Consent Policy

November | 2018

Responsible Committee: Clinical Governance Team
Date Effective: November 2018
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Supersedes: January 2015
Next Review Due: November 2019
Version Number: V4
Comments (details of change)

No decision about me without me'[1] – Shared decision-making in practice

1. INTRODUCTION

South East London Doctors Co-operative (SELDOC) provides out-of-hours and unscheduled primary care services to patients registered with a GP practice in Lambeth, Lewisham or Southwark PCT and unregistered patients residing within its boundaries.
The service SELDOC provides is for urgent medical conditions, not for routine or planned care such as minor surgery or procedures.

2. LEGAL, ETHICAL AND GOOD PRACTICE GUIDANCE FOR CONSENT

This policy has been created to provide advice and guidance on consent processes and it has adopted the principles from the General Data Protection Regulation (GDPR) as the GDPR sets a high standard for consent. Consent requires a positive opt-in, and SELDOC will not use pre-ticked boxes or any other default method to evidence consent.

The general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation for a person has been enshrined in *The NHS Constitution for England 2010*[2].
The Department of Health set out guidance on how to achieve this in *Good practice in consent implementation guide: consent to examination or treatment 2001*[3]. This was supported by *HSC2001/023 Good practice in consent: achieving the NHS Plan commitment to patient-centred consent practice*[4], and reinforced through the *Reference guide to consent for examination or treatment 2009*[5] which sets out the legal and ethical principles for obtaining valid consent within the NHS.

Further legal, ethical and good practice requirements for gaining valid consent with children, people with mental health issues and those with decreased capacity are detailed in *Seeking consent: working with children*[6] the *Code of Practice: Mental Health Act 1983 (2007)*[7] *Mental Capacity Act 2005 Code of Practice*[8] respectively.
The General Medical Council also identifies, in its document *Good Medical Practice*[9], that doctors must be satisfied that they have consent or other valid authority before they undertake any examination or investigation, provide treatment or involve patients in teaching. This responsibility is further detailed in *Consent: patients and doctors making decisions together*[10].

[1] White Paper, *Equity and Excellence: Liberating the NHS*: (DH, 2010)
[2] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_113613
[3] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005762
[4] http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Healthservicecirculars/DH_4003736
[5] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643
[6] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007005
[7] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_084597
[8] http://www.justice.gov.uk/guidance/protecting-the-vulnerable/mental-capacity-act/index.htm
[9] http://www.gmc-uk.org/guidance/good_medical_practice.asp
[10] http://www.gmc-uk.org/static/documents/content/Consent_0510.pdf

3. KEY PRINCIPLES TO CONSIDER

To comply with the GDPR regulation, consent needs to be:

1. **Freely Given:** Consent needs to be obtained freely without coercion. The data subject must not be intimidated/ misled into providing consent. Consent is not considered to be freely given if:
    - The data subject has no genuine choice in providing consent or cannot easily and without detriment withdraw consent.
    - There is a clear imbalance between controller and data subject (e.g. service and patient, or employer and employee).

2. **Specific:** Consent must be obtained for specific processing operations. It needs to be given (separately) for all specific processing operations covering all purposes. Blanket consent for unspecified data processing operations is not valid consent.

3. **Informed:** The request for consent should be easily distinguishable from other matters. It must be presented in clear and plain English. Consent cannot be wrapped within terms and conditions and the data subject must be informed about the extent to which they are consenting, and they must also be informed of their right to withdraw consent.

4. **Unambiguous:** The way in which consent is obtained should leave no room for doubt about the subject's wishes and intentions when consenting. The controller must be able to demonstrate that the data subject has provided consent. Consent records must be kept for verification purposes.

5. **Signified by a statement or clear affirmative action:** Affirmative action is required for consent to be considered freely given, specific, informed and unambiguous. Consent can be obtained in writing, or by completing a form, or by ticking a box, however, pre-ticked boxes do not constitute consent.

The documents cited above are clear on the following principles:

The principles of consent apply to all decisions about care: from the treatment of minor and self-limiting conditions, to major interventions with significant risks or side-effects.

If you are the doctor undertaking an investigation or providing treatment, it is your responsibility to discuss it with your patient and gain valid consent.

