POLICY ON CONSENT OR REFUSAL TO CONSENT TO TREATMENT

Section 1 - *INTRODUCTION*

Consent can be defined as the voluntary and continuing permission of a patient to receive a particular medical treatment, based on an adequate knowledge of the purpose, nature, likely effects, and risks of that treatment, including the likelihood of its success and any alternatives to it. Permission given under any unfair or undue pressure is not true consent.

Further, consent may be defined as acquiescence. It must be given freely, without duress or deception, and with legal competence and sufficient mental capacity.

A patient has the right under common law, regardless of age, disability, race, gender or sexual orientation, to give or withhold consent to medical examination or treatment. This is a basic principle of health care and a fundamental right, which is founded on the moral principle of respect for autonomy. An autonomous person has the right to decide what may, or may not, be done to him. Any treatment, investigation, or even deliberate touching, may be construed as a battery if no consent has been given.

Four components must be present to make a patient's consent valid and an act of autonomy:

1. Capacity
2. Sufficient information
3. Voluntariness
4. Continuing at the time of the procedure.

Failure to obtain consent, or to proceed in the light of a withdrawal or refusal of consent may be:

a) a Civil wrong
b) a Criminal act
c) Professional misconduct

All Clinical departments should be aware of the guidance available and train staff from the most junior to the most senior level about the need to communicate clearly with patients in order to obtain valid consent to treatment or investigation.

Section 2 – *THE RIGHTS OF THE PATIENT*

Every patient is presumed to have the capacity to consent to or refuse consent medical treatment unless and until that presumption can be rebutted.
Re MB (1998)

No other person, whether a relative or not, may give consent on behalf of another adult.

As long as the patient is a mentally competent adult, they may refuse treatment or other medical intervention for any reason, even if to refuse the treatment is not in their own best interests. Their reasons may be rational, irrational, morally repugnant (Re MB), or they may not have a reason at all, but their wishes must still be respected (Sidaway).

However, there are times when a person's refusal to consent may be in doubt:

- Mental Incapacity

A person lacks capacity if some impairment or disturbance of mental functioning renders the person unable to make a decision whether to consent or refuse treatment. That inability to make a decision will occur when:

a) the patient is unable to comprehend and retain the information which is material to the decision, especially as to the likely consequences of having or not having the treatment.

b) The patient is unable to use the information and weigh it in the balance as part of the process of arriving at the decision.

This guidance formed part of the obiter dicta in *Re C (Refusal of Medical Treatment) (1994).* Thorpe J stated:

'If a compulsive disorder or phobia suffered by a patient stifles belief in the information presented to her, then the decision may not be a true one.'

Also, according to *Re MB*, the graver the consequences of the decision, the commensurately greater the level of competence is required to take the decision.

- Patient physically unable to give or refuse consent i.e. unconscious or in PVS

Re F (1989): The House of Lords held that in many cases it will not only be lawful for doctors, on the ground of necessity, to operate or treat adult patients disabled from giving their consent, but it will also be their common law duty to do so. However, the treatment has to be necessary to preserve the life, well-being or health of the patient.

This is a matter of clinical judgment, but it also has to be what a responsible body of Medical Practitioners skilled in that speciality would have done in the same

circumstances (*Bolam*) and, further, the judgment of the Clinician must be logically supportable (*Bolitho*)

- Patient is a Minor

Children have the right to be informed and give or refuse consent to treatment irrespective of age.

As a result of the *Gillick* case, a child can now be considered competent when he or she is under 16 but is regarded by the Doctor to have sufficient understanding to understand the consequences of the consent or refusal. This understanding will vary with age, type of treatment and severity of treatment.

Young people aged 16-18 can consent to treatment but a Court will not let them refuse to consent if it will endanger their lives *(Re J).*

If the parents refuse consent to emergency treatment, the Health Authority may apply to the Court to have their decision overruled, or it can rely on judgment of doctors after full discussion with parents. In the latter situation, the Clinician should obtain written statement of support from a colleague that the child's life is in danger if treatment is withheld, and he should discuss the need to treat with the parents in the presence of a witness. This should then be recorded in the notes with the witness countersigning.

- Patient has not been properly informed

A Doctor will have to use his professional skill and judgment in deciding what risks a patient should be warned of, and the terms in which the warning should be given. However, a doctor has a duty to warn the patient of any substantial or unusual risk inherent in any proposed treatment.

In *Sidaway v Bethlem,* Lord Bridge indicated that a decision on what degree of disclosure of risks is best calculated to assist a particular patient to make a rational choice as to whether or not to undergo a particular treatment must primarily be a matter of clinical judgment. However, a judge might, in certain circumstances, conclude that the disclosure of a particular risk was so obviously necessary to an informed choice that no reasonably prudent medical man would fail to make it. Lord Templeman added that no doubt a doctor ought to draw the attention of a patient to a danger which may be special in kind or magnitude, or special to the patient.

When a patient has not been given appropriate information, then their consent may be made invalid.

