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ADVANCING SURGICAL CARE

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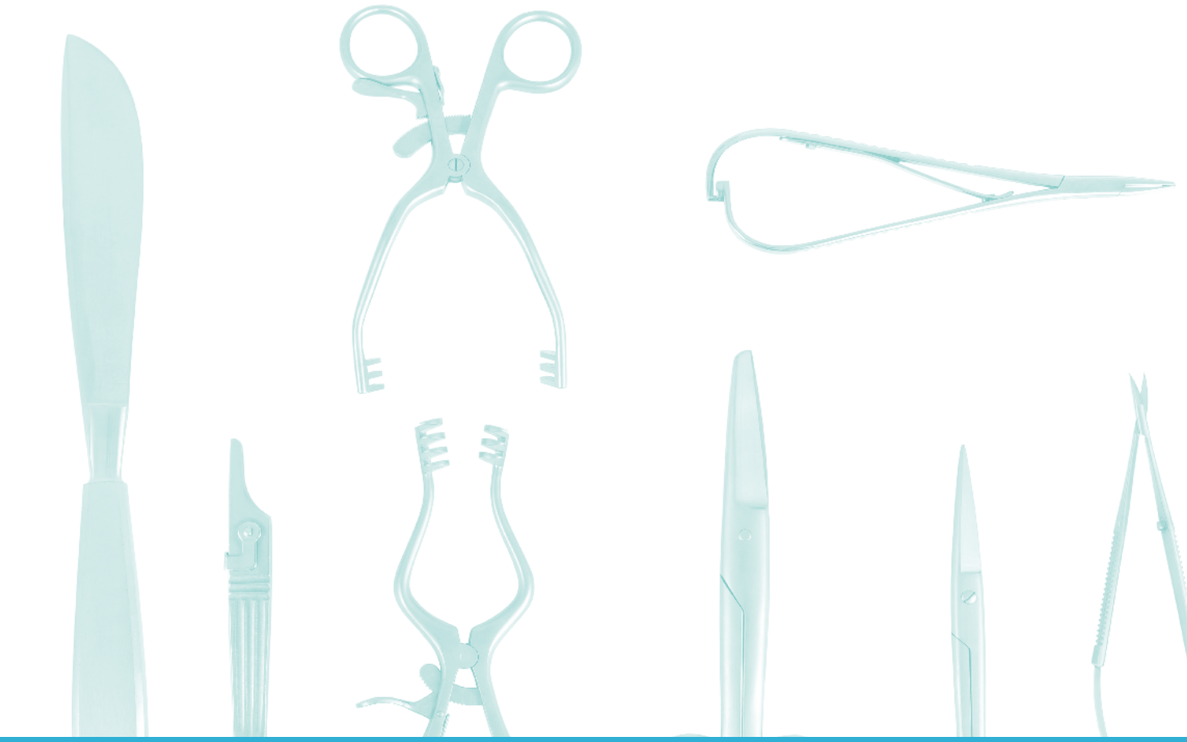

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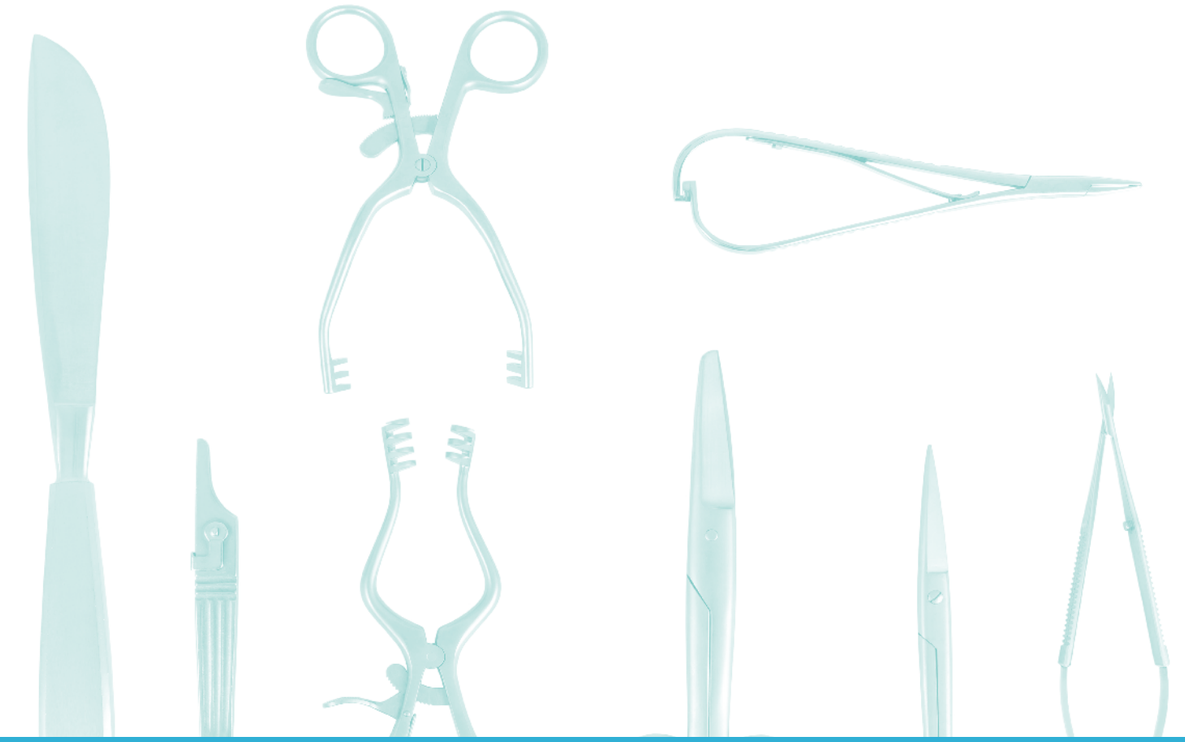
CONSENT:
SUPPORTED
DECISION-MAKING

Royal College of Surgeons
ADVANCING SURGICAL CARE

CONSENT: SUPPORTED DECISION-MAKING

A Guide to Good Practice



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RCS Professional and Clinical Standards
November 2018

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1. Introduction

The Supreme Court case of Montgomery vs Lanarkshire Health Board in 2015 was a landmark decision for the doctor-patient relationship and the process of informed consent. Although guidance by the General Medical Council had consistently supported patient autonomy by stating that doctors should not make assumptions about the information a patient might want or need, until 2015 established clinical practice – as well as a large body of case law – followed a more paternalistic approach. This was reflected in the Bolam principle, which saw the judgement of medical experts (what a responsible body of doctors would do) as the main criterion for assessing reasonable care in negligence cases and for deciding what risks should be communicated to the patient for a chosen treatment. The Montgomery case closed the gap between regulatory guidance and case law by shifting the focus of consent towards the specific needs of the patient. According to the judges in the Montgomery case, doctors must take reasonable steps to ensure that patients are aware of any risks that are material to them, and they should inform their patients of alternative treatments. It should be noted that the Bolam principle still applies in all other aspects of clinical practice apart from consent.

