the name of the clinician should be given.

There are situations where other qualified (and appropriately trained in the consent process) health professionals, e.g. Nurse Practitioners, take consent for a procedure or treatment (e.g. inoculation in special circumstances) which they will carry out (BMA 2001).

Separate consent for anaesthesia

There is no legal requirement for separate consent for anaesthesia. The anaesthetic should be explained in detail by the anaesthetist at the time of pre-operative assessment and discussion recorded. There may be situations where it is appropriate to have more than one clinician involved in taking consent if the procedure has particularly complex implications ranging over more than one specialty (Association of Anaesthetists of Great Britain and Ireland, 1999).

When a child refuses to consent

If a child or young person is able to understand the nature, purpose and possible consequences of the proposed surgery, as well as the consequences of non-treatment, the child can refuse to undergo surgery. It should be borne in mind that:

- At age 16 a young person has the same right to consent or refuse as adults
- Under age 16 children/young people may have the capacity to decide, depending on their ability to understand what is involved
- The best interests of the child or young person must not be compromised by their refusal to consent to a procedure or to treatment
- If a competent child/young person refuses treatment, those with parental responsibilities cannot authorise procedures. Legal advice may be helpful in how to deal with such cases.

Failure to respect a competent child's or young person's wishes and treating him or her without consent can, as it does with adults, leave health professionals open to criminal charges, civil actions and allegations of professional misconduct.

If consent is refused by a competent child or young person for urgent treatment, the medical practitioner should consider taking legal advice. In some circumstances, the refusal of consent by or on behalf of a child or young person may be overridden by the courts which in terms of the Children (Scotland) Act 1995 (Section 11(2)) may authorise medical treatment. The UNCRC (Incorporation) (Scotland) Bill may also be relevant. Any person with an interest which could include a medical practitioner can apply to the court which will decide the matter on the basis of the best interests of the child. Such circumstances are likely to be limited but could arise in a life or death situation.

When a child or young person and their parent disagree
It is good practice to encourage children or young people to involve their parents in making healthcare decisions. Occasionally there may be a difference of opinion between the child or young person and the parent but dealing with the situation professionally and tactfully may help reach an agreement.

Where a child or young person has the capacity to make the healthcare decision in question, then the Age of Legal Capacity (Scotland) Act 1991 requires the child or young person's decision be respected, even if it is different from the parent's views or the healthcare professional's views. In other words, the decision of a competent child or young person may not be overruled by a parent or health professional.

Where to obtain advice
In the event that clarification about consent is required, advice should be sought from an experienced colleague.

If further clarification is required advice is available from:

- The Central Legal Office
- The Medical and Dental Defence Union for Scotland
- The General Medical Council
- The Child Law Centre.
- Hospital Liaison Committee (in Jehovah's Witness cases)

Confidentiality
To protect confidentiality, there are circumstances where it is appropriate to discuss matters with a young person without the parents present e.g. prior to X-raying a female or preoperatively, in case of pregnancy. It is however good practice to include the parents later in the general discussion.

Literacy in the child or parent
Where there is a question about literacy in either a competent child or young person or in the parent, information giving and discussion should be carried out in the presence of a witness and documented in the case notes.

Equality
Where there is doubt about comprehension i.e.:

- the parent or carer does not understand the procedure (if the child lacks capacity)
- English is not the first language of the child or young person or of the parent
- The child or young person or the parent use British Sign Language.

Information giving and discussion should be carried out in the presence of a witness and documented in the case notes.

To proceed with the latter two, without appropriate language support, could contravene the Race Relations (Amendment) Act, 2000 or the Disability Discrimination Act, 2005.

Adults with Incapacity

Where the patient is 16 years or more and lacks capacity, the Adults with Incapacity (Scotland) Act, 2000 applies. See Section 6 of main policy.

Health care within school education

Where medical examination or treatment e.g. vaccination in the course of school education is concerned, if the child or young person has capacity then s/he must still give his/her own consent. In the event that the child or young person lacks capacity, then parental consent should be obtained (HDL(2006)34).

Looked after or accommodated children or young people

Where a child or young person who is looked after or accommodated by a local authority has capacity, s/he can give their own consent; no other consent is required.

If a child is accommodated by Social Work under Section 25 of the Children Scotland Act (1995) or is subject to a Child Protection Order the parent retains full responsibility for consenting to health care procedures or treatment. In such cases, the child should have a BAAF Health Record booklet which contains a section where the parent should have signed consent for urgent medical and dental treatment at the time of the child becoming accommodated. The Essential Core Record document contains a similar section. Where this is not the case, or where the signature of the parent is required for a particular reason, the child's Social Worker should be contacted for clarification.

If a Court has made a Parental Responsibilities Order in favour of a local authority and if a child or young person lacks the capacity to consent, the consent of the authority would be required (HDL(2006)34).

A Children's Hearing

A Children's Hearing may make a supervision requirement to oblige a child or young person to submit to any medical examination or treatment.
If the child or young person has capacity then s/he must still give their own consent.
In the event that the child or young person lacks capacity then parental consent should be obtained (HDL(2006)34).

Consent to disclose healthcare information

A young person aged 12 years or more can give permission for either the patient themselves or for other people to see identifiable information about him/her (Data Protection Act, 1998).

In the case of a child under 12 years, the parent's written permission is needed before identifiable information about their child can be shared with other people.

There are some exceptions to the above rule which include:

- The statutory requirement to report particular events
- Where a court requires a disclosure
- Clinical situations where disclosure of healthcare information may be a matter of public safety.
- Cognisance should be given to any potential child protection issues in respect of

information sharing.

Non-identifiable information can be used for audit purposes and for healthcare planning without consent.
Guidance is available from Data Protection Officers, Caldicott Guardians and publications (Data Protection Act 1998, NHS Code of Practice on Protecting Patient Confidentiality).

Non therapeutic procedures

Tissue donation. In Scotland, those aged 16 or more and those under 16 years who have legal capacity can consent to non-therapeutic procedures such as tissue donation. There is BMA guidance about e.g. donation of whole organs (BMA 2001 p58).

Where non-therapeutic procedures or those of uncertain therapeutic benefit e.g. circumcision for non-therapeutic reasons, the child's best interests – which may include cultural or religious benefits - must be considered. The Age of Legal Capacity (Scotland) Act 1991 applies, i.e. only one parent with parental responsibility and rights is required to consent. The GMC recommends that in the case of non-therapeutic circumcision both parents should be asked to give consent where possible.

Research

There is specific national guidance on undertaking research with children of different ages and young people. See the Central Office for Research Ethics Committees (COREC) website and the Royal College of Paediatrics and Child Health website http://www.rcpch.ac.uk/ for guidance.

Involvement with the Media

Written consent is required from any child or young person and their parent having their photograph taken by/for the media or for NHS publications.