Consent: assessing and communicating risk

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Abstract

The consent process is a fundamental part of modern medicine, and can be challenging for both surgeons and patients. It is a complex interaction of many factors, including surgical factors, individual patient factors and legal and ethical considerations. Informed consent requires a thorough understanding of the risks involved in any intervention for a particular patient. Risk assessment is therefore of fundamental importance. For accurate assessment, population data must be combined with individual factors about the patient and the proposed procedure to give as accurate an assessment of risk to that particular patient as possible. Individuals interpret information about risk subjectively, and it is important for the surgeon to use methods of communication that minimize bias and allow for clear understanding. Using combinations of numerical and descriptive terms, examples from other areas of life, visual aids, and avoidance of vague terms and confusing statistical data, will all help the patient to understand the risks discussed more completely.

Keywords Consent; communication; risk; risk assessment; risk disclosure; scoring systems

Consent

Surgeons are entrusted with the unique privilege of being permitted to cause physical injury to other people, while remaining immune from prosecution. However, this immunity must be actively obtained by the surgeon in the form of a valid consent from the individual who is submitting to that 'injury'. Failure to obtain *any* consent from the patient renders the surgeon liable to the same criminal convictions as the ordinary citizen, and failure to gain an *adequate* and fully informed consent lays the surgeon open to a negligence claim from the patient. Therefore getting the consent process right is of fundamental importance to all surgeons.

However the consent process is also of enormous importance to patients, who are considering whether to subject their bodies to invasive procedures about which they may have little or no understanding. Adult patients have a fundamental right to decide what happens to their bodies, and surgeons have a duty to provide patients with enough knowledge and understanding to allow them to make their own autonomous choices in treatment decisions.

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Who can provide consent?

The details of age of consent, capacity and the relationship between ethical and legal considerations will vary significantly around the world. This article principally discusses the situation in the UK.

All adults over the age of 18 can provide a legally valid consent to treatment, provided they have the mental capacity to make that decision.[1] In addition they have the right to refuse treatment. The Mental Capacity Act 2005 declares that all adults in England and Wales are assumed to have capacity to consent, irrespective of age, appearance or condition. They are only deemed to lack capacity if it can be demonstrated that they suffer from a disorder of mind or brain and, in addition, despite maximal assistance, they must remain incapable of:

- understanding the relevant information
- retaining the information
- using or weighing that information to make a decision and
- communicating that decision.

Adults who are able to perform these tasks for a specific decision are entitled to make any choice they wish about their treatment options, and their choice is legally binding. Those deemed to lack capacity must be given treatment in their best interests by their treating team.

Valid consent cannot be provided by relatives of incompetent adults (unless they hold a valid lasting power of attorney). It is good practice however to consult relatives of incapacitated adults if invasive procedures are being considered, as this can demonstrate that clinicians are seeking to act in the patients' best interests, by obtaining the opinions of their loved ones.[2]

Young people aged 16 and 17 are assumed to have capacity to consent to treatment and are legally allowed to do so.[3] Children under 16 may also be mature enough to consent to simple treatment, and can be allowed to do so if the surgeon is sure they fully understand what is proposed.[4] However, under the age of 18, consent can also be provided by someone with parental responsibility for the child or by the courts. As such, children and young people have no absolute right to refuse treatment.

Who should obtain consent?

The surgeon carrying out a procedure is responsible for ensuring that a valid consent exists. They may delegate this task to a colleague or trainee, but they must ensure that person is suitably qualified and has sufficient knowledge to obtain that consent. It remains the overall responsibility of the operator to check that the information that has been provided to the patient is complete and understood.[5]

When should you obtain consent?

The Department of Health (DoH) recommends that consent is taken well in advance for major procedures.[6] This gives the patient time to consider the information, seek further opinions if desired and reach an unhurried decision. The DoH cautions that the validity of a consent may be in real doubt if taken just before a procedure is due to start, at a time when the patient may be feeling particularly vulnerable. Leaving consent until immediately before the procedure also risks invalidating consent, particularly if they have received premedication prior to general anaesthesia.