This resolute move away from the more paternalistic traditional model of consent and towards a patient-centred perspective requires a change in attitude from surgeons in discussions about consent, as they are no longer the sole arbiter of determining what risks are material to their patients. Although surgeons are aware that they need to form partnerships with patients to support them in making decisions about their care, the time and workload pressures facing clinical teams pose significant challenges in providing the right level of support to patients throughout the consent process.

ABOUT THIS GUIDE

Gaining the patient's consent and documenting this sufficiently is an issue that often presents difficulties and the recent changes in case law have highlighted even more the need to tailor information to the patient's individual needs. An inadequate consent process can damage the surgeon-patient relationship and also result in legal challenges and litigation.

This guide sets out principles for working with patients through a process of supported decision-making and takes into account key guidance on the subject of consent, including *Good Surgical Practice* (RCS, 2014), *Consent: Patients and Doctors Making Decisions Together* (GMC, 2008), *Reference Guide to Consent for Examination or Treatment* (DH, 2009), *Standards for the Dental Team* (GDC, 2014), *Consent* (Dental Protection, 2015). It aims to offer surgeons and other healthcare professionals practical advice on how to meet the legal and regulatory requirements around the consent process and how to protect a patient's rights to make decisions about their treatment. Throughout this document the term 'surgeon' includes dental surgeons.

KEY PRINCIPLES

The following key principles underpin the consent process as outlined in this document:

- The aim of the discussion about consent is to give the patient the information they need to make a decision about what treatment or procedure (if any) they want.
- The discussion has to be tailored to the individual patient. This requires time to get to know the patient well enough to understand their views and values.
- All reasonable treatment options, along with their implications, should be explained to the patient.
- Material risks for each option should be discussed with the patient. The test of materiality is twofold: *whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would likely attach significance to it.*
- Consent should be written and recorded. If the patient has made a decision, the consent form should be signed at the end of the discussion. The signed form is part of the evidence that the discussion has taken place, but provides no meaningful information about the quality of the discussion.
- In addition to the consent form, a record of the discussion (including contemporaneous documentation of the key points of the discussion, hard copies or web links of any further information provided to the patient, and the patient's decision) should be included in the patient's case notes. This is important even if the patient chooses not to undergo treatment.

The principles set out in this document apply to treatment in an elective situation when the patient has time to consider their options. In an urgent or emergency situation where it is imperative to save life or limb, or prevent serious deterioration, the surgeon will have to proceed with limited discussion or even without consent (see Appendix 1 on acting in the patient's best interests).

An overview of the consent process is outlined in Section 5 of this document.

2. What is valid consent?

Patients have a fundamental legal and ethical right to decide what happens to their bodies. It is therefore essential that patients have given valid consent for all treatments and investigations. For the purpose of this document, consent refers to the right of patients to decide what, if any, clinical care they are to receive and the duty of surgeons to ensure that patients have given their permission prior to any treatment, examination or intervention.

Touching another person without permission is the definition of battery, so the patient's consent is a necessary step prior to starting any treatment. Patients and surgeons should work together in partnership through a process of supported decision-making, with the surgeon providing the information the patient wants and needs to make a decision and ensuring that the patient has understood the details and implications of what is involved.

Consent to treatment must be confirmed in writing. For consent to be valid, it must be:

- Given by a person with the capacity to make the decision in question
- Given voluntarily
- Based on appropriate information (informed) and understood.

If any of these factors are missing, the patient is not considered to have given permission to proceed to treatment.

2.1 CAPACITY FOR CONSENT

It is the surgeon's responsibility as the treating clinician to assess the capacity of their patients to make decisions about their care. In this assessment, surgeons must comply with the Mental Capacity Act 2005 (England or Wales), the Adults with Incapacity Act 2000 (Scotland), or the Mental Capacity Bill 2015 (Northern Ireland), including the Codes of Practice that accompany them as well as relevant regulatory guidance (see Section 6 of this document).

2.2 VOLUNTARY CONSENT

When helping a patient reach a decision about treatment, surgeons must be satisfied to the best of their knowledge that the patient gave or withheld consent to treatment autonomously, without coercion or unwelcome influence from other persons, including family members, friends, employers, insurers, carers or medical staff. Although patients will value in many cases the support of a friend or family member for comfort and help through their decision-making process, it is important to ensure that any decision represents the patient's own views and is not unduly influenced by the wishes of another person. To be voluntary, consent must be continuous throughout each stage of investigation or treatment and it must be understood by the patient as something that can be withheld or withdrawn even during treatment if this is provided under local anaesthetic and the patient is conscious (for example, in dental treatment).

2.3 INFORMED CONSENT

Surgeons must be satisfied that their patient has received and understood sufficient information about their diagnosis – as well as the proposed treatment and its implications – to allow them to make a decision they deem to be in line with their own values and wishes. Different options for treatment, including the option of no treatment, should be presented side by side and the benefits and material risks should be given objectively (for materiality, see Section 4.3 of this document).

3. Principles of supported decision-making

3.1 PRESUMPTION OF CAPACITY

Section 1 (2) of the Mental Capacity Act 2005 states that 'a person must be assumed to have capacity unless it is established that he lacks capacity'.

When undertaking a discussion about treatment with an adult, surgeons must work on the presumption that they are capable of deciding what, if any, examinations, investigations or treatments they are to receive. A patient should be regarded as lacking capacity only where it has been sufficiently demonstrated that, despite having received all the help and support necessary, the patient is still unable to understand, weigh up and use the information they have been given to make an informed decision.

3.2 ASSESSING CAPACITY

For the purposes of consent to treatment, capacity is both time-specific and decision-specific. It refers to the patient's ability to make the specific decision at the particular time at which it is made and for the particular treatment for which it is made. Because of this, the person who assesses capacity is the clinician providing treatment and not a mental health expert.

