Consent: assessing and communicating risk

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Abstract

The consent process is a cornerstone of the patient–doctor relationship. It can be a complex process presenting challenges to both doctor and patients due to the interaction of multiple different factors, including ethical and legal considerations. Ensuring the patient has informed consent requires a through understanding of the risks of an intervention for a particular patient; therefore risk assessment is of fundamental importance. Accurate risk assessment can be done through assessment of individual patient factors and the proposed procedure combined with population data. Communication of this risk to the patient is key and the surgeon should use clear language to avoid bias or misunderstanding. Use of adjuncts such as visual aids, examples from other areas of life, with avoidance of statistical data and vague terms may help the patient understand the risks more completely.

Keywords Advance directives; communication; consent; DNACPR; risk assessment and risk disclosure

Consent

The Oxford dictionary defines consent as, 'the permission for something to happen or agreement to do something'. Obtaining consent from patients is an important aspect of the patient–doctor relationship. It allows investigations and procedures to be performed, which would otherwise be considered as a trespass or assault against the patient. As such, a doctor could face possible criminal convictions if proper consent was not sought.

Consent is centered on the ethical principle of autotomy – that competent adults have the right to make informed decisions regarding their medical care. Therefore doctors need to be able to provide patients with enough knowledge and understanding that they are able to weigh up the risks and benefits of any proposed procedures or investigations. This consent should be voluntary and not influenced by others to be valid.

The details of age of consent, capacity and legal considerations vary across the world. This article refers to the UK professional guidance and the legal stance in England and Wales.

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When to seek consent

Consent should always be sought before examining or treating patients. Consent may be given explicitly, through verbal or written consent, or implied where the patient may implicate consent by behaviors such as rolling up a sleeve and offering an arm for a blood test.

For major procedures, the Department of Health recommends consent should be taken well in advance of the procedure date.[1] This allows time for the patient to consider all of the information provided, and allows them the opportunity to seek further information or opinions on the proposed treatments.

Consent taken in advance will be valid if the patient continues to agree to the proposed treatment and the patient's condition remains the same. It is good practice to check and reconfirm the consent, especially if a significant amount of time has passed since it was first discussed. Leaving consent until immediately before the procedure should be avoided where possible, as consent may not be valid if the patient has not had time to fully consider the procedure and associated risks. Patients may have received premedication prior to the anaesthetic, which can impair capacity and therefore consent should not be taken after this time.

Who can consent?

According to The Mental Capacity Act 2005 (MCA2005) adults over the age of 18 years are assumed to have capacity to provide consent, unless it is demonstrated otherwise. Adults are assumed to have capacity if they are able to:

- understand the information
- retain the information
- weigh or use the information to reach a decision
- communicate the decision.

Minors

Children aged 16 and 17 years of age are presumed to have capacity and therefore are able to consent for themselves.[2] Children below the age of 16 years may be considered to have capacity to consent if the surgeon feels they are able to fully understand the proposed treatment or procedure.[3] This is known as Gillick competency. The person taking consent must carefully consider the individual circumstances of the case, including the complexities of the procedure, and the maturity of the child.

Consent for patients under 18 years of age can also be provided by someone with parental responsibility or through a court order. Clinicians must ensure the individual they are talking to have the legal entitlement to consent.

If a child or young person refuses treatment, especially life-sustaining procedures or treatments, there needs to be a careful and sensitive approach to the situation. The potential harm to the patient must be weighed against their individual rights, and usually in these circumstances a multidisciplinary approach is taken, with senior support and an independent advocate appointed for the child. In England and Wales, a parent's right to override the patient's wishes is a complex issue, and seeking legal advice is recommended in these situations.

Adults without capacity

Patients may lose the ability to consent acutely, i.e. though a loss of consciousness or delirium, or chronically due to illness such as

dementia. In these cases doctors should act in the patients best interests, and within these circumstances it is best practice to gather information regarding the patient's wishes or preferences from other sources such as relatives. However, no person is able to provide consent for another adult over 18 years, unless they have a valid lasting Power of Attorney.

