Royal College of Surgeons
ADVANCING SURGICAL CARE

PERIOPERATIVE CARE

Ann R Coll Surg Engl 2019; **101:** 44–49
doi 10.1308/rcsann.2018.0140

Informed consent: the view from the trenches

D Ricketts[1], T Roper[1], B Rogers[1], J Phadnis[1], S Elsayed[1], D Sokol[2]

[1]Brighton and Sussex University Hospital Trust, Royal Sussex County Hospital, Brighton, East Sussex, UK
[2]Barrister, Temple, London, UK

ABSTRACT
We review some of the recent literature on consent for surgical procedures and suggest a scheme for obtaining surgical consent.

KEYWORDS
Consent forms – Informed consent – Risk – Surgeons – Operative surgical procedures

Accepted 2 June 2018

CORRESPONDENCE TO
David Ricketts, E: consultdmr@aol.com

Introduction

A properly conducted and documented consent process has many advantages: the surgeon is prompted to consider the evidence base concerning the proposed treatment and its alternatives, the patient is properly informed, their autonomy respected and their expectations managed. Good consent also defends against legal claims or complaints based on alleged deficiencies in the consent process: consent is the third most common reason for legal disputes regarding surgical treatment.[1] Anecdotally, the number of 'lack of consent' claims against doctors has gone up in the past two years.

Despite these advantages, many surgeons probably obtain consent with a sense of unease. Fulfilling all the ethical and legal requirements for informed consent all the time may be challenging, such as when time is short or the patient's English is poor. Further, the requirements evolve with a trend towards more information and discussion: following the Thefaut and Montgomery cases (discussed below) surgeons have been advised to urgently update their consent processes.[2–4] Failure of surgeons to follow General Medical Council guidance 'will put their registration at risk'.[5] Even the popular press now publishes details of consent disputes.[6] This narrative review surveys the recent literature concerning informed consent and suggests improvements to the consent process.

Methodology

MEDLINE and EMBASE were searched using relevant natural and controlled vocabulary terms. Final searches were conducted using the National Institute for Health and Care Excellence Evidence Healthcare Databases advanced search interface on 26 January 2018.

The current literature regarding consent

What is consent?

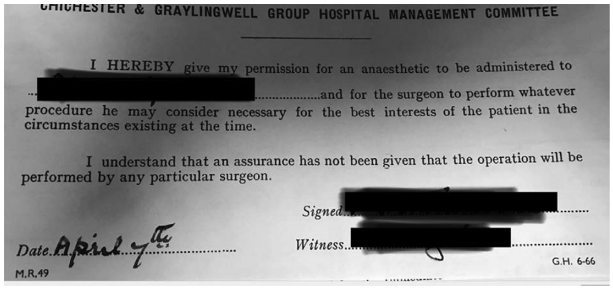
The NHS definition of consent is, 'the principle that a person must give permission before they receive any type of medical treatment, test or examination. This must be done on the basis of an explanation by a clinician. Consent from a patient is needed regardless of the procedure, whether it's a physical examination, organ donation or something else…' For consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision.[7] Consent can be presumed, implied, verbal or written.[7] Written consent is required for investigation or treatment associated with risk or consequences for the patient either at the time or later (Figs 1 and 2).[8]

Who can give consent?

Adults with capacity can give consent. A person has capacity if he or she can understand, retain and weigh the information given and communicate the decision (see section 3(1) of the Mental Capacity Act 2005).[9] Capacity is assumed for patients over 16 years of age unless the patient, even with support, is incapable.[9] Support, if needed, should be provided as early as possible and the circumstances documented.[10]

Consent must be given without coercion or undue influence from other persons (family members, friends, employers, insurers, carers or medical staff).[11] Ideally, any interpreter should not be from the patient's family to avoid family influence.

For adults without capacity, the reasons why capacity is lacking must be clearly documented, and treatment must be provided in the patient's best interests. For an


CHICHESTER & GRAYLINGWELL GROUP HOSPITAL MANAGEMENT COMMITTEE

I HEREBY give my permission for an anaesthetic to be administered to [redacted] and for the surgeon to perform whatever procedure he may consider necessary for the best interests of the patient in the circumstances existing at the time.

I understand that an assurance has not been given that the operation will be performed by any particular surgeon.

Signed [redacted]

Date April 7th Witness [redacted]

M.R.49 G.H. 6-66

Figure 1 A completed consent form from 1967.

