

Standards in consent for cataract surgery

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Consent forms for cataract surgery performed at Burnley General Hospital (BGH) and Blackburn Royal Infirmary (BRI) from October 4 to December 7, 2004, were prospectively reviewed to ensure that the East Lancashire Hospital's National Health Service (NHS) Trust Policy on consent to treatment and Department of Health (DoH) guidelines were being followed when seeking consent for cataract surgery. A set of 22 criteria derived as standards were formulated from the reference guide published by the DoH and from the East Lancashire trust policy document for consent to treatment. Each consent form was measured against these standards. Cases were randomly selected between BRI and BGH prospectively. All consent forms completed by physicians involved in formulating the standards were excluded. The review showed the NHS Trust Policy and DoH guidelines were largely followed when seeking consent for cataract surgery. However, certain areas were found to be deficient. If a health professional fails to obtain proper consent and the patient suffers harm as a result of treatment, it may be a factor in a claim of negligence against that health professional. Subsequent recommendations may include simple solutions that can be implemented to improve clinical practice when obtaining informed consent.

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A study was done to ensure that the East Lancashire Hospital's National Health Service (NHS) Trust Policy on consent to treatment and Department of Health (DoH) guidelines were being followed when seeking consent for cataract surgery.

MATERIALS AND METHODS

A prospective review of consent forms for cataract surgery performed at Burnley General Hospital (BGH) and Blackburn Royal Infirmary (BRI) from October 4 to December 7, 2004, was conducted. A set of 22 criteria derived as standards were formulated from the reference guide published by the DoH and from the East Lancashire Trust Policy document for consent to treatment. Each consent form was measured against these standards.

Cases were randomly selected between BRI and BGH prospectively. Health care providers who obtained consent

were operating surgeons (physicians) and cataract nurse specialists. Consent was taken during (at the end of) preoperative assessment, a process that lasts approximately 35 to 40 minutes. All forms filled out by those involved in formulating the standards in this study were excluded. The source of standards were the East Lancashire Hospital's NHS Trust Policy on consent to investigation or treatment¹ and the DoH reference guide to consent for examination or treatment.²

Standards

Data were collected from the case notes and consent forms. The standards against which each form was audited are shown in [Figure 1](#).

RESULTS

Seventy-five consent forms were analyzed in the study, and the corresponding patients were asked to fill in a questionnaire for auditing the standards for provision of information. Consent was taken during the preoperative assessment and the questionnaires filled out by patients on the day of surgery. Due to the working patterns of anesthesiologists, nurse-led nature of preoperative assessment, and cataract operation being performed as a day procedure, anesthesiologists in the United Kingdom tend to meet patients on the day of surgery; therefore, the risks of general anesthesia were communicated on the day of surgery. Because of the anonymity assurance given to patients to exclude response bias, no patient details were recorded. The sample, however, demographically

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<p>Provision of Information</p> <ol style="list-style-type: none"> 1. Patients should receive information on the following before agreeing to a procedure: <ol style="list-style-type: none"> a. Information about their condition. b. Information about possible treatments. c. Risks and benefits of different treatment options. d. Risks/benefits of doing nothing. 2. Whether additional procedures may be necessary. 3. Patients should be provided with time to make a decision about a procedure before admission for that procedure. <p>Discussion and Agreement to Procedure</p> <ol style="list-style-type: none"> 4. All patients who have an elective procedure should receive the 'consent to treatment' leaflet. 5. It should be indicated on the consent form that a 'consent to treatment' leaflet has been given to the patient. 6. It should be indicated on the consent form that a procedure-specific leaflet or tape has been provided to the patient. 7. For written consent the health professional providing the information must either <ol style="list-style-type: none"> a. Be able to carry out the procedure or b. Have received specialist training in advising patients about the procedure. 8. Written consent using the Trust's consent form should be obtained for procedures involving significant risks, side effects or complications. 9. Consent forms 1 – 4 should be used appropriately. 10. It should be documented on a consent form whether the following has been explained: <ol style="list-style-type: none"> a. The intended benefits of treatment b. Any serious or frequently occurring risks c. Any extra procedure which may become necessary during the procedure d. What type of anesthesia is involved 11. Patients should be provided with the opportunity to discuss anesthesia with the anesthetist before the procedure. 	<ol style="list-style-type: none"> 12. Patients should sign and date the consent form under the statement of patient. 13. If a patient cannot sign the form but has indicated his consent, a witness should sign the form. 14. If a patient has communication needs, an interpreter should sign the consent form to indicate that all information has been translated to the patient in a way he understands. 15. Changes to a consent form, made after the form has been signed by the patient, should be initialed and dated by both patient and health professional. 16. Completed consent forms should be kept with the patient's notes. 17. The following information should be documented when form 4 is used: <ol style="list-style-type: none"> a. Details of the assessment of the patient's capacity b. Why the health professional believes the treatment to be in the patient's best interest c. The involvement of people close to the patient 18. After consenting to a procedure patients should receive information about: <ol style="list-style-type: none"> a. What will happen in hospital b. Where to go c. How long will they be in hospital d. How they will feel afterwards 19. The patient should receive a copy of the consent form <p>Confirmation of Consent</p> <ol style="list-style-type: none"> 20. Where consent has been given in advance of the procedure the health professional should confirm that the patient still wishes to go ahead when the patient is admitted for the procedure. 21. Patients should be provided with opportunity to ask any further questions before confirming consent. 22. The health professional confirming the consent should sign and date the consent form under the statement of confirmation.
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Figure 1. Standards against which each form was audited.

