Primary Care Services

Consent Policy
Version 1.0

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Contents

1. Executive Summary

Circulation

This Policy should be read by all primary care staff involved in the consent process and applies equally to staff in a permanent, temporary or contractor role acting for or on behalf of primary care teams within East London Foundation Trust.

Scope
This policy addresses the procedures and responsibilities for obtaining consent to examination or treatment.

Definitions
"Consent" is a patient's agreement for a health professional to provide care or treatment. For consent to be valid, the patient must:

- Have capacity to make the particular decision
- Have received sufficient information to make it
- Not be acting under duress

Reason for Development

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. This right is enshrined in the Mental Capacity Act 2005, the Human Rights Act 1998 and in common law. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery (excluding compulsory treatment for mental disorder under Part IV of the Mental Health Act 1983).

Whilst gaining valid consent protects healthcare staff from charges of assault, battery or the criminal charge of ill treatment or neglect under the Mental Capacity Act, it is also a matter of common courtesy between health professionals and patients. Staff who take consent are responsible for ensuring they are familiar with the patient's medical history.

Aims and Objectives

- To ensure that consent is obtained lawfully and consistently
- To ensure that patients make informed decisions when they have the capacity to do so
- To ensure that patients who do not have capacity have decisions made regarding their treatment in line with the Mental Capacity Act

Standards

The giving of consent by a patient to a particular intervention does not constitute the consent process. The consent process encompasses the whole process of information provision, discussion and decision-making as part of "seeking consent".

2. General Consent

Before you examine, treat or care for competent adult patients you must obtain their consent. Adults are always assumed to be competent unless demonstrated otherwise. If you have doubts about their competence, the question to ask is: "Can this patient understand and weigh up the information needed to make this decision?" Unexpected decisions do not prove the patient is incompetent, but may indicate a

need for further information or explanation. Patients may be competent to make some health care decisions, even if they are not competent to make others.

Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them.

Before examining, treating or caring for a child, you must also seek consent. Young people aged 16 and 17 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, someone 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. Legally, a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare.

It is always best for the person actually treating the patient to seek the patient's consent. However, you may seek consent on behalf of colleagues if you are capable of performing the procedure in question, or if you have been specially trained to seek consent for that procedure. This arrangement is referred to as 'delegated consent'.

Patients need sufficient information before they can decide whether to give their consent: for example, information about the benefits and risks of the proposed treatment, and alternative treatments. If the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid. Consent must be given voluntarily: not under any form of duress or undue influence from health professionals, family or friends.

Consent can be written, oral or non-verbal. A signature on a consent form does not itself prove the consent is valid – the point of the form is to record the patient's decision, and also increasingly the discussions that have taken place.

3. Refusal of Treatment

Competent adult patients are entitled to refuse treatment, even when it would clearly benefit their health. The only exception to this rule is where the treatment is for a mental disorder and the patient is detained under the Mental Health Act 2007 in which case the patient can receive care or treatment relating to his mental health disorder/illness without giving consent. However, in this situation the patient still retains the right to give or refuse consent for any other care or treatment should he/she be deemed competent to do so. A competent pregnant woman may refuse any treatment, even if this would be detrimental to the foetus.

Adults Who Are Not Competent to Give Consent

No-one can give consent on behalf of an incompetent adult. However, you may still treat such a patient if the treatment would be in their best interests. 'Best interests' go wider than best medical interests, to include factors such as the wishes and beliefs of the patient when competent, their current wishes, their general well-being and their spiritual and religious welfare. People close to the patient may be able to give you information on some of these factors. Where the patient has never been competent, relatives, carers and friends may be best placed to advise on the patient's needs and preferences. If an incompetent patient has clearly indicated in the past, while competent, that they would refuse treatment in certain circumstances (an 'advance refusal'), and those circumstances arise, you must abide by that refusal. Any 'advance refusal' regarding life sustaining treatment in a life threatening situation must be witnessed and signed by the patient and the witness.