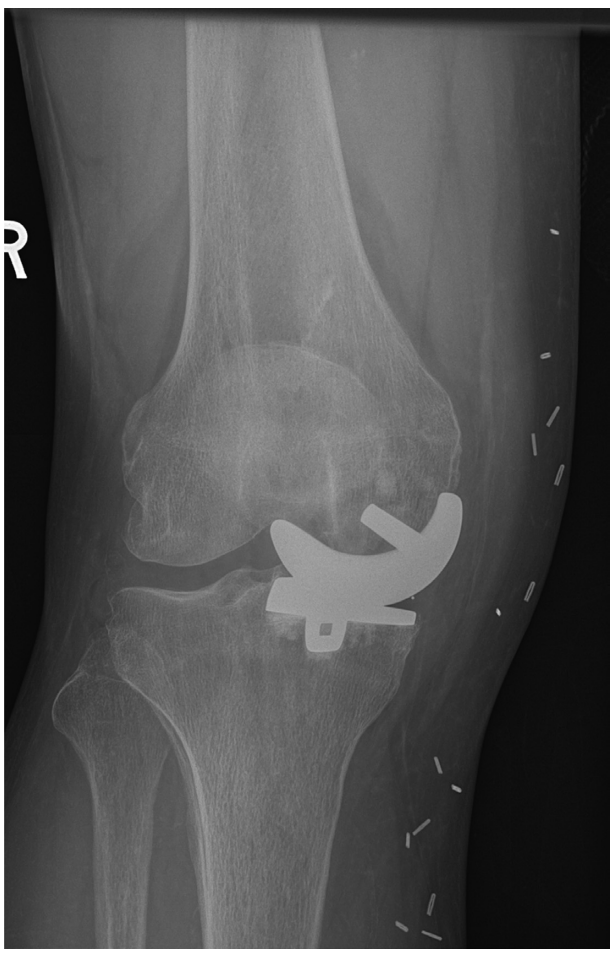


Figure 2 A dislocated knee hemiarthroplasty.

unconscious or ventilated patient, seek consent from the patient's supporter or person authorised with a lasting power of attorney and involve a consultant colleague.[10] Consent is unnecessary for incapacitated patients needing lifesaving treatment or for emergency procedures during an operation.[7]

Children under the age of 16 years are not presumed to have capacity for consent (unless the child is assessed to have enough maturity and understanding to consent).[12] Only a capable parent (not any other family member) may give consent on a child's behalf.

Qualified consent is where patients may consent to some aspects of treatment but not others (for example, a Jehovah's Witness giving consent to an operation but not to a blood transfusion). Consent is not a one-off event, such as the signing of the consent form, but is an ongoing process. The conscious patient can withhold or withdraw consent before or during treatment.[11]

Who should obtain consent?

Consent should be obtained either by the surgeon providing treatment or by a clinician with sufficient knowledge of the procedure, risks, complications and alternative treatments. The surgeon is responsible for ensuring that the patient has been given the information, has been offered enough time to make an informed decision and has given their consent before treatment commences.[10] It is assumed that the treating surgeon will operate. If not, this should be made clear to the patient promptly. A court recently found the consent invalid when a patient was informed of a late change of surgeon on the way to the operating theatre.[13]

Material risk

A key part of consent is discussing and documenting the material risks of the treatment and its alternatives. The definition of a material risk is one that 'in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk'.[5,11] To satisfy this requirement, doctors must engage in a tailored dialogue with the patient and take account of that patient's particular values, circumstances and needs.[5,11] Acquiescence where the person does not know what the intervention entails is not valid consent.[14] Although inviting questions is an important for consent, it is not sufficient to ask the patient if they want to know anything else, as patients cannot be expected to know what they do not know about their condition or treatment options.[11]

The amount and the nature of information disclosed to the patient should be guided by the question: 'What would a reasonable patient, or indeed this particular patient, probably regard as significant when coming to a decision about which – if any – of the available options to accept?'.[13] The way the information is provided is also important: it must be done in a way that will be understood by the patient. Bombarding the patient with written and verbal information is unacceptable and runs the risk of confusing rather than enlightening the patient.[15]

If percentages are used to express risk they must be accurate.[16] A problem for surgeons is that required information may not be available in the literature; there are few papers summarising all the risks of given procedures.[17] The risks also change over time. If the surgeon has relevant data regarding his results these data should also be provided. Conditions can make it difficult to obtain

adequate consent from patients of widely differing ages, races, cultures and languages.[18]

The consent form

The routine signing of a consent form 'does not by itself mean anything in terms of consent'.[3] The signed form suggests that a discussion took place but provides no information about the quality or duration of the discussion.[11] Surgeons often take the only written consent for anaesthesia (a few lines of text in the surgical consent form). Interestingly, legal claims regarding anaesthetic consent appear to be infrequent.[18]

Anaesthesia guidelines state that written consent for anaesthesia is not required.[19] The responsible anaesthetist should ensure written information concerning the anaesthetic procedure is given to patients at preoperative assessment and that this information is discussed with the patient on the day of surgery to ensure that it was understood. The discussion, risks, benefits and alternatives to the proposed procedure should be written down.