Advanced care planning (advanced decisions/living wills)

Advanced care planning may be used in a progressive illness, where there is anticipation that a deterioration in the patient's clinical condition will occur in the future. It can be made by any adult with capacity, and allows the patient to document their wishes for or against any treatments if they were to lose capacity in the future. This includes refusing life sustaining treatment such as ventilation or cardiopulmonary resuscitation (CPR).[4]

Advance decisions are part of the Mental Capacity Act 2005, and are legally binding if deemed valid. When deciding the validity of the advance decision, the doctor must ensure it meets the circumstances of the current clinical situation as well as being satisfied that the decision:

- Was made by a competent adult of their own accord.
- Specifies the treatment and the circumstances that they wish to refuse and clearly states it is to apply even if life is at risk.
- Is written and signed by the patient and a witness, especially if refusing life sustaining treatment.
- There is no evidence that the patient has changed their mind since making the advance decision.

A patient may appoint a Lasting Power of Attorney (LPA), which allows another person or persons to make healthcare decisions on behalf of the patient; this may be consenting to, or refusing, treatment. For a LPA to be valid it must be registered with the Office of Public Guardian, and it must specifically cover health and welfare decisions.[4]

Do Not Attempt CPR (DNACPR) decisions

DNACPR are made in order to allow a patient to have a dignified and peaceful death. A DNACPR may be instituted when a dying patient is at risk of cardiorespiratory arrest and attempting CPR is unlikely to be successful, or when a patient with capacity has expressed their wish not to be resuscitated. Following recent legal cases, it is now unlawful for a DNACPR to be made and documented without discussing it with the patient and those close to the patient, unless the discussion would cause physical or psychological harm.[5] Such discussions should be made sensitively and as part of a wider discussion about the patient's wishes for their care and treatment. Barriers such as the time of day or fear of causing distress are no reason to avoid these discussions.

Who can take consent?

The doctor who will be performing the procedure should ideally take consent. However, this may not always be practical and therefore it may be delegated to another colleague. The person taking consent should be appropriately trained and have sufficient knowledge of the procedure, the risks involved and be able discuss these with the patient.

If obtaining consent has been delegated to another, it is still the operating doctor who is responsible to ensure the patient has received and understood all the information regarding the procedure before proceeding.

What should be included in the consent discussion?

The GMC states that enough information should be provided in the consent discussion to enable the patient to reach an informed decision about the correct course of action for themselves. The process of shared decision making (SDM) is becoming more prominent in surgery. SDM is a collaborative approach with the patient to involve them in healthcare decision making. It helps to indentify what is important to the patient and supports the patient to select the most appropriate treatment option for themselves. Therefore when discussing options the clinician should describe all available treatments, including the risks, benefits, side effects and clinical course, and this should also include the option of no treatment. The clinician may offer their professional opinion based on clinical knowledge and experience, but it is ultimately for the patient to choose their preferred treatment. This has been reflected in the recent Montgomery case,[6] which stated that patients should be supported to make decisions and that they should be made aware of all material risks relevant to the treatment. A material risk is one a reasonable person in the patient's position would likely attach significance to. This supersedes the previous Bolam rule for issues of consent, where a clinicians duty to warn the patient of risk was judged acceptable if they had acted in line with a responsible body of medical opinion.[7]

How to document consent

For non-invasive or minor procedures verbal consent can be given, or consent may be implied. More significant or invasive procedures and examinations require explicit verbal consent, although it is good practice to obtain written consent as well. Written consent is only legally required for certain procedures such as fertility treatment.

Written consent and documentation in the notes demonstrates a consent discussion has occurred, and is widely practiced in the UK. However, a signed consent form does not necessarily represent informed consent. If a patient is unable to sign the consent form due to disability, the absence of a signature does not preclude treatment if a valid discussion has taken place and is documented in the notes.[1]

Risk assessment

Risk is the probability of an event occurring as the result of an intervention. The average risk of an intervention can be given as a statistic to the patient; however, this is an approximation of the risk. The assessment of risk for a patient is more complex and includes factors such as variations in surgical performance, time variations and patient factors.