When assessing a person's capacity to make a decision, the Mental Capacity Act 2005 sets out a two-stage test of capacity, consisting of the following questions:

1. Does the person have an impairment of the mind or brain, or is there some sort of disturbance affecting the way their mind or brain works? (It does not matter whether the impairment or disturbance is temporary or permanent.)
2. If so, does that impairment or disturbance mean that the person is unable to make the decision in question at the time it needs to be made?

In answering the second question of the capacity test, surgeons should consider whether the patient is able to:

- Understand information relevant to the decision
- Retain the information long enough to make a decision
- Use or weigh up that information as part of the decision-making process, and
- Communicate a decision by any means eg sign-language or talking.

The assessment of capacity is task-specific and therefore lack of capacity to make a decision at one time does not indicate lack of capacity to make other decisions or that the patient will not have capacity to make the same or similar decisions at a later time. If the impairment is temporary, consideration should be given as to whether the decision could safely be deferred until the patient has regained capacity.

If your assessment leaves you in doubt as to whether your patient has capacity to give consent you should seek advice from colleagues, those close to the patient, those involved in caring for the patient or others who may be aware of the patient's usual or current ability to make decisions. If this does not remove doubt then you should seek advice from colleagues with relevant specialist experience, such as psychiatrists (in the case of a concern about possible mental health issues). If you are still unsure as to the patient's capacity, you must seek legal advice with a view to asking a court to determine the capacity of the patient.

3.3 TREAT EACH PATIENT AS AN INDIVIDUAL

Patients should be treated as individuals. Surgeons must not assume that a patient lacks capacity to make a decision solely because of their age, disability, appearance, behaviour, medical condition (including mental illness), their beliefs, their apparent inability to communicate, or the fact that they make a decision with which you disagree.

3.4 RESPECT THE PATIENT'S VIEWS AND WISHES

Surgeons should listen to their patient and respect their views about their health. The options for treatment should be discussed in relation to the patient's own wishes and values. Working in partnership with patients requires learning their views and expectations about their treatment and working together to inform patients of the options available for achieving the best outcome for them as individuals.

3.5 NO TREATMENT AS AN OPTION

When discussing options for treatment, these must always be compared with the option of not receiving any treatment. Patients should be given the relevant information to make a decision as to whether they wish to undergo any available treatment or to allow the condition to remain untreated.

3.6 RESPECT THE PATIENTS' DECISIONS

At times patients with mental capacity may make decisions that may have negative implications for their health. Even in cases where patients choose to refuse treatment and this path is potentially dangerous or fatal, surgeons must respect the patient's decision. (An example of this can be seen in the RCS guidance: *Caring for Patients Who Refuse Blood – A Guide to Good Practice*, RCS, 2016).

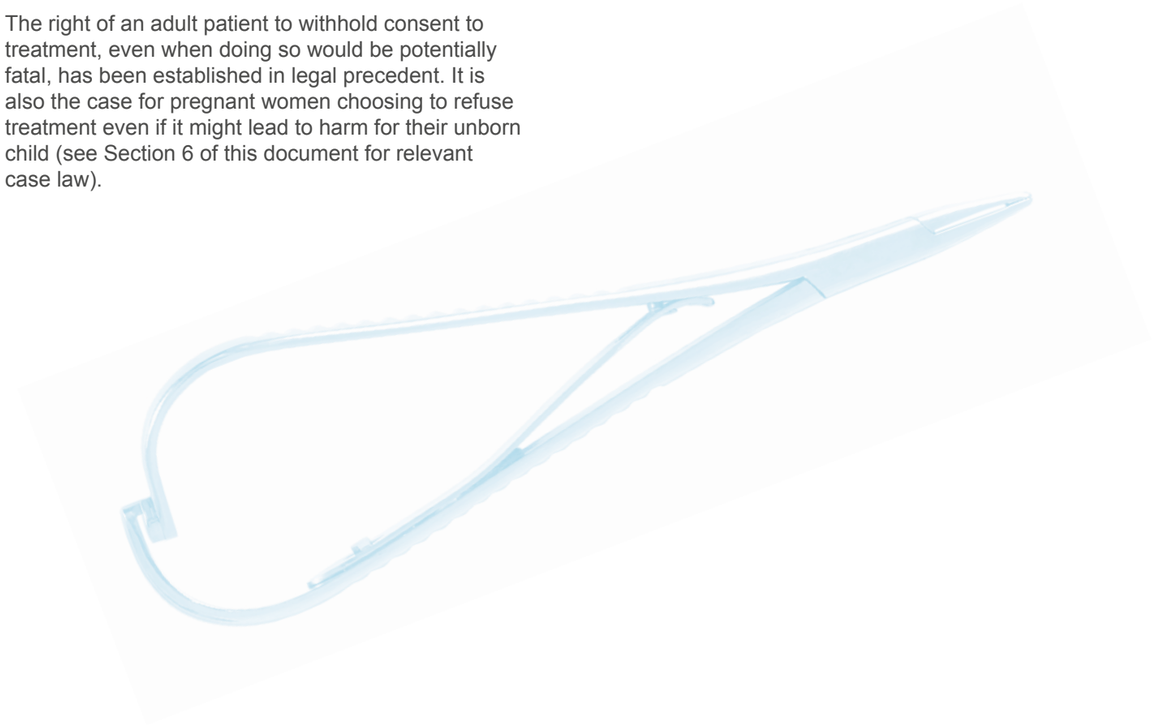
The right of an adult patient to withhold consent to treatment, even when doing so would be potentially fatal, has been established in legal precedent. It is also the case for pregnant women choosing to refuse treatment even if it might lead to harm for their unborn child (see Section 6 of this document for relevant case law).

Surgeons should discuss with the patient the implications of their chosen course of action or inaction, including the risks and benefits associated with that action. However, this should be aimed at helping the patient make an informed decision and should not influence the patient to take a course of action that is not in keeping with their wishes, even if this course of action has been proposed by the multidisciplinary team.

Patients should be made aware of their right to refuse treatment at any time and assumptions must not be made about the patients' awareness of their right to make treatment decisions.

3.7 ACTING IN THE PATIENTS' BEST INTERESTS

Patients in medical emergencies, such as patients who are admitted to hospital unconscious, will require decisions about their care to be made urgently or immediate action to be taken to preserve life or limb. In these cases, it will be inappropriate to delay treatment to try to facilitate the patient's autonomous decisions. Healthcare staff should act in the patient's best interests and attempt to communicate with them to keep them informed wherever possible.