The explanation is of paramount importance, the signing of a consent form is secondary. Failure to provide sufficient information may constitute a breach of a Clinician's duty of care to a patient, and if harm results, the patient may be entitled to compensation.

Linked to this is the situation where the treatment that the patient is being asked to give consent to is actually of an experimental nature, or it is part of clinical trials.

In *Gold v Haringey Health Authority (1988)*, the Court of Appeal specifically rejected the proposition that there was any distinction between advice given in a therapeutic context and that given in a non-therapeutic context.

However, the *Bolam* test is capable of different interpretations and where experimental treatment or clinical trials are concerned, further duties are arguably placed upon clinicians with the task of obtaining consent.

M. Jones ('*Medical Negligence*', 2nd Ed., p.374) argues that the existence of a research intention actually changes the nature of a procedure, irrespective of whether the patient is exposed to any additional risk by virtue of the research aspect. If then there is a failure to inform the patient or his relatives of the research intention, no valid consent has been obtained because the patient has not been informed in broad terms of the nature of the procedure that is intended.

The GMC published guidance in November 1998 'Seeking Patients' Consent: the Ethical Considerations':

'*If you carry out or participate in research involving patients or volunteers, it is particularly important that you ensure as far as possible that the research is not contrary to the patient's best interests and that participants understand that it is research.*'

It is therefore clear that there must always be an obligation upon doctors to disclose to their patients that the treatment forms part of a clinical trial, and if such information is withheld, this could vitiate consent altogether.

In *Wilsher v Essex Area Health Authority (1988)*, the House of Lords was unwilling to countenance the automatic condemnation of a treatment that was comparatively untried purely because, subsequently, something went wrong. However, the more untried a procedure is, the more incumbent it must be upon those practicing it to explain its untried nature and the extent of those risks that are known.

- Consent has been given or refused under undue influence or under drugs/medication

The temporary factors which may render a person unable to give consent were mentioned in *Re T*:

Confusion, shock, pain, drugs. These factors may completely erode capacity but a Doctor must be satisfied that such factors are operating to such a degree that the ability to decide is absent. Another factor may be panic induced by fear. If a Clinician believes that his patient is of this state of mind, he must carefully scrutinise the evidence because fear of an operation may be a rational reason for refusal to undergo it. Fear may also, however, paralyse the will and thus destroy the capacity to make a decision.

Section 3 – *GUIDANCE FOR CLINICIANS AND HEALTH AUTHORITIES*

* PATIENTS WHO LACK CAPACITY TO CONSENT

In general, medical treatment can be undertaken in an emergency even if, through lack of capacity, no consent has been given, provided that the treatment is:

1. necessary
2. does no more than is reasonable required in the best interests of the patient.

However, treatment must not be given if the patient has ever previously refused the treatment and this refusal, given when the patient was competent, is clearly applicable to the present circumstances.

When doctor can examine patient without consent:

1. Life saving procedures where patient unconscious
2. under virtue of a statutory power requiring it eg. Public Health Act (NI) 1967
3. Sometimes when patient is a Minor Ward of Court and the Court decides the treatment is in the child's best interests
4. treatment for mental disorder
5. treatment for physical disorder where patient also suffers mental disorder

If a patient is incapable of giving/refusing consent, either long-term or temporarily, the patient must be cared for according to the Authority's judgment of the patient's best interests. Where a patient has given an Advance Directive, this should be followed unless there is reason to doubt its reliability. If this is the case, then an application for a declaration by the Court should be made.

Where there is concern over capacity, Authorities should

1. Identify this as soon as possible
2. seek legal advice
3. inform the patient's Advisors/Official Solicitor
4. establish key facts
5. identify relevant players
6. assemble all documentation
7. notify parties.

Where a patient lack the capacity to consent, for whatever reason, the Authority should expect Clinicians to undertake whatever treatment is necessary in the best interests of the patient to ensure the patient's life or health is maintained, and to record the reasons for this in the patient's notes.

In *Re T* it was stated that Doctors should not hesitate to use the Courts where there is doubt as to the refusal or if the procedure is particularly invasive or life threatening.

* COMPETENT PATIENTS

If a patient is competent and refuses consent to treatment, an application to the High Court to overrule their refusal is pointless. As long as the patient has been properly informed, and refuses treatment on that basis, the doctor must respect his wishes.

Informed decision-making involves the exchange and understanding of relevant information and emphasises the autonomy of the individual. Information should include:

(a) the proposed treatment or intervention
(b) the benefits of the treatment
(c) the risks of the treatment
(d) the alternatives to the treatment
(e) the likely prognosis if there is no treatment.

The patient should be given time to think and discuss the options - consent to any treatment should be obtained without haste, and when the patient is in a stable emotional state.

The patient's ability to appreciate the significance of the information should be evaluated and recorded. An interpreter or patient advocate should be used if necessary.

In a teaching Hospital, it must not be assumed that a patient has consented to be available for teaching purposes. Where consent has been obtained, it is not to be assumed that this permits several examinations by different students.

