Summary and Key Recommendations

- Consent should be informed, voluntary and from a person who has capacity.
- Consent is a process and should involve shared decision making principles and / or frameworks.
- Pre-assessment clinics have an important role in the consent process by:
  - Providing patients with key information related to the procedure and anaesthetic, especially written information.
  - Identifying patient specific factors which may impact on the “material risks” to a particular patient.
- Pre-assessment staff should be with familiar with how to recognise if a patient does not have capacity and how to manage this situation in their organisation.
- A consent form for an elective surgical procedure should usually have been signed prior to the patient attending for nurse-led pre-assessment.
- It is not necessary to take separate written consent for anaesthesia which is performed to facilitate a surgical procedure.
Introduction

There are two areas of consent that staff in pre-assessment will encounter – consent for a surgical procedure and consent for anaesthesia. These are inextricably linked, with each influencing the other. The purposes of a pre-assessment appointment are closely aligned with the consent process. The appointment is an opportunity for the peri-operative team to identify patient factors (medical or social) which may impact on the risks of surgery or anaesthesia and also to provide the patient with information related to their hospital admission, surgical procedure (including anaesthesia) and recovery. The risks of both surgery and anaesthesia will vary according to patient factors which may be first identified at a pre-assessment appointment. The pre-operative appointment is therefore a key point in the consent process for elective surgery.

This chapter covers information about consent relevant to pre-assessment teams and therefore concentrates on elective and expedited surgery in adults. It does not cover urgent or emergency surgery, or consent for surgery in the obstetric or paediatric population although many of the principles still apply.

There is comprehensive and extensive guidance about consent published by the Department of Health [1], GMC [2], the Association of Anaesthetists [3] and the Royal College of Surgeons [4]. This chapter covers the key principles regarding consent in these guidance documents and is intended to be a practical guide to implementing them. The reader is referred to the nationally published guidance for further information and clarification.

Footnote: The legal frameworks and terminology for decision making and consent vary according to the country with which the surgery is being performed, even across the UK. For example, in England, Wales and Northern Ireland the term “best interests” is used in decision making, whereas Scottish law refers to “benefits” to the patient. The Association of Anaesthetist Guidance summarises the differences in legal frameworks for decision making in its Appendix 1 [3].

What is valid consent?

For consent to be considered valid, the following three conditions must be in place.

1. It must be from a person who has capacity.
2. It must be given voluntarily, with no coercion from others (family, friends or healthcare professionals).
3. It must be informed. This means the patient must be given the information they need about the overall benefits of the procedure, the risks of having the procedure and the alternative options, including doing nothing. This information should be provided in appropriate format(s) for that particular patient, over a time-scale which allows them to consider the options, with consideration to the factors that matter to the patient.

Please note that documentation of consent is not a pre-requisite for it to be valid, although there are some procedures where it is legally required in the UK, such as fertility treatment. Documentation is, of course, important, as it provides evidence of the consent process. It is discussed further below.

Why do we need to gain consent?

Gaining valid consent for performing a procedure is a professional, ethical and legal obligation of any healthcare professional that performs procedures. Modern medicine has moved far away from the paternalistic approach of previous years, and the principles of decision making and consent emphasise the importance of doing this in partnership with patients. Performing an elective procedure without valid consent is against legal and GMC guidance and may result in prosecution (for assault / battery, or more commonly for negligence) and GMC referral.
Who can give consent?

For adults, only the person having the procedure, or their legally appointed deputy, can consent to a procedure. If the person is unable to consent, due to an impairment of their capacity (temporary or permanent) then a decision about whether to perform a procedure needs to be made by the responsible medical team, after consultation with relevant other parties (see below).

How is capacity defined?

Mental capacity is the ability to make a decision. The starting point for capacity is that it is presumed to be present and this presumption must not be influenced by patient demographics such as age, ethnicity or disability [5].

How is capacity assessed?

In order to demonstrate capacity, a person must be able to do all of the following:

• Understand relevant information relating to the decision, such as what the procedure involves and what its risks and benefits are
• Retain this information
• Use the information to make a decision
• Communicate the decision to others

It is the responsibility of the person taking consent, to take all reasonable steps to help the patient understand the information and to communicate that decision. It is important to remember that patients with capacity may make unwise decisions or ones that others do not understand. (This is most often seen in the context of a refusal for treatment. It is of note that a patient cannot demand a healthcare professional to perform a specific treatment which is not indicated.) This does not mean that they do not have capacity.

Usually, a lack of capacity will have been identified prior to the patient attending a pre-assessment appointment. However, capacity is time and procedure specific, and may fluctuate, so it is possible that a person may have been felt to have capacity in the outpatient setting, but then this be questioned in the pre-assessment setting, or indeed vice versa. If the patient cannot recall the operation they are having and the reason for this, this is a red flag that they do not have capacity.

Who can assess capacity?

Capacity can be assessed by any healthcare professional and organisations often have mental capacity assessment forms to help with the assessment and documentation of this [6].

