

**[XXXXXHEALTH BOARD/TRUST]**

# **Model policy for consent to examination or treatment**

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## Glossary

|                  |  |
|------------------|--|
| <b>AC</b>        | <b>Approved clinician (Supplementary guidance only)</b>            |
| <b>ADRT</b>      | <b>Advance Decision to Refuse Treatment</b>                        |
| <b>BMA</b>       | <b>BMA – British Medical Association</b>                           |
| <b>BNF</b>       | <b>British National Formulary (Supplementary guidance only)</b>    |
| <b>CAD</b>       | <b>Court Appointed Deputy</b>                                      |
| <b>CANH</b>      | <b>Clinically Assisted Nutrition and Hydration</b>                 |
| <b>CoP</b>       | <b>Court of Protection</b>   |
| <b>CTO</b>       | <b>Community Treatment Order (Supplementary guidance only)</b>     |
| <b>DBD</b>       | <b>Donation after brainstem death</b>                              |
| <b>DCD</b>       | <b>Donation after circulatory death</b>                            |
| <b>DNA</b>       | <b>Deoxy-ribo Nucleic Acid</b>                                     |
| <b>DNACPR</b>    | <b>Do Not Attempt Cardiopulmonary Resuscitation</b>                |
| <b>ECT</b>       | <b>Electroconvulsive Therapy</b>                                   |
| <b>EPO</b>       | <b>Emergency Protection Order</b>                                  |
| <b>GMC</b>       | <b>General Medical Council</b>                                     |
| <b>HFEA 1990</b> | <b>Human Fertilisation and Embryology Act 1990</b>                 |
| <b>HFEA</b>      | <b>Human Fertilisation and Embryology Authority</b>                |
| <b>HIW</b>       | <b>Healthcare Inspectorate Wales (Supplementary guidance only)</b> |
| <b>HRA</b>       | <b>Human Rights Act 1998</b>                                       |
| <b>HTA 2004</b>  | <b>Human Tissue Act 2004</b>                                       |
| <b>HTA</b>       | <b>Human Tissue Authority</b>                                      |
| <b>HTA 2013</b>  | <b>Human Transplantation (Wales) Act 2013</b>                      |
| <b>IMCA</b>      | <b>Independent Mental Capacity Advocate</b>                        |

|                   |   |
|-------------------|---|
| <b>IMHA</b>       | <b>Independent Mental Health Advocate (Supplementary guidance only)</b> |
| <b>ICSI</b>       | <b>Intracytoplasmic sperm injection</b>                                 |
| <b>IVF</b>        | <b><i>In vitro</i> fertilisation</b>                                    |
| <b>LPA</b>        | <b>Lasting Power of Attorney</b>  |
| <b>MCA</b>        | <b>Mental Capacity Act 2005</b>   |
| <b>MHA</b>        | <b>Mental Health Act 1983</b>   |
| <b>MCS</b>        | <b>Minimally Conscious State</b>  |
| <b>Montgomery</b> | <b>Montgomery v Lanarkshire NHS Health Board</b>                        |
| <b>OPG</b>        | <b>Office of the Public Guardian</b>                                    |
| <b>PPO</b>        | <b>Police Protection Order</b>  |
| <b>PDOC</b>       | <b>Prolonged Disorder of Consciousness</b>                              |
| <b>PVS</b>        | <b>Persistent Vegetative State</b>                                      |
| <b>SCT</b>        | <b>Supervised Community Treatment (Supplementary guidance only)</b>     |
| <b>SOAD</b>       | <b>Second Opinion Doctor (Supplementary guidance only)</b>              |
| <b>WHC</b>        | <b>Welsh Health Circular</b>  |

## Foreword

The Supreme Court ruling in *Montgomery v Lanarkshire Health Board* [2015] fundamentally changed the legal framework for consent to examination and treatment in the UK, focusing the consent process on the specific needs of the individual patient.

Existing best practice guidance from the General Medical Council (GMC) and other regulatory bodies, already highlighted the importance of individual autonomy and the active involvement of an informed patient in a shared decision-making process. The *Montgomery* judgement closed the gap between the legal and regulatory frameworks. The practical implications for clinical practice are clear, but so too is the legal framework.

The core part of this Policy provides general guidance on consent to examination and treatment in line with current legal and regulatory frameworks in Wales and England. Guidance is also incorporated for decision-making when patients temporarily or permanently lack capacity. Supplementary guidance is provided for specific scenarios which may be encountered in Obstetrics and Gynaecology or Mental Health settings.

We recognise that this is a lengthy policy document, but wanted to provide a detailed point of reference for healthcare professionals covering different situations they may encounter in their clinical practice. This policy also refers to the recently updated 'Guide to Consent for Examination or Treatment', produced by the Welsh Assembly Government, which provides a detailed overview of the current legal framework.

# Executive summary

## What is consent?

- Consent is a patient's ongoing agreement to treatment or care
- It is a process – not a one-off event
- For consent to be valid –
  - the patient must have the mental capacity to make the relevant decision about their treatment or care
  - consent must be given voluntarily
  - he or she must be properly informed about the proposed intervention
- Compliance, where a patient is not able to make an informed decision, is not “consent”

## What information should be provided?

Patients must be provided with all the information they require, in a format and language they can understand, so that they can make an informed decision about what treatment, if any, they want to receive. The following should be discussed with the patient:

- All reasonable treatment options
- All of the intended benefits and material risks.
- Any requirement to take and retain tissue samples, photographs etc.
- The presence of any trainees or students
- The use of any experimental techniques
- Any requests for further information or clarification should be met
- Outside an emergency setting, patients should be given adequate time to consider all of the relevant information

## What is a material risk

The test of 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 clinician is, or should be, reasonably aware that the particular patient would be likely to attach significance to it

### **What are the exceptions to the duty to disclose all relevant information?**

- Where the patient has made it clear that they do not want to know the risks involved; or
- Where treatment is required urgently, but the patient is unconscious or unable to make the decision for any reason (treatment is provided on the grounds of necessity); or
- Where advising the patient of the risks would be seriously detrimental to their health (this 'therapeutic exception' is limited and should not be abused)

### **When do healthcare professionals need to obtain consent?**

- Before any kind of treatment or care is provided, if the patient has capacity to consent

### **Who is the right person to seek consent?**

- The healthcare professional providing the intervention
- Seeking consent can be delegated to an appropriately trained colleague
- If you have been asked to obtain consent but don't feel competent to do so, you must refuse

### **How does a patient give consent?**

- Consent is given through an ongoing dialogue between the patient and healthcare professional
- Consent will normally be given verbally or in writing, but consent may also be implied in certain circumstances
- The consent form is a record of the patient's decision, along with the record of any related discussions in a patient's medical or nursing notes
- A signature on a consent form does not prove that valid consent has been obtained
- This consent policy explains when you should obtain written consent

### Can children (aged under 16 years) give consent for themselves?

- Children under 16 years who are *Gillick* competent can give consent
- Where a child is not *Gillick* competent, someone with parental responsibility must give consent on their behalf, unless the situation is an emergency and they cannot be contacted
- If a competent child consents to treatment, a parent **cannot** over-ride that consent
- If a competent child refuses necessary treatment, legal advice should be sought
- Not all parents have parental responsibility for their children (e.g. unmarried fathers do not automatically have such responsibility)
- If you doubt whether a patient has parental responsibility for a child, you must check

### What about patients (aged 16 years and over) who lack capacity to give consent?

- Patients (aged 16 years and over) are presumed to have mental capacity unless demonstrated otherwise. A patient lacks capacity to make a specific decision if:
  - They have an impairment or disturbance that affects the way their mind or brain works; and
  - That impairment or disturbance causes them to be unable to make a specific decision at the time it needs to be made
- An assessment of a patient's capacity must be based upon their ability to make a specific decision at the time it needs to be made. A patient with an "impairment or disturbance" is unable to make a decision if they cannot do one or more of the following:
  - **Understand** the information relevant to the decision
  - **Retain** the information long enough to make a decision
  - **Use or weigh up** the information as part of a decision-making process
  - **Communicate the decision** – this could be by talking or using sign language and includes simple muscle movements such as blinking or squeezing a hand

A patient is not to be treated as unable to make a decision unless all practicable steps to help the patient do so have been taken without success. A patient can only be said to be unable to communicate when all forms of communication have been explored.

- A person who has authority under a Health and Welfare Lasting Power of Attorney (LPA) or a Court Appointed Deputy (CAD) with appropriate authority can give consent when the patient lacks capacity

- In the absence of a person with authority under a Health and Welfare LPA or CAD, or a valid and applicable advance decision to refuse treatment, you must determine the patient's best interests in accordance with Mental Capacity Act 2005 (MCA)
- 'Best interests' includes past and present wishes, feelings, beliefs and values of the patient lacking capacity and any other factors which they would take into account if they were able to do so
- You must, where practical and reasonable, consult people who care for, or have an interest in the welfare of the patient, about the patient's wishes and beliefs
- Where there is nobody with whom you can consult, apart from paid staff, an Independent Mental Capacity Advocate (IMCA) must be instructed where decisions are needed about serious medical treatment (including Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) orders). The only exception to this duty occurs when an urgent decision is required e.g. to save the patient's life. IMCAs will not make a decision for the patient, but healthcare professionals have a legal duty to consider their views.

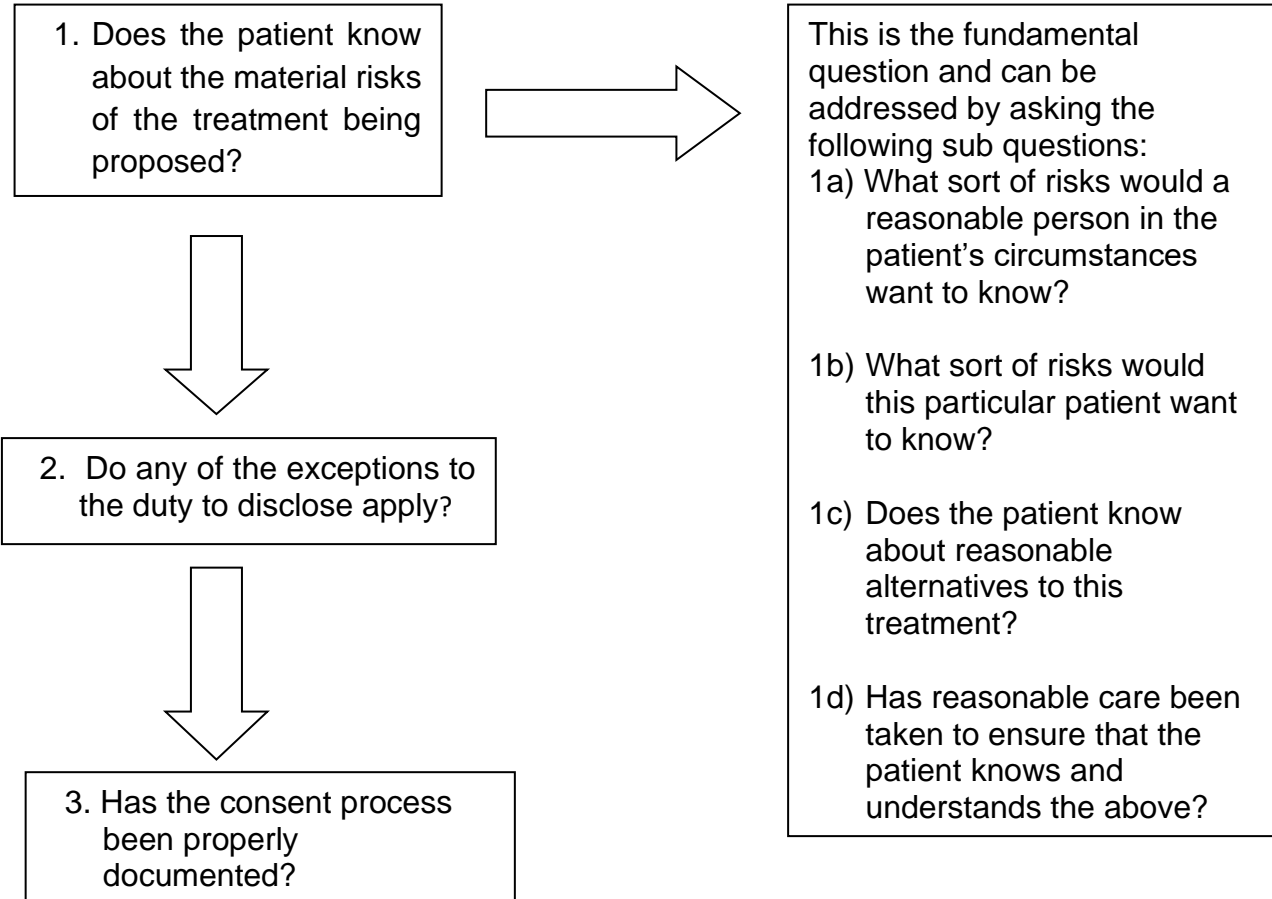
### What about refusal of treatment?

