Mandatory Training Workbook 2015

Consent

Medical Staff

Checklist

- ***Read through this section of the workbook.***
- ***Complete the on-line assessment on*** My PACT
- ***If further information is required please contact Dr Nick Palmer***

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Seeking consent is also a matter of common courtesy between health professionals and patients.

What consent is – and isn't

The context of consent can take many different forms, ranging from active request by a patient for a particular treatment (which may or may not be appropriate or available) to the passive acceptance of a health professional advice.

"Consent" is a patient's agreement for a health professional to provide care. Patients may indicate consent non-verbally (for example by presenting their arm for their pulse to be taken), orally, or in writing. For the consent to be valid, the patient must:

• be competent to take the particular decision.
• have received sufficient information to take it.
• not be acting under duress.

In some cases, the health professional will suggest a particular form of treatment or investigation and after discussion the patient may agree to accept it. In others, there may be a number of ways of treating a condition, and the health professional will help the patient to decide between them. Some patients, especially those with chronic conditions, become very well informed about their illness and may actively request particular treatments. In many cases, seeking consent is better described as 'joint decision-making',

the patient and health professional need to come to an agreement on the best way forward, based on the patient's values and preferences and the health professional's clinical knowledge.

Where an adult patient lacks the mental capacity (either temporarily or permanently) to give or withhold consent for themselves**, no one else can give consent on their behalf.** However, treatment may be given if it is in their best interests, as long as it has not been refused in advance in a valid and applicable advance directive.

Stages for Obtaining Consent

When a patient formally gives their consent to a particular intervention, this is only the *endpoint* of the consent process. It is helpful to see the whole process of information provision, discussion and decision-making as part of seeking consent. This process may take place at one time, or over a series of meetings and discussions, depending on the seriousness of what is proposed and the urgency of the patient's condition.

Single stage process

In many cases, it will be appropriate for a health professional to initiate a procedure immediately after discussing it with the patient. For example, during an on-going episode of care a physiotherapist may suggest a particular manipulative technique and explain how it might help the patient's condition and whether there are any significant risks. If the patient is willing for the technique to be used, they will then give their consent and the procedure can go ahead immediately. In many such cases, consent will be given *orally*.
If a proposed procedure carries significant risks, it will be appropriate to seek written consent, and health professionals must take into consideration whether the patient has had sufficient chance to absorb the information necessary for them to make their decision. As long as it is clear that the patient understands and consents, the health professional may then proceed.

Two or more stage process

In most cases where *written* consent is being sought, treatment options will generally be discussed well in advance of the actual procedure being carried out. This may be on just one occasion (either within primary care or in a hospital out-patient clinic), or it might be over a whole series of consultations with a number of different health professionals. The consent process will therefore have at least two stages: the first being the provision of information, discussion of options and initial (oral) decision, and the second being confirmation that the patient still wants to go ahead. The consent form should be used as a means of documenting the information stage(s), as well as the confirmation stage.
Patients receiving elective treatment or investigations for which written consent is appropriate should be familiar with the contents of their consent form before they arrive for the actual procedure, and should have received a

copy of the page documenting the decision-making process. They may be invited to sign the form, confirming that they wish treatment to go ahead, at any appropriate point before the procedure: in out-patients, at a pre-admission clinic, or when they arrive for treatment. If a form is signed before patients arrive for treatment, however, a member of the healthcare team **must** check with the patient at this point whether they have any further concerns and whether their condition has changed. This is particularly important where there has been a significant lapse of time between the form being signed and the procedure. When confirming the patient's consent and understanding, it is advisable to use a form of words which requires more than a yes/no answer from the patient: for example beginning with "tell me what you're expecting to happen", rather than "is everything all right?"

While administrative arrangements will vary, it should always be remembered that for consent to be valid, the patient must feel that it would have been possible for them to refuse, or change their mind. It will rarely be appropriate to ask a patient to sign a consent form after they have begun to be prepared for treatment (for example, by changing into a hospital gown), unless this is unavoidable because of the urgency of the patient's condition.

Process for obtaining consent

- At the time of Consultation with Consultant/SpR the patient will be provided with information pertaining to diagnosis, natural history of condition and treatment options including no treatment, as well as potential benefits and risks relating to the procedure.

- At this Consultation, the patient will receive all information regarding pre procedure, post procedure recovery and discharge.

- The SpR/Nurse Practitioner understands that if further information is required by the patient in order for them to make informed consent, and the SpR/Nurse Practitioner is unable to provide this information, they will contact the patients Consultant, and that until this is done, informed consent has not been given.