What to do if you feel a patient does not have capacity

The following steps should be taken if it is felt that a patient does not have capacity in the pre-assessment clinic:

1. Document the reasons for this on appropriate paperwork.
2. Contact the lead clinician to co-ordinate a best interests meeting.
3. Refer the patient to the organisations safeguarding team or equivalent, to assist with the best interests meeting.
What is a best interests meeting?

A best interests meeting is between the healthcare professional(s) proposing a treatment, a patient who does not have capacity and those close to the patient such as their next-of-kin and other relatives / friends / carers. It may also involve other healthcare professionals involved in the patients care. The patient's representatives are involved in order to help establish the patient’s “needs, preferences, values and priorities” and not to consent on their behalf. This information enables the healthcare professionals to determine what treatment will be of overall benefit to them.

If the patient does not have any next-of-kin who are able to be consulted (for example if the next-of-kin is too frail or does not wish to be involved), then an Independent Mental Capacity Advocate (IMCA) must be appointed and consulted at the meeting instead [7]. Organisations will have their own referral systems for IMCAs.

What is a legally appointed deputy?

There are two forms of legally appointed deputy for healthcare decisions, a Lasting Power of Attorney (LPA) for Health and Welfare and (less commonly) a Court Appointed Deputy. A LPA is appointed by the Office of the Public Guardian [8]. Both will have documentary evidence, which should be included in the patient’s notes and neither has the power to refuse life-sustaining treatment.

Advance directives

A patient may make decisions regarding future medical care in advance of losing capacity. This is known as an advance directive. They may state their wish to refuse routine or life-saving treatments (for example a Jehovah’s witness may refuse to receive blood products). A refusal of life-saving treatment must be in writing and witnessed. If a patient expresses that they have an advance directive to pre-assessment staff, they should ensure that this information is highlighted to those who will be involved in their care and a copy of a written directive should be included in the patient’s medical notes.

Who should take consent?

Consent should ideally be taken by the person who is going to perform the procedure. The GMC guidance states that it may be delegated to another healthcare professional providing that that person has appropriate qualifications and training and sufficient knowledge of the proposed procedure and its risks and benefits and has skills in shared decision making. It also states that it is the responsibility of the person delegating to ensure these conditions are met, and that the person they delegate to understands and agrees to refer any queries or requests for further information back to an appropriate person.

Pre-assessment nursing staff should not be expected to take consent for either a surgical or anaesthetic procedure. However, as mentioned above, they are a vital part of the consent process, with respect to the provision of information and / or identification of patient factors which may increase the patients’ risk. They are also a point in the admission process where the patient can raise any questions and where the need for a further discussion regarding the procedure may be identified. It should be expected and accepted that there will be times when the pre-assessment team refer patients back to the surgeons for further discussion.

A patient may also ask questions related to the surgical procedure at anaesthetist-led appointments. Whilst anaesthetists may be able to answer some of these questions, and this is important to help the patient understand the nature of the procedure, they should only do this within the limits of
their capability. They should refer back to the responsible surgeon if there are questions that they cannot answer.

In the similar way, a surgeon should not take consent for the anaesthetic needed for a procedure. However, they should be able to provide information and mention anaesthetic options. They should then refer the patient to an anaesthetist for more information.

**When should consent be taken?**

For elective and expedited surgery, consent for the surgical procedure should be taken in advance of being admitted to hospital for the procedure, using the shared decision making principles described below. This allows opportunity for the patient to reflect on the information which has been given to them and to decide if they have any questions.

For high-risk surgical patients, consent for anaesthesia and any associated procedures, should also be taken in advance of being admitted to hospital, for example in a high-risk anaesthetic clinic.

For other patients, it is acceptable to take consent for anaesthesia on the day of surgery, providing that information has been given to the patient in advance of admission, either at the time of booking surgery or at the pre-assessment appointment. It is not acceptable to take consent for anaesthesia or provide new information to an elective patient in the anaesthetic room, immediately before induction of anaesthesia.

**What should be discussed?**

Valid consent requires that the patient is informed about the nature and purpose of the intended procedure, the risks of harm from the procedure and the alternatives to it. Importantly these must be discussed in relation to the individual patient, accounting for their medical and personal circumstances and the amount of information provided should also be tailored accordingly. If patients wish to involve others in this discussion, this should be accommodated wherever possible and the patient should always be given the opportunity to ask questions.

**Shared decision making**

The GMC guidance on consent from both 2008 and 2020 emphasizes the importance of involving patients in decision making related to their treatment and/or care, a practice known as Shared Decision Making (SDM). SDM is “the process whereby patients and clinicians work together to make evidenced based decisions centred on patient values and preferences” [9]. The concept is backed by NICE [10], NHS England and HEE [11] and has been evaluated in a Cochrane review [12]. Specifically, SDM should involve establishing what matters to an individual patient, in order that the discussion can be tailored accordingly and relevant information exchanged.

Although this concept is not new, the landmark legal case of Montgomery vs Lanarkshire Health Board, brought the law in line with previous professional guidance, confirming the importance of understanding what matters to an individual patient when taking consent. The judgement in this case stated that it was expected that the person taking consent should explain all “material risks” relevant to that patient. Materiality was defined as “...whether a reasonable person in the patients’ position would be likely to attach significance to the risk, or the doctor should reasonably be aware that the particular patient would be likely to attach significance to it“ [13].