- Adults with capacity are entitled to refuse treatment or withdraw consent for any reason, at any time, no matter how unwise this may seem. The exception is where the treatment is for mental disorder and the patient is detained under the Mental Health Act 1983 (MHA)
- A pregnant woman with capacity may refuse any treatment, even if this would be detrimental to the health of the foetus. If a woman in labour refuses treatment seek urgent legal advice
- If an *un-sedated* patient confirms that they do wish to withdraw consent, and there is no immediate risk to stopping the procedure, then the procedure should be terminated immediately and the event recorded in the notes
- If a patient lacks capacity but has clearly indicated in the past, while competent, that they would refuse treatment in specified circumstances (an advance decision), and those circumstances arise, you must abide by that decision if it is **valid** and **applicable**
- Advance decisions (made by patients with capacity aged 18 years or over) about life-sustaining treatment **must be** made in writing and contain a statement that the advance decision is to apply even if their life is at risk. The document must be signed by the patient (or by someone appointed by them), in the presence of a witness, who must also sign the document.

# Informed Consent Flowchart

If a patient has capacity, they are entitled to decide which, if any, of the available treatments to undergo and their consent must be obtained before treatment.

In order to obtain and document informed consent the three questions below, together with the sub-questions, should be addressed:



# CORE POLICY

## 1. Introduction

### About this policy

1. This [Health Board / Trust] recognises that people have a fundamental legal and ethical right to determine what happens to their own bodies and this is reflected in this policy. Valid consent to treatment is absolutely central in all forms of healthcare, from providing personal care to undertaking major surgery. Seeking consent is not only a legal obligation but also a matter of common courtesy between healthcare staff and patients. Both the [Health Board / Trust] and healthcare staff may be liable to legal action if valid consent is not obtained.
2. Doctors, Nurses and Allied Health Professionals must at all times follow professional standards as set out in GMC, NMC, HCPC and other regulatory guidance. The Welsh Government's (WG) updated Welsh Health Circular: [WHC 2023/021](#) - Consent for Examination or Treatment refers to the WG's Guide which sets out the legal framework for consent and can be found on the following link - [Guide to Consent for Examination or Treatment - Revised guidance](#). The Supreme Court ruling in *Montgomery v Lanarkshire NHS Health Board*, has fundamentally changed the legal framework for consent to examination and treatment, enshrining the concepts of **informed consent** and **material risk** in UK law (discussed later in chapter 3), bringing the law on consent in line with existing regulatory guidance. Healthcare staff in this [Health Board / Trust] should comply with the standards and procedures in this policy, which should be applied in conjunction with the principles set out in the Guide.
3. While this policy is primarily concerned with healthcare and refers to healthcare staff in all NHS settings, social care colleagues should also be aware of their obligations to obtain consent before providing certain forms of social care, such as those that involve touching the patient or client.
4. A patient may either be an adult or a child. Reference in this policy to an adult means a patient of 18 years or above and a child is a patient who is under the age of 16. Reference in this policy to a young person means a child aged 16 or 17 years.

### What consent is – and isn't

5. Consent is a patient's ongoing agreement for healthcare staff to provide care or treatment. Before providing care or treatment, healthcare staff should be satisfied that the patient has given his or her **consent**. Consent will only be valid if:

- the patient has capacity to give consent
  - it is given freely and not under duress
  - the patient has been properly informed
6. Consent can be given in writing, verbally or even indicated non-verbally (for example by presenting an arm for a pulse to be taken). In all cases it is essential that an adequate record of the consent is maintained for future reference.
  7. The context of consent can take many different forms, ranging from the active request by a patient for a particular treatment (which may or may not be appropriate or available) to the passive acceptance of advice from a healthcare professional. In some cases, the healthcare 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 healthcare staff will help the patient to decide between the available options.

#### **The relevant questions to consider**

8. In seeking to obtain valid consent, healthcare staff should ask themselves a series of questions, as follows.

#### **Is there reason to doubt the patient's capacity to give consent?**

9. In determining whether an adult or young person lacks the mental capacity (either temporarily or permanently) to give or withhold consent, healthcare professionals must act in accordance with the MCA and the MCA Code of Practice. It is important to remember that nobody can give consent on behalf of an adult, unless they are an appointed attorney with authority under a Health and Welfare LPA or Court Appointed Deputy. A patient who lacks capacity can, however, be given treatment if it is in their best interests in accordance with the MCA, unless there is a valid and applicable advance decision refusing treatment (advance decisions are valid only for adult patients).
10. When treating patients who may lack capacity, healthcare professionals should give careful consideration to chapter 8 of this policy and the Guide, particularly the paragraphs set out below.

#### **Is the consent given freely?**

11. Pressure to agree to a particular treatment can be intentionally or unintentionally applied by family, friends or healthcare professionals. Professionals should be alert to this possibility, and where appropriate, arrange to review the patient on their own to establish that the decision is autonomous.

12. When patients are seen and treated in environments where involuntary detention may be an issue, such as prisons and mental health hospitals, there is a potential for treatment offers to be perceived coercively, whether or not this is the case. Coercion invalidates consent and care must be taken to ensure that the patient makes a decision freely. Coercion should be distinguished from providing the patient with appropriate reassurance concerning their treatment, or pointing out the potential benefits of treatment for their health. However, threats such as withdrawal of any privileges or loss of remission of sentence for refusing consent, or using such matters to induce the patient to give consent are not acceptable. Consent will not be valid in these circumstances.

**Is the patient aware of all of the material risks and benefits of the proposed treatment and or any alternatives, including no treatment?**

13. The healthcare professional must inform the patient about all the material risks, benefits and available alternatives, including no treatment. 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 healthcare professional need to come to an agreement on the best way forward, based on the patient's values and preferences and the healthcare professional's clinical knowledge.
14. The informed person may either be the patient or someone with parental responsibility. Where a patient lacks capacity to give consent to the specified treatment, the decision should be made in the patient's best interests in accordance with MCA 2005. It is important that a person acting under a Health and Welfare LPA or a CAD for health and welfare decisions is also aware of all material risks, benefits and available alternatives, including no treatment.

**Cultural issues**

15. Cultural diversity issues should be actively considered whilst obtaining patient's consent. Members of some religious faiths, for example, are extremely modest in relation to exposure of parts of the body and may only consent to examination or treatment if it is undertaken by someone of the same sex. Please refer to local organisational policies and guidelines.
16. If there is any doubt or uncertainty in relation to particular consent issues contact [insert details of local process].

## 2. Documentation

17. Healthcare professionals must clearly document the information provided to a patient and any related discussions during the consent process. This may be recorded on a consent form (with further detail in the patient's medical notes as necessary) or within an entry in the patient's medical notes. (See chapter 3).
18. Where the signing of a consent form is not required, healthcare professionals must document the consent process followed within an entry in the patient's medical notes, including details of any information provided or related discussions.

### Valid forms of consent

19. It will not usually be necessary to obtain a patient's written 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 advisable to do so.
20. It is rarely a legal requirement to seek written consent<sup>1</sup>, 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 healthcare professionals would describe as 'side-effects' or 'complications');
  - the procedure involves general/regional anaesthesia or sedation;
  - providing clinical care is not the primary purpose of the procedure;
  - there may be significant consequences for the patient's employment or personal life;
  - the treatment is part of a project or programme of research approved by this [Health Board / Trust] (see chapter 17 of this policy).
21. If you are in doubt about whether a procedure requires written consent, then the safest course of action is to complete an appropriate consent form.
22. It is important to note that the place in which the treatment or procedure is to be carried out e.g. outpatients / theatre / clinic / in the patient's home, etc. should not affect the type of consent taken. The nature of the consent (i.e. written, verbal or implied) should be appropriate to the procedure concerned.

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<sup>1</sup>The Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 require written consent in certain circumstances

23. Abbreviations should never be used on consent forms.
24. Completed forms should be kept with the patient's medical 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 the relevant healthcare professional.
25. A patient's signature on a consent form does not prove that valid consent has been provided. If a patient has made a decision on the basis of inadequate information, or has not had sufficient time to make a decision, consent may not be valid. Conversely, if a patient has given valid verbal consent, the fact that they have not signed a consent form does not mean that consent is not valid. Patients may withdraw consent after they have signed a form; it is not a binding contract.

### **Standard consent forms – Consent Forms 1 and 2**

26. There are two versions of the standard consent form:
  - **Consent Form 1** for adults, young people or Gillick competent children:
  - **Consent Form 2** for parental consent for a child under 16 who is not Gillick competent
27. The consent forms have been designed to allow the patient to be given a copy in either Welsh or English. It is essential that the original top copy, which is in English, is the one filed in the patient's medical notes. See appendix A.

### **Form for patients aged 16 years and over who are unable to consent for themselves – Form 4**

28. The standard consent forms (**Consent Forms 1 and 2**) should never be used for adult patients and young people who are unable to consent for themselves. Where an adult patient or young person does not have the capacity to give or withhold consent to a significant intervention, this should be documented in **Form 4 - Treatment in best interests: form for patients aged 16 years and over who lack capacity to consent to examination and treatment**. See appendix A.
29. Although Form 4 is referred to as a consent form, it should be noted that no-one, other than a person who has authority under a Health and Welfare LPA or a CAD for health and welfare decisions can give consent on behalf of an adult patient. If a person who has authority under an LPA or a CAD is giving consent then they should sign the appropriate section of Form 4. A copy of Form 4 should be offered to this person.
30. Form 4 requires healthcare professionals to document why the patient lacks the capacity to make this particular healthcare decision, and why the proposed treatment would be in his or her best interests, in accordance with the Mental Capacity Act 2005. Where the patient's family and friends have been consulted about the patient's wishes and feelings (in order to inform the determination of what is in the patient's best interests) the details of this discussion must also be recorded on the form. For further information regarding patients who lack mental capacity to give or withhold consent, see chapter 8 of this policy. For more minor

interventions, this information should be entered in the patient's medical notes

### **Patient information leaflet**

31. Patients may find consent forms daunting or confusing and an explanatory leaflet "**About the consent form**" is available for patients with questions or concerns (Appendix E).

### **Availability of forms**

32. Consent Forms 1 and 2 and Form 4 can be ordered via the Oracle system.

### **Procedure/condition specific consent forms**

33. Procedure specific consent forms may offer advantages for clinical practice and service organisations, providing standardised information about significant risks, benefits and alternative treatment(s). Space must be provided on these forms so that any additional material risks, which are specific to individual patients, can be recorded. The forms should also meet Welsh language requirements in line with the Welsh Language Standards.
34. [Health Boards/Trusts] must develop clear guidance on the development of procedure specific consent forms which must be approved through appropriate governance arrangements.

### 3. When should consent be sought?

35. Outside an urgent setting, it is good practice to seek the patient's consent to the proposed procedure well in advance, so that there is time to respond to questions and provide adequate information for the individual patient to make a fully informed decision. Seeking consent should be viewed as a process rather than a one off event, reflecting a dialogue between the individual patient and the healthcare professional. The provision of information and related discussion are components of the shared decision-making process.
36. This process may take place at one time, or over a series of meetings and discussions, depending on the seriousness and/or urgency of the situation. Healthcare professionals should take reasonable care to ensure that patients are made aware of all of the intended benefits, material risks and alternatives to the proposed treatment.

#### What is a “material risk”?

37. The test of 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 healthcare professional is or should be reasonably aware that the particular patient would be likely to attach significance to it.
38. All clinical staff should have regard to the ruling in the case of *Montgomery v Lanarkshire Health Board*<sup>2</sup> given on 11th March 2015.
39. Following this Supreme Court ruling, healthcare professionals are reminded of their professional responsibility to take “reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.”
40. This standard of consent is similar to that required in GMC Guidance – Good Medical Practice 2013 – namely, work in partnership with patients. Listen to, and respond to their concerns and preferences. Give patients the information they want or need in a way they can understand. Respect patients’ right to reach decisions with you about their treatment and care<sup>3</sup>.
41. Healthcare professionals must be satisfied that:
  - The patient knows and understands all the material risks of the proposed treatment;
  - The patient is aware of all reasonable alternatives;
  - He/she has taken reasonable care to ensure that the patient understands all of the relevant information

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<sup>2</sup><https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf>

<sup>3</sup>[http://www.gmc-uk.org/guidance/good\\_medical\\_practice.asp](http://www.gmc-uk.org/guidance/good_medical_practice.asp)

- Valid exceptions to the duty to disclose apply.
42. The three exceptions to the duty to disclose are:
- The patient tells the healthcare professional that he or she prefers not to know the risks;
  - The healthcare professional reasonably considers that telling the patient something would cause serious harm to the patient's health and wellbeing
  - Consent is not required as the patient lacks capacity and urgent treatment is required.
43. The Informed Consent Flowchart set out at the beginning of this document provides a useful reference guide for staff on the practical implications of the Montgomery case and is also available online<sup>4</sup>.

### Single stage process

44. In many cases, it will be appropriate for a healthcare professional to initiate a procedure immediately after discussing it with the patient. For example, during an ongoing 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 gives their consent, the procedure can go ahead immediately. Verbal consent will often be provided in this situation. This should be recorded in the patient's medical notes.
45. If a proposed procedure/treatment involves significant and important material risks for the patient concerned, it may be appropriate to seek written consent. Healthcare professionals should also consider whether the patient has had sufficient opportunity or time to process the information required for them to make the relevant decision.