represented the population of patients attending East Lancashire NHS Trust for cataract surgery. The questionnaire was directly related to the 22 criteria (standards) outlined above. Table 1 shows the percentage of consent forms with provided information meeting the corresponding standard.

Discussion

The working definition of consent is that of a competent individual who understands the treatment fully and agrees to the procedure.^{2,3}

Valid Consent

For consent to be valid, it must be given voluntarily by an appropriately informed person. For a person to have capacity, he or she must be able to comprehend and retain information material about the decision.³

Capacity

The patient is entitled to make a decision based on his or her belief or value system, even if others perceive it to be irrational. In practice, patients also need to be able to communicate their decision. Clinicians should be able to make an informed professional decision regarding the patient's capacity and if necessary provide any evidence that influenced the decision that they believe is relevant. Care should be taken not to

underestimate the ability of a patient to communicate, whatever his or her condition.³

Voluntary

To be valid, consent must be given voluntarily and freely, without pressure or undue influence exerted on the patient either to accept or refuse treatment.³ Coercion invalidates consent,³ and care must be taken to ensure that the patient makes a decision freely. Coercion should be distinguished from providing the patient with appropriate reassurance concerning his or her treatment or pointing out the potential benefits of treatment for the patient's health. It may be argued that specialist training in advising patients "incentivizes" health professionals. However, skills encompassing communication, risk management, task management, and bias analysis are vital in obtaining consent and patient-centered training directs health professionals in the patient's favor.

To give valid consent, the patient needs to understand in broad terms the nature and purpose of the procedure. Any misrepresentation of these elements will invalidate consent. Clear information is particularly important when students or trainees perform procedures to further their own education.⁴

Some patients may wish to know very little about the treatment that is being proposed. If information is offered and declined, it is good practice to record this fact in the notes. However, the patient's wishes

Table 1. Percentage of consent forms with provided information meeting the corresponding standard.

Standard	Percentage Meeting Standard
1. Patients should receive information on the following before agreeing to the procedure:	
1a. Verbal and/or written information about their condition	97
1b. Information about treatment	100
1c. Risks of treatment	90
1c. Benefits of the treatment	93
1d. Risks/benefits of not having treatment	68
2. Whether additional procedures might be necessary	63
3. Patients should be provided with time to make a decision about a procedure before admission for that procedure.	100
4. All patients who have an elective procedure should have received the consent to treatment (cataract surgery) leaflet.	88
5. It should be documented on the consent form that consent to treatment (cataract surgery) leaflet has been given to the patient. (Documented on 1 consent form. Not applicable in 2 cases [incapacity].)	1
6. It should be documented on the consent form that a procedure-specific leaflet or tape has been provided to the patient. (Documented on 9 consent forms.)	12
7. For written consent the health professional providing the information must either	
a. Be able to carry out the procedure or	
b. Have received specialist training in advising patients about the procedure. (doctor, 22; specialist nurse, 52; not legible, 1)	100
8. Written consent using the Trust's consent form should be obtained for procedures involving significant risks (side effects or complications).	99
9. Consent forms 1–4 should be used appropriately (pro forma).	100
10. It should be documented on a consent form whether the following has been explained:	
a. Intended benefits of treatment	93
b. Risks of treatment	73
c. Extra procedure	1
d. Type of anesthesia	90
11. Patients should be provided with the opportunity to discuss anesthesia with the anesthetist before the procedure. (Two patients had general anesthesia, and both stated they had opportunity to discuss this with the anesthetist.)	100
12. Patients should sign and date the consent form under the statement of patient. (Seventy-four patients signed and dated consent form in the right place; 1 signed under the statement of witness.)	99
13. If a patient cannot sign the form but has indicated his consent, a witness should sign the form.	50
14. If a patient has communication needs, an interpreter should sign the consent form to indicate that all information has been translated to the patient in a way he understands.	100
15. Changes to a consent form, made after the form has been signed by the patient, should be initialed and dated by both patient and health professional.	NA*
16. Completed consent form should be kept with the patient's notes.	100
17. The following information should be documented when form 4 is used:	
a. Details of the assessment of the patient's capacity	50
b. Why the health professional believes the treatment to be in the patient's best interest	100
c. The involvement of people close to the patient	100
18. After consenting to a procedure patients should receive information about	
a. What will happen in hospital	97
b. Where to go	93
c. How long they will be in hospital	97
d. How they will feel afterwards	93
19. The patient should receive a copy of the consent form. (Fifty-seven patients received a copy of the consent form. Both copies were filed in the in case notes in 18 cases.)	76
20. Where consent has been given in advance of the procedure the health professional should confirm that the patient still wishes to go ahead when the patient is admitted for the procedure.	97
21. Patients should be provided with opportunity to ask any further questions before confirming consent.	95
22. The health professional confirming the consent should sign and date the consent form under the statement of confirmation.	100

*No changes were made to the consent forms.