Whilst it is expected that SDM conversations will have occurred prior to patients attending
pre-assessment appointments, it is nevertheless helpful for pre-assessment staff to understand these principles and how they may be put into practice. SDM is also relevant to anaesthetists performing high-risk anaesthetic clinics, where often further discussion related to surgical and anaesthetic risk occurs. To aid this process, models for SDM have been proposed. One such model describes three different stages to SDM conversations, “team talk”; “option talk” and “decision talk” [14]. Similarly, tools for evaluating the effectiveness of these conversations have also been developed [15].

Decision making frameworks

Decision making frameworks are designed to assist with the SDM process. One example of a framework is the “BRAN” decision making framework, developed by Choosing Wisely UK which is part of a global initiative, aimed at improving conversations between patients and clinicians [16]. This framework encourages the patient to ask four questions to enable better decision making:

- What are the Benefits?
- What are the Risks?
- What are the Alternatives?
- What if we do Nothing?

A leaflet can be downloaded to help with this conversation [17].

What information should be provided?

At a nurse-led pre-assessment appointment, patients should be provided with written and verbal information about their procedure and the peri-operative care pathway, if this has not been done at an earlier point in the pathway. With respect to the consent process, this should include:

- Information about what the patient can do to prepare for surgery and minimise their peri-operative risks, for example the Fitter, Better, Sooner leaflet from the RCoA [18], information about thromboprophylaxis and post-operative recovery and rehabilitation.
- Information about the admission process, such as fasting, pre-medication, transfer to theatre, ward information
- Information about the side effects and risks of harm of the anaesthetic and analgesic techniques they are likely to be offered. This should be in the form of an evidenced-based patient information leaflet. (This may mean the patient is given information about both general and regional anaesthesia, as well as information about other options for pain relief).
- Information about when they will have opportunity to ask further questions and meet key staff who will be involved in their care.

Many hospitals choose to use national evidence-based patient information leaflets such as those by the RCoA [19], RCS [20], and / or subspecialty or local leaflets as necessary.

What if patients refuse information?

If a patient declines information about the procedure or risks, then it is important to explain to them that this makes it harder to know whether their consent is valid. It is useful to ask if some basic information such as the reason for the proposed procedure and the most serious risks could be mentioned, and also to try to find out why the person does not wish to know the information. As one of the conditions for valid consent is that it must be informed, if a patient attending pre-assessment refuses information, then the responsible clinician should be told. It may be necessary to involve other parties, but this will depend on the procedure being proposed. Documentation of the discussion is vital.
How should consent be documented

The following aspects of the consent process should be documented:

1. The decision making conversation regarding the surgical procedure, including any alternative options offered to the patient as well as the option of doing nothing. This should be documented in the medical notes and also on correspondence with the patient and GP. This is usually done prior to the pre-assessment appointment.
2. The benefits of having the procedure and the potential risks of harm which have been discussed. These should be documented on the consent form, which is then signed and dated by the patient and the healthcare professional.*
3. Any information (verbal / written / electronic) that the patient has been given. This includes patient information leaflets in the pre-assessment clinic.
4. The planned mode of anaesthesia should be included on the consent form for the surgical procedure. This is usually general / regional anaesthesia or local anaesthesia.
5. If the patient is seen in a high-risk anaesthetic clinic, the details of this conversation, including the options for analgesia and anaesthesia which have been discussed, should be documented in the medical notes. Any risks of harm discussed should also be documented.
6. The surgical consent form should be re-signed on the day of surgery, to reflect that the patient has not changed their mind. When patients attend pre-assessment, they can be reminded that they will have this opportunity for further information and questions.
7. Details of the anaesthetic pre-assessment visit, including consent for anaesthesia are usually documented on the anaesthetic chart. Often a tick box system is used to help with this.

*If a patient does not have capacity then a consent form 4 is used (see table).

Guidance states that a patient does not need to provide separate written consent for anaesthesia performed as part of a surgical procedure and therefore a separate consent form specific for the anaesthetic is not required.

<table>
<thead>
<tr>
<th>Type of consent form</th>
<th>When is it used</th>
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<tbody>
<tr>
<td>Consent form 1</td>
<td>For all adult patients with capacity. (It may also be used for “legally competent” children.)</td>
</tr>
<tr>
<td>Consent form 2</td>
<td>For parental consent for a child or young person.</td>
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<tr>
<td>Consent form 3</td>
<td>For patient or parental consent for procedures where consciousness is not impaired (i.e. an anaesthetist is not involved in the patient’s care).</td>
</tr>
<tr>
<td>Consent form 4</td>
<td>For an adult patient who does not have capacity. This needs to be signed by two healthcare professionals.</td>
</tr>
</tbody>
</table>
References

6. Examples of mental capacity assessment forms
16. Choosing Wisely UK. https://www.choosingwisely.co.uk/shared-decision-making/
19. RCoA Patient Information Leaflets. https://www.rcoa.ac.uk/patient-information