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CONSENT PROTOCOL

Introduction

The purpose of this protocol is to set out Refine Surgical's approach to consent and the way in which the principles of consent will be put into practise. It is not a detailed legal or procedural resource due to the nature and complexity of the issues surrounding consent.

Consent has three main elements:

- It must be voluntary – the decision to either consent or not to consent to treatment must be made by the person themselves, and must not be influenced by pressure from medical staff, friends, or family
- It must be informed – the person must be given all of the information in terms of what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments, and what will happen if treatment doesn't go ahead
- The patient must have capacity – the person must be capable of giving consent, which means they understand the information given to them and they can use it to make an informed decision

Where possible, a clinician must be satisfied that a patient understands and consents to a proposed treatment, immunisation, or investigation, as well as the nature, purpose, benefits, and risks of the procedure. Drawings, interpreters, videos, or other means may be used to help ensure that the patient understands the situation and has enough information to give **'Informed Consent'**.

As a result of case law, consent must be clarified regarding not just the available options, but also the risks. The doctor is under a duty to take reasonable care to ensure that the patient is aware of any material risks particular to them involved in proposed treatment, and of reasonable alternatives. A risk is "material" if a reasonable person in the patient's position would be likely to attach significance to it, or if the doctor is or should reasonably be aware that their patient would be likely to attach significance to it.

Implied Consent

Implied consent will be assumed for many routine physical contacts with patients. Where implied consent is to be assumed by the clinician, in all cases, the following will apply:

- An explanation will be given to the patient with regards to what the clinician is about to do, and why.
- The explanation will be sufficient for the patient to understand the procedure.
- In all cases where the patient is under 18 years of age, a verbal confirmation of consent will be obtained and entered into the medical record.
- Where there is a significant risk to the patient, **"Expressed Consent"** is to be obtained in all cases (see below).

In emergency situations where the patient may not be able to give consent then there is always an implied consent to save life. Once the patient is able to communicate fully, the treatment they underwent must always be explained to them.

Expressed Consent

Expressed consent (written or verbal) will be obtained for any procedure which carries a risk that the patient is likely to consider as being substantial. A note will be made in the medical record detailing the discussion about the consent given and the risks of the procedure. A Consent Form [*] may be used for the patient to express consent (see below) which should then be attached to the clinical record.

Expressed consent may be given over the telephone and in those cases, it will be good practice to record the information clearly in the patient's electronic record.

Obtaining Consent

- Consent (Implied or Expressed) will be obtained prior to the procedure, and prior to any form of sedation.
- The clinician will ensure that the patient is competent to provide a consent (i.e. is 16 years old or over) or has "Gillick Competence" if under 16 years. Further information about Gillick Competence and obtaining consent for children is set out below.
- Consent will include the provision of all information relevant to the treatment.
- The clinician should explain the proposed treatment and any alternatives available to the patient, the risks, and benefits of each option, and support the patient choice about which treatment best meets your needs.
- Questions posed by the patient will be answered honestly, and information necessary for the informed decision will not be withheld unless there is a specific

reason to withhold. In all cases where information is withheld then the decision will be recorded in the clinical record.

- The person who obtains the consent will be the person who carries out the procedure (i.e. a nurse carrying out a procedure will not rely on a consent obtained by a doctor unless the nurse was present at the time of the consent).
- The person obtaining consent will be fully qualified and will be knowledgeable about the procedure and the associated risks.
- The scope of the authority provided by the patient's consent will not be exceeded unless in an emergency.
- The clinic acknowledges the right of the patient to refuse consent, delay the consent, seek further information, limit the consent, or ask for a chaperone.
- Clinicians will use a Consent Form [*] where procedures carry a degree of risk or where, for other reasons, they consider it appropriate to do so (e.g. malicious patients).
- No alterations will be made to a Consent Form once it has been signed by a patient. Should consent be subsequently withdrawn, the patient should do so in writing and include in their note that withdrawal has been made after the implications have been explained to them.
- Clinicians will ensure that consents are freely given and not under duress (e.g. under pressure from other present family members etc.).
- If a patient is mentally competent to give consent but is physically unable to sign the Consent Form [*], the clinician should complete the Form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

Other aspects which may be explained by the clinician include:

- Details of the diagnosis, prognosis, and implications if the condition is left untreated.
- All options for treatment, including the option not to treat.
- Details of any subsidiary treatments (e.g. pain relief).
- Patient experiences during and after the treatment, including common or potential side effects and the recovery process.
- Probability of success and the possibility of the need for further treatments.
- The option of a second opinion.

Consent for children

All patients treated at Refine Surgical are adults over the age of 18 and consent should therefore not be taken from children.

Mental Capacity Act [*]

The **Mental Capacity Act (MCA)** 2005 became fully effective on 1st October 2007 in England & Wales and provides a framework to empower and protect people who may lack capacity to make some decisions for themselves. 'A person who lacks capacity' is defined as a person who lacks capacity to make a particular decision or take a particular action for themselves at the time the decision or action needs to be taken. The lack of this capacity could be due to a mental health condition, a severe learning disability, a brain injury, a stroke or unconsciousness due to an anaesthetic or sudden accident and may be on either a temporary or a permanent basis.

(In Scotland the Adults with Incapacity (Scotland) Act 2000 provides similar legislation for people over the age of 16. In Northern Ireland, decision-making is governed by the common law. The Northern Ireland Assembly is working towards statutory provisions for treating adults lacking mental capacity but it is not known when this will be introduced.)

The MCA makes clear who can take decisions in which situations, and how they should go about this. Practice staff must always ensure that should any patient have made a Lasting Power of Attorney for their Health (as opposed to finance), a copy is obtained and scanned to the clinical file.

Deprivation of Liberty Safeguards [*]

The Deprivation of Liberty Safeguards (DoLS) can only apply to people who are in a care home or hospital. This includes where there are plans to move a person to a care home or hospital where they may be deprived of their liberty. The care home or hospital will work with the Local Authority in authorising a DoLS and the practice may be asked to contribute to the decision.

There is no valid advance decision (Living Will) to refuse treatment or support that would be overridden by any DoLS process (see Living Wills below). If a DoLS is not able to be authorised it may mean that the care home or hospital has to change its care plan so that the person can be supported in a less restrictive way.

Living Wills

A Living Will is a form of advance consent made by someone with capacity to do so as to how their treatment should be conducted in the future. It must be made by a patient in writing, signed by them and witnessed. It must be specific about the treatments it covers and the situations where it is to apply and in particular should it cover refusal for a life-saving treatment it must make it clear and unambiguous.

Clinic staff who are made aware of a patient with a Living Will must ask the patient to provide a copy and it should be appended to their clinical record.

Resources

Consent Form (For Patient) * - See clever clinic electronic patient software for procedure specific consent forms

Mental Capacity Act/DoLS Policies [*]

Gillick competence and Fraser guidelines | NSPCC Learning

NHS Consent advice: https://www.nhs.uk/conditions/Consent-to-treatment/

Living Wills: https://www.nhs.uk/conditions/end-of-life-care/advance-decision-to-refuse-treatment/

BMA Consent toolkit: https://www.bma.org.uk/advice/employment/ethics/consent/consent-tool-kit