### Two or more stage process

46. In most cases where *written* consent is being sought, treatment options will generally be discussed well in advance of the actual procedure. This may be on just one occasion or it might be over a whole series of consultations with a number of different healthcare professionals. The consent process will therefore have at least two stages: the first being the provision of information, discussion of options and initial (verbal) decision, and the second being confirmation that the patient still wants to go ahead<sup>5</sup>. A careful record of the information provided and the related discussion with the patient should be detailed in the patient's medical notes. The consent form may be used as a means of recording the information stage(s), as well as the confirmation stage.

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<sup>4</sup><http://howis.wales.nhs.uk/sitesplus/documents/861/Legal%20and%20Risk%20-%20Montgomery%20flowchart.pdf>

<sup>5</sup><https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/consent/>

47. 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 consent form documenting the decision-making process (either in Welsh or English). 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. However, if a form is signed before patients arrive for treatment, a member of the healthcare team (for example a nurse admitting the patient for an elective procedure) **must** check with the patient at this point whether they understand the procedure and the risks involved, whether they have any further questions or 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;
  - new information becomes available regarding the proposed intervention (for example, new evidence of risks or new treatment options);
  - the patient's condition has changed significantly in the intervening period;
  - the patient's responsible clinician has changed since the form was signed.
48. Similarly, if a patient is returning on multiple occasions for a course of treatment, a member of the healthcare team must check with the patient on each occasion that they still consent to the procedure. This confirmation of consent should be recorded on the consent form, or, if insufficient space, in the patient's medical notes.
49. 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?"
50. 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.
51. The patient's consent may be obtained by post, as this gives the patient time to read and reflect on the consent form and information provided. However, any person carrying out a procedure must ensure, at the earliest opportunity following admission, that the patient has understood the information and that they still give their consent. If the patient has queries or concerns he or she must be given time to consider any additional information. It is important to remember that, whether a patient does or does not have capacity to consent, no relative or carer can sign on his or her behalf (unless provided for in accordance with the MCA – see chapter 8 of this policy) and under parental responsibility: if the competent child or young person wishes the parent to take the decision for them).

52. Patients should not be given pre-operative sedation before being asked for their consent to proceed with treatment (although women in labour can consent to a caesarean section even if they have received sedation – see paragraph 274 of this policy). If a situation arises where a change to the consent form is required after the patient has received sedation, this should only be done if the doctor responsible for the patient's care is clearly able to demonstrate that the patient still has capacity to be involved in the decision to make the required change. This must be documented in the patient's medical notes. The outcome of the assessment, any changes made to the consent form and the reasons for the changes must also be clearly documented in the patient's medical notes. If it is found that the patient does not have capacity due to the administration of sedation, any changes to the consent form should be delayed until capacity is regained (i.e. the effects of the sedation have worn off). If the urgency of the situation is such that a delay in undertaking the procedure would lead to harm to the patient, any decision that is made about continuing has to be made in the best interests of the patient. Best interests decisions and the reasons for them should be documented in the patient's medical notes. Chapter 8 of this policy provides further guidance on assessing capacity and making best interest decisions.

### **Seeking consent for anaesthesia**

53. 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 significant or material risks with the patient. In an elective setting 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 may not be able to make a considered decision about whether or not to undergo anaesthesia. Patients should therefore either receive a general leaflet about anaesthesia in an outpatient setting, 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 recorded in the anaesthetic record, the patient's medical notes or on the consent form. Where the healthcare professional 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.
54. 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 been provided all the necessary information. In such cases, the anaesthetist and dentist will therefore share that responsibility.

### **Emergencies**

55. Clearly in emergencies, the two stages (discussion of options and confirmation that the patient wishes to go ahead) may follow straight on from each other, and it may often be appropriate to use the patient's medical 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 and should still include benefits, significant and important (material) risks and alternatives relevant to the individual circumstances of the patient.

## **Treatment of children and young people**

56. When treating children and young people, healthcare professionals should take particular care to ensure that they are familiar with the relevant law and consider carefully whether the child or young person is competent to give his or her consent to the treatment. Chapter 7 of this policy provides further information.

## **Withdrawal of consent**

57. A patient with capacity is entitled to withdraw consent at any time. Where a patient does object during treatment, it is good practice for the healthcare professional, if at all possible, to stop the procedure, establish the patient's concerns, and explain the consequences of not completing the procedure. If the patient confirms that they do wish to withdraw consent, and there is no immediate risk to stopping the procedure, then the procedure should be terminated immediately.
58. The healthcare professional should try to establish whether at that time the patient has capacity to withdraw consent. This is particularly important if the patient has been given sedation. If a patient lacks capacity, it may be justified to continue in the patient's best interests in accordance with the MCA.
59. If a sedated patient or one who otherwise lacks mental capacity to consent begins to struggle or resists treatment either verbally or physically, it is the responsibility of the healthcare professional to act in the patient's best interests. If this event occurs at a crucial time, which will have an impact on a successful outcome, then it would be wise to pause, attempt to regain co-operation and complete, perhaps with additional sedation. If the situation deteriorates, is irretrievable, and patient safety is likely to become compromised, then termination of the procedure is recommended. This must be recorded in the patient's medical notes.
60. Issues relating to withdrawal of consent by patients being treated in accordance with sections 57, 58 or 58A of the Mental Health Act are discussed in chapter 18 of this policy.

## 4. Provision of Information

61. The provision of information is central to the consent process. Before patients can make an informed decision about their treatment, they need comprehensible information about their condition and any reasonable treatment options and their risks and benefits (including the risks/benefits of doing nothing). Patients also need to know the scope of the intended treatment and whether additional procedures are likely to be necessary, for example blood transfusion or the removal of particular tissue.
62. Patients will differ in how much information they want about a proposed treatment. Some patients will want as much detail as possible, including details of rare risks, while others will ask healthcare professionals to make decisions for them. In such circumstances, the healthcare professional should explain the importance of understanding the significant risks and benefits of a recommended treatment, and making an informed decision. The *presumption* must be that the patient wishes to be well informed about the material risks and benefits of the various treatment 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 and the patient may be asked to sign the record to confirm their decision. It must be made clear to the patient that they can change their mind and have more information at any time.

### Has the patient received sufficient information?

63. To give valid consent the patient needs to be provided with sufficient information to understand in broad terms the nature and purpose of the procedure. Information about any significant and material risks and benefits of the proposed treatment and any alternative options should be provided, including the option of no treatment. Any misrepresentation of these elements will invalidate consent. Where relevant, information about anaesthesia must be given (see paragraph 56 above) as well as information about the procedure itself.
64. The information provided should be tailored to the individual patient.
65. The use of patient information leaflets can help healthcare professionals to provide patients with the information they need, in order to arrive at an informed decision. Wherever possible patients should be sent information prior to their appointment so that they have time to read and absorb it, and can consider what questions they would like to ask when they meet with the relevant healthcare professional. This will help to ensure that they fully understand the treatment being proposed and can make an informed decision regarding consent. However, the use of leaflets does not remove the healthcare professional's responsibility to provide a verbal explanation of often much the same information. In this context, the use of patient information leaflets is considered to be an example of best practice. The use and provision of the patient information leaflet should be documented on the consent form or in the patient's health records. A copy of the patient information leaflet should be inserted into the patient's health record. If an EIDO information leaflet has been used, its name, number and date can be documented.
66. Patient information in different formats and languages must be made available.

## Communication Issues

67. A patient must not be assessed as lacking capacity to consent to the particular investigation, treatment or care merely because they have a limited ability to communicate. Care should be taken not to underestimate the ability of a patient to communicate, whatever their condition. Healthcare professionals should take all reasonable steps to facilitate communication with the patient, using communication aids as appropriate. Particular consideration should be given to the way in which information is presented to the patient. Drawings, diagrams and models may be useful for example. In emergency situations, taking these steps may not be possible, but good practice would be to record the reasons for this in the patient's medical notes.
68. Where appropriate those who know the patient well, including their family, friends, carers or staff from professional or voluntary support services, may be able to advise on the best ways to communicate with the patient.[Insert details of local guidance].

## Provision for Welsh speaking patients

69. The Welsh Language (Wales) Measure 2011 has given the Welsh language official status in Wales by placing Welsh Language Standards on organisations – [insert link to the Health Board / Trust's Welsh Language Standards Document]. The duties deriving from the standards mean that the Health Board / Trust and its staff should not treat the Welsh language less favourably than the English language. In line with the Welsh Language Standards, the language preference of the patient must be offered, established, recorded, acted upon and relayed to others within the [Health Board / Trust]. Welsh speaking healthcare professionals should ideally obtain consent from patients whose preferred language is Welsh. If the relevant healthcare professional is not Welsh speaking, consent should be obtained with the support of Welsh speaking colleagues or simultaneous translation.
- [Insert detail of local arrangements for providing Welsh language services to patients in line with the Welsh Language Standards of the Health Board / Trust.]
70. The All Wales consent forms provided with this policy (see chapter 2 of this policy) have been designed bilingually so that the patient can be given a copy in either English or Welsh. It is essential that the top copy, which is in English, is completed and added to the patient's medical notes. Availability of bilingual consent forms ensures that:
- Welsh and English versions of consent forms are equally accessible to patients;
  - both the patient and healthcare professional are clear about what is being agreed to in circumstances where a non-Welsh speaking healthcare professional is dealing with a Welsh speaking patient; and
  - the needs of mixed-language families, other mixed-language audiences and

Welsh learners are met.

### **Provision for patients whose first language is not English or Welsh**

71. This [Health Board/Trust] is committed to ensuring that patients whose first language is not English or Welsh receive the information they need and are able to communicate appropriately with healthcare staff. This includes British Sign Language (BSL). In order to safeguard the consent process, unless the healthcare professional is fluent in the patient's language, an interpreter should always be used when seeking consent from the patient (except for minor, routine procedures). It is not appropriate to use children or family members to interpret for patients who do not speak English.

|   |
|---|
| [Insert local details of how to access translation and interpreting service, what materials are available in which languages etc. Reference other relevant local policies or guidance – e.g. on use of interpreting.] |
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### **Access to more detailed or specialist information**

72. Patients may sometimes request more detailed information about their condition or a proposed treatment than that provided in general leaflets.

### **Access to healthcare professionals between formal appointments**

73. After an appointment with a healthcare professional, patients will often think of further questions which they would like answered before making a decision. Where possible, it will be much quicker and easier for the patient to contact the healthcare team by phone than to make another appointment or wait until the date of an elective procedure, by which time it is too late for the patient to reflect upon the information. Patients should be provided with appropriate contact details at the time of their appointment.
74. The provision of advice over the telephone needs to be undertaken by suitably qualified staff and must follow agreed guidelines, policies and procedures. Advice given must be evidence based and up to date. A record must be kept in the patient's medical notes. Where advice deviates from accepted guidance, the advice given must be clearly documented and the reasons for such deviation stated.

### **Open access clinics**

75. Where patients access clinics directly, it should not be assumed that their presence at the clinic implies consent to particular treatment. You should ensure that they have the information they need to give their consent before proceeding with an investigation or treatment.

### **Consent and inpatients**

76. Irrespective of whether the patient is an inpatient or outpatient, the process of seeking consent must be adhered to. Just because a patient is already in a hospital bed, consent for examination and treatment cannot be assumed. As stated

previously, the patient needs to be provided with sufficient time and information to understand in broad terms the nature and purpose of the procedure.

## 5. Who is responsible for seeking consent? -

77. The healthcare professional carrying out the procedure is ultimately responsible for ensuring that the patient has given valid consent for the proposed treatment or procedure. He or she will be held responsible in law if the validity of consent is subsequently challenged.
78. Where verbal or non-verbal consent is being sought at the point the procedure will be carried out, this will be done by the healthcare 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 e.g. providing information about the treatment or procedure.

### Competence of those seeking consent

79. Consent must be obtained by a healthcare professional who is competent 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. Inappropriate delegation (e.g. where the healthcare professional seeking consent has inadequate knowledge of the procedure) may mean that the consent is not valid.
80. It is a healthcare professional's own responsibility:
  - to ensure that when they require colleagues to seek consent on their behalf they are confident that the colleague is competent to do so; and
  - to work within their own competence and not to agree to perform tasks which exceed that competence.
81. If you feel that you are being pressurised to seek consent when you do not feel competent to do so, discuss with [insert local details of whom to contact, such as clinical governance lead.]
82. The Wales Deanery and the Welsh Government have made it clear that F1 doctors can only take consent in specific clinical situations where they have undertaken formal training and their competency has been assessed. Healthcare professionals are responsible for knowing the limits of their own competence and should seek the advice of appropriate colleagues when necessary.

### Completing consent forms

83. The standard consent form provides space for a healthcare professional to provide information to patients and to sign confirming that they have done so. The healthcare professional providing the information must be competent to do so.

84. If the patient signs the form in advance of the procedure (for example in out-patients or at a pre-assessment clinic), a healthcare professional involved in their care on the day should sign 'Confirmation of Consent' section of the form to confirm that the patient still wishes to go ahead and has had any further questions answered. It will be appropriate for any member of the healthcare team (for example a nurse admitting the patient for an elective procedure) to provide the second signature, as long as they have access to appropriate colleagues to answer questions they cannot handle themselves.