You must work in partnership with your patients to ensure good care.

You must:
a) listen to your patient and respect their views about their health b) discuss your patient's diagnosis, prognosis, treatment and care involved with them c) share information with your patient that they need or want to make a decision d) support your patient's ability and opportunity to make decisions for themselves e) respect your patient's decision

4. PARTNERSHIP- BASED CONSULTATIONS

SELDOC expects the following principles to be followed by all doctors providing unscheduled care:

4.1 All consultations should be based on openness, trust and good communication.

4.2 You must adapt your consultation style to suit each patient and each situation.

4.3 You should assume each patient has the capacity to make decisions for themselves and:

- make an assessment with the patient of their condition, taking account of their medical history, views, experience and knowledge
- use this information alongside your specialist knowledge and skills to identify the best course of action for your patient
- explain the possible options to your patient, setting out the benefits and risks of each option
- enable your patient to weigh up the best option for them, including the option to have no treatment
- if your patient asks for a treatment you do not consider would be of overall benefit to them, you do not need to provide it BUT you must explain your reasons and document them on ADASTRA

4.4 If your patient is not able to make decisions for themselves, you must work closely with them and their carers or relatives, following sections 7 and 9 of this policy where applicable.

5. MAKING DECISIONS WITH PATIENTS

5.1 You must share all relevant information with your patient and:

- take account of their individual needs and capacity
- do not make assumptions about what information your patient might need or want
- give your patient all the information they need or want to make a decision
- check that your patient has understood the information they have been given
- give your patient time to make their decision

5.2 Do not withhold any clinical information from your patient.

5.3 You should respect your patient's wishes if they want another person to be involved to help them make a decision.

5.4 You must provide clear, accurate information to your patient about any adverse outcomes that may result from your proposed treatment options. These will include: side effects

- complications
- failure of an intervention to achieve the desired aim

5.5 You must assess and communicate the risk to your patient by:

- considering the nature of their condition, their general health and other circumstance
- taking account of their preferences or concerns about different outcomes
- telling them about serious adverse outcomes even if the likelihood is very small and less serious side effects that occur frequently
- giving information in a balanced and unbiased way, using clear, simple language
- checking that they have understood the information

5.6 You must respect your patient's right to refuse consent or withdraw it BUT you must explain the risks and benefits of doing so and fully document on ADASTRA.

6. DIFFERENT FORMS OF CONSENT AND APPROPRIATE DOCUMENTATION

Before accepting a patient's consent, you must ensure that you have met sections 4 and 5 of this policy. SELDOC expects the following principles to be followed by all doctors providing unscheduled care:

6.1 The care provided by SELDOC is limited to minor or routine investigations or treatments.

6.2 Oral or implied consent (by complying with the proposed examination or treatment, for example, by rolling up their sleeve to have their blood pressure taken) is appropriate so long as you are satisfied that your patient understands what you propose to do and why.

6.3 You must record fully your discussion with your patient in their clinical record on ADASTRA.

7. INVOLVING CHILDREN AND YOUNG PEOPLE IN MAKING DECISIONS

SELDOC expects all doctors to involve children and young people as much as possible in discussions about their care and to encourage them to share their decision with their parents or carers if they have the capacity to consent.

7.1 You must clearly document on ADASTRA the details of the person calling on behalf of a child or accompanying them on a base visit, including details of parental responsibility.

7.2 When children lack the capacity to give consent then you must seek the consent of at least one parent.

7.3 Young people aged 16 and over can be presumed to have capacity to make most decisions about their treatment and care.

7.4 You should assess individual young people under 16 for their ability to understand and weigh up options to make a decision and determine whether they are able to

understand the nature, purpose and possible consequences of investigations or treatments you propose.

7.5 The young person must be able to understand, retain, use and weigh this information and communicate their decision to others to be able to give consent.

7.6 You must always respect confidentiality whenever this is requested by a child who is competent to make their own decision unless:

- there is an overriding public interest in the disclosure
- the disclosure is required by law

8. RESPONDING TO ADVANCED CARE PLANNING

SELDOC expects all doctors to act in accordance with patient's wishes where an advanced care plan is in place.