Process for recording Consent

The standard consent form provides space for a health professional to provide information to patients and to sign confirming that they have done so. The health professional providing the information must be competent to do so: either because they themselves carry out the procedure, or because they have received specialist training in advising patients about this procedure, have been assessed, are aware of their own knowledge limitations and are subject to audit.

- Once the patient has received all the necessary information and is happy with the information given a formal recording of consent will be taken by the patient and Consultant/SpR/Nurse Practitioner.

- A copy of the consent form will be given to the patient for their own personal records

- This consent form which details the communications with the patients Consultant/SpR will be filed in the patient's health records until such time as the procedure is performed and thereafter for the life of the medical record.

- Confirming of consent will occur before the procedure is performed by a registered health professional to ensure the patient is satisfied with all information given throughout the consent process.

- Confirmation of consent should occur if the consent form was signed more than 24hours ahead of the planned procedure. When consent occurs on the day of the procedure or the previous day conformation of consent is not necessary

Seeking consent for anaesthesia

Where an anaesthetist is involved in a patient's care, it is their responsibility (not that of a surgeon) to seek consent for anaesthesia, having discussed the benefits and risks. However, in elective treatment it is not acceptable for the patient to receive no information about anaesthesia until their pre-operative visit from the anaesthetist: at such a late stage the patient will not be in a position genuinely to make a decision about whether or not to undergo anaesthesia. Patients should therefore either receive a general leaflet about anaesthesia in out-patients, or have the opportunity to discuss anaesthesia in a pre-assessment clinic. The anaesthetist should ensure that the discussion with the patient and their consent is documented in the anaesthetic record, in the patient's notes or on the consent form. Where the clinician providing the care is personally responsible for anaesthesia (e.g. where local anaesthesia or sedation is being used), then he or she will also be responsible for ensuring that the patient has given consent to that form of anaesthesia.
In addition, where general anaesthesia or sedation is being provided as part of dental treatment, the General Dental Council currently holds dentists responsible for ensuring that the patient has all the necessary information. In such cases, the anaesthetist and dentist will therefore share that responsibility.

Emergencies

Clearly in emergencies, the two stages (discussion of options and confirmation that the patient wishes to go ahead) will follow straight on from each other, and it may often be appropriate to use the patient's notes to document any discussion and the patient's consent, rather than using a form. The urgency of the patient's situation may limit the quantity of information that they can be given, but should not affect its quality.

Treatment of young children

When babies or young children are being cared for in hospital, it will not usually seem practicable to seek their parents" consent on every occasion for every routine intervention such as blood or urine tests or X-rays. However, one should remember that, in law, such consent is required. Where a child is admitted, you should therefore discuss with their parent(s) what routine procedures will be necessary, and ensure that you have their consent for these interventions in advance. If parents specify that they wish to be asked before particular procedures are initiated, you must do so, unless the delay involved in contacting them would put the child's health at risk.

Only people with 'parental responsibility' are entitled to give consent on behalf of their children. You must be aware that not all parents have parental responsibility for their children (for example, unmarried fathers do not automatically have such responsibility although they can acquire it). If you are in any doubt about whether the person with the child has parental responsibility for that child, you must check.

Who is responsible for seeking consent?

The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later.
Where oral or non-verbal consent is being sought at the point the procedure will be carried out, this will naturally be done by the health professional responsible. However, team work is a crucial part of the way the NHS operates, and where written consent is being sought it may be appropriate for other members of the team to participate in the process of seeking consent.

New medical staff at SpR level joining Liverpool Heart and Chest Hospital will be identified by the Consultant for that speciality they are joining as able to obtain consent for specific procedures. The record will identify who is to undergo training in order to take procedure specific consent.

SpR starters who have previously rotated to this organisation in the past, and who have been identified as able to take consent by the Consultant, having received procedure specific training will be required to undertake refresher training, to be delivered by the Consultant for that speciality, either on a one to one basis, or as part of a training programme. It is the Consultants responsibility to ensure that medical staffs under their supervision have completed record of competency forms prior to undertaking consent for a procedure on their behalf.

Formal records of new starter SpR and re-joining SpR staff who are identified as not capable of performing the procedure but who are authorised to obtain consent will be kept by the Post Graduate Medical Education Department.

They will not undertake to obtain consent until they have received procedure specific training and have been found competent to undertake consent for that procedure.
Staff who obtain consent for a procedure without the authority to do so, will be identified by means of auditing the consent process. They will be referred to the Post Graduate tutor or team leader.