4. Types of Consent

Implied Consent

The majority of examinations provided by health professionals are carried out under implied consent. This is no longer considered best practice as staff should not rely on a patient's apparent compliance with a procedure as a form of consent i.e. the fact that a patient lies down on an examination couch does not in itself indicate that the patient has understood what is proposed and why. For consent to be legal, the professional must demonstrate through documentation that the patient understands the process, procedure, problems and outcome. If there is an alternative to this procedure, this must also be fully discussed.

Verbal Consent

Verbal consent should be sought before any procedure takes place. A clear explanation of what is to be done, any risks to consider and any alternative should be discussed with the patient. The discussion which takes place should be recorded in the case notes. Written evidence of consent should include how you tested that the patient understood what was going to be done to them; this will demonstrate that informed consent was given. As with all entries to case notes, the date and time must be recorded, and the entry signed.

Written Consent

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. Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment. Patients may, if they wish, withdraw consent after they have signed a form: the signature is evidence of the process of consent-giving, not a binding contract.

It is good practice to get written consent if any of the following circumstances apply:

- the treatment or procedure is complex, or involves significant risks (the term 'risk' is used throughout to refer to any adverse outcome, including those which some health professionals would describe as 'side-effects' or 'complications')
- the procedure involves general/regional anaesthesia or sedation
- providing clinical care is not the primary purpose of the procedure eg videoing of consultation for education and training
- there may be significant consequences for the patient's employment, social or personal life
- the treatment is part of a project or programme of research

Completed consent forms should be scanned onto the patient's notes. Any changes to a consent form, made after the form has been signed by the patient, should be clearly documented.

It will not usually be necessary to document a patient's consent to routine and low risk procedures, such as providing personal care or taking a blood sample. However, if you have any reason to believe that the consent may be disputed later or if the procedure is of particular concern to the patient (for example if they have declined, or become very distressed about, similar care in the past) it would be helpful to do so.

5. Mental Capacity Act 2006

The Mental Capacity Act 2005 (the Act) provides the legal framework for acting and making decisions on behalf of individuals who lack the mental capacity to make particular decisions for themselves. Everyone working with and/or caring for an adult who may lack capacity to make specific decisions must comply with this Act when making decisions or acting for that person, when the person lacks the capacity to make a particular decision for themselves. The same rules apply whether the decisions are life-changing events or everyday matters.

Where an adult patient does not have the capacity to give or withhold consent to a significant intervention, this fact should be documented, along with the assessment of the patient's capacity, why the health professional believes the treatment to be in the patient's best interests, and the involvement of people close to the patient. Standard consent forms should never be used for adult patients unable to consent for themselves. For more minor interventions, this information should be entered in the patient's notes.

The Mental Capacity Act introduced a duty on NHS bodies to instruct an independent mental capacity advocate (IMCA) in serious medical treatment decisions when a person who lacks the capacity to make a decision has no one who can speak for them, other than paid staff. The Act allows people to plan ahead for a time when they may not have the capacity to make their own decisions: it allows them to appoint a personal welfare attorney to make health and social care decisions, including medical treatment, on their behalf or to make an advance decision to refuse medical treatment. Further guidance is available in the Mental Capacity Act (2005) Code of Practice.

An apparent lack of capacity to give or withhold consent may in fact be the result of communication difficulties rather than genuine incapacity. You should involve appropriate colleagues in making such assessments of incapacity, such as specialist learning disability teams and speech and language therapists, unless the urgency of the patient's situation prevents this. If at all possible, the patient should be assisted to make and communicate their own decision, for example by providing information in non-verbal ways where appropriate.

Occasionally, there will not be a consensus on whether a particular treatment is in an incapacitated adult's best interests. Where the consequences of having, or not having, the treatments are potentially serious, a court declaration may be sought.