Operator effect

Between different surgeons and teams there will be variations in techniques and practices which can result in different outcomes. This can also be influenced by factors such as anaesthetic

technique, postoperative care location, and nursing care amongst others.

Variations over time

An operator will likely improve in technique and experience over time, and repetition and practice of the procedure can result in a reduction of potential complications. Conversely, when an operator is learning a new technique there is an increase in the potential for adverse outcomes.

Patient effects

A significant effect on outcome is the patient's own health. There is a complex interaction of health and lifestyle factors that can influence the risk a patient is exposed to when undergoing a procedure. It is known that certain health conditions, such as diabetes, are associated with higher rates of complications following surgical procedures, and thus individual assessment of risk allows tailoring of the consent process to reflect this.

Risk stratification

Risk for patients can be stratified using general scoring systems or more specific individualized risk assessments for the patient.

General

The most commonly used scoring system in the UK is the ASA classification of physical status (Table 1). A high ASA score is predictive of increased postoperative complications and mortality in surgical patients.[8] Other scoring systems such as POSSUM, cr-POSSUM, v-POSSUM predict more specifically risk for general, colorectal and vascular surgery respectively. When using these scoring systems, it should be remembered that they relate to specific populations and have wide inter-user variability, and therefore should not be used alone to predict individual risk.

Specific

A more individualized method of calculating a patient's risk is by the use use of cardiopulmonary exercise testing. This defines a patient's anaerobic threshold, in combination with other physiological markers preoperatively, and is used to predict outcome after major surgery. Patients can be then stratified into higher or lower risk and appropriate preoperative optimization and postoperative destination can be planned. Risk calculators can be used to further indicate specific patient risk. Other more novel methods include measuring patients' biomarkers. Elevated biomarkers can be predictive of organ dysfunction which may put the patient at greater risk.

American Society of Anesthesiologists' status classification

Class	Description	Mortality (%)
I	Healthy	**0.1**
II	Mild systemic disease – no functional limitation	**0.7**
III	Severe systemic disease – definite functional limitation	**3.5**
IV	Severe systemic disease – constant threat to life	**18.3**
V	Moribund patient unlikely to survive 24 h with or without operation	**93.3**
E	Emergency operation	

From Boyd O, Jackson N. How is risk defined in high-risk surgical patient management?[8] (with permission).

Table 1

Communicating risk

Communicating risk to patients can be complex with multiple challenges. The way that the risk is communicated to patients may be pivotal in the acceptance or refusal of treatment. It is the duty of the doctor to present the risks to the patient in a way that they can understand, and so it is meaningful and useful.

Patients need to know not only the likelihood of an adverse outcome happening, but also the timing of potential complications, which may not occur for a significant time after the event. Patients will place different importance on these outcomes depending on the time scale. Other factors to consider are the permanence of the complication, as a transient negative outcome is generally more acceptable to patients than permanent ones.

Adverse outcomes are viewed differently by individuals depending on their age, lifestyle, occupation and normal functional status. For one patient a particular outcome may represent a catastrophic result, while for another it may have little or no impact.[9]

How much risk should be discussed

Surgeons should have a thorough understanding of the procedures as well as the risks that are pertinent to the patient and communicate these. It can be difficult to know exactly what to share with the patient, and there is no fixed standard in this area.

Historically, a doctor would inform the patient about what they felt was 'prudent' for the patient to know. However, guidance from the GMC, as well as recent legal cases, now means that the expectation is that discussion is tailored to the patient, and all risks that a reasonable person would wish to know are disclosed.

In practice it is usually regarded that major risks such as death, disability and disfigurement are disclosed, as well as the common potential complications (1% risk or greater).

Disclosing all risks may lead a patient to refuse a procedure that they would otherwise accept. This does not mean the clinician should withhold information from the patient. Ultimately it is the courts that decide what is considered reasonable practice, and if there has not been full discussion of risks it may be viewed as negligence.

How to communicate risk

Effective communication of risk is indispensable; however, it can be variable between medical practitioners. How it is understood by the patient is influenced by a number of factors.