4. The consent discussion

4.1 PROVIDING THE RIGHT INFORMATION

Surgeons must ensure that the patient is provided with the information they need to make an informed decision about treatment. It may be appropriate, in order to facilitate discussion, to send information to the patient in advance.

In practice, this means that surgeons should provide information about:

- The patient's diagnosis and prognosis
- The right of the patient to refuse treatment and make their own decisions about their care
- Alternative options for treatment, including non-operative care and no treatment
- Advice on lifestyle that may moderate the disease process
- The purpose and expected benefit of the treatment
- The nature of the treatment (what it involves)
- The likelihood of success
- The clinicians involved in their treatment
- Potential follow-up treatment
- The material risks inherent in the procedure and in the alternative options discussed (for materiality, see Section 4.3)
- For private patients, costs of treatment and potential future costs in the event of complications.

Surgeons should make patients aware of national guidelines on treatment choices, such as NICE (National Institute for Health and Care Excellence) and SIGN (Scottish Intercollegiate Guidelines Network) guidelines. If your recommended treatment is not in keeping with current guidelines, you must explain your reason for not following current standard guidelines.

You should also ensure that options are presented side by side and that the relative risks and benefits of the different options for treatment are discussed. You should not make assumptions regarding the wishes of a patient and what they might perceive as the best option available. You should not assume that the patient has the same set of values, wishes or life priorities as you would have in a similar situation.

When advising patients which treatment will, in your medical opinion, be the most conducive to the good health of the patient, it is important that the advice given is impartial and factual. Surgeons must not allow their personal views and preferences to have an impact on the description or emphasis given for each of the options. It may be that, once the options are presented, the patient will ask the surgeon for their view – it is reasonable to give a view so long as it does not push the patient into a decision that would not have been their choice.

4.2 THE THERAPEUTIC EXCEPTION

The traditional concept of the therapeutic exception (sometimes referred to as therapeutic privilege) describes the situation in which a doctor may claim exemption from the duty to provide certain information to a patient if the doctor deems that this might cause the patient psychological harm to a degree which outweighs the benefits of informing them.

The possibility of this exception presents significant legal difficulties for doctors. The Supreme Court in the Montgomery case made clear that the therapeutic exception should only be used in rare cases. Litigation is a likely consequence of the use of the therapeutic exception and surgeons should ensure that, if they use it at all, their reasons should be documented at the time. Where contentious issues are involved, legal advice should be sought.

4.3 WHAT CONSTITUTES MATERIAL RISK

The Supreme Court has repositioned the focus of the legal requirements regarding what information should be provided to patients prior to making a decision about their care.

Formerly, the decision of whether or not information regarding the risks of any given treatment was significant, and as such whether it should be disclosed to the patient, was based on the Bolam test (derived from the Bolam v Friern Hospital Management Committee [1957] 1 WLR 582). The Bolam test is whether the person seeking consent 'has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art'. This placed the opinion of medical practitioners at the centre of any judgement about breach of duty. This approach was challenged in subsequent cases but the Montgomery case was the first ruling to find decisively against the Bolam principle and shift the focus to a more patient-centred approach. The judges in the Montgomery case held that there was a duty for a doctor to warn a patient of a **material risk** inherent in the treatment and discuss this with them. What constitutes a material risk will vary from patient to patient. Therefore consent has to be patient-specific. The new test for materiality is 'whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would likely attach significance to it'. The judges pointed out that 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.

4.4 WRITTEN AND MULTIMEDIA INFORMATION

Where possible, written information describing the diagnosis and available treatment options should be provided to patients. Information may be in the form of booklets or information sheets but surgeons can also direct patients to relevant websites or available literature. Whenever written information is given to the patient, a copy of that information should be included in the patient's notes along with the consent form.

However, the provision of written information is not in itself sufficient to ensure that the patient is able to make an informed decision. For example, the use of a preprinted proforma outlining risks of a specific procedure is not sufficient, as it is not tailored to the particular patient. The treating surgeon must be satisfied that the patient has understood the information received and can use it to make a decision.

4.5 COMMUNICATION

Surgeons and other members of the healthcare team must ensure that any information is suitable for the individual patient and takes into account any issues that may impair effective communication, such as patients' eyesight or hearing, English-language ability and literacy levels.

4.6 WHO SHOULD HAVE THE DISCUSSION WITH THE PATIENT?

The Montgomery case has changed the focus of the consent process from one in which the surgeon would explain the procedure to the patient and obtain their consent to proceed, to one in which the surgeon sets out the treatment options and allows the patient to decide. This change requires the surgeon to take time to explore the patient's values and wishes about their care and to have sufficient experience to fully understand the risks and benefits that are material to the patient. It follows therefore that the discussion about options lies with the surgeon responsible for the patient's care or, if this is not practical, with an experienced member of the surgical team who has the time and skill to gain sufficient understanding of the patient's views and wishes. **The surgeon discussing treatment with the patient should be suitably trained and qualified to provide the treatment in question and have sufficient knowledge of the associated risks and complications, as well as any alternative treatments available for the patient's condition.** The surgeon responsible for providing treatment remains responsible for making sure that the patient has been given enough time and appropriate information to make an informed decision and has given their consent before they start the treatment.

Trainers will need to give particular consideration to how trainees can acquire the skills needed to comply with the new standards set out in this guidance and in law.

This discussion with the patient is the key to the consent process. As the signed consent form is part of the evidence to confirm that an appropriate discussion has taken place, it follows that the same surgeon who has had the discussion about consent should also complete and sign the consent form at the end of that discussion (provided that the patient has made a decision to go ahead with the treatment). The patient can then be given a copy of the form to take away.

For minor investigative procedures (eg arthroscopy, gastroscopy, colonoscopy, cystoscopy) as opposed to treatment, it is reasonable for staff who have had specific training to carry out the consent discussion with the patient.

4.7 REFERRALS BETWEEN SPECIALTIES

There is a particular risk with patients being transferred between specialties. Patients can come to harm when there is lack of clarity about which doctor is responsible for the management of the patient. When a surgeon refers a patient for another procedure (eg interventional radiological procedure), it is the referring doctor who should formally hold the first part of the consent discussion and document it, as they understand the risks and benefits of the proposed options and any alternatives (including doing nothing) and can discuss these with the patient. The final confirmation of informed consent remains the responsibility of the doctor who will carry out the procedure.