Consent taken in advance remains valid as long as the patient continues to agree to the proposed treatment, the patient's condition remains the same, and the options available also remain unchanged. It is good practice however to re-confirm the consent at the time of treatment, particularly if a significant amount of time has elapsed.

What form should consent take?

For minor procedures, patients can provide a valid implied consent. For example, the patient who attends a consultation about their inguinal hernia and lifts their shirt when the surgeon asks to examine the hernia, is presumed to have implied their consent to examination. More intimate or significant examinations and procedures require an explicit verbal consent. It is good practice to obtain written consent for major procedures, but in law only certain procedures, such as fertility treatment, require written consent.

The written consent form does however provide a useful demonstration that a consent discussion has taken place, and is widely used for all surgical procedures in the UK. Doctors must be aware that a signature on a form does not guarantee that the consent is valid if there has been either coercion to sign, or if the patient does not have sufficient understanding of the information given. Conversely, if a person has been unable to sign in an emergency or due to a disability, the absence of a signature does not preclude treatment if a valid verbal discussion has taken place.[6] In this situation the consent discussion should be documented fully in the notes.

What should be included in the consent discussion?

The content of the consent discussion is of fundamental importance, and for major procedures this discussion should take some time. The General Medical Council (GMC) states that a consent process should provide a patient with enough information to allow them to reach a decision about which treatment option is best for them. The clinician should lay out all the treatment options available to the patient (including no treatment) and explain the benefits, risks, burdens and side effects of each option.[5] The treating clinician may make a professional recommendation based on knowledge and experience, but patients are entitled to choose which option they ultimately prefer.

How is risk assessed?

The assessment of risk for an individual patient is a complex process. Statistics for a patient cohort are used as a simple way to give an average risk for a given intervention. However, applying such a risk statistic to individual patients in individual cases will only be a very crude approximation of the actual risk for that patient. Additional factors have to be taken into account. These include variations between persons performing interventions, variations over time, and most importantly variation between patients themselves.

Operator effect

There will be variations between different operating surgeons and teams, which may well cause variations in risk for particular procedures. In addition, other persons involved in patient care and other factors may influence the development of complications, for example anaesthetic technique, location of postoperative care, nursing care and so forth. Reference to crude complication and mortality data for a procedure for a given surgeon or institution can therefore be misleading. Care also needs to be taken when using such data that the absolute numbers of procedures and time periods analysed are appropriate.

Variation over time

Improvements in techniques and experience over time will no doubt cause a reduction in the risk of complications for individuals and institutions. Conversely, using new techniques and treatments may increase the likelihood of adverse outcomes not previously experienced.

Patient effects

In the health service today there are safeguards in place to prevent interventions and treatments being carried out by practitioners without sufficient training or study. Therefore the most significant effect on risk for an individual patient is more often than not their own health state. The variation in risk presented by patients themselves is a complex interaction of health and lifestyle factors. It is known that certain disease processes are associated with adverse outcomes following surgical procedures, and the assessment of individual risk allows tailoring of the consent process to reflect this.[7]

Risk stratification – general

Scoring systems are used to predict outcome and as a marker of risk for individual patients. The most widely used system is the American Society of Anesthesiologists (ASA) grading system (Table 1). A high grade indicates an increased likelihood of postoperative complications and mortality in the non-cardiac surgical population.[8] Other systems include the Physiological and Operative Severity Score for the Enumeration of Morbidity and mortality (POSSUM) score for general surgery, Goldman Index for stratification of risk of myocardial events, and EuroSCORE for predicting mortality risk for those undergoing cardiac surgery. These risk assessment systems are limited to the specific populations and outcomes they refer to, and should not be used to predict individual patient risk alone. See related articles on preoperative assessment in this issue for more detail.

American Society of Anesthesiology (ASA) grading system

ASA score	Description
1	Healthy, no systemic disease
2	Mild systemic disease, no functional limitation
3	Moderate systemic disease, functional limitation
4	Severe systemic disease which is a constant threat to life
5	Moribund patient unlikely to survive with or without intervention

Table 1