Numerical

Risk can be communicated to a patient in numerical terms as a percentage – 'there is a 1% risk' – or described as chance –

'there is a 1 in 100 chance'. Be aware that some patients find comprehending a risk as a percentage difficult, but most patients across age and educational levels are more likely to understand risk if presented in terms of frequency (i.e. 1 in 100). When using frequencies, use multiples of 10 as a denominator, as this is easier for patients to follow.

When describing risks to patients, it is often easier for them to understand absolute risk rather than relative risk.

Language

Descriptive language such as 'common' or 'rare' are often used when discussing risk with patients but can be interpreted differently depending on the patient. Therefore, when using descriptive terms a denominator should be used to give the patient a frame of reference. For example, 'The risk of nerve damage is rare, about 1 in 10,000'.

Framing

How an outcome is presented to the patient can have a significant impact on the patient's perception of the risk. The risk can be presented as either a positive (gain) or negative (loss). For example the risk of death is 2 in a 100 (loss), compared to there is a 98 in a 100 chance that you would survive (gain). Negative framing appears to be more effective when there is uncertainly and risk.[10] It is probably best to provide the patient with both positive and negative framing of risk.[11]

Other aids

Visual aids can be very effective when discussing risk with patients, especially those with poor numerical skills. visual aids such as dot diagrams and Paling Palette may help to depict outcomes.[11] These can help the patient visualize negative outcomes and help the patient put them in to perspective.

Other aids to help in the decision making process can include the use of leaflets, posters, video and websites.

Bias in risk perception

Perception of risk is not only determined by facts but also by emotions, perceptions and prejudices. This may introduce a bias when considering risk.

'Availability bias' occurs when the likelihood or frequency of an event occurring is overestimated due the ease that the occurrence comes to mind. This will be influenced by previous complications experience by the patient, friends or family, or those with a high profile in the media.

'Anchoring bias' is the tendency of an individual to estimate their risk of an adverse outcome based on another event or similar experience in the past.

'Compression bias' is the tendency to overestimate rare risks while underestimating common risks.

'Miscalibration bias' is when the patient becomes overconfident in the accuracy of their own knowledge, and they believe their own risk is lower than that of the general population.[9]

Good communication and delivery of information in a way that the patient can understand, helps reduce the effect of bias. Also exploring any concerns the patient may have as a result of previous surgery, or recent media coverage regarding a particular procedure, can be beneficial.

Conclusion

Gaining consent from a patient is a two-way process, involving good communication regarding all options so that an agreed course of action can occur. The patient needs to be aware of all the risks and unwanted outcomes of the options so that they can ultimately choose the correct course for themselves. Use of clear numerical terms, using conjunction with other aids to help the patients understanding. Discussion of the risk of procedures should be accurate and tailored to each individual patient, using a combination of population data and patient factors. This then allows the patient to make an informed choice. ◆

REFERENCES

1 Department of Health. Reference guide to consent for examination or treatment. 2nd edn. 2009.
2 Family law reform act 1987 section 8.
3 Gillack v W Norfolk AHA, 1985. 3 ALL 402.
4 BMA ethics department. Advance decision and proxy decision-making in medical treatment and research.
5 Hall CC, Lugton J, Spiller JA, et al. CPR decision-making conversations in the UK: an integrative review. *BMJ Supp Palliat Care* 2018; **0:** 1–11.
6 Montgomery v Lanarkshire Health Board. UKSC 11, 2015.
7 Bolam v friern hospital management committee, 1957. 1 WLR 582.
8 Boyd O, Jackson N. How is risk defined in high-risk surgical patient management? *Crit Care* 2005; **9:** 390–6.
9 Bogardus S, Holmboe E, Jekel J. Perils, pitfalls and possibilities in talking about medical risk. *J Am Med Asoc* 1999; **281:** 1037–41.
10 Fagerlin A, Zikmund-Fisher B, Ubel P. Helping patients decide: ten steps to better risk communication. *JNCI* 2011; **5:** 1436–43.
11 Paling J. Strategies to help patients understand risk. *Br Med J* 2003; **327:** 745–8.