4.8 TIMEFRAME FOR CONSENT DISCUSSIONS AND THE SIGNING OF THE CONSENT FORM

Consent must always be given and the patient's decision documented prior to any procedure, once the patient has made a decision to go ahead with the procedure. The consent discussion may vary in duration, depending on a range of factors including:

- The complexity or severity of the patient's condition
- The complexity, risks and range of treatment options and their likelihood of success
- The patient's level of understanding.

Patients should be given enough time to make an informed decision regarding their treatment, wherever this is possible and not adverse to their health. This may require that the discussion takes place over more than one session for particularly complex or life changing decisions. The process of consent should begin well in advance of the treatment, and the amount of time required for each individual stage of the process may vary significantly based on the complexity of the procedure.

As outlined above and set out in *Good Surgical Practice* (RCS, 2014), the consent form should be signed at the end of the discussion, provided the patient has reached the decision to go ahead with a treatment. This will allow the patient to take away a copy of the form alongside all relevant information, for reference and reflection. For an elective procedure they should also receive a letter or a copy of the letter to the GP/the referring doctor that gives an account of the discussion that has taken place. At the time of admission, the surgeon should check with the patient if anything has changed since the consent discussion. If there has been a significant delay since the original signing, the relevant section on the form should be signed by the doctor to confirm consent. The patient does not need to sign again.

If the patient cannot decide which option to pursue, then the discussion should resume at a later time.

4.9 LIMITS TO CONSENT VALIDITY

There is no time limit to the validity of a patient's consent. Consent will cease to be valid only when, in the intervening period between the consent discussion and the procedure, circumstances have changed in a way that has significantly altered the patient's condition, the material risks or any other aspect of the treatment.

4.10 A DECISION-MAKING RECORD

The signing of a consent form by a patient does not amount to valid consent for treatment and is not sufficient evidence for it in a court of law. The signed form is only confirmation that a process has been followed whereby the patient has agreed to proceed to the next stage of treatment. However, the patient's consent will be invalid if they have not been given the appropriate information, communicated in a way that they can understand well enough to make a decision.

In addition to completing the consent form, surgeons should maintain a written decision-making record that contains a contemporaneous documentation of the key points of the consent discussion (see Section 4.1 for the information that needs to be provided) – and the patient's decision, even if the patient decided not to undergo a procedure or have any treatment. This could be in the form of a letter to the patient and their GP/referring doctor. The record should also contain documentation of any discussion around consent with the patient's supporters and with colleagues. Any written information given to the patient should also be recorded and copies should be included in the patient's notes.

4.11 TIME PRESSURES AND CONSENT DISCUSSIONS

The reality facing surgeons in current practice is that time pressures can leave little opportunity to discuss at length the diagnoses or available treatment options. However, this does not change the fundamental legal requirement that surgeons and doctors allocate sufficient time for a discussion that will allow them to understand the individual patient and their needs. According to the judges in the Montgomery case, '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'.

Complying with the standards set out by the Supreme Court may well involve setting aside more time for the discussion about consent to treatment and surgeons may have to discuss this with their Medical Director.

With a robust and well-defined consent process, and by using patient decision aids, checklists and information leaflets provided in advance of the consultation, the time available can be optimised to ensure that patients are empowered with the information they need to make a decision and take responsibility for their care.

5. Overview of the consent process

Step	Task	Comments
1	Explain the diagnosis to the patient.	Ensure that the information is given in a format that the patient can understand. Explain the prognosis if untreated.
2	Explain the options for treatment.	Explain the risks and benefits of various treatment options side by side and ensure that not having any treatment is included amongst the options. Describe the likelihood of success of the various options and the impact that treatments will have on the patient's life.
3	Explain the consent and decision-making process so the patient understands what is expected of them.	Ensure that the patient understands that they are expected to make a supported decision, and their rights within this process. Do not assume that the patient will be familiar with the concept of supported decision-making and check whether they have a supporter.
4	Time for deliberation and homework for the patient.	Where relevant, surgeons should allow sufficient time for patients to deliberate on available options and to consider their goals and wishes in terms of their treatment. This may include reading further information or accessing online resources to provide them with more information on their condition and treatment options.
5	Discuss the patient's wishes, needs, views and expectations regarding any treatment they might undertake.	It is important not to make assumptions regarding what a 'good' outcome from treatment would look like for the patient. Different patients will have different life priorities and different views regarding what the best available outcome might be or what risks are acceptable to them. Sufficient time is given to ensure that the patient's views are understood and respected.
6	Discuss trade-offs with the patient in light of their needs, goals and expectations.	Explain how different options will or will not achieve their goals and any potential impact that the options will have.

7	Provide any relevant information not already covered, or any emerging information that may have altered the conditions surrounding the various options for treatment.	Is there any further information that would have a bearing on the decision that the patient is being asked to make that has not already been discussed and/or understood by the patient? If so, ensure that these factors are explained and if necessary go back to an earlier stage in the process and repeat in light of the new knowledge. This is of particular importance in cases where the process has spanned a period of time where changes may have occurred in the patient's condition or around the risks and benefits of any of the treatment options available.
8	Has the patient understood?	Prior to any decision it is imperative that the person seeking consent is satisfied that the patient has understood the information that they have been given and that any decision they make will be made independently and from an informed position.
9	Respect the patient's decision.	You must always respect the decision made by an adult patient with capacity.
10	The signing of the form and maintaining a decision-making record.	The consent form as part of the decision-making record should be signed at the end of the discussion, provided the patient has made a decision. The patient should be given a copy of the form to review and retain. Details about the discussion with the patient and copies of any information given to the patient should be included in the patient's notes.

The following process aims to optimise the time available for providing the required information and discussing options for treatment to facilitate patient decision. This process is aimed at adult patients with capacity.

6. Resources and further reading

Treatment should only be given once valid consent has been obtained. Prior to undertaking any intervention, the person providing the treatment should be satisfied that the consent obtained for the procedure is still valid.

REGULATION AND GUIDANCE

General Medical Council

- Good Medical Practice. GMC, 2013
- Consent: Patients and Doctors Making Decisions Together. GMC, 2008
- Confidentiality. GMC, 2009

General Dental Council (UK)

- Standards for the Dental Team. GDC, 2014

Royal College of Surgeons of England

- Good Surgical Practice. RCS, 2014
- Caring for Patients Who Refuse Blood – A Guide to Good Practice. RCS, 2016
- Professional Standards for Cosmetic Surgery. RCS, 2016

Royal College of Radiologists

- Standards for Patient Consent Particular to Radiology. RCR, 2016

Department of Health

- Reference Guide to Consent for Examination or Treatment, 2nd ed. Department of Health, 2009

LEGISLATION

The Mental Capacity Act 2005 (England and Wales)

The Mental Capacity Act 2005 provides the conditions under which people can be deemed to lack the capacity to make decisions regarding their healthcare and covers England and Wales. It provides a framework within which healthcare can be provided for those people who lack capacity without their being able to provide valid consent for the treatment.