### **Attendance by students and trainees (i.e. pre-registration clinicians from any discipline)**

85. Where a student or trainee healthcare professional is undertaking examination or treatment of the patient where the procedure will further the patient's care – for example taking a blood sample for testing – then, assuming the student is appropriately trained in the procedure, the fact that it is carried out by a student does not alter the nature and purpose of the procedure. It is therefore not a legal requirement to tell the patient that the healthcare professional is a student, although it would always be good practice to do so and consent in the usual way will still be required.
86. In contrast, where a student proposes to conduct a physical examination which is not part of the patient's care, then it is essential to explain that the purpose of the examination is to further the student's training and to seek consent for that to take place. Verbal consent must be obtained and a record made in the patient's medical notes.
87. A patient's consent should be obtained when a student is going to be present during an examination or treatment purely as an observer. Patients have the right to refuse consent in these circumstances without any detrimental effect on their treatment. Written consent must be obtained if students or trainees are going to be present during examination or treatment using sedation or anaesthetic.
88. Patients must be informed that they have the right to refuse consent to being observed, attended to or examined by students without any detrimental effect on their treatment.
89. It is essential that appropriate supervision of students is carried out in all of the above situations and that, where consent is required, the supervisor is reassured that valid consent has been obtained.

### **Attendance by company representatives**

90. On occasions when company representatives need to be present for a procedure/treatment (e.g. where equipment is being used for the first time and the representative is there to assist with its use), written consent from the patient must be obtained.

## 6. Adults with Capacity – Refusal of treatment

### Right to refuse treatment

91. An adult patient who has capacity can refuse any treatment, except in certain circumstances governed by the *Mental Health Act 1983* (see chapter 13 of this policy). The following paragraphs apply primarily to adults. In determining whether a patient has capacity to make this decision the MCA must be applied. See chapter 8 of this policy.
92. An adult with capacity may make a decision which is based on their religious belief (e.g. Jehovah's Witnesses) or value system. Even if it is perceived by others that the decision is unwise or irrational, the patient may still make that decision if he or she has capacity to do so and it is a voluntary and informed decision. Any attempt to treat that patient against his or her wishes could amount to a criminal offence. It is the right of an adult patient with capacity to refuse treatment even if that refusal might result in their death. However in cases of doubt, healthcare professionals should always seek legal advice.
93. If, after discussion of possible treatment options, a patient refuses treatment, this fact should be clearly documented in their notes. If the patient has already signed a consent form, but then changes their mind, the healthcare professional (and where possible the patient) should note this on the 'Patient has withdrawn consent' section of the consent form.
94. Where a patient has refused a particular intervention, the healthcare professional must ensure that he or she continues 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.
95. If a patient consents to a particular procedure but refuses certain aspects of the intervention, the healthcare professional must explain to the patient the possible consequences of their partial refusal. If the healthcare professional genuinely believes that the procedure cannot be safely carried out under the patient's stipulated conditions, he or she is not obliged to perform it. They must, however, continue to provide any other appropriate care. Where another healthcare professional believes that the treatment can be safely carried out under the conditions specified by the patient, he or she must on request be prepared to transfer the patient's care to that healthcare professional.
96. Whilst a patient has the right to refuse treatment this does not mean that they have the right to require a particular course of treatment.

### Self harm and attempted suicide

97. Cases of self harm present a particular difficulty for healthcare professionals but the same law and guidance, as set out above, applies to treatment of these cases. Where the patient is able to communicate, an assessment of their mental capacity should be made as a matter of urgency.

98. If the patient is judged not to have capacity, decisions about their physical health treatment need to be made in accordance with the MCA (see chapter 8 of this policy). If treatment is required for their mental health, the MHA will apply. If a patient has attempted suicide and is unconscious, and there is insufficient time to undertake the usual best interests decision making process then he or she should be given emergency treatment unless the healthcare professional is satisfied that an advance decision to refuse treatment exists which is valid and applicable to the life-sustaining treatment in these circumstances.
99. Adult patients with capacity do have the right to refuse life-sustaining treatment, both at the time it is offered and in the future even if the healthcare professional believes that the patient's decision is unwise. If a patient with capacity has harmed themselves and refuses treatment, it may be appropriate to consider obtaining a psychiatric assessment. Unless the adult patient with capacity is detained under the Mental Health Act 1983 and the treatment is for, or a symptom of, a mental disorder, then their refusal must be respected although attempts should be made to encourage him or her to accept help and healthcare professionals should consult legal advisers.

#### **Patients who refuse blood or blood components (e.g. Jehovah's Witnesses)**

100. The same legal principles apply to any patient who refuses treatment whether they do so out of religious convictions or otherwise. No patient should be considered to be likely to refuse blood products merely on the basis of their religion. Every patient needs to be asked and informed individually.

#### **Further information on Jehovah's Witness Patients**

101. It is important to remember that not all Jehovah's witnesses refuse blood products. Most practising Jehovah's Witnesses who do will carry with them a clear, signed and witnessed advance decision card prohibiting blood transfusions and releasing clinicians from any liability arising from this refusal. If an applicable and valid advance decision is produced, then this should be acted upon. If the patient does not have capacity and a valid and applicable advance decision cannot be produced, the clinical judgement of a doctor should take precedence over the opinion of relatives or associates.
102. Further information can be found at the following:
- Royal College of Surgeons (2016) *Caring for patients who refuse blood: a guide to good practice for the surgical management of Jehovah's Witnesses and other patients who decline transfusion.*
  - Association of Anaesthetists of Great Britain and Ireland, 2<sup>nd</sup> Edition, (2005) *Management of Anaesthesia for Jehovah's Witnesses.*
  - Hospital Information Services for Jehovah's Witnesses (2005) *Care plan for women in labour refusing a blood transfusion.*

- UK Blood Transfusion and Tissue Transplantation Services (<http://www.transfusionguidelines.org.uk/index.asp?Publication=BBT&Section=22&pageid=510> *Better Blood Transfusion Toolkit: Appropriate Use of Blood: Pre-operative Assessment – Jehovah's Witnesses.*
  - Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee chapter 12: Management of patients who do not accept transfusion
103. Further information or advice on the clinical management of this group of patients can be obtained from:
- A Consultant Haematologist within the Health Board / Trust
  - The local Hospital Liaison Committee for Jehovah's Witnesses.

## 7. Treatment of children and young people

104. When treating or caring for children and young people, healthcare professionals should take account of chapter 5 of the Guide.

### **Children or young people with capacity to consent to treatment**

105. When treating children and young people, healthcare professionals should take particular care to ensure that they are familiar with the relevant law.
106. Careful consideration should be given to whether the child is competent to give his or her consent to the specified treatment. A child under the age of 16, who has sufficient maturity and intelligence to be capable of understanding the treatment and making a decision based on the information provided (Gillick competent) will have capacity to consent to treatment and care. If a competent child consents to treatment a parent cannot over-ride that consent. As with adults, consent will only be valid if it is given voluntarily by an appropriately informed patient who has capacity to consent to the particular treatment.
107. Young people aged 16 or 17 with capacity are assumed in law to be competent and can give consent for their own treatment. If a 16 or 17 year old consents to treatment a parent cannot over-ride that consent. This applies equally to young people with capacity who are to be admitted (informally) to hospital for treatment for a mental disorder.
108. It is not a legal requirement but it is advisable to include the child/young person's family in discussions regarding treatment. However, this can only be done with the consent of the child/young person.

See Appendix D for guidance on assessing whether a child is Gillick competent.

### **Children who are not competent to consent to treatment**

109. If the child is not competent to give consent, then the healthcare professional may give treatment on the basis of parental consent. Parental consent may be given by any person who has parental responsibility for the child, provided that person has capacity to give such consent. This may not necessarily be the parents but, for convenience, "parents" in this policy means all persons with parental responsibility.
110. Healthcare professionals need to make reasonable enquiries as to who holds parental responsibility for the child. Every effort should be made to include all those with parental responsibility in discussions regarding treatment options.
111. Not all parents have parental responsibility for their children. For example, unmarried fathers do not automatically have such responsibility but they can acquire it. If you have any doubt about whether the person with the child has parental responsibility for that child, you must check. The Children Act 1989 (which applies to both children and young people) sets out the persons who may have responsibility for a child.

Parental responsibility is vested in:

- the mother automatically on the birth of the child
- the father if his name has been registered on the child's birth certificate (this only applies to births from 1<sup>st</sup> December 2003)
- the father/partner when he/she is married to the mother at the time of the birth
- an unmarried father can acquire parental responsibility in the following ways:-
  - by jointly registering the birth with the mother (only applies to births from 1<sup>st</sup> December 2003)
  - by entering into a Parental Responsibility Agreement with the mother
  - by applying to the courts for a Parental Responsibility Order
  - by being appointed as guardian either by the mother or the court (although he will usually only assume parental responsibility upon the mother's death)
  - by obtaining a residence order
  - by marrying the mother and agreeing with her that he will assume parental responsibility
  - marrying the mother and upon his application to the court
  - by adopting the child
- legally appointed guardian
- a person who has been granted a residence order in respect of the child
- a step-parent who has entered into a Parental Responsibility Agreement with the mother
- a local authority in whose favour a care order has been made<sup>6</sup>
- a person who has been granted an emergency protection order
- an adopter of a child in accordance with section 46 of Adoption and Children Act 2002
- a husband and wife in whose favour a parental order has been made under section 30 of the Human Fertilisation and Embryology Act 1990
- an adoption agency in accordance with section 25 of the Adoption and Children Act 2002
- the court in wardship procedures
- some same-sex partners in certain situations

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<sup>6</sup>Care should be sought as a Local Authority has the power to restrict the parental responsibility of the parents in relation to health care. It should always be established who has parental responsibility when an order is made and in what circumstances the parental responsibility can be exercised.

112. If you are in any doubt about whether a person has parental responsibility or whether a parent is acting in the best interests of the child you should seek legal advice.
113. Consent is usually only needed from one person holding parental responsibility. However there have been legal cases where the Court has advised that all parties with parental responsibility must give consent; if consent cannot be agreed an order from the Family Division of the High Court must be obtained. Those cases have included:
- sterilisation for contraceptive purposes
  - non-therapeutic male circumcision
  - hotly contested issues of immunization.
114. Where consent is being given on behalf of a child who is not competent to consent, the healthcare professionals, the child and the person with parental responsibility must meet to discuss and consider treatment options. This is particularly important if more than one person has parental responsibility for a child.
115. When children who are not competent to give consent are being cared for in hospital, it may not seem practicable to seek the consent of the parents on every occasion for every routine intervention such as blood or urine tests or X-rays. However, healthcare professionals should remember that, in law, such consent is required, although consent may be given in advance. Where a child is admitted, the healthcare professional should discuss with the parents what routine procedures will be necessary, and, if it is not practicable to seek consent for every intervention, they may ask the parents if they are content to give their consent in advance for these routine procedures. If the parents are not content to give their consent, then consent should be obtained on every occasion. The parents may specify that they wish to be asked before particular procedures are initiated. You must then do so, unless the delay involved in contacting them would put the child's health at risk.
116. It is important to be aware that neither an Emergency Protection Order (EPO) nor a Police Protection Order (PPO) confers the consent for examination. If the person who has parental responsibility is not available, consent with directions, must be obtained from the Family Division of the High Court.
117. A healthcare professional should not rely on the consent of a parent if he or she has any doubts about whether the parent is acting in the best interests of the child. In order to consent on behalf of a child, the person with parental responsibility must also have mental capacity themselves.
118. For forensic examinations different rules may apply.

### **Young people (age 16 to 17 years) without capacity to consent to treatment**

119. Healthcare professionals must follow the Mental Capacity Act when the young person lacks capacity to decide about treatment.

### **Children who are competent or young people (aged 16 or 17) with capacity who refuse treatment**

120. Healthcare professionals should be very careful in cases where a young person or child refuses treatment. Such cases can be controversial and raise complex legal issues. Healthcare professionals should have particular regard to chapter 3 of the Guide [*Set out Health Board / Trust's arrangements for dealing with such*]case e.g. *who should be contacted.*]
121. Where a young person of 16 or 17 who has capacity, or a child under 16 who has been assessed as “Gillick” competent, refuses treatment, a person with parental responsibility for the child / young person or the Courts can be used as alternative sources of consent<sup>7</sup>. In such circumstances legal advice should be sought. See Appendix C.
122. Where a child has refused treatment, and a decision is made to give treatment on the basis of parental consent, it must be exercised on the grounds that the welfare of the child is paramount. The psychological effect on the child of having their decision over-ruled must also be considered.
123. Where a young person aged 16-17 who has capacity is to be admitted to hospital for treatment for a mental disorder, the MHA provides that where that person refuses to be admitted to hospital for treatment for a mental disorder, a person with parental responsibility for that person cannot overrule that refusal. The MHA should be used where appropriate.

### **Person with parental responsibility refusing treatment**

124. If consent for treatment is refused by one or more of those with parental responsibility, or where an agreement cannot be reached between the persons with parental responsibility, seek legal advice. See Appendix C.