To be valid, consent must be given voluntarily and freely, without pressure or undue influence being exerted on the person either to accept or refuse treatment. Such pressure can come from partners or family members, as well as health or care practitioners. Practitioners should be alert to this possibility and where appropriate should arrange to see the person on their own in order to establish that the decision is truly their own. Coercion invalidates consent, and care must be taken to ensure that the person makes decisions freely. Coercion should be distinguished from providing the person with appropriate reassurance concerning their treatment or pointing out the potential benefits of treatment for the person's health.

6. Treatment of Young Children

Parental responsibility: The mother of a child, and the child's father (if he is married to the mother) automatically have parental responsibility. If the parents are not married, the father will have parental responsibility if he acted with the mother to have his name recorded in the registration of the child's birth and the child's birth was registered after 1 December 2003.

An unmarried father can also obtain parental responsibility by later marrying the mother, by making a parental responsibility agreement with her, or by getting a court order. Parental responsibility can also be granted to other people by the courts, such as a legally appointed guardian. Members of staff are advised to check carefully and record details of parental responsibility in the child's records. Parents and those with parental responsibility can only provide or refuse consent if they are thought to be capable and can communicate their decision. Children who are under 16 years of age can also consent or refuse treatment if it is thought that they have sufficient intelligence, competence, and understanding to fully appreciate what is involved in their treatment. This was recognised in the House of Lords in the Fraser case of 1986 which resulted in the concept of 'Fraser Competent' :-Refer to Fraser Guidelines (1986)

7. Teenagers and Consent & Confidentiality

Teenagers who are 16 or 17 years of age are entitled to consent to their own treatment.

8. Who Is Responsible for Seeking Consent?

The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later. Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this must be done by the health professional responsible. Delegated consent should not routinely be used in primary care settings.

9. Consent Procedure

The giving of consent by a patient to a particular intervention does not constitute the consent process. The consent process encompasses the whole process of information provision, discussion and decision-making as part of “seeking consent".

The consent process may also involve reviewing a consent decision after the initial decision to consent has been made. For example, advising the patient of new evidence of risks or new treatment options and reconfirming their consent. This process may take place at one time, or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient’s condition.

10. Consent Process

Single Stage Process

In many cases, it is appropriate for a health professional to initiate a procedure immediately after discussing it with the patient. For example, during an ongoing episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the patient’s condition and whether there are any significant risks. If the patient is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In many such cases, consent will be given orally.

As outlined in the policy, if a proposed procedure carries significant risks, it will be appropriate to seek written consent, and health professionals must take into consideration whether the patient has had sufficient opportunity to absorb the information necessary for them to make their decision. As long as it is clear that the patient understands and consents, the health professional may then proceed.

Two or more stage process

In most cases where written consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion, or it might be over a whole series of consultations with a number of different health professionals. The consent process will therefore have at least two stages, i.e. the information stage and the confirmation stage.

Information stage

This stage involves the provision of information about the treatment/investigation, discussion of options between the patient and the healthcare professional, and the patient’s initial (oral) decision. Before patients can come to a decision about treatment, they need comprehensive information about their condition and about possible treatments/investigations and their risks and benefits (including the risks/benefits of doing nothing). Healthcare professionals must ensure that they provide patients with sufficient information to enable them to make an informed judgment on whether to give or withhold consent. It is advisable for healthcare professionals to inform the patient of any significant, unavoidable or frequently occurring risks.

With patients for whom English is not their first language, healthcare professionals must ensure that all appropriate steps are taken to facilitate patients' understanding of the information provided. This may be via the use of an interpreter, or patient information leaflets printed in their language.

Confirmation stage

If a form is signed before a patient arrives for treatment, the member of the healthcare team responsible for the procedure must check with the patient at this point whether they have any further concerns, whether their condition has changed and whether they wish to continue with the procedure. This is particularly important where there has been a significant lapse of time between the form being signed and the procedure.

It should always be remembered that for consent to be valid, the patient must feel that it would have been possible for them to refuse or change their mind.