The provision of information is central to the consent process. Before patients can come to a decision about treatment, they need comprehensible information about their condition and about possible treatments/investigations and their risks and benefits (including the risks/benefits of doing nothing). They also need to know whether additional procedures are likely to be necessary as part of the procedure, for example a blood transfusion, or the removal of particular tissue. Once a decision to have a particular treatment / investigation has been made, patients need information about what will happen: where to go, how long they will be in hospital, how they will feel afterwards and so on.

Patients and those close to them will vary in how much information they want: from those who want as much detail as possible, including details of rare risks, to those who ask health professionals to make decisions for them. There will always be an element of clinical judgement in determining what information should be given. However, the *presumption* must be that the patient wishes to be well informed about the risks and benefits of the various options. Where the patient makes clear (verbally or non-verbally) that they do not wish to be given this level of information, this should be documented.

Written consent

Consent is often wrongly equated with a patient's signature on a consent form. A signature on a form is *evidence* that the patient has given consent, but is not *proof* of valid consent. If a patient is rushed into signing a form, on the basis of too little information, the consent may not be valid, despite the signature. Similarly, if a patient has given valid verbal consent, the fact that they are physically unable to sign the form is no bar to treatment. Patients may, if they wish, withdraw consent after they have signed a form: the signature is evidence of the process of consent-giving, not a binding contract.
It is rarely a legal requirement to seek written consent, but it is good practice to do so if any of the following circumstances apply:

- The treatment or procedure is complex, or involves significant risks (the term 'risk' is used throughout to refer to any adverse outcome, including those which some health professionals would describe as 'side-effects' or 'complications': See below 'How much information should be provided?')

- The procedure involves general/local anaesthesia or sedation

- Providing clinical care is not the primary purpose of the procedure

- There may be significant consequences for the patient's employment, social or personal life

- The treatment is part of a project or programme of research approved by this Trust.

How much information should be provided?

Health care professionals must use clinical judgement to provided adequate and relevant information and must include as a minimum:

1. Nature of intervention
2. Its purpose
3. Benefits
4. Risks and side effects
5. Alternatives (including the option of no treatment)

Sufficient information needs to be given that will allow the patient to make an informed decision based on the balance between risk and benefit. To help patients make decisions based on risk clinicians need to tailor explanations to each individual whilst allowing them to apply their own value judgements. When relaying degrees of risk health care professionals will need to find out what 'high', 'medium' and 'low' mean to the patient by describing these in easily understandable terms. When determining how to inform the patient the expected *frequency* (rate) of any adverse outcome and its potential *impact (severity)* on the patient's lifestyle needs to be considered. The impact of an adverse outcome will vary between patients. For example, disfigurement may be more serious for a young person than for an elderly one, a speedy return to fitness may be significant for a worker and less so for someone who is retired. But only the individual can make those judgements, health care professionals cannot know and should not make assumptions.

Care needs to be taken when presenting statistics, as they are useful only when supplied in a relevant context for the patient. All statistical information should be validated although a combination of statistics and stories can be used if necessary. When quoting percentages – pictorial examples (e.g. 1 in 100 dots on a page) can be useful.

Patients need to be informed that the impact of a particular adverse event will vary according to the individual. The predicted frequency of an event will vary according to unit, surgeon and patient specific factors and individual surgeons should know their own rates of mortality and morbidity and when they vary from national or international data.

The *Frequency* (rate) of an event can be described as:

- Very low (improbable) <0.01%
- Low (unlikely) 0.01% to 0.1%
- Moderate (potential) 0.1% to 1%
- High (possible) ≥1%

The *Impact* on lifestyle can be divided into:

- **Catastrophic** – permanent disability or death
- **Severe** – marked reduction in quality of life which is permanent or which has a recovery period of more than 12 months
- **Moderate** – permanent or semi-permanent loss that results in disability requiring support, treatment or medication that could modify the patient's future life.
- **Low/Slight** – fully or almost fully recoverable loss that has minimal impact on the patient's future life.

Completed forms should be kept with the patient's notes. Any changes to a form, made after the form has been signed by the patient, should be initialled and dated by both patient and health professional.

It will not usually be necessary to document a patient's consent to routine and low-risk procedures, such as providing personal care or taking a blood sample. However, if you have any reason to believe that the consent may be disputed later or if the procedure is of particular concern to the patient (for example if they have declined, or become very distressed about, similar care in the past); it would be helpful to do so.

The Mental Health Act 1983, 2005, 2007 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances.