Finding time for the consent process

The process of consent may take time, particularly for patients with language difficulties,[19] and for major interventions. One study found that a consent process of 15–30 minutes' duration provided the highest comprehension of consent.[20] The Supreme Court, in Montgomery v Lanarkshire Health Board, commented 'even those doctors who have less skill or inclination for communication, or are more hurried, are obliged to pause and engage in the discussion which the law requires'.[16] No matter how senior or skilled, all surgeons must find the time to obtain valid consent with no shortcuts. Surgeons are advised by the Royal College of Surgeons to discuss with their medical director the extra time needed (part 4.11).[11]

What do patients want?

The current consent process reflects legal requirements and the guidance of the General Medical Council. In one study, patients ranked their information needs as recovery time, options for treatment, their legal rights and 'meeting the surgeon'.[21] Another study found the highest retention of data was after a tailored explanation including the use of models.[22] Even so, patients recall of the facts is low and declines further postoperatively.[23] This may account for the occasional patient who at their final follow-up appointment memorably asks 'so … what did you do exactly?'.

Discussion

Many legal, regulatory and advisory bodies produce advice regarding the consent process but practical help for surgeons is lacking. Currently, each surgeon must seek out and assimilate information regarding consent. To improve the efficiency of the consent process we suggest the following changes:

1. A plan for obtaining consent for elective surgical procedures

A clinic letter should document the discussion about the consent process and be sent to the patient with a copy to the general practitioner. The letter should list all the required material facts and relevant discussion and should be sent even if the patient decides not to go ahead with surgery. Any additional information must be documented (patient leaflets and online material). The required information can be organised using the mnemonic 'DORIS'[2] which stands for:

- Diagnosis: the diagnosis and natural history of the condition.
- Options: doing nothing, nonoperative and operative treatment. For procedures, we recommend a brief description of the operation, the usual sequelae, recovery for important activities, follow-up and outcome.
- Risks: clarify that any procedure, however minor, may have a 10% complication rate.[16] The known material risks for each option should be listed using these guidelines:
  - general medical complications (i.e. stroke, urinary retention)
  - general surgical complications (i.e. haematoma, wound infection)
  - specific surgical complications (i.e. frozen shoulder after shoulder arthroscopy; Figs 3 and 4).
  - rare but significant complications (i.e. amputation after knee replacement).
- Individual factors: particular factors important to that patient (often return to driving, work or sport). The patient can change their mind or seek more information should they wish.
- Shared decision: clearly state the agreed outcome of the discussion.

Particular attention is needed for consent for elective surgery in private practice. There is a typically a shorter time between consultation and operation. Patients may have unrealistically high expectations and additional disputes about fees can arise.[3]

2. The consent form

We suggest the anaesthesia part of the consent form should be deleted. This leaves two alternatives for the remaining surgical part of the form. The first is a much shorter consent form to be used for all procedures, stating that the patient has read and agrees with the facts set out in the clinic letter. A second option is a longer procedure-specific form listing the relevant facts given in point 1 above. Specialist associations and regulatory bodies could agree these forms, ensuring that they were comprehensive, contemporaneous and accurate. There is support for this from associations,[24] but few available forms are available and they need updating.[25]