### **Young people aged 16 and 17 who refuse life-sustaining treatment**

125. Where a young person aged 16 or 17 refuses life-sustaining treatment (e.g. a blood transfusion on the basis of their religious conviction) healthcare professionals should exercise extreme caution. In these circumstances, legal advice should be sought and, if necessary, the matter should be referred to the court. See Appendix C

<sup>7</sup> [NHS Trust v X \(In the matter of X \(A Child\) \(No 2\)\) \[2021\] EWHC 65 \(Fam\) \(18 January 2021\) \(bailii.org\)](#)

126. The management of a young person in an emergency situation, who is likely to die or suffer serious permanent harm without immediate treatment, is viewed in law in a different light. There may not even be time for emergency application to the court. Senior clinicians may decide to treat without consulting the court. Parents may not prevent clinicians from administering treatment to their children if their child's life or health is in imminent danger. This includes cases where the parents wish to refuse blood products for their child on religious grounds. Staff may rely on the support of the courts to endorse decisions that are taken in good faith and in the best interests of the young person concerned. It is important, however that two doctors of consultant status should make an unambiguous, signed and dated entry in the patient's medical notes that the treatment is essential to save life or prevent serious permanent harm. The doctor who stands by and allows a 'minor' patient to die in circumstances where treatment might have avoided death may be vulnerable to criminal prosecution.
127. The courts have often commented that such a situation does not detract from the loving and responsible reputation of the parents involved, and they have stressed the need for parents to be fully informed of the clinical developments regarding their child and of the intended action by clinicians.
128. When treating children or young people in these circumstances, healthcare professionals should consider carefully the guidance in chapter 5 of the Guide.

### **Parents refusing life-sustaining treatment for a child**

129. Where a parent or parents intend to refuse life-sustaining treatment for a child under the age of 16, staff must always seek legal advice (see Appendix C). The well-being of the child is paramount and, if the parents refuse to give permission for the treatment, it may be necessary to apply for a court order to administer the treatment lawfully. Healthcare professionals should note that a court order can be obtained out of hours when necessary.

### **Emergency treatment**

130. A life threatening emergency may arise in connection with a child when consultation with either a person with parental responsibility or the court is impossible, or the persons with parental responsibility refuse consent despite such emergency treatment appearing to be in the best interests of that child. In such cases the courts have stated that doubt should be resolved in favour of the preservation of life and it will be acceptable to undertake treatment to preserve life or prevent serious damage to health.

## **8. Patients who lack capacity to give or withhold consent**

131. In determining whether a patient aged 16 years and over lacks the mental capacity - either temporarily or permanently - to give or withhold consent for themselves, healthcare professionals must act in accordance with the MCA. A patient who lacks capacity can be given treatment if it is in their best interests, as long as the patient (when aged 18 years and over) has not made a valid and applicable advance decision refusing that specific treatment.
132. When treating patients who may lack capacity, healthcare professionals must have due regard for the MCA Code of Practice.

### **Does the patient have capacity?**

133. The MCA applies in relation to determining whether a patient has capacity to give their consent. It is a key principle of the MCA that a patient is assumed to have capacity to make decisions for themselves unless it is established on the balance of probabilities that they do not.
134. In ascertaining a patient's capacity, the healthcare professional must not make a judgment on the basis of the patient's age, appearance, assumptions about their condition or any other aspect of his or her behavior. It is important to take all possible steps to try and help the patient make a decision for themselves (see chapter 3 of the MCA Code of Practice). Where there is doubt about a patient's capacity, an assessment should be carried out and the healthcare professional must be able to justify their conclusions.
135. It is the healthcare professional proposing treatment or examination who should assess the patient's capacity to consent. More complex decisions are likely to need more formal assessments, which may include a professional opinion (for example from a speech and language therapist/psychologist), but the final decision about the patient's capacity must be made by the person intending to carry out the action.
136. Healthcare professionals who carry out actions related to the care and treatment of patients who lack capacity to consent to them at that time may be protected from liability if they reasonably believe (having assessed the patient's capacity where there is doubt) that the patient lacks capacity to make that particular decision at the time it needs to be made and the action is in the patient's best interests. (For further guidance see chapter 6 of the MCA Code of Practice and note that the MCA imposes limitations on acts which can be carried out with protection from liability – including where there is inappropriate use of restraint or where the patient who lacks capacity is deprived of their liberty).
137. A patient lacks capacity if he or she is unable to make a specific decision for themselves in relation to a matter at the time it needs to be made because they have an impairment or disturbance of the mind or brain. This impairment or disturbance can either be temporary or permanent.

138. The MCA provides that a patient with an “impairment or disturbance” is unable to make a decision if they are unable to do one or more of the following:
- a) understand the information relevant to the decision; or
  - b) retain that information; or
  - c) use or weigh that information as part of the process of making the decision; or
  - d) communicate his or her decision, whether by talking, using sign language or any other means.
139. If a patient cannot do one or more of these as a result of their impairment they will be treated as being unable to make the decision. Point d) only applies in situations where the patient cannot communicate their decisions in any way.
140. The British Medical Association has published advice on the assessment of capacity - [www.bma.org.uk/](http://www.bma.org.uk/)
141. Capacity should not be confused with a healthcare professional’s assessment of the reasonableness of the patient’s decision. The patient is entitled to make a decision which is based on their own religious belief or value system, even if it is perceived by others to be unwise or irrational.
142. Where there is any doubt about a patient’s capacity to make a particular decision, after support has been provided without success, an assessment must be carried out. This should be done in accordance with the requirements of the Mental Capacity Act 2005 and the assessment must be recorded e.g. using Form 4.
143. An apparent lack of capacity to give or withhold consent may in fact be the result of communication difficulties rather than genuine incapacity. The healthcare professional undertaking the assessment of capacity is required by the MCA to take all practicable steps to help the patient make the decision, therefore they should involve appropriate colleagues, such as specialist learning disability teams and speech and language therapists, unless the urgency of the patient’s situation prevents this. If at all possible, the patient should be assisted to make and communicate their own decision, for example by providing information in non-verbal formats where appropriate.

### **Advance decisions to refuse treatment (ADRT)**

144. In accordance with the MCA, a person who is 18 or over and has capacity can make an ADRT. An ADRT may be withdrawn or altered at any time whilst the person has capacity.
145. Any ADRT that is valid and applicable to the treatment that is proposed is legally binding. A healthcare professional must follow a valid and applicable ADRT. If they do not, they could face criminal prosecution and or civil liability.
146. A valid and applicable ADRT that is made after a Health and Welfare LPA overrules the decision of any Attorney.

147. If a patient has made a valid and applicable ADRT but that treatment is for a mental disorder, a healthcare professional may still give that treatment to the patient if he or she has authority to do so under Part 4 and 4A of the MHA and consent is not required. Informal patients are not covered by Part 4 of the MHA and their advance decisions refusing treatment are enforceable if valid and applicable.

### **Validity of an ADRT**

148. An ADRT is valid if made voluntarily by an appropriately informed adult (aged 18 years or over) with capacity.

149. An ADRT is **not** valid if the individual:

a) was under 18 years of age when it was drawn up; or

b) did not have capacity when the decision was made; or

c) was acting under duress; or

d) has withdrawn the advance decision (verbally or in writing) at a time when he/she had capacity to do so; or

e) has done anything else clearly inconsistent with the ADRT remaining his fixed decision; or

f) creates an LPA after the date when the ADRT was made, conferring authority on the attorney to give or refuse consent to the treatment to which the ADRT relates.

150. Healthcare professionals should ensure that the ADRT that is being considered has been regularly reviewed and updated. However, ADRT made long in advance of incapacity are not necessarily invalid unless, for example, there are reasonable grounds for believing that circumstances have since arisen which mean the patient would have changed their mind if they still had capacity. For example, there may be a medical advancement which the patient was unaware of at the time he or she made the advance decision, which could significantly improve their condition.

151. There are no specific legal requirements concerning the format of an ADRT (unless it involves life-sustaining treatment – see below). It may be a written document, a witnessed verbal statement, a signed printed card, a smart card, or a note of discussion recorded in a patient's health record. Although there is no legal requirement, if possible patients should be encouraged to put their ADRT in writing so that there is a clear record of their wishes

152. If an ADRT relates to refusal of life-sustaining treatment, it will only be valid if it is in writing, contains the words 'even if life is at risk' (or words to that effect) and is signed, dated and witnessed.

## **Applicability of an ADRT**

153. An ADRT must clearly specify the treatment that is being refused and in what specific circumstances it applies. It must be unambiguous and applicable to present circumstances. If the decision to be made falls outside of the scope of the ADRT, it will not be applicable.
154. An ADRT cannot authorise anyone to do anything which is unlawful (for example assist an individual in committing suicide), or make anyone carry out a particular treatment.

## **Responsibility of healthcare professionals**

155. It is the responsibility of the person making the ADRT to ensure that it will be drawn to the attention of healthcare professionals when it is needed. However, healthcare professionals are also responsible for asking patients or their representatives about the existence of ADRT.
156. If a healthcare professional knows or has reasonable grounds to believe that an ADRT exists, and time permits, then they should make reasonable enquiries regarding its existence and content. Emergency treatment should not be delayed in order to look for an ADRT if there is no clear indication that one exists.
157. If an ADRT relates to refusal of life-sustaining treatment, then the healthcare professional must see a written, signed and witnessed ADRT which contains the words 'even if life is at risk' (or similar).
158. A healthcare professional will not be acting unlawfully if he or she treats a patient and is genuinely unaware of the existence of an ADRT. Similarly they will not act unlawfully if they act in accordance with an ADRT that they believe is valid and applicable at the time but is later proved to be invalid/ not applicable.
159. If there is any doubt about the validity or applicability of an ADRT it may be necessary to refer the matter to the Court of Protection (CoP). In this situation, healthcare professionals may provide life-sustaining treatment or treatment that prevents serious deterioration in the patient's condition whilst the decision of the court is awaited.
160. If an ADRT is not valid and applicable, it should still be noted as an expression of the patient's feelings and wishes about what should happen to them, and should be taken into account in deciding what is in their best interests.

## **Advance statements**

161. An advance statement is different to an advance decision to refuse treatment in that it generally outlines a patient's wishes or preferences in relation to care or treatment that they want to have, as opposed to being a refusal of treatment. Although an advance statement is not legally binding it should be noted as an expression of the patient's feelings and wishes about what should happen to them if they lack capacity to decide for themselves, and should be taken into account in deciding what is in their best interests.

162. Some advance statements will express the patient's wishes that a particular course of action should be taken or that they should receive a particular type of treatment in the event that they no longer have capacity. The healthcare professional is not under a legal obligation to provide treatment because the patient demands it. The decision to treat is ultimately a matter for his or her professional judgement acting in the context of a best interests decision. In making that decision the healthcare professional will, however, be required to take into account the patient's wishes as expressed in determining what is in his or her best interests.
163. Further information about ADRT is available in chapter 9 of the MCA Code of Practice.

### **Decisions made in the patient's best interests**

164. In determining what is in the patient's best interests, the healthcare professional must look at the patient's circumstances as a whole and not just at what is in the patient's best medical interests. They must try to work out what the patient would have wanted if he or she had capacity, rather than what that professional believes to be in his or her best interests. The healthcare professional must make all reasonable efforts to ascertain:
- the patient's past and present wishes and feelings,
  - any beliefs and values that would be likely to influence the patient's decision, and
  - any other factors that the patient would be likely to consider if they were making the decision.
165. Lack of capacity to make the decision in question will not automatically mean that the patient is unable to participate in the decision making process, and every assistance should be given to enable him or her to do so.
166. A healthcare professional must not make assumptions about someone's best interests simply on their age, appearance, condition or behaviour. They should also consider whether the patient is likely to regain capacity and if so whether the decision can be deferred.
167. They must also, so far as is practicable, consult representatives of the patient to see if they have any information about the patient's wishes, feelings, beliefs and values. In particular, they should try to consult:
- any unpaid person who is named by the patient as a person who should be consulted on such matters
  - anyone engaged in caring for the patient or interested in his welfare
  - any person who has been granted an LPA by the patient; and
  - any deputy appointed for the patient by the CoP to make decisions for that patient.
168. The purpose of consulting is to ascertain what the patient would have wanted if they had capacity, not what the persons consulted believe should happen. Where

a patient has made a Health and Welfare LPA or a deputy of the CoP (for personal welfare) has been appointed, and if it is within their authority, it will be for the attorney or deputy to make the decision on the patient's behalf. However, they too must act in the patient's best interests and, where practicable and appropriate, consult the people indicated above.

169. If a patient has no one who can be consulted, healthcare professionals must consider whether the circumstances are such that an Independent Mental Capacity Advocate (IMCA) should be instructed (see below).
170. If the patient has made an advance statement (other than a valid and applicable ADRT), then the healthcare professional should still take that statement into account in deciding what is in the patient's best interests, as it is a reflection of the patient's wishes and feelings. However, if it is the healthcare professional's judgement that to act in accordance with the advance statement would not be appropriate and not in the patient's best interests, he or she is not bound to do so.

### **Temporary incapacity**

171. Patients may suffer a temporary loss of capacity, for example, where they are under a general anaesthetic or sedation, or unconscious after a road accident. As with any other situation, an assessment of that patient's capacity must only examine their capacity to make a particular decision when it needs to be made. Unless the patient has made a valid and applicable ADRT of which you are aware, then they may be treated insofar as is reasonably required in their best interests pending recovery of capacity. This will include, but is not limited to, routine procedures such as washing and assistance with feeding. If a medical intervention is thought to be in the patient's best interests but can be delayed until the patient recovers capacity and is able to consent to (or refuse) the intervention, it must be delayed.