The Act stipulates that all adults (persons over the age of 16) have the right to make decisions for themselves unless they can be shown to lack the capacity to make a decision for themselves at the time the decision needs to be made. The Act further states that people must be provided with all reasonable help and support to enable them to make decisions for themselves or, where this is not possible, to maximise their participation in any decision-making process.

The Act aims to balance the patient's right to autonomy in deciding which, if any, treatments they are to receive with the right to protection from harm for those patients who lack the capacity to make decisions for themselves. It states that any decision made on behalf of someone who lacks capacity must be made in their best interests and should, where it does not negate their best interests, minimise any infringement of their basic rights and freedoms.

Adults with Incapacity Act 2000 (Scotland)

This act covers decisions for treatment regarding people over the age of 16 who do not have the capacity to make some or all of the decisions about their treatment owing to mental disorder or communication difficulties. Incapacity means being incapable of acting on, making, communicating, understanding, or remembering decisions by reason of mental disorder or inability to communicate due to physical disorder.

According to this Act, any intervention must be:

- Necessary and benefit the person
- The minimum required to achieve the purpose
- Those making decisions must:
  - Take into account the person's present and past wishes and feelings, and must try every possible means of communicating with the person to find out what these are
  - Take into account the views of the person's nearest relative and primary carer, and of any other person with powers to intervene in the person's affairs or personal welfare, or with an interest in the person, so far as it is reasonable and practical to do so
  - Encourage the person to use any skills they have to make decisions
  - Consider whether it would be possible to intervene without using the Act.

The Act is supported by Codes of Practice setting out guidance for those acting under the legislation, including doctors and other healthcare professionals who are treating adults with incapacity. Part 5 of the Code of Practice covers decisions about medical treatment and research.

Mental Capacity Bill: Deprivation of Liberty Safeguards 2015 (Northern Ireland)

In Northern Ireland, a new Mental Capacity Bill: Deprivation of Liberty Safeguards was introduced in 2015. It aims to protect people who lack mental capacity to consent to care or treatment and who need limits placed on their liberty to keep them safe.

Human Rights Act 1998

The Human Rights Act 1998 incorporates the rights set out in the European Convention on Human Rights (ECHR) into domestic British law. National legislation must be read and given effect in a way that is compatible with the ECHR. In addition, all public bodies must ensure that everything they do is compatible with the convention unless an Act of Parliament makes that impossible.

These articles may seem a bit distant from clinical practice, but a dispute about consent to investigation or treatment, or the right to withhold or withdraw consent, might involve consideration of a number of these rights.

The Convention Articles most relevant to decisions about medical and dental investigations and treatment are:

Article 2 (the right to life)

Article 3 (the right to be free from inhuman or degrading treatment)

Article 5 (the right to liberty and security)

Article 8 (the right to respect for privacy and family life)

Article 9 (the right to freedom of thought, conscience and religion)

Article 10 (the right to freedom of expression, which includes the right to hold opinions and to receive information)

Article 14 (the right to be free from discriminatory practice in respect of these rights).

COMMON LAW

Montgomery (Appellant) v Lanarkshire Health Board (Respondent) [2015] UKSC 11

On appeal from [2013] CSIH 3 Since Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] A.C 871.

The case of Montgomery clarifies the correct test to material risk in the consent process and repositions the focus of legal requirements regarding what information should be provided to patients prior to their making of a decision regarding healthcare.

The case was brought as the claimant, Mrs Montgomery, a type 1 diabetic, was not told of her increased risk of shoulder dystocia during vaginal delivery because, in the doctor's opinion, the possibility of it causing a serious problem for the baby was very small and advising of the risk would lead to most women electing for a Caesarean section. During delivery the umbilical cord was occluded, depriving the baby of oxygen and resulting in a subsequent diagnosis of dyskinetic cerebral palsy. The claimant argued that had she been told of the risk of shoulder dystocia she would have elected for a Caesarean section.

The Supreme Court held that there was a duty for a doctor to warn a patient of a material risk inherent in the treatment and that there was a duty for the doctor to discuss this with the patient. The test for materiality was whether a reasonable person in the position of this particular patient would think the risk significant. In the claimant's case it was found that the risk of shoulder dystocia was substantial and should have been disclosed, as had the risk been discussed the claimant would have elected to have a Caesarean.

Chester v Afshar [2004] UKHL 41 – The duty to warn patients about risk

Ms Carole Chester was left partially paralysed after surgery for lumbar disc protrusion. The Court held that Mr Afshar had failed to warn Ms Chester that this was a foreseeable (1–2%) but unavoidable risk of the surgery. The House of Lords concluded that, although the failure to warn was not a direct cause of injury, it did result in negligence.

Patients should be told of any possible significant adverse outcomes of a proposed treatment.

In this case, a small but well-established risk of a serious adverse outcome was considered by the House of Lords to be 'significant'.

Rogers v Whitaker (1992) 175 CLR 479 HC (Aus)

This was an Australian ophthalmology case in which the patient developed sympathetic ophthalmitis (after the other eye was removed). The risk was estimated at 1 in 14,000. The patient was not informed. The court held that 'a risk is material if: a reasonable person… if warned of the risk would be likely to attach significance to it'.

Re C (Adult, refusal of treatment) [1994] 1 All ER 819 – Refusal of treatment by a competent adult

This case asserts the principle that mental illness does not automatically call a patient's capacity into question.

C had paranoid schizophrenia and was detained in Broadmoor secure hospital. He developed gangrene in his leg but refused to agree to an amputation, which doctors considered was necessary to save his life. The court upheld C's decision.

The fact that a person has a mental illness does not automatically mean they lack capacity to make a decision about medical treatment for a physical condition. Patients who have capacity (that is, who can understand, believe, retain and weigh the necessary information) can make their own decisions to refuse treatment, even if those decisions appear irrational to the doctor or may place the patient's health or their life at risk.

