1 Consent

Abha Govind

Overview

Obtaining consent and understanding its implications form an important part of a clinician's practice. This chapter discusses aspects of consent typically encountered by a clinician, including the recent Montgomery Ruling.

Introduction

In recent years, great emphasis has been placed on obtaining **consent** for surgical procedures to avoid litigation. This has become an integral part of clinical risk management and governance. Generally, consent should be obtained before any procedure. It is important to understand that a **competent adult** has the fundamental right to give, or withhold, consent to examination, investigation or treatment, founded on the moral principle of respect for autonomy. An **autonomous** person may decide what may or may not be done to her.

In **English civil law** deliberately touching another person without consent is called **battery,** which is punishable by law. Equally, patients can take out a **civil action** for **negligence** for not receiving enough information about a procedure, particularly if they have not been told enough about the **risks.** This could result in an action for damages, or even **criminal proceedings,** and potentially in a finding of a **serious professional misconduct** by a professional registration body, e.g. the General Medical Council (GMC).

Types of Consent

There are three different types of consent in everyday working practice. **Tacit** consent is when you tell a patient you want to take a blood test and she holds out her arm whilst you put a needle in and take the blood sample. **Verbal** consent is when you ask a patient if you can do a vaginal examination and she says yes and allows the procedure. Finally, **written** consent should be taken for all **invasive procedures**, those involving **risk** and where regional or **general anaesthesia** is required. It is not absolutely necessary to defend an action for assault/battery but it affords **documentary evidence.** If an action is brought several years after the event, the judge may prefer the patient's evidence over that of the practitioner, if

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a signed and witnessed consent form cannot be produced.

What Makes Consent Valid?

Consent must be given **voluntarily,** without coercion, by a woman who is **fully informed** about the procedure or investigation in question, and who has capacity. It is not valid if she agrees to an operation without full knowledge. If possible, **visual or written aids** can be used to help, and an **interpreter** should be used if needed. Consideration also needs to be given to patients with learning difficulties.

When Should You Obtain Consent?

Ideally, well in advance so that the patient has time to ask questions. It is good practice to obtain consent in **outpatient** clinics, then **confirm** consent prior to the procedure. In certain cases, women are listed for theatre within days of being seen in clinic (e.g. women with cancer) and in this instance it is important that the woman has been given the opportunity to reflect on the procedure and to ask questions. The GMC recommends an appropriate **cooling off** period before signing.

How Long Is Consent Valid for?

If a woman consents to a procedure, generally it is assumed that this consent is valid **indefinitely.** However, in a few situations consent may need to be **reconfirmed,** e.g. if the patient's condition changes, if there is a long time period between signing and the procedure, or if the procedure has changed or new risks or side effects are known (DOH 2009).

Who Can Obtain Consent?

The responsibility for obtaining consent lies with the **clinician performing the operation.** Consent may not be valid if obtained by someone with inadequate knowledge of the procedure. If you are a junior trainee in this situation you have a duty to ensure you have the correct knowledge, and if you do not, refer the woman to another practitioner who does.

Fully Informed Consent

Ensure that your patient understands the **nature** of the condition, **intervention** and likely **benefits** and **risks** of the procedure for which the consent is proposed. She should also be told of the risks of the **procedure not being carried out.** When using consent forms in the UK, there is a space on the form to document any **procedures** that your patient **would not wish to have done.** For example, a person who is a **Jehovah's Witness** will not accept blood products, or a woman who wishes to retain her cervix with consent only for a subtotal hysterectomy.

Material Risk

These are defined as those to which a **reasonable person** in the patient's position would be likely to attach **significance.** It is an aspect of consent which has been contentious in terms of how much information regarding risks is given to patients. Several court cases have led to the current view that **as much information** as possible should be given to the patient.

The **'Bolam test'** is a defence to the charge of **negligence,** when a group of doctors within the same specialty agree that at the time they would have taken the same actions or decisions to the same standard (**Bolam v Friern Hospital Management Committee** (1957)). In the Sidaway case (**Sidaway v Board of Governors of the Bethlem Royal Hospital** (1985)), the patient was suffering from symptoms of nerve compression and

underwent cord decompression. As a complication she suffered paraplegia, a recognised but uncommon complication (1–2%). This was not included in the consent. The patient reported negligence because of this but the court rejected the argument based on the Bolam test as other practitioners agreed it was not necessary to inform the patient of every risk. However, the House of Lords later concluded that a doctor has a duty to provide to their patients **sufficient information** for them to reach a **balanced judgement.** Since the **Sidaway** case, law courts are more willing to be critical of medical opinion, i.e. a clinician may be held accountable for an action being negligent or harmful, even if a body of professionals felt their action was reasonable according to the Bolam test.