### **Fluctuating capacity**

172. It is possible for a patient's capacity to fluctuate. In such cases, it is good practice to establish whilst the patient has capacity their views about any clinical intervention that may be necessary during a period of incapacity and to record these views. The patient may wish to make an advance decision to refuse certain types of treatment (see paragraphs 144 to 160). If the person does not make a relevant ADRT, the patient's treatment when incapacitated should accord with the principles for treating the temporarily incapacitated (see above).

### **Lasting Power of Attorney (LPA)**

173. LPA was introduced by the MCA. An LPA may be executed by any person of 18 years or over whilst they have capacity and takes effect when they no longer have capacity. A Health and Welfare LPA appoints a person to act as an attorney to make decisions about a person's welfare and medical treatment when that person lacks the capacity to make that particular decision. The attorney acting under a Health and Welfare LPA must make the decision in the person's best interests. The LPA must be registered with the Office of the Public Guardian (OPG) before it can be used and it is essential that healthcare professionals see the sealed (OPG

stamp) LPA document to confirm that it has been registered, and to assure themselves of the authority that it confers on Attorney(s). An LPA does not authorise an attorney to refuse or give consent to life-sustaining treatment unless this is explicitly stated in the LPA. If two or more people have been appointed as attorneys, they may either be appointed to act jointly or jointly and severally. If they are acting jointly, any decision must be made by consensus. However if they are acting jointly or severally, then either of the attorneys can make a decision independently of the other.

174. If the patient has made a valid and applicable ADRT to refuse treatment, then this can be overridden by an attorney providing that the LPA was made after the advance decision and his or her authority under the LPA extends to making decisions about treatment that is the subject of the advance decision. An attorney, like any person who is making a decision on behalf of a patient who lacks capacity, must act in accordance with the MCA and must have regard to the MCA Code of Practice.
175. When acting on the basis of a decision by an attorney, a healthcare professional should, so far as is reasonable, try to ensure that the attorney is acting within their authority. Any disputes between a healthcare professional and an attorney that cannot be resolved, or cases where there are grounds for believing that the attorney is not making decisions that are in the best interests of the patient, should be referred to the CoP.

### **Court Appointed Deputies (CAD)**

176. Whilst a decision made by the Court is always preferred, the MCA now provides that the Court can appoint deputies to make decisions on its behalf. This may be necessary if there are a number of difficult decisions to be made in relation to the patient. The CAD will normally be a family member, partner, friend or person who is well known to the patient. Healthcare professionals must always ensure that they see a sealed (CoP stamp) copy of the deputyship order so that they are clear what authority the CAD holds.
177. As with attorneys appointed under a LPA, a CAD may only make decisions where they have reasonable grounds to believe that the person they are acting for does not have capacity, and any decisions they take will be strictly limited to the terms specified by the Court and in accordance with the MCA. A CAD is also subject to a number of restrictions in the exercising of their powers. For example, a CAD cannot refuse consent to the carrying out or continuation of life-sustaining treatment for the patient, nor can he or she direct a person responsible for the patient's healthcare to allow a different person to take over that responsibility. A deputy cannot restrict a named person from having access to the patient.
178. Healthcare professionals should co-operate with the CAD with the aim of doing what is best for the patient. Where a CAD acting within their authority makes a decision that a treatment (that is not life-sustaining) should be withheld or withdrawn the healthcare professional must act in accordance with those instructions. However a CAD cannot require a healthcare professional to give a particular type of treatment, as this is a matter of clinical judgement. In such cases where a healthcare professional has declined to give treatment, then it is good practice to seek a second opinion, although the CAD cannot insist that the

healthcare professional steps aside to allow another professional to take over the case. A CAD is supervised by the OPG, and where a healthcare professional suspects that a deputy is not acting in the interests of the patient, he or she should refer the matter to the Public Guardian.

179. A valid and applicable ADRT overrules the decision of the CAD.

### **Independent Mental Capacity Advocates (IMCA)**

180. If a patient aged 16 years or older who lacks capacity is to receive serious medical treatment, and that patient has no one else to consult and support them other than paid or professional staff, then unless a decision has to be made urgently (e.g. to save the person's life), an IMCA must be instructed. The duty to instruct rests with the Health Board / Trust in the case of treatment provided in hospital. (Note that there are other situations when an IMCA must be instructed – e.g. decisions about whether to place people into accommodation (for example a care home or a long stay hospital and under the Deprivation of Liberty Safeguards.)

181. The role of the IMCA is to represent and support the patient. They will not make decisions on the patient's behalf. Such decisions will still be made by the healthcare professional on the basis of what is in the patient's best interests. However the IMCA will speak to the patient and, so far as possible, try to engage them in the decision process. They will assist in determining what is in the patient's best interests and the healthcare professional must take into account the views of the IMCA in deciding what actions to take. The IMCA is entitled to information about the patient and to see his or her relevant health records.

182. Where serious medical treatment is proposed, they will discuss with the professional the proposed course of treatment or action and any alternative treatment that may be available and may, if they consider it necessary, ask for a second medical opinion.

183. Serious medical treatment for this purpose means treatment which involves providing, withdrawing or withholding treatment in circumstances:

- where there is a fine balance between the benefits and burdens the treatment would have on the patient and taking into account the likely risks
- where there is a choice of treatments, a decision as to which one to use is finely balanced or
- what is proposed would be likely to involve serious consequences for the patient

### **Referral to the Court of Protection**

184. Where there are difficult or complex decisions to make on behalf of a patient who lacks capacity, the matter must be referred to the Court of Protection if all other options for making the decision or resolving differences have been exhausted.

185. The Court of Protection can deal with any matters covered by the Mental Capacity Act 2005.

Act 2005, such as:

- whether the patient has capacity to make a particular decision
- whether an ADRT is valid and applicable
- what course of action/decision would be in a patient's best interests
- where there is a dispute between healthcare professionals, members of the family, partners, carers or any other interested persons such as an Independent Mental Capacity Advocate or the attorney of a Lasting Power of Attorney about what is in the patient's best interests
- where there is doubt about whether the patient lacks capacity to make a decision for themselves and is not likely to regain capacity in the short term
- where treatment of an experimental nature is proposed.

186. Where a patient lacks capacity then ***a referral to the Court must be made*** in the following circumstances:

- where it is proposed that the patient should undergo non-therapeutic sterilisation (e.g. for contraceptive purposes)
- cases involving organ or bone marrow donation by a patient who lacks capacity to consent;
- where it is proposed to withdraw / withhold nutrition and hydration from a patient with a prolonged disorder of consciousness (PDOC) and for example, the case seems 'finely balanced', or where there are differences of opinion between treating clinicians, or between treating clinicians and patients' families as to whether ongoing treatment is in the patient's best interests or where a dispute has arisen and cannot be resolved. The term PDOC encompasses both permanent vegetative state (PVS) and minimally conscious state (MCS)
- where there are doubts or a dispute about whether a particular treatment would be in the best interests of the patient.

This is not an exhaustive list and the courts may extend the list of procedures that should always be referred. Legal advice should be sought

187. If the MCA and MCA Code of Practice and regulatory framework are observed correctly, there is agreement as to what is in the patient's best interests and a second independent clinical opinion is available which supports the best interests decision and that the clinical decision to withdraw Clinically Assisted Nutrition and Hydration CANH is reasonable in the circumstances, given the diagnosis, life sustaining treatment (including CANH) can be withdrawn/withheld without the need to make an application to the court. The second clinical opinion should be sought from a consultant with experience of PDOC, who has not been involved in the patient's care and who should, so far as reasonably practical, be external to this [Health Board / Trust]. The consultant should examine the patient and review the patient's medical notes and the information that has been collected. Healthcare

professionals should make a very detailed) entry/record in the medical notes, outlining any relevant discussions or meetings that have taken place and the reasons for the opinion that has been provided. Legal advice can be sought to support the decision

188. The Court has held that therapeutic abortion and sterilisation where there is a medical necessity does not automatically require a referral, although such procedures can give rise to special concern about the best interests and rights of a patient who lacks capacity. In the case of a patient with learning disabilities, it is good practice to involve a learning disability consultant psychiatrist, the multidisciplinary team and the patient's family/partner as part of the decision-making process and to document their involvement. Less invasive or reversible options should always be considered before permanent sterilisation.
189. Appendix C provides advice for healthcare professionals who need legal advice when they are faced with a situation that may require the intervention of the Court of Protection. Guidance on referring matters to the Court of Protection has also been issued by the General Medical Council and the BMA.  
[http://www.gmc-uk.org/guidance/ethical\\_guidance/consent\\_guidance\\_index.asp](http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp)  
<https://www.bma.org.uk/advice/employment/ethics/mental-capacity/mental-capacity-toolkit/12-court-of-protection-and-court-appointed-deputies>
190. Where an adult or young person has been assessed to lack the capacity to give or withhold consent to a significant intervention, this fact should be documented on Form 4: Treatment in best interests (see chapter 2 of this policy) along with full details of the assessment of capacity and best interests.

## 9. Human Tissue

### Removal, storage and use of human tissue

191. The Human Tissue Act 2004 (HTA 2004) makes consent the fundamental principle underpinning the lawful retention and use of body parts, organs and tissue from the living or deceased for specified health related purposes and public display. Human tissue is defined as material which has come from a human body and consists of, or includes human cells. Live gametes and embryos are excluded as they are regulated under the Human Fertilisation and Embryology Act 1990 (HFEA).
192. The Human Tissue Act Codes of Practice and Standards issued by the Human Tissue Authority (HTA) contain detailed provisions on consent to the storage and use of relevant material from the living and the deceased. The Codes and Standards can be found on the following link: <https://archive.hta.gov.uk/hta-codes-practice-and-standards-0>
193. The HTA 2004 creates an offence of DNA theft. It is unlawful to obtain and store human tissue with the intention of its DNA being analysed, without consent of the patient from whom the tissue was obtained.
194. The HTA 2004 allows material taken from the living to be stored and used without consent for the following scheduled purposes on the basis that these are bound up with the general provision of clinical and diagnostic services:
  - clinical audit
  - education or training relating to human health
  - performance assessment
  - public health monitoring and
  - quality assurance
195. However, if a patient actively objects to the use of their samples for such purposes, then that objection should be complied with. The Act and the Code contain a complex set of rules around the need for consent being required for the above purposes if the tissue is removed after death. There is also a set of rules about relevant material taken from a patient in their lifetime continues to be treated as such after death. It is the point at which the material is removed that determines how it is affected by the Act. The Code refers to concepts such as nominated representatives and qualifying relationships for the purpose of consent. It is too detailed to quote fully here and it should be consulted where relevant decisions need to be made.

196. Consent is required to store and use tissue removed from the living for:
- obtaining scientific or medical information about a patient which may be relevant to any other person (now or in the future)
  - public display
  - research into disorders, or the functioning of the human body and
  - transplantation.
197. The system must be well-publicised and transparent, making provision for patients to record their consent or objection to the use of such tissue and for this to be notified to the laboratory. Patients must also be able to record any objections to particular uses or use of particular tissues.
198. In the [Health Board / Trust] written consent must be obtained from the patient either at the time of their procedure, or retrospectively, to indicate whether or not they give their consent to the use of removed tissue for a specific research project.

### **Consent to post mortem examinations**

199. The [Insert details of Health Board / Trust Policy] should be referred to for necessary details.
200. If a post mortem examination is ordered by the coroner, the consent of relatives is not required.
201. Other post-mortem examinations are hospital post-mortem examinations which are usually carried out at the request of doctors who have been caring for the patient or, sometimes, at the request of close relatives wishing to find out more about how a patient died. In some circumstances it may be appropriate to limit the examination to a particular region of the body.
202. All post mortems are carried out under an HTA licence held by the Health Board / Trust. It is a requirement of the HTA 2004 that appropriate consent is taken before a post-mortem can be carried out or any other tissue removed from the body of a deceased person. This consent must be obtained from a person in a "qualifying relationship" (see also above). The request for a hospital post-mortem should be made by the Clinician who, after discussions, will liaise with the appropriate persons to ensure all statutory requirements are met.
203. For further information on post mortems the *Human Tissue Authority Code of Practice – Post Mortem Examination (Code B, 2012)* should be consulted. For further information on retention of tissues, organs and body fluids, please seek advice from the pathologist.

## **Transplantation - Living Donation**

204. The HTA is responsible for the regulation, through a system of approvals, of the donation from living people of solid organs, bone marrow and peripheral stem cells for transplantation into others. Information on the legal requirements is available - <https://www.hta.gov.uk/>

## **Transplantation - Deceased organ donation**

205. Consent to organ donation in Wales is governed by the Human Transplantation (Wales) Act 2013. There is an associated Code of Practice - [https://bts.org.uk/wp-content/uploads/2018/01/HTA\\_CoP\\_on\\_Human\\_Transplantation\\_Wales\\_Act\\_2013\\_-\\_Final\\_-\\_May\\_2014.pdf](https://bts.org.uk/wp-content/uploads/2018/01/HTA_CoP_on_Human_Transplantation_Wales_Act_2013_-_Final_-_May_2014.pdf). This system operates on the basis of deemed consent; it is assumed that the individual had no objection to organ donation unless they have registered or expressed a decision not to donate their organs following their death. Patient representatives should be consulted to obtain any evidence that a patient did not wish to be an organ donor.
206. Express consent to organ donation is required where a patient has not been an ordinary resident in Wales for more than 12 months before dying

# 10. Clinical photography, video recordings and audio recordings

## Making and using visual or audio recordings of patients

207. This chapter focuses on the consent aspect of making photographic, video or audio recordings of patients. 'Recordings' in this chapter means originals or copies of audio recordings, photographs and other visual images of patients that may be made using any recording device e.g. video.