8.1 All doctors must check the following sources for evidence of an advanced care plan:

- special notes on ADASTRA
- the GOLD register (palliative care)
- hard copy of the plan in the patient's or carer's possession

9. ASSESSING CAPACITY

If you need to make a decision about treatment and care for patients who lack capacity you must comply with the *Mental Capacity Act 2005* which sets out the criteria and procedures you need to follow.

9.1 In line with 4.3 you must work on the presumption that every adult patient has the capacity to make decisions about their care until it is clear that they cannot understand, retain, use or weigh up the information needed to make that decision, or communicate their wishes.

9.2 You must not assume that a patient lacks capacity to make a decision solely because of their age, disability, appearance, behaviour, medical condition (including mental illness), their beliefs, their apparent inability to communicate, or the fact that they make a decision that you disagree with.

9.3 Remember to give your patient enough accessible information and time to make their decision so that their ability to make decisions is maximised. You may want to consider:

- asking the patient what would help them make a decision
- speaking to those close to the patient about the best ways of communicating with your patient, taking account of confidentiality issues supporting with written information
- using the following communication aids:
    - The interpreting service for patients whose first language is not English
    - Type-talk for the hard of hearing
    - Simplified language and Easy-read materials for those with learning disabilities

9.4 You must assess a patient's capacity to make a particular decision at the time it needs to be made.

9.5 Your patient would be deemed to lack capacity to consent if they cannot:

- understand the information relevant to that decision, including understanding the likely consequences of making, or not making the decision
- retain that information
- use or weigh that information as part of the process of making the decision
- communicate their decision (whether by talking, using sign language or any other means)

9.6 You should assess your patient's capacity with advice from their relatives or carers who may be aware of their usual ability to make decisions.

9.7 You must fully document your decisions about assessing your patient's capacity to consent or not to treatment on the ADASTRA system.

10. CONSENT IN AN EMERGENCY

If an emergency arises either at the base site or during a home visit and it is not possible to find out a patient's wishes, you can treat them without their consent, provided the treatment is immediately necessary to save their life or to prevent a serious deterioration of their condition.

10.1 You must provide treatment that will be the least restrictive of the patient's future choices.

10.2 When the patient regains capacity while in your care, you should tell them what has been done, and why, as soon as they are sufficiently recovered to understand.

10.3 You must document your actions in your patient's medical record.

11.REVIEWING CONSENT

It is important to review consent and that the patient is given opportunities to ask further questions and to review their decision. Where there has been significant interval between the patient agreeing to a treatment option and the commencement of the treatment, consent must be reaffirmed to ensure that their consent is fully informed, freely given, specific, unambiguous and affirmative.

12.INDIVIDUAL RIGHTS

Under the GDPR, data subjects have the following rights:

The right to be informed- data subjects must be made aware of the processing of their data. This is usually provided in a Privacy Notice or Privacy Statement.

The right of access- data subjects must be provided with confirmation that their data is being processed and that they can have access to their data for free (unless the request is manifestly unfounded or excessive). Consent must be obtained for the release of data.

The right to rectification- data subjects can have their personal data rectified if it is inaccurate or incomplete. Compliance to this request must not exceed on month from receipt of the request.
The right to erase- data subjects have the right for their data to be erased where the personal data is no longer necessary in relation to the purpose for which it was collected or processed; or where the data subject withdraws their consent objects to the processing and there are no overriding legitimate interests to continue processing.
The right to restrict processing- data subjects have the right to restrict the processing of personal data where they have contested its accuracy; they have objected to the processing or the processing is unlawful.
The right to data portability- the right to data portability only applies where processing is based on consent or the performance of a contract or; where processing is carried on by automated means.
The right to object- data subjects have the right to object to processing based on legitimate interests, the performance of a task in the public interest or the exercise of official authority; direct marketing or; processing for scientific/historic research or statistics.
Rights in relation to automated decision-making and profiling- data subjects have the right not to be subject to a decision where it is based on automated processing; and it produces a legal effect or a similarly significant effect on the individual. "Profiling" is any form of automated processing intended to evaluate certain personal aspects of a data subject, e.g. to analyse or predict their performance at work, health, personal preferences, reliability, behaviour and location.