Since the **Chester v Afshar** case (2004), it is now advised that when obtaining consent, practitioners should **inform** patients about **all significant** possible adverse outcomes. In this case, the patient sought advice from a neurosurgeon about their back pain and was advised to have an operation. This operation carried a 1–2% risk of **worsening the symptoms,** which the patient subsequently suffered but this was not discussed within the consent. Crucially, the court judged that the surgeon breached their duty as although the complication was not because of the surgeon's negligence during the operation, the link between omitting the risk during consent and the complication was causal – the claimant reported if they had been told of this risk they would have sought alternative advice or treatment (Chester v Afshar 2004). It is therefore imperative that practitioners should inform patients about **all significant possible adverse outcomes** and document this, and advise the patient if any intervention may result in a serious adverse outcome, even if the likelihood is very small (GMC 2008).

The law on consent has progressed from being **doctor led** to **patient focused.** When seeking consent to treatment, the question of whether the information given to a patient is adequate is judged from the perspective of a reasonable person in the patient's position. For the purposes of consent, the ruling from **Montgomery** replaces the previous tests founded in Bolam and refined in Sidaway. Doctors have a duty to take reasonable care to ensure that patients are aware of **'material risks'.**

Montgomery v Lanarkshire Health Board

Mrs Montgomery was a primigravida with type I diabetes who booked under consultant-led care in 1999. She was noted to have a large baby at her 36-week scan and was induced at 38 + 5 weeks of gestation. Although she expressed concerns about the size of the baby, the risk of shoulder dystocia (9–10% in diabetic mothers) was never discussed with her. Her consultant, who advised a vaginal delivery, defended her practice saying that in her estimation, 'the risk of a grave problem for the baby arising as a result of shoulder dystocia was very small (0.1%)'. The baby was delivered by forceps, but this was complicated by shoulder dystocia and there was a delay of 12 minutes between the delivery of the fetal head and body. Her son developed severe dyskinetic cerebral palsy as a result of hypoxia during delivery (Cheung et al. 2016). Her obstetrician had not disclosed the increased risk of this complication in vaginal delivery, despite Montgomery asking if the baby's size was a potential problem. Montgomery sued for negligence, arguing that, if she had known of the increased risk, she would have requested a Caesarean section. The Supreme Court of the UK announced judgement in her favour in

March 2015. The ruling overturned a previous decision by the House of Lords (Sidaway v Board of Governors of the Bethlem Royal Hospital 1985; Heywood 2015). It established that, rather than being a matter for clinical judgment to be assessed by professional medical opinion, a patient should be told whatever they want to know, not what the doctor thinks they should be told.

The judgement therefore means that doctors must share all such material risks, as well as any to which it would be reasonable for them to think the individual patient would attach significance. Although Montgomery changed the legal position, the principle of involving patients in their treatment and sharing information with them about risks has been in place for some time. The Medical Defence Union (**MDU)** has consistently been advising members to that effect for many years, and the **GMC** does the same in its guidance, entitled, '**Consent: doctors and patients making decisions togethe**r' (GMC 2008).

The practitioner should also bear in mind that their own perception of risk may differ to the woman's perception of risk, and so using terms which are clear and understandable is very important. For example, describing the likelihood of a complication as the likelihood of it affecting one person in a village, small town or large town.

Do Not Exceed the Authority Given by the Patient

Consent is given on the basis that the patient understands that any procedure in addition to the investigation or treatment described '… will only be carried out if it is necessary and in my best interest and can be justified for medical reasons' (DOH, consent Form 1). This covers what becomes necessary during the operation for the preservation of the patient's life or health. It **does not** allow the surgeon to **contravene** the **expressed wish** of the patient and to undertake albeit well-meaning procedures for which the patient has not given consent. She is entitled to be told what procedures may reasonably be expected to be carried out. It would be wise to tell the patient whilst consenting her for general anaesthesia, if an analgesics suppository is to be inserted. In 1995, the GMC made a finding of serious professional misconduct against an anaesthetist who inserted the suppository without giving such a warning. In 1997, a gynaecologist was accused of **serious professional misconduct** by the GMC after he removed the ovaries of a patient during a routine operation for a hysterectomy. He believed the findings at the operation justified removal of the ovaries, but he had not obtained specific consent for their removal (Dyer 2000).

With **medical students,** it is important that consent is taken for procedure or examinations which are performed by students or trainees solely for their own education or training.

Establishing Capacity

The Mental Capacity Act (MCA) **assumes** that all adults have **capacity** until proven otherwise (Mental Capacity Act 2005). In order to be sure your patient has capacity to consent there are four important principles: she must **understand** the information, **retain** information long enough to decide, be able to **weigh up** the available information and be able to **communicate her decision** back. A person lacks capacity if they have a disturbance of mind or brain which means they cannot make a specific decision. It is important to remember that capacity is decision- and time-specific. A woman may not have capacity to decide

whether to have a hysterectomy for menorrhagia, but can consent to have a blood test to test her haemoglobin. It is important that capacity is not confused with a practitioner's impression that a decision is incorrect or against medical advice.