Procedures to follow when patients lack capacity to give or withhold consent

Procedures to follow when patients lack capacity to give or withhold consent
The Mental Capacity Act 2005 provides a statutory framework to empower and protect vulnerable people who are not able to make their own decisions. It makes it clear who can take decisions, in which situations, and how they should go about this. It enables people to plan ahead for a time when they may lose capacity. The Act was implemented in April 2007.

Guidance on the Act is provided in a Code of Practice. People who are placed under a duty to have regard to the Code include those working in a professional capacity e.g. doctors and social workers.

The Act is underpinned by a set of five key principles stated at Section 1 of the Act:

1. A presumption of capacity - every adult has the right to make his or her own decisions and must be assumed to have capacity to do so unless it is proved otherwise;

2. The right for individuals to be supported to make their own decisions - people must be given all appropriate help before anyone concludes that they cannot make their own decisions;

3. That individuals must retain the right to make what might be seen as eccentric or unwise decisions;

4. Best interests – anything done for or on behalf of people without capacity must be in their best interests; and

5. Least restrictive intervention – anything done for or on behalf of people without capacity should be the least restrictive of their basic rights and freedoms.

Occasionally, there will not be a consensus whether a particular treatment is in an incapacitated adult's best interests. This may have to be referred to the Court of Protection. Please seek advice from the Clinical Risk Manager.
Full details can be found in the Policy and Procedure for Staff Relating to the Mental Capacity Act, found on the Trust website.

Refusal of treatment

If the process of seeking consent is to be a meaningful one, refusal must be one of the patient's options. A competent adult patient is entitled to refuse any treatment, except in circumstances governed by the *Mental Health Act 1983*. The situation for children is more complex: see the Department of Health's *Seeking consent: working with children* for more detail. The following paragraphs apply primarily to adults.

If, after discussion of possible treatment options, a patient refuses all treatment, this fact should be clearly documented in their notes. If the patient has already signed a consent form, but then changes their mind, you (and where possible the patient) should note this on the form.

Where a patient has refused a particular intervention, you must ensure that you continue to provide any other appropriate care to which they have consented. You should also ensure that the patient realises they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they should be advised accordingly.
If a patient consents to a particular procedure but refuses certain aspects of the intervention, you must explain to the patient the possible consequences of their partial refusal. If you genuinely believe that the procedure cannot be safely carried out under the patient's stipulated conditions, you are not obliged to perform it. You must, however, continue to provide any other appropriate care. Where another health professional believes that the treatment can be safely carried out under the conditions specified by the patient, you must on request be prepared to transfer the patient's care to that health professional.

Tissue

The legal position regarding the use of human tissue (including blood samples and other bodily fluids provided for testing) raises some difficult issues and is

currently under review. Such tissue can be very valuable in education and research, and its use may lead to developments in medical knowledge and hence improvements in healthcare for all. At present, this Trust requires that patients should be given the opportunity to refuse permission for tissue taken from them during surgery or other procedure to be used for education or research purposes. All patients who are potential participants in our on-going research program undergo an informed consent process specific to the research in question, supported by a patient information leaflet. Tissue will only be removed from patients giving this consent; a copy of their consent form is filed in the case notes.

Explicit consent is not necessary for public health surveillance using the unlinked anonymous method, but a well-publicised opt-out policy must apply. The provision of information during informed consent should include detail of any potential for retained tissue to be utilised for public health surveillance.

Pending the outcome of the review of the law governing the use of human organs and tissue, the Department of Health believes that tissue samples may be used for quality assurance purposes without requiring specific patient consent *provided* there is an active policy of informing patients of such use. This is essential to ensure the high quality of service which all patients have the right to expect. Wherever possible, samples of tissue used in this way should be anonymised or pseudonymised. The provision of information during informed consent should include detail of any potential for retained tissue to be utilised for quality assurance.

Clinical photography and conventional or digital video recordings

Photographic and video recordings made for clinical purposes form part of a patient's record. Although consent to certain recordings, such as X-rays, is implicit in the patient's consent to the procedure, health professionals should always ensure that they make clear in advance if any photographic or video recording will result from that procedure.

Photographic and video recordings which are made for treating or assessing a patient must not be used for any purpose other than the patient's care or the audit of that care, without the express consent of the patient or a person with parental responsibility for the patient. The one exception to this principle is set out in paragraph 3 below. If you wish to use such a recording for education, publication or research purposes, you must seek consent in writing, ensuring that the person giving consent is fully aware of the possible uses of the material. In particular, the person must be made aware that you may not be able to control future use of the material once it has been placed in the public domain. If a child is not willing for a recording to be used, you must not use it, even if a person with parental responsibility consents.