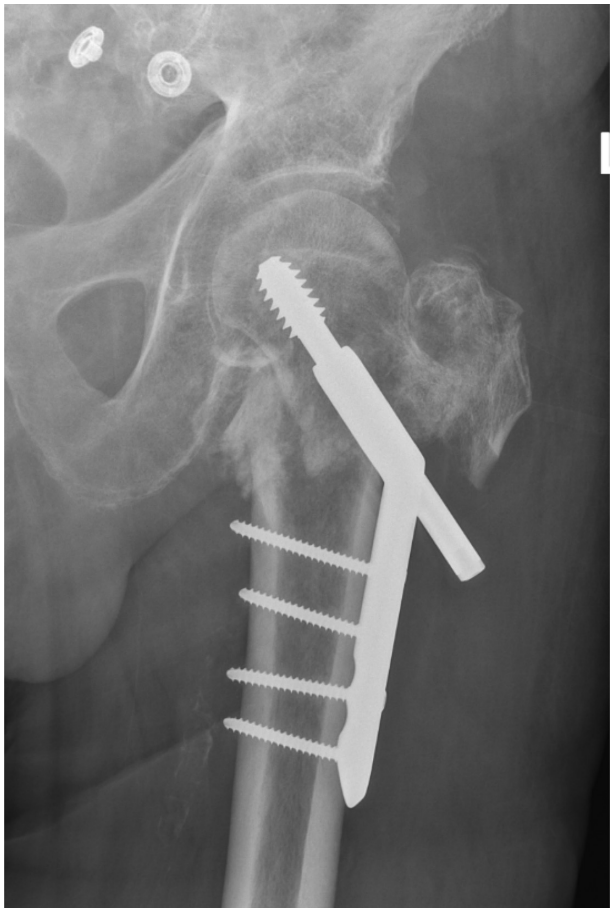


Figure 3 Fractured neck of femur treated with a dynamic hip screw: Sliding of the screw leading to fracture compression and leg shortening.

The consent form can be signed at the end of the consent discussion (the patient should take a copy for reference and reflection) or on the day of surgery. A signed consent form, however sophisticated or full of detail, is unlikely to eradicate complaints about inadequate consent. What matters is not the form, but the discussion that accompanies it.

3. A plan for obtaining consent for emergency surgery

Circumstances make it difficult to obtain consent (limited time, comprehension problems due to trauma, the sudden change in circumstances and medication effects).[26] Prepared printed information may not reflect the patient's individual circumstances. We suggest that a form (Box 1) is used to reflect the consent discussion (time permitting). More than one page may be needed. The original is filed and a copy given to the patient. The consent form can then be completed.

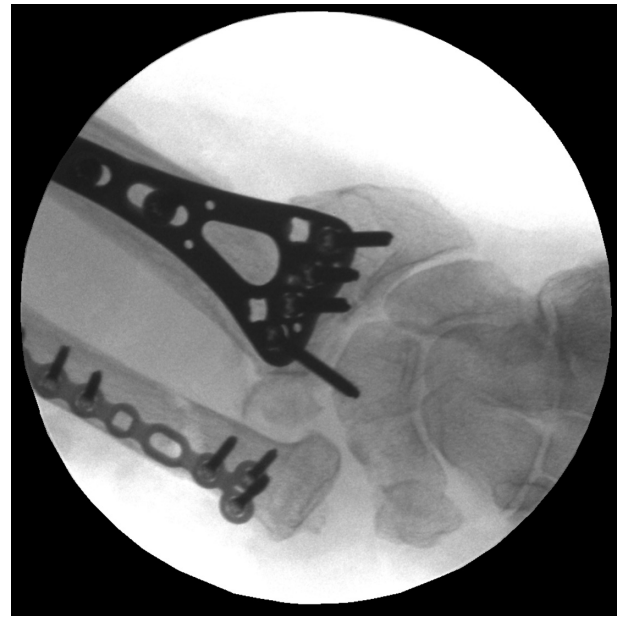


Figure 4 Fracture fixation of the wrist with a plate and screws: Perforation of the wrist joint by a screw.

3. Informing surgeons

We recommend that each trust formulates a policy on consent procedures. This could be included in annual mandatory training. Like surgical techniques, obtaining consent is a skill that can be improved with practice.

Conclusion

There are ten million surgical procedures each year in the NHS requiring consent.[27] Use of the suggested standardised clinic letter, standard lists of the risks and benefits for a procedure and written advice from the employing trust should improve the consent process. None of these measures is a substitute for a clear, informed, patient and patient-centred discussion between surgeon and patient about the proposed treatment and its reasonable alternatives, occurring some time before the procedure itself, to allow the patient to reflect and discuss the decision with family and friends.

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Date:……/…../….. Time:……

Doctor:……

Witness:……

Diagnosis:……

Individual factors:……

What is likely to happen without surgical intervention:……

……

Treatment options available:

Name of treatment option			
Brief description			
Recovery			
Expected outcome			
Benefit of treatment			
Risks and complications			

Discussion:

Signed: Doctor ……

Patient……

Witnesses……

Box 1 Consent discussion for emergency surgery.

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