208. Visual and audio recordings of patients may be made for any of the following reasons:

- As part of assessment, investigation or treatment of a patient, to be kept in the patient's medical notes.
- For use in teaching, training or assessment of fellow healthcare professionals and students or other appropriate groups e.g. at a conference.
- For use in clinical research.
- For publication e.g. in a book, a journal, a patient information leaflet, on a poster or in publicity material, any of which may also be accessible on the internet.
- As potential evidence e.g. following injuries sustained as the result of an accident or an assault or where there is suspected non-accidental injury [see Health Board / Trust Policy].

209. Because it is sometimes possible for people to be identified by tattoos or other distinguishing marks or features, or from the sound of their voice in an audio recording, it is this Health Board/Trust's policy that written consent must always be obtained prior to making a visual or audio recording of a patient or their art work for any of the purposes described in paragraph 208 (for exceptions see paragraph 215 below).

210. Healthcare professionals should always ensure that they ask for a patient's written consent in advance if any photographic, video or audio recording will result from a procedure (unless the patient is temporarily unconscious – see paragraph 224).

211. If you only obtain consent for use of photographic, video or audio recordings as part of treating or assessing a patient you must not use them for any purpose other than the patient's care or the audit of that care, without obtaining further consent from the patient.

## General Principles

212. When making or using recordings you must respect the patient's privacy and dignity and their right to make or participate in decisions that affect them. The following general principles apply to most photographic, video and audio recordings:

- seek permission to make the recording and get consent for any use or

disclosure.

- give patients adequate information about the purpose of the recording when seeking their permission.
- make recordings only when you have appropriate consent or other valid authority for doing so.
- ensure that patients are under no pressure to give their permission for the recording to be made.
- stop the recording if the patient asks you to, or if it is having an adverse effect on the consultation or treatment.
- do not participate in any recording made against a patient's wishes.
- eyes or faces must not be blacked out in an attempt to conceal identity after the recording has been made. Every effort must be made to conceal the identity of the patient whilst the recording is being taken. You must ensure that the patient is informed if their face will be visible in the recording.
- ensure that the recording does not compromise patients' privacy and dignity.
- do not use recordings for purposes outside the scope of the original consent for use, without obtaining further consent.
- make appropriate secure arrangements for storage of recordings.

213. Before the photograph, video or audio recording is made, healthcare professionals must ensure that patients:

- understand the purpose of the recording, who will be allowed to see/hear it, the circumstances in which it will be shown/played, that copies are likely to be made if the recording is for educational purposes, and that the recording will be stored securely within the Health Board / Trust.
- understand that, in the case of publication, they will not be able to withdraw their consent or control future use of the material, once the recording is in the public domain.
- understand that withholding permission for the recording to be made, or withdrawing permission during the recording, will not affect the quality of care they receive.
- are given time to read explanatory material and to consider the implications of giving their written permission. Explanatory material should not imply that permission is expected. It should be written in language that is easily understood. If necessary, translations should be provided.
- have completed and signed consent form which is broken down into granular statements for the various purposes, clearly indicating which statements they consent to and which ones they don't.

214. After the recording, the healthcare professional must ensure that:

- patients are asked if they want to vary or withdraw their consent to the use of the recording.
- recordings are used only for the purpose for which patients have given consent.
- patients are given the chance, if they wish, to see the recording in the form in which it will be shown.
- recordings are given the same level of protection as with patient's medical notes against improper disclosure.
- if a patient withdraws or fails to confirm consent for the use of the recording, the recording is not used and is erased as soon as possible

### **Recordings for which consent is not required**

215. Permission and consent is not needed to make or use the recordings listed below, provided that, before use, they are effectively anonymised by the removal of any identifying marks (writing in the margins of an x-ray, for example):

- Images taken from pathology slides
- X-rays
- Laparoscopic or endoscopic images
- Images of internal organs (however, it is best practice to obtain written consent if the recording is to be used in education or publication and will be accompanied by verbal or written information which may enable inadvertent identification of the patient)
- Recordings of organ functions
- Ultrasound images

### **Children and young people**

216. Where children lack the understanding to give their permission to photographic, video or audio recordings, healthcare professionals must get permission to record from the person with parental responsibility. Children under 16 who have the competence to give permission for a recording may sign the consent form themselves. Healthcare professionals should make a note of the factors taken into account in assessing the child's competence. Young people are assumed in law to be competent and can give permission to recordings themselves, unless they lack capacity.

217. In cases of suspected non-accidental injury of a child, photographs may be taken without parental consent if necessary. However these photographs must only be used as part of the clinical record, or as potential evidence. They must not be used

for education, publication or research without written consent. If written consent is given for use in education, publication or research, it is recommended that images are not used for these purposes before or during likely legal proceedings.

### **Vulnerable adults**

218. In the case of suspected non-accidental injury of a vulnerable adult, efforts should be made to obtain written consent to the taking and use of photographs as potential evidence.
219. If the patient is unwilling for recordings to be made for evidential purposes, then the patient should still be asked for consent to photographs being taken for their clinical record, if it is a valid addition to the record, or if it is not appropriate to seek their consent for evidential purposes at that time e.g. if the alleged perpetrator is present. Photographs taken for the clinical record cannot be used as evidence, unless, at a later date, the patient changes their mind. In this case the consent form can be modified at this later date, and these modifications must be signed and dated by the patient.

### **Fetal loss, stillbirth and neonatal death**

220. Photographs taken solely for the purpose of giving them to the bereaved parents do not qualify as clinical photographs and therefore do not come under the auspices of this policy. Photographs taken on behalf of the bereaved must not be used for any other purpose without written consent from the person with parental responsibility.
221. If photographs are required for any other purpose (except during the course of a post mortem examination) the written consent of those with parental responsibility must be obtained.

### **Adults and young people who lack the capacity to consent for themselves**

222. When adults or young people lack capacity to make a decision about an audio or visual recording for themselves, any decision must be made in accordance with the MCA.
223. As a general principle you should 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.
224. The situation may sometimes arise where 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.

### **Adults and young people who lack capacity - Recordings made as part of clinical care, or as potential evidence**

225. If it can be demonstrated that it is in the patient's best interests, then photographs, video and audio recordings can be made as part of the patient's clinical care, or as

potential evidence. If someone holds a Health and Welfare LPA or is a CAD, they should be asked to consent on behalf of the patient. Otherwise the healthcare professional making the recording must confirm that they have assessed capacity and are acting in the patient's best interests.

### **Adults and young people who lack capacity - Recordings made for education and publication**

226. If adults or young people lack capacity to make a decision about photographs, video or audio recordings for themselves, then recordings can only be taken and used for education or publication if it has been determined to be in the patient's best interests.

### **Patients who have capacity but are unable to sign the consent form**

227. Physical inability to sign a consent form does not detract from an individual's ability to give consent. Patients can indicate their consent verbally or non-verbally, in the presence of a witness, who should then sign the consent form to confirm that the patient's consent was given. Recordings can then be used in the same way as if the patient had signed the consent form.

### **Withdrawal of consent**

228. Patients have the right to withdraw consent for the use of their audio or visual records at any time. This should be documented on the consent form and the form, or the appropriate section of the form, should be scored through. In the case of publication, it is particularly important to make it clear to patients, when consent is originally obtained, that once the recording is in the public domain there is no opportunity for effective withdrawal of consent.

### **Further information**

229. The above information is drawn from the GMC guidance: Making and using visual and audio recordings of patients (2011), which gives further detailed advice in the use of recordings when treating or assessing patients.

[Insert details of Health Board / Trust procedure for safe storage and disposal of recordings]

### **Telemedicine**

231. Telemedicine should be viewed as a form of examination, and valid consent should be obtained in the same way as in any other examination, not just to the recording and exchange of information but to the process of telemedicine. The patient should understand that:

- it is not the same as seeing a healthcare professional in a face-to-face meeting
- the information/diagnosis received may be compromised by the technology
- they have a right to decline review via telemedicine

Healthcare professionals must abide by their IT Security Policy and Data Protection Policies in the handling of all images/recordings and data

# 11. Consent to Specific procedures

## Consent to screening

232. Healthcare professionals must ensure that anyone considering whether to consent to screening can make a properly informed decision. As far as possible, they should ensure that screening would not be contrary to the individual's interest. Particular attention must be paid to ensuring that the information the patient wants or ought to have is identified and provided. Those taking consent should be careful to explain clearly:

- the purpose of the screening;
- the likelihood of positive/negative findings and possibility of false positive/negative results;
- whether there are any reasonable alternatives
- the uncertainties and material risks attached to the screening process;
- any significant medical, social or financial implications of screening for the particular condition or predisposition;
- follow up plans, including availability of counselling and support services.

233. If healthcare professionals are considering the possibility of screening adults and young people who do not have capacity to consent to the screening they must act in accordance with the MCA and ensure that decisions made are in the patient's best interests. In appropriate cases, account must be taken of the guidance issued by bodies such as the Advisory Committee on Genetic Testing.

## Consent to Cosmetic Treatments (surgical and non-surgical)

234. From **1 June 2016** new GMC guidance for Doctors applies to both surgical (such as breast augmentation) and non-surgical (such as Botox) procedures. A link to this guidance can be found here: [http://www.gmc-uk.org/static/documents/content/Guidance\\_for\\_doctors\\_who\\_offer\\_cosmetic\\_interventions\\_080416.pdf](http://www.gmc-uk.org/static/documents/content/Guidance_for_doctors_who_offer_cosmetic_interventions_080416.pdf)

## **12. Seeking consent for genetic investigations (or investigations likely to reveal the diagnosis as being a genetic disorder)**

236. Consent to genetic investigations is a particularly complex and controversial area.

### **Information and likely implications**

237. When obtaining consent for investigations which may reveal genetic disorders, it is important that patients have been given full information about the likely implications of the test. There are points to note about the types of result that might come from a diagnostic genetic investigation, and which should be understood by the person giving consent:

- a clear explanation of the patient's problems or features
- no relevant findings, even if the problem has a genetic cause
- a variant of uncertain significance (VUS) (on chromosomal microarray or on the DNA sequencing of a gene, a panel of genes, the exome or the whole genome). It may become possible to clarify the interpretation of such a VUS at some point in the future, so a reinterpretation after a few years might be appropriate
- an incidental finding may emerge of no relevance to why the test was performed, but is still of some possible clinical importance to the patient and perhaps to other members of the family. For example, a test may be performed to investigate neurodevelopmental difficulties. The results may or may not explain those problems, but the test might find some other variant that indicates a serious risk of an inherited cancer or of cardiac disease or late-onset dementia etc.
- as understanding of genetics improves rapidly, the result may be subject to reinterpretation in the future. Regard must be given to many results issued now being somewhat provisional.

238. If healthcare professionals are considering the possibility of performing investigations on adults and young people who do not have capacity to consent to the investigation, they must act in accordance with the MCA and ensure that they make decisions in the patient's best interests.

239. It is recommended that reference should be made to specialist guidelines such as guidance issued by the Joint Committee on Medical Genetics: <https://www.bsgm.org.uk/healthcare-professionals/confidentiality-and-genetic-information/>.

## 13. Withholding or withdrawing life – sustaining treatment

### General

240. The GMC guidance Treatment and care towards the end of life: good practice in decision making (2010) provides detailed guidance on withdrawing and withholding life - sustaining treatment.
241. A competent patient should always be consulted when making a decision to withhold or withdraw life-sustaining treatment unless the healthcare professional forms a view that involvement will actually ‘harm’ the patient. Recent case law has underlined the extent of the duty of the healthcare professionals to consult a competent patient<sup>8</sup> or those with an interest in the welfare of the patient, where that patient lacks mental<sup>9</sup> be involved in the decision.
242. Any valid and applicable ADRT is legally binding and must be respected unless a patient has subsequently made a Health and Welfare LPA giving the attorney authority to make decisions regarding the provision of life-sustaining treatment.
243. Where the patient lacks capacity to be involved in the decisions, and the patient has not made a Health and Welfare LPA giving an attorney appropriate authority, the healthcare professional must consult the patient’s relatives, friends, or carers and other professionals involved in their care when making a best interests decision about the withholding or withdrawal of life-sustaining treatment. If there is no-one other than paid staff to consult with, an IMCA must be instructed. Where an urgent decision is required and a patient’s representatives cannot be contacted, the reasons for this must be carefully recorded in the patient’s medical notes. See reference in paragraphs 164 - 171 above.
244. There is an important distinction between withdrawing or withholding treatment which is of no clinical benefit to the patient or is not in the patient’s best interests, and taking a deliberate action to end the patient’s life. A deliberate action which is intended to cause death is unlawful. Equally, there is no lawful justification for continuing treatment which is not in a patient’s best interests.
245. Once a decision has been reached to withhold or withdraw life-prolonging treatment, the basis of the decision and the details of any discussions with the patient and/or their representatives must be recorded in the medical notes. Decisions to withhold or withdraw life-prolonging treatment should be reviewed periodically and following any relevant change in a patient’s circumstances.