Re MB (Adult, medical treatment) [1997] 38 BMLR 175 CA – Capacity to refuse treatment

MB needed a Caesarean section, but panicked and withdrew consent at the last moment because of her needle phobia. The hospital obtained a judicial declaration that it would be lawful to carry out the procedure, which was a decision that MB appealed. However, she subsequently agreed to induction of anaesthesia and her baby was born by Caesarean section.

The Court of Appeal upheld the judge's view that MB had not, at the time, been competent to refuse treatment, taking the view that her fear and panic had impaired her capacity to take in the information she was given about her condition and the proposed treatment. In assessing the case the judges reaffirmed the test of capacity set out in the Re C judgement.

An individual's capacity to make particular decisions may fluctuate or be temporarily affected by factors such as pain, fear, confusion or the effects of medication – therefore, assessment of capacity must be time and decision-specific.

Re B (Adult, refusal of medical treatment) [2002] 2 All ER 449 – Right of a patient who has capacity to refuse life-prolonging treatment

B was a 43-year-old woman who had become tetraplegic and who no longer wished to be kept alive by means of artificial ventilation. She asked for ventilation to be withdrawn but the doctors caring for her were unwilling to agree to this. B, whose mental capacity was unimpaired by her illness, sought and obtained a declaration from the court that the hospital was acting unlawfully.

This case asserts the principle that a competent patient has the right to refuse treatment and their refusal must be respected, even if it will result in their death.

St George's Healthcare NHS Trust v S; R v Collins and others, ex parte S [1998] 3 All ER 673 – The right of a competent pregnant woman to refuse treatment even if that refusal may result in harm to her or her unborn child

S was diagnosed with pre-eclampsia requiring admission to hospital and induction of labour, but refused treatment. Although competent, S was detained for assessment under the Mental Health Act. A judge made a declaration overriding the need for her consent to treatment, and her baby was delivered by Caesarean section.

The Court of Appeal held that S's right to autonomy had been violated, her detention had been unlawful and that the judicial authority for the Caesarean had been based on false and incomplete information. A competent pregnant woman can refuse treatment even if that refusal may result in harm to her or her unborn child. Patients cannot lawfully be detained and treated for a physical condition without their will, under the terms of the Mental Health Act. (Application of the Mental Health Act 1983).

Re T (Adult) [1992] 4 All ER 649 – The effect of coercion/pressure on patient consent

A 20-year-old pregnant woman was injured and developed complications that required blood transfusions. She did not indicate on admission that she was opposed to receiving transfusions but after spending some time with her mother, who was a practising Jehovah's Witness, she decided to refuse the treatment.

The Court of Appeal considered that she had been pressurised by her mother and that her ability to decide about the transfusions was further impaired by her treatment. The court allowed the blood transfusions to proceed.

This case asserts the principle that a patient's consent to a particular treatment may not be valid if it is given under pressure or duress exerted by another person.

Mr Leslie Burke v GMC [2005] EWCA Civ 1003 – Requests for treatment

For the purposes of this guidance, the key point of this case is that doctors are under no legal or ethical obligation to agree to a patient's request for treatment if they consider the treatment is not in the patient's best interests.

Gillick v West Norfolk and Wisbech AHA [1986] AC 112 – Children and young people's competence to consent to treatment

Mrs Gillick challenged the lawfulness of Department of Health guidance that doctors could provide contraceptive advice and treatment to girls under the age of 16 without parental consent or knowledge in some circumstances.

The House of Lords held that a doctor could give contraceptive advice and treatment to a young person under the age of 16 if:

- She had sufficient maturity and intelligence to understand the nature and implications of the proposed treatment
- She could not be persuaded to tell her parents or to allow her doctor to tell them
- She was very likely to begin or continue having sexual intercourse with or without contraceptive treatment
- Her physical or mental health were likely to suffer unless she received the advice or treatment
- The advice or treatment was in the young person's best interests.

This case was specifically about contraceptive advice and treatment, but the subsequent case of **Axon, R (on the application of) v Secretary of State for Health [2006] EWHC 37 (Admin)** makes clear that the principles apply to decisions about treatment and care for sexually transmitted infections and abortion, too. As a result of this decision, a young person under 16 with capacity to make any relevant decision is often referred to as being 'Gillick competent'.

Appendix I –
MENTAL CAPACITY ACT 2005

THE FIVE STATUTORY PRINCIPLES

The Mental Capacity Act 2005 sets out five statutory principles on which the legal requirements are based. The five statutory principles are:

1. A person must be assumed to have capacity unless it is established that they lack capacity.
2. A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success.
3. A person is not to be treated as unable to make a decision merely because he makes an unwise decision.
4. An act done or decision made for or on behalf of a person who lacks capacity must be done, or made, in his best interests.
5. Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action.

WHAT DOES 'LACKS CAPACITY' MEAN?

Section 2(1) of the Mental Capacity Act states: 'For the purposes of this Act, a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.'

The impairment or disturbance of the functioning of the mind described in Section 2(1) refers to any disturbance that affects the person's ability to make the specific decision in question at the specific time it needs to be made. This impairment does not need to be permanent and may only be partial.

That a person has been judged to lack capacity in relation to a previous decision regarding their care does not entail that they lack capacity to make decisions in all situations. The patient should be assessed as to their capacity to make decisions on a case-by-case basis. Capacity to make a decision can vary with the nature of the decision and can change over time.

LIMITED CAPACITY

A patient's capacity to make decisions regarding their treatment may fluctuate owing to the conditions of their health or other factors and so it is important to ensure that wherever possible a patient is able to offer as much input to the discussions as is within their capability and wishes. Patients should be supported to maximise their ability to make decisions for themselves.

All reasonable efforts to plan for changes in a patient's capacity to make decisions should be made to ensure that discussions about treatment are made at times and in situations where the patient is able to make decisions themselves or, where this is not possible, to maximally contribute to the decision process.

WHAT IS MEANT BY ‘BEST INTERESTS’?

Understanding what constitutes acting in the best interests of a patient who lacks capacity can present challenges for healthcare workers and disagreements regarding what the person’s best interests are.

Section 5 of the Mental Capacity Act 2005 states that:

‘An act done or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his best interests.

And that, as long as these acts or decisions are in the best interests of the person who lacks capacity to make the decision for themselves, or to consent to acts concerned with their care or treatment, then the decision-maker or carer will be protected from liability.’

