Informed Consent – Fylde Sports Injury Clinic

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Purpose

A patient has a fundamental right to:

- Receive sufficient verbal and written information to enable an informed decision to be made.
- Grant or withhold consent prior to any examination or treatment.
- Unless the patient is an adult with incapacity
- Or a child

Introduction

Consent is only legally valid if certain conditions are satisfied. This means that in any particular case a clinician must satisfy him/herself that any consent obtained from a patient meets these conditions:

- the patient is legally competent (i.e. capable of consenting).*
- the consent has been given freely (i.e. no coercion)
- the patient has been adequately informed and has understood the information given
- the patient has been given sufficient time to reflect on the information provided before giving consent
- if a significant period of time has elapsed between consent and the procedure, new consent will be obtained
- if the treatment proposed has changed significantly, new consent will be obtained

Rationale

Successful relationships between clinicians and patients depend on trust. A patient must be properly informed about the risks, benefits and consequences of any proposed treatment and its possible alternative **before** signing a consent form. A fully informed patient is less likely to have cause to complain or to resort to litigation. Consent is a process rather than a one-off decision. The steps in the process include discussions with patients, the giving of verbal and written information and the explanation of risks and benefits. **All** these steps should be formally documented. Obtaining a signature on a consent form is normally the concluding part of the consent process. It is important to realise that if the patient has not been given appropriate information then consent may not be valid despite the signature on the form. Consent forms are evidence of a process **not** the process itself.

Definition of CONSENT

Consent is the voluntary and continuing permission of the patient to: **receive a particular treatment or procedure based upon adequate knowledge and understanding of the**

- purpose
- nature
- likely effects
- significant risks of that treatment including the likelihood of its success and outcomes
- consequences of either no treatment or alternative treatment

Permission given under unfair or undue pressure is not consent.

Adults: Capacity and Incapacity

In the case of an adult, consent can only be given by those with capacity to give it. The Mental Capacity Act 2005 and accompanying statutory Code of Practice provide a framework for decision making on behalf of adults (age 16 or over) who lack capacity to make decisions of their own behalf. Further information is given in the BMA Toolkit on Mental Capacity which is included as an appendix to this policy.

In practical terms to demonstrate capacity an adult should be able to:

- understand in simple language what the medical treatment is, its purpose and nature and why it is being proposed
- understand its principle risks benefits and alternatives
- understand in broad terms, what will be the consequences of not receiving the proposed treatment
- retain the information
- make the choice freely

Things to remember:

- Adults should be assumed to have capacity unless it is proven otherwise
- Adults should be supported to make their own decisions before it can be decided that they lack capacity. For example, advocacy and communications support might be necessary
- Adults have the freedom to make unwise decisions. For example, someone with musculoskeletal pain may attend with the agenda to find out what their diagnosis is, but may chose not to receive any form of treatment for their pain. This must be respected. On the other hand, practitioners have a responsibility to recommend evidence based treatments, so if a patient were to decide to ask the practitioner to treat him/her in a way that goes against clinical judgement/reasoning then the practitioner should refuse and explain why that is not possible (e.g. moral and ethical responsibility to offer evidence based treatments on the basis of a risk/benefit analysis)
- If a patient presents with a condition but then refuses to undergo a clinical examination, despite being informed that this is necessary to try to establish the diagnosis, this should be respected. Sometimes, a patient may feel happier about consenting to an examination if there is a chaperone or family member present, but if this is not the case, the practitioner should use the information gathered during the history taking process to discuss possible diagnostic options with the patient and should offer to refer them back to their GP or to another healthcare practitioner if this is more appropriate.

- People who are deemed to lack capacity may still be able to make some decisions for themselves. Alternatively, their capacity may fluctuate and where this is the case, consideration should be given to deferring the decision to another time when they may be capable of making it.
- Sometimes, adults who lack capacity may have appointed a Lasting Power of Attorney (LPA) for Personal Welfare (This is often a close relative of the incapacitated person). Under certain circumstances, the LPA may be able to give consent on behalf of a person who lacks capacity (see BMA toolkit)
- In a lifesaving emergency situation, one needs to assume consent to emergency treatment to stabilise and preserve life since we would not be expected to know about the existence or validity of any advance decision.

Children

Before examining, treating or caring for a child, the clinician must also seek consent. Young people aged 16 and over are presumed to have the competence to give consent for themselves. Younger children who understand fully what is involved in the proposed procedure can also give consent (although their parents will ideally be involved). In other cases, some-one with parental responsibility must give consent on the child's behalf, unless they cannot be reached in an emergency. **If a competent child consents to treatment, a parent cannot over-ride that consent.**

When a baby or a young child is admitted to Hospital, the clinician should discuss with the parents what routine procedures will be necessary and ensure that they have given their consent for these interventions in advance. If parents specify that they wish to be asked prior to particular procedures being initiated, this must be adhered to unless any delay involved in contacting them would put the child's health at risk.