Mental Capacity Act

There are **five key principles** to the law relating to the MCA (2005). You must **presume** patient has **capacity** and if you doubt that they have capacity, then you should prove that they lack this. Every effort should be made to support the patient making their own decisions. This may mean simplifying or translating the information as appropriate. One must respect the patient's autonomy to make their own decision, even if you personally think the **decision is unwise.** Where a patient has no capacity, the concept of **best interests** comes into play. When a decision about what a women's best interests may be needs to be taken, a practitioner should seek another senior practitioner's **opinion** and may need **legal advice**. In some instances, an **Independent Mental Capacity Advocate** (IMCA**)** may have a role to play. Finally, whatever action you take it must be least restrictive of the patient's human rights.

When a Patient Lacks Capacity

In line with the MCA (2005), when a person lacks capacity, a health professional must **act in their best interests** and choose the **least restrictive options.** In acting in the patient's best interest, the health professional can take into account the person's **past and present wishes** and feelings, including relevant **written statement** made by her when she had capacity.

Apart from healthcare professionals, there are only two other parties who may make decisions on a patient's behalf. The first is someone with **lasting power of attorney** (MCA 2005), which is a person nominated by the patient, when she had capacity, who will make decisions on her behalf when she lacks capacity. Alternatively, the court can appoint an **IMCA,** whose role is to act in the best interest of patient. An IMCA can weigh up the information an make a decision in the best interest of patient.

Furthermore, when considering decisions which need to be made about a patient who lacks capacity, the practitioners must consult any **advanced directives** that may exist. A woman can make a decision in advance to refuse treatment, which is applicable for a time in the future when she does not have capacity. An advanced directive can be withdrawn by the patient at any time, as long as they retain capacity at the time of withdrawing it.

Right to Refuse Consent

A **competent adult** has the right to refuse treatment even if others, including doctors, believe that the refusal is neither in their best interests nor reasonable.

One case illustrating the right of a competent adult to refuse medical treatment is the case concerning a schizophrenic patient who suffered persecutory delusions and believed himself to be a doctor of international repute. This patient had refused to give consent for the amputation of his leg which had become gangrenous. The patient was considered by the judge to **have capacity** to make treatment decisions on his own behalf. This case also upholds the principle that mental illness does not automatically call a patient's capacity into question **(Re C. Adult: refusal of treatment 1994)**.

Consent Forms

The Department of Health has produced **four** different consent forms for use in practice in the UK. **Form 1** is consent by **competent adults or Gillick competent** child for general or local anaesthetic. This is the form generally used for consent, e.g. laparoscopy under general anaesthetic (GA). **Form 2** is consent by a **parent for a child** or young person less than 16 years of age. **Form 3** is used when **consciousness is not impaired** or no anaesthetic is needed, e.g. outpatient hysteroscopy or treatment in the colposcopy department. **Form 4** is used when an adult is unable to consent or in **adults without capacity**.

Special Situations

If a woman wishes to undergo a permanent form of contraception, e.g. **sterilisation,** it is important to discuss all risks and benefits with her. It is advisable to give the patient a cooling off period between consenting for the sterilisation and the procedure. It is important to stress that the **decision** for sterilisation **lies with the woman** and not with any partner she may have. When consenting for a **termination of pregnancy,** the decision lies solely with the woman; however, it is good practice to discuss with the patient's partner where relevant and to take into account their thoughts and views.

Fraser and Gillick Competence

Fraser guidelines and Gillick competence relate to issues of consent around children. Initially, these guidelines related to capacity and consent surrounding **contraception and child protection** issues. However, the Gillick case and subsequent Fraser guidelines are now used more widely to establish if a child under the age of 16 has the **maturity and capacity** to make a decision about their care and understand the implications of the decision.

Gillick competence is used to assess whether a child, 16 years or younger, is able to consent to his or her own medical treatment without the need for parental permission or knowledge.

The Gillick case involved a mother who took her local health authority to court to prevent them from giving contraceptive advice and treatment to girls under the age of 16 **(Gillick v West Norfolk and Wisbech AHA 1986)**. It was ruled that children who have sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent to that intervention. This is sometimes described as being **'Gillick competent'**.

Lord Fraser concluded that the doctor would be justified in proceeding without parental consent/or even knowledge if the girl, under 16 years of age, **understood** his advice.

Finally, recording video footages or images of the pelvis at operation (to form part of the operation record) is allowed but consent is needed if these are used for teaching purposes or publication.

Summary

- A **valid consent** shows it is allowed and that you are doing what is agreed.
- A legally recognised consent is one that is **fully informed** and given **without coercion.**
- Before taking consent, ascertain that the woman is **competent,** i.e. she can understand, retain, weigh the pros and cons and is able to communicate the information back.
- **Assume** all women over the age of 16 years have the **capacity** to give consent unless proven otherwise.

- A **Fraser competent** child is able to give voluntary and valid consent.
- Inform women of all **common and potentially serious risks** with due care and formality.
- The **Mental Capacity Act 2005** is used when patients lack capacity.
- Refer to **any advanced directives** when making decisions in those without capacity.
- In **emergencies** doctors must act in the **best interest** of the patient who is unable to consent.

Further Reading

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