When trying to work out the best interests of a person who lacks capacity to make a particular decision, you should:

- Encourage patients take part in the decision-making process and take all reasonable steps to improve their ability to be involved in making the decision.
- Identify, as far as possible, all factors that patients lacking capacity would consider, were they to decide for themselves.
- Make all reasonable efforts to establish the patient’s views, including past wishes, beliefs, behaviour, decisions and values (eg religious, moral, political, cultural or personal) and any other relevant factors that may have a bearing on their best interests. Reasonable efforts include talking to family members and, where appropriate, seeking the support of an individual mental capacity advocate.
- Avoid making assumptions on a person’s interests based solely on factors such as age, race, gender, condition or other.
- Decide whether the person may regain capacity at a later time and, if so, whether the decision can be safely delayed until this is possible.
- Never be motivated in any way by a desire to bring about the person without capacity’s death in decisions concerning life-sustaining treatment.

Where possible and appropriate, consult other people to establish their views regarding what the person lacking capacity’s best interests would be.

When consulting with others to establish the best interests of a person without capacity to make decisions, it is important to consider that the person has a right to privacy and that it is not appropriate to share all information with everyone.

Appendix II –
SPECIFIC CONSIDERATIONS

COSMETIC SURGERY

In the case of cosmetic surgery, follow the requirements for consent set out in the *Professional Standards for Cosmetic Surgery* (RCS, 2016). For invasive cosmetic procedures, the consent requirements include a two-stage process of consent with a period of at least two weeks between the stages to allow the patient to reflect on the decision. You must be able to identify the psychologically vulnerable patient and ensure that there is rapid and easy access to mental health services for help with the assessment and management of problem cases.

CHILDREN AND YOUNG PEOPLE

Good Surgical Practice states that surgeons should involve young people and children in discussions and decisions around their care as outlined in the GMC guidance *0–18 Years: Guidance for All Doctors* (GMC, 2007). According to the GMC, young people are presumed to have capacity to give consent at 16 years of age. You should assess the capacity of children under 16 years to give consent on a case by case basis, depending on their maturity and capacity to understand the different courses of action involved in their treatment.

Not all children progress in the level of their capacity to consent to treatment at the same, or even similar, pace. This presents difficulties for healthcare staff in understanding consent for treatment of a person under 16. The following guidance provides principles to guide consent discussions when working with children and young people.

ASSESSING CAPACITY OF YOUNG PEOPLE, UNDER 16 YEARS, TO CONSENT

The capacity of young persons under 16 years to consent to treatment or investigations depends on their ability to understand retain and deliberate on information regarding the options available to them rather than their age (see case of Gillick in Section 6 of this document).

Surgeons must assess their maturity and understanding on an individual basis and with respect to the complexity and severity of the consequences relating to the decision in question. You must decide whether the patient is capable of weighing up the different risks and consequences of any options for treatment alongside the impact of not having any treatment.

a. **Children and young people who have capacity to consent**

   If a child has the capacity to consent to a treatment you should usually abide by their decision.

   You should encourage young people to involve their parents or guardians in making important decisions; however, if they do not wish to involve them you should respect their decision.

b. **Children and young people who lack capacity to consent**

   If a child (person under 16 years) lacks capacity to consent, you should ask for their parents or guardians’ decision. In most cases it is sufficient to have the consent of one parent or guardian.

c. **The legal framework for the treatment of 16- and 17-year-olds who lack the capacity to consent**

   The legal framework for the treatment of 16- and 17-year-olds who lack the capacity to consent differs across the UK.

In England and Wales, parents can consent to investigations and treatment that are in the young person’s best interests. Young people (under the age of 18) cannot refuse to undergo treatment that their parents and doctor think it is in their best interests.

In Northern Ireland, the Northern Ireland Assembly has introduced its own Mental Capacity Bill in 2015. Treatment can be provided in the young person’s best interests, although legal advice should be sought to applying for court approval for significant (other than emergency) interventions.

In Scotland, 16- and 17-year-olds are assumed to have capacity and any lack of capacity is assessed according to the process for adults who lack capacity. Treatment may be given in their best interests to safeguard or promote their health.

FRAIL ELDERLY PATIENTS

All adults with capacity have the right to decide which, if any, treatment available they receive. The age of an adult patient should at no time be taken as indicative of a patient's capacity. Physical frailty is not indicative of a patient's lack of mental capacity.

When seeking consent for treatment from a frail and elderly adult patient with capacity, you must pay particular attention that:

- Consent is given by the patient for any treatment prior to it taking place. The discussion about treatment should take place in an appropriate environment, at a suitable time of the day for them and with appropriate support.
- The patient's decisions about treatment are not unduly influenced by other people, and are given freely and without coercion from others.
- The patient is given enough information, in a format which they are able to understand, to make an informed decision as to which if any treatments they receive. It important to be aware of any hearing or vision impairment that may hamper understanding of the information given.

PHYSICAL EXAMINATION

Before undertaking a physical examination of a patient consent must be given. Any physical examination without the patient's consent constitutes assault. The extent to which this must be documented is commensurate to the degree of risk, discomfort, complication or side effect that the examination will encompass.

When undertaking a physical examination that does not present any significant risk, it is typically sufficient to obtain verbal consent.

a. Intimate examination

What constitutes an intimate examination will vary according to the views and beliefs of the patient. This will in most cases include any examination of the breasts, rectum and genitalia; however, it may extend to any examination where it is necessary to remove items of clothing, touch or even be in close proximity to the patient.

Cases where an intimate examination of a patient is required can be embarrassing or distressing to patients and every reasonable attempt to maintain a patient's dignity, where this does not impinge on their healthcare or safety, should be made.

Before conducting an intimate examination, you must:

- Explain what you are going to do and why it is necessary.
- Explain what the examination will involve and any pain or discomfort they may feel.
- Get consent from the patient prior to commencing the examination and record that the patient has given it.
- Offer the patient the option of having an impartial chaperone present – this applies regardless of whether the patient is the same gender as you (if the patient declines you should consider carefully whether to proceed).
- Allow the patient to privacy to dress and undress.

Do not attempt to assist the patient to remove their clothes unless requested to do so, or you have asked if they would like you to assist and been given permission. While conducting an intimate examination you should:

- Stop the examination if asked to by the patient.
- Keep the patient covered as much as possible to maintain their dignity.
- Keep discussions relevant and do not make unnecessary personal comments.
- Conduct yourself in a professional manner at all times and take all reasonable measures to show respect for the dignity of the patient.

b. Intimate examinations of anaesthetised patients

Before you carry out an intimate examination on an anaesthetised patient, or supervise a student who intends to carry one out, you must make sure that the patient has given consent in advance, usually in writing.