Only people with "parental responsibility" are entitled to give consent on behalf of their children. It is essential to establish who has responsibility for the child if the parents are not available, i.e. if the child is in the care of the local authority social services. It is important to remember that not all parents have parental responsibility for their children.

If a parent or parents refuse to give consent for treatment thought to be appropriate by clinical staff, consideration can be given to making the child a ward of court. In situations where blood transfusion is denied, the local Jehovah's Witness hospital liaison workers can be involved.

Who obtains consent?

It is the responsibility of the practitioner providing the treatment, carrying out an investigation or performing a surgical operation or other procedure, to discuss it with the patient, provide information necessary for the patient's understanding and to obtain consent.

Obtaining a signature on a consent form may be delegated to a person who:

- Is suitably trained and qualified
- Has sufficient knowledge of the proposed investigation or treatment (including knowledge of the risks involved)
- Acts in full accordance with both this policy and their professional guidance
- Has appropriate training about obtaining consent

Additionally, there are situations in which it may be regarded as standard practice for one person to refer a patient to a colleague to carry out a particular procedure or investigation or aspect of treatment. An example could be referral of a patient by a surgeon for diagnostic or interventional radiology.

In these circumstances, the referring clinician should explain the general need for the proposed referral, possibly using information provided by the "receiving" clinician, and take consent on that basis. It would be for the "receiving" clinician 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 those situations when further written consent was necessary.

Regardless of who has provided the information and obtained consent, all discussions and consent should be recorded in the patient records. 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

- That all the other requirements of this policy have been met.

Provision of Information

The amount of information provided to each patient will vary according to factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure and the patient's own wishes. All clinicians should take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment. A careful balance needs to be struck between listening to what the patient wants and providing enough information in order that the patient's decisions are informed.

The type of information the clinician should provide is:

- The purpose of the investigation or treatment
- Details and uncertainties of the diagnosis
- Options for treatment including the option not to treat
- Explanation of the likely benefits and probabilities of success for each option
- Known side effects and risks
- The name of the clinician who will have overall responsibility for the treatment proposed
- A reminder that the patient can change his or her mind **at any time** even after signing the consent form

The clinician should also:

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

There is no agreed definition of what constitutes a "significant risk" and clinicians must form their own view on what it is appropriate to tell patients, guided by what other reasonable clinicians do in the same situation.
Information must be given to the patient in a way that can be readily understood. The information may be given verbally, in writing or using audio-visual material. Written or audio-visual material may be departmental, Trust specific or externally produced. The clinician should record in the case records all information actually provided for each patient, including any key points of discussions held.

CONSENT FORMS

In some cases, verbal consent is acceptable. However, clinicians must get express (written) consent for:

- procedures that carry a significant risk
- any procedure to be carried out under general anaesthesia, sedation or using local anaesthesia (other than topically or by simple infiltration)
- any procedure which could be considered new, novel or experimental
- any situation where there are implications for "third parties"

If the clinician is in any doubt about the need for written consent then it is preferable to obtain consent or at the very least record any discussion with the patient in the patient notes.

Scope of Consent

Following the provision of appropriate information, a patient consents to a **specific** investigation, procedure or treatment being carried out. Additional or alternative procedures must only be carried out on anaesthetised or sedated patients where this is unequivocally in the patient's best interests and can be fully justified.

It is, however, difficult to cite examples of such additional or alternative procedures that would definitely satisfy a court as being unequivocally in the patient's best interests. The desire to spare a patient a second anaesthetic is definitely **not** sufficient justification in itself. Procedures unconnected with that for which consent has been obtained are very unlikely to be justifiable. The consent form provides an opportunity for the patient to note procedures that the practitioner may **not** carry out without discussing the matter further with the patient. Patients may withdraw their consent at any time - including during a procedure although they would need to be advised of the consequences of doing so.

Timing of Consent

The timing of consent will depend on the degree of urgency of the procedure. Whilst there is no recognised absolute minimum period of time which should elapse between giving information/obtaining consent/carrying out the 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.

It is good practice to confirm with the patient prior to the procedure that he or she has not had a change of mind.

Refusal to consent

A patient's refusal to consent, with the reasons for refusal, must be fully documented in the patient's notes. If there is no signed consent form available, it should be presumed consent has not been given.

Special Circumstances

The assessment of a patient's capacity to make a decision about his or her own health care is a matter of clinical judgement, guided by current professional practice and subject to legal requirements. It is the personal responsibility of any clinician proposing treatment to determine whether the patient has the capacity to give valid consent and to proceed only if the treatment is in the best interests of the patient.

Consent may not be needed:

- Where treatment is urgently required in order to save life, or alleviate pain and/or suffering
- where the patient is unconscious and cannot indicate his or her wishes.