Table 2. Criteria that did not meet the 90% standard.

Standard	Percentage Meeting Standard
1d Risks/benefits of not having treatment	68
2 Whether additional procedures might be necessary	63
4 All patients who have elective procedure should have received the consent to treatment (cataract surgery) leaflet.	88
5 It should be documented on the consent form that consent to treatment (cataract surgery) leaflet has been given to the patient.	1
6 It should be documented on the consent form that a procedure-specific leaflet or tape has been provided to the patient.	12
10b It should be documented on a consent form whether the risks of the procedure have been explained.	78
10c It should be documented on the consent form whether any extra procedures have been explained.	1
13a If a patient cannot sign the form but has indicated his consent, a witness should sign the form.	50
17a Details of the assessment of the patient's capacity	50
19 The patient should receive a copy of the consent form.	76

may change over time and it is important to provide opportunities for him or her to express this.⁴

Who Should Seek Consent?

The clinician providing the treatment or investigation is responsible for ensuring that the patient has given valid consent before treatment begins, although the consultant responsible for the patient's care will remain ultimately responsible for the quality of medical care provided.¹

When Should Consent Be Sought?

Seeking and giving consent is usually a process rather than a one-time event. For major interventions, it is good practice, when possible, to seek the patient's consent to the proposed procedure well in advance,⁵ when there is time to respond to the patient's questions and provide adequate information.⁶

Written consent merely serves as evidence of consent. If the elements of the voluntary nature of the consent, appropriate information, and capacity have not been satisfied, a signature on a form will not make the consent valid. Although completion of a consent form is not a legal requirement in most cases (exceptions include certain requirements of the Mental Health Act 1983 and of the Human Fertilisation and Embryology Act 1990), the use of such forms is good practice when an intervention such as surgery is to be undertaken.

When a patient gives valid consent to an intervention, the consent generally remains valid for an indefinite duration unless the patient withdraws it. Similarly, if the patient's condition has changed significantly in the intervening time, it may be necessary to seek consent again on the basis that the likely benefits and/or risks of the intervention may have also changed.

A patient with capacity is entitled to withdraw consent at any time, including during the performance of a procedure. When a patient does object during treatment, it is good practice for the practitioner, if at all possible, to stop the procedure, establish the patient's concerns, and explain the consequences of not completing the procedure.

In this study, the East Lancashire Hospitals NHS Trust Policy on consent to treatment and the DoH guidelines were largely being followed when seeking consent for cataract surgery. However, certain areas were found to be deficient. Criteria that failed to meet the 90% standard are shown in Table 2.

Having identified such areas, recommendations can be made to the Trust and its staff to improve consent in line with U.K. health policy. First, by simply communicating these deficiencies to health professionals involved in obtaining consent, it is possible to raise awareness and initiate a change in practice in completion of the consent form (including provision of the patient copy) and the information given to the patient. It is current practice in some U.K. centers for nurse practitioners to obtain consent for cataract surgery at the preoperative assessment. Hence, consent in this U.K. study should apply to health professionals rather than physicians. Second, the Trust must supply adequate resources for the provision of patient leaflets^{7,8} and opportunity for staff training, including yearly reevaluation of practice. It is a general, legal, and ethical principle that valid consent must be obtained before starting treatment for a patient. Although there is no English statute setting out the general principles of consent, case law ("common law") has established that touching a patient without valid consent may constitute the civil or criminal offense of battery.

Ethical and medicolegal issues are therefore important factors in the process of consent. Informed consent

is used as a secondary cause in more than 90% of all ophthalmology-related malpractice cases.^{9,10} Knowledge of ethical issues is reported to be important to the work of both physicians and nurses; however, many of these professionals are unaware of their importance or unable to appropriately deal with these issues.¹¹ If health professionals fail to obtain proper consent and the patient suffers harm as a result of treatment, it may be a factor in a claim of negligence against the health professional involved. Patients' recall of information at the time of consent has been shown to be poor, even though the dedicated cataract form and information leaflet were easy to understand.¹² Recent publications describe the likely explanation of "cognitive dissonance" in patients who could not recall crucial details of their preoperative conversation as little as 1 day after surgery.¹³ This occurs when paradoxical information, such as the positive associations of the benefits of surgery, becomes connected with negative aspects of the consent message (risks and complications), leading to a cognitive stress situation (cognitive dissonance) and selective inconsistency of information.

Health organizations must therefore evaluate their policies on consent to comply with national guidelines. Subsequent recommendations may include education of health professionals and knowledge management solutions that can be implemented to improve clinical practice when obtaining informed consent.

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