Clinical Research must meet the standards of the local research ethics committee. Written consent must be obtained whether in therapeutic or non-therapeutic setting.

Consent given for one procedure or episode does not give an automatic right to repeat it or any other procedure unless consent cannot reasonably be requested, treatment is necessary, and patient has not previously stated that the treatment would be unacceptable.

Consultation and Examination

Medical and nursing staff must:

1. give patients the information they ask for or need about their condition, its treatment and prognosis
2. give patients this information in a way they can understand
3. warn patients of the material risks in a way they can understand
4. respect patients' rights to be fully involved in decisions about their care
5. respect patients' right to refuse treatment or participate in teaching/research
6. obtain consent before giving any treatment/care
7. recognise the right of competent adult patients to refuse treatment, even in life threatening circumstances.
8. consult the family and friends of the patient where necessary.

Recording Information and Note-Taking

Medical and nursing staff must:

1. record in the patient's notes all explanations provided of the risks and benefits of the proposed treatment/investigation, and any other options.
2. ask patient to sign consent form for any procedure or treatment carrying a substantial risk or side effect.
3. record in patient's records the occasions when patient has refused treatment and reasons for this.
4. store in records the written info given to patients.
5. record in notes the occasions when has been possible to obtain consent and where treatment given without consent because it was in best interests of patient.
6. record discussions held with relative e.g. if patient is minor or unable to give consent.
7. give copy of explanation to patient
8. keep approved consent forms under review, with someone appointed to recommend changes. Ensure consent forms readily available.
9. Seek written consent for any procedure or treatment carrying any substantial risk or side effect e.g. General anaesthesia, surgery, certain forms of drug therapy (cytoxic therapy) and use of ionising radiation. Forms must always be signed not too far in advance of procedure. Always check time of procedure if possible.
10. ensure consistency, avoid omissions and duplication – good, clear notes mean good communication between health care professionals

How should information be presented?

As impartially as possible and in a form best suited to the individual patient e.g. orally, written, video, audio. Doctors should use up-to-date written material and other aids to explain complex aspects.
It is essential to be considerate about distressing information. Percentages or proportions of risks may not always be helpful. It may, however, be useful to present risks in a number of different ways. Clinicians should take time when explaining and answer truthfully.
When providing information, Clinicians should think what patients want to know and should know – think about individual needs and priorities e.g. religious beliefs.
Surgeons should seek consent to treat problems which may arise in surgery and ascertain whether there are any procedures which the patient might object to.
Clinicians must keep patient abreast of changes in condition/treatment.

There is an obligation on doctors to have regard for patient's best interests when disclosing risks, but also to make sufficient information available to enable patient to reach balanced judgment.

What information should be given?

At a minimum, a patient should be told about the nature of the condition, the likely outcome if nothing is done or if treatment is given, and the likely benefits and harms of various options. The more serious the possible harm, the more important it is to mention it, even if it is relatively uncommon.

Who should present information?

The person discussing the procedure with the patient must be either someone capable of carrying out the procedure or another health care professional who is trained for the purpose. It would be preferable to have someone who knows the patient's condition well. Information must be accurate and consistent, whatever the source.

What if the patient changes their mind?

A signed consent form is not legally binding. A competent person can still refuse treatment. It is important for the relevant Clinician to discuss the reasons for this change of heart

It is worth noting that demonstrating that a physician or surgeon failed to obtain informed consent is not enough. There must be a causal relationship between the lack of informed consent and the ultimate injury to the patient. Patient must be able to show that had they been informed properly, they would not have consented to the medical treatment and that their medical outcome would have been different.

* OTHER ACTION

1. Key staff should be educated.
2. There should be clear guidance on who is to be contacted when these situations arise, including out-of-hours support.
3. There should be access to relevant guidelines
4. There should be emergency access to a Solicitor or the Official Solicitor, when appropriate.
5. Could provide leaflets or videos on common elective procedures which identify risks, benefits, and alternatives.
6. A uniform approach should be taken which is coordinated centrally.
7. A telephone helpline could be set up to deal with patient's queries and ready to give information.
8. Information centres located inside Hospitals could also be set up.

* PROBLEMS WHICH CAN ARISE

1. Last minute Court Applications
2. Failure to provide relevant information
3. Lack of legal representation for patient

4. Inappropriate use of the Mental Health Act
5. Unnecessary applications

Section 4 - *CONCLUSION*

Refusal to consent to treatment should not be deemed evidence of inability to understand, or as part of a symptomology. Rather it may be an act of self-determination and freedom.

S v McC & M v W (1972)

In this case, Lord Reid stated:

'English law goes to great lengths to protect a person of full age and capacity from interference with his personal liberty. We have too often seen freedom disappear in other countries not only by coups d'etat but by gradual erosion; and too often it is the first step that counts. So it would be unwise to make even minor concessions.'

This sums up the attitude of the Courts in relation to respecting patients' right to autonomy, even today.

/AMcC
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