Photographic and video recordings, made for treating or assessing a patient and from which there is no possibility that the patient might be recognised, may be used within the clinical setting for education or research purposes

without express consent from the patient, as long as this policy is well publicised. However, express consent must be sought for any form of publication.

If you wish to make a photographic or video recording of a patient specifically for education, publication or research purposes, you must first seek their written consent (or where appropriate that of a person with parental responsibility) to make the recording, and then seek their consent to use it. Patients must know that they are free to stop the recording at any time and that they are entitled to view it if they wish, before deciding whether to give consent to its use. If the patient decides that they are not happy for any recording to be used, it must be destroyed. As with recordings made with therapeutic intent, patients must receive full information on the possible future uses of the recording, including the fact that it may not be possible to withdraw it once it is in the public domain.

The situation may sometimes arise where you wish to make a recording specifically for education, publication or research purposes, but the patient is temporarily unable to give or withhold consent because, for example, they are unconscious. In such cases, you may make such a recording, but you must seek consent as soon as the patient regains capacity. You must not use the recording until you have received consent for its use, and if the patient does not consent to any form of use, the recording must be destroyed.
If the patient is likely to be permanently unable to give or withhold consent for a recording to be made, you should seek the agreement of some-one close to the patient. You must not make any use of the recording which might be against the interests of the patient. You should also not make, or use, any such recording if the purpose of the recording could equally well be met by recording patients who are able to give or withhold consent.

12 key points on consent: the law in England

When do health professionals need consent from patients?

1. Before you examine, treat or care for competent adult patients you must obtain their consent.

2. Adults are always assumed to be competent unless demonstrated otherwise. If you have doubts about their competence, the question to ask is: “can this patient understand and weigh up the information needed to make this decision?” Unexpected decisions do not prove the patient is incompetent, but may indicate a need for further information or explanation.

3. Patients may be competent to make some health care decisions, even if they are not competent to make others.

4. Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them.

Can children give consent for themselves?

5. Before examining, treating or caring for a child, you must also seek consent. Young people aged 16 and 17 are presumed to have the competence to give consent for themselves. Younger children who understand fully what is involved in the proposed procedure can also give consent (although their parents will ideally be involved). In other cases, someone with parental responsibility must give consent on the child's behalf, unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent **cannot** over-ride that consent. Legally, a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare.

Who is the right person to seek consent?

6. It is always best for the person actually treating the patient to seek the patient's consent. However, you may seek consent on behalf of colleagues if you are capable of performing the procedure in question, or if you have been specially trained to seek consent for that procedure.

What information should be provided?

7. Patients need sufficient information before they can decide whether to give their consent: for example information about the benefits and risks of the proposed treatment, and alternative treatments. If the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.

8. Consent must be given voluntarily: not under any form of duress or undue influence from health professionals, family or friends.

Does it matter how the patient gives consent?

9. No: consent can be written, oral or non-verbal. A signature on a consent form does not itself prove the consent is valid – the point of the form is to record the patient's decision, and also increasingly the discussions that have taken place. Your Trust or organisation may have a policy setting out when you need to obtain written consent.

Refusal of treatment

10. Competent adult patients are entitled to refuse treatment, even when it would clearly benefit their health. The only exception to this rule is where the treatment is for a mental disorder and the patient is detained under the Mental Health Act 1983. A competent pregnant woman may refuse any treatment, even if this would be detrimental to the foetus.

Adults who are not competent to give consent

11. **No-one** can give consent on behalf of an incompetent adult. However, you may still treat such a patient if the treatment would be in their best interests. 'Best interests' go wider than best medical interests, to include factors such as the wishes and beliefs of the patient when competent, their current wishes, their general well-being and their spiritual and religious welfare. People close to the patient may be able to give you information on some of these factors. Where the patient has never been competent, relatives, carers and friends may be best placed to advise on the patient's needs and preferences.

12. If an incompetent patient has clearly indicated in the past, while competent, that they would refuse treatment in certain circumstances (an 'advance refusal'), and those circumstances arise, you must abide by that refusal.

This summary cannot cover all situations. For more detail, consult the *Reference guide to consent for examination or treatment,* available from the NHS Response Line 08701 555 455 and at www.doh.gov.uk/consent

ACTIVITY: CONSENT

Do not forget to complete the on-line assessment on My PACT

Please note:

- If you achieve 80% or more you have been successful
- If you do not achieve 80% you will not be deemed as compliant with your essential mandatory training and will need to repeat the test.