### Prolonged disorder of consciousness

246. If the MCA and MCA Code of Practice and regulatory framework are observed correctly, there is agreement as to what is in the patient’s best interests and a

<sup>8</sup>[Tracey v Cambridge University Hospital NHS Foundation Trust & Ors](#)

<sup>9</sup>[Elaine Winspear v City Hospitals Sunderland NHS Foundation Trust](#)

second independent clinical opinion is available which supports the best interests decision, life sustaining treatment (including CANH) can be withdrawn/withheld without the need to make an application to the court. For more detail see paragraphs 186 and 187 above.

247. Additional information is available from:

- Royal College of Physicians – Prolonged disorders of consciousness: national clinical guidelines - 2015
- BMA (2007) Withholding and withdrawing life-prolonging medical treatment: guidance for decision making, 3rd edition.
- GMC (2010) Treatment and care towards the end of life: good practice in decision making.
- An Interim Guidance document produced in December 2017 by the GMC, BMA and RCP entitled “Decisions to withdraw clinically-assisted nutrition and hydration (CANH) from patients in permanent vegetative state (PVS) or minimally conscious state (MCS) following sudden-onset profound brain injury”.

# 14. Medical treatment of patients with a mental disorder

## Basic principles

248. This chapter provides information regarding consent issues relating to the medical treatment of patients with a mental disorder. It should not be read in isolation from the rest of this policy, since the principles contained throughout this document apply to all patients from whom consent is sought, irrespective of whether or not they have a mental disorder.
249. The principle of self-determination and autonomy of the individual, described in chapter 1 of this policy, applies equally to those who are suffering from mental disorder; a key distinction being that, in the circumstances authorised by the Mental Health Act 1983 (referred to as the MHA), treatment for a mental disorder may be given in the absence of the recipient's consent. Nevertheless, consensual treatment should always be sought in line with the principle of provision within the least restrictive context.
250. Part 4 of the MHA is concerned with consent to treatment. The reader should also refer to the MHA 1983 Code of Practice for Wales, 2016 generally and particularly chapters 24 and 25 for further information about consent and the Mental Health Act 1983.
251. Patients suffering from mental disorder, including those detained under the MHA are not necessarily incapable of giving valid consent and each patient's capacity to consent has to be judged individually in the light of the decision required and the patient's mental state at the time. Lack of capacity can be permanent or temporary and can also vary over time. Assessment of capacity should follow the principles described in the Mental Capacity Act 2005 (see chapter 8 of this policy).
252. The approved clinician in charge of the treatment has a duty to ensure that the patient is provided with sufficient information to enable him/her to understand:
- the nature, purpose, likely and intended effects of the treatment,
  - their right to withdraw consent at any time, and
  - how and when treatment can be given without their consent, including the legal authority for the treatment.
253. A record of the discussion at which consent is obtained or sought must be fully recorded in the health records.
254. Inpatients in Wales, whether detained or informal, and those subject to conditional discharge, a community treatment order, or guardianship are eligible for an independent mental health advocate (IMHA). All patients being considered for s57 type treatments (i.e. psychosurgery or implantation of hormones to reduce male sex drive) and children under 16 years being considered for ECT are also eligible. The only exception is a patient detained in a place of safety under s135 or s136 of the MHA. Further information about the role of the IMHA may be found in chapter 6 of the MHA Code of Practice for Wales, 2016.

## **Medical treatment for mental disorder**

255. Psychiatric in-patients may be classified into three groups when considering consent to treatment for their mental disorder:
- a. patients detained under the Mental Health Act 1983,
  - b. informal patients who possess capacity to consent to treatment, and
  - c. informal patients who lack capacity to consent to treatment.

### **a. Patients detained under the Mental Health Act 1983**

256. Where a patient is capable of giving consent and refuses, non-consensual treatment may only be given if it is for a mental disorder and the healthcare professional has the legal authority in accordance with the provisions of the MHA and the necessary certification requirements. Medical treatment includes nursing, psychological intervention and specialist mental health rehabilitation and rehabilitation and care the purpose of which is to alleviate, or prevent a worsening of, the disorder or one or more of its symptoms or manifestations.
257. Medical treatment for mental disorder (except treatments under s57 i.e. psychosurgery and implantation of hormones to reduce male sexual drive) may be lawfully administered without the patient's consent provided:
- the patient is detained under the Mental Health Act 1983 (excluding patients detained under ss4 (4) (a), 5(2), 5(4), 35, 135, 136, 37(4)), and
  - the proposed medical treatment falls within the provisions of
    - s58 (a second opinion is required for patients who are refusing or incapable of consenting after three months of treatment),
    - s62 (urgent treatment), or
    - s63 (treatment for the first three months of detention) of the MHA.

### **b. Informal patients who possess capacity to consent to treatment**

258. Where informal patients possess the required capacity to give valid consent to medical treatment for mental disorder or to a plan of treatment, then their consent must be obtained. Where appropriate, this should be written consent. Where informal patients with capacity refuse treatment for their mental disorder consideration may be given to detaining the patient under the provisions of the MHA.

### **c. Informal patients who lack the capacity to consent to treatment**

259. An assessment of capacity should be undertaken in accordance with the MCA. If a patient is found to lack capacity to consent to treatment then a determination of their best interests must be undertaken before any treatment is provided. In assessing someone's best interests it is essential to consult people who are close to the patient.
260. Section 5 of the Mental Capacity Act 2005 (MCA) provides that treatment may be given to a patient who lacks capacity to consent provided that it is in his or her best interests to do so. Section 6 of the MCA provides that a patient may only be restrained to give care or treatment if it is necessary to prevent harm and it is a proportionate response to the likelihood and severity of that harm - *provided that it is in his/her best interests*.
261. If a patient who lacks capacity to consent to treatment appears to be objecting to treatment, then consideration should be given to detaining the patient under the MHA.

### **Patients detained under the Mental Health Act 1983 requiring treatment for a physical disorder**

262. Part IV of the MHA is concerned with medical treatment for mental disorder. The MHA cannot be used to enforce treatment for a physical disorder, which is unrelated to a mental disorder, where a patient refuses consent. For patients who lack capacity to consent to medical treatment for a physical illness the provisions of the MCA would be engaged.
263. The patient's mental disorder may affect their capacity to consent. This should be assessed as a priority in line with the MCA, as treatment for the physical disorder might proceed in the patient's best interests. However, it should not be assumed that the patient lacks capacity simply because they have a mental disorder.
264. Section 63 of the MHA may allow for the treatment of a physical disorder, without the patient's consent, where it is 'ancillary to the treatment of the mental disorder' for example:
- Nasogastric feeding a patient with anorexia nervosa (*Re KB (Adult)*(1994))
  - Taking blood for patients on clozapine
  - Treating self-inflicted wounds
265. The term 'medical treatment' in section 63 of the MHA refers to treatment which, taken as a whole, is calculated to alleviate or prevent a deterioration of the mental disorder from which the patient is suffering. This includes a range of acts ancillary to the core treatment including those which prevent the patient from harming herself or those which alleviate the symptoms of the disorder (*B v Croydon HA* [1995])
266. If uncertainty exists as to a patient's capacity to consent to treatment, or whether the physical disorder may be treated as a symptom of the mental disorder, legal advice should be sought. See appendix C.

## **15. Consent to research and innovative treatment**

### **Research**

267. Any research undertaken within the Health Board / Trust must be registered with the Health Board/Trust's Research & Development Office, from where additional advice can be obtained. All research and development must be approved before it can be commenced. [Insert details for local process]
268. Consent to clinical trials is covered by the 'Medicines for Human Use Regulations (2004)
269. The same legal principles apply when seeking consent from a patient for research purposes. GMC guidance states that patients 'should be told how the proposed treatment differs from usual methods, why it is being offered, and if there are any additional risks or uncertainties'.
270. Where the proposed treatment is of an experimental nature, but not part of a research trial, this fact must be clearly outlined to the patient along standard alternatives – including no treatment – during the consent process.

### **Patients who lack capacity to consent to being involved in research**

271. There are strict rules within the MCA concerning the involvement of people who lack capacity in research. (See MCA Code of Practice and Welsh Government's Guide to Consent for Examination and Treatment). In determining whether the patient should participate in the proposed research, the patient's wishes and feelings about being involved in research should be respected. It should be stressed that many research studies are non-therapeutic, i.e. they will not benefit the research participants personally. Carers or other persons who have an interest in the patient's welfare must be consulted. If there is no one who can be consulted, then a person who is unconnected with the research project must be appointed to advise on whether the patient should take part in the research. If at any time during the research it appears that the patient is upset or unhappy, it must cease immediately. [Insert details of organisation's requirements in relation to research].
272. Where a patient lacks capacity, experimental/innovative treatment cannot be given unless it is in their best interests. Where there is no alternative treatment available, it may be reasonable to consider an experimental treatment, with unknown risks and benefits, where treatment may benefit the patient.

### **Consent to research and innovative treatment in children**

273. The legal approach to consent to therapeutic research in children is similar to any other proposed examination or treatment: the treatment must be in the child's best interests.
274. Health Board / Trust staff should contact the R&D Department for further advice on obtaining consent for children aged under 16 years. The approach will differ depending on whether the study is a clinical trial or not, and whether or not the proposed research will take place in an emergency setting.

## 16. Training

[Insert details of training available on consent in this organisation, covering both basic training on the law of consent, and training on any specific procedures used in this organisation.]

Dated:

Person responsible for policy:

Policy approved by:

Policy to be reviewed by [date]:

# Supplementary Guidance

## 17. Consent in obstetrics and gynaecology

### Pregnant women

275. A pregnant woman with capacity may refuse any treatment, even if this would be detrimental to herself and/or her foetus(es). Any treatment involving the foetus will require maternal consent. However, it should be stressed that maternal refusal of treatment thought to benefit one or both parties is a rarity.

### Caesarean section (including refusal)

276. If a caesarean section is required, the standard Consent Form 1 must be used. Women in labour can consent to a caesarean section even if they have received sedation.
277. It is important to ensure that all pregnant women have a good understanding of the different ways in which they may give birth and the associated benefits and material risks. This will include information about the circumstances in which a caesarean birth will be offered. A pregnant woman with capacity may refuse a caesarean birth, even if “the consequence may be the death or serious handicap of the child she bears, or her own death” (Court of Appeal Re MB). In other words a mentally competent woman in labour has the same right under common law to consent to or refuse consent to treatment as any other patient. United Kingdom law does not currently grant the foetus any legal rights, therefore a caesarean birth cannot be authorised by a Court against a competent woman’s will and action cannot be taken in the best interests of the pregnant woman or the foetus. In this situation all advice given to the woman should be recorded in her notes. Unequivocal assurances should be obtained from the woman (and recorded in writing) that the refusal represents an informed decision: that is, that she understands the nature of and reasons for the proposed treatment and the risks and the likely prognosis involved in the decision to refuse or accept it. It is good practice to ask the woman to sign the written indication of her refusal. It is also good practice to involve another senior colleague to indicate that a body of senior medical opinion considers caesarean birth to be the most appropriate course and that the patient has refused consent for a caesarean birth.
278. If the woman is unwilling to sign a written indication of this refusal, this too should be recorded in the notes. Such a written indication is merely a record for evidential purposes. It should not be confused with or regarded as a disclaimer.
279. There have been a number of cases where doubts have arisen, for various reasons, as to a woman’s capacity to make a valid decision about a caesarean birth. Temporary factors such as fear, shock, fatigue, pain or drugs may affect capacity. If there is reason to doubt capacity, support should be provided to help the woman make a decision. If that fails, a capacity assessment must be undertaken.

280. Where there is any doubt about a woman's capacity and/or where a refusal would lead to serious consequences for the pregnant woman or her unborn child, then legal advice should be obtained. If a pregnant woman refuses a caesarean birth (or any other intervention) and it has been demonstrated (in line with the Mental Capacity Act) that she lacks the capacity to make such a decision, an application to the CoP will be required to decide whether or not such treatment can be carried out [insert details of how this can be done out of hours or in an emergency situation within your Health Board/Trust]. In the case of *Re S*, the Court of Appeal laid down general principles that should be applied in future cases. If the mother lacks capacity, avoiding the foetus' death may be seen by the Court as being in the best interest of the mother.
281. Where a pregnant woman lacks capacity due to unconsciousness and so is incapable of giving consent, the caesarean birth may be carried out if it is in her best interests, unless a valid and applicable advance decision to refuse treatment exists. The most usual form of advance decision used by pregnant women is the birth plan. However, if there is reason to doubt the reliability of the advance decision (e.g. it might sensibly be thought not to apply to the circumstances which have arisen – see chapter 8 of this policy) then legal advice should be sought. See Appendix C.

## **Sterilisation**

282. Men and women requesting sterilisation should be given information about alternative long-term reversible methods of contraception. This should include information on the risks, benefits and relative failure rates of each method. Non-operative methods of long-term contraception should have been specifically rejected by the patient before a decision is taken to proceed with sterilisation.
283. Both vasectomy and tubal occlusion should be discussed with all men and women requesting sterilisation. Women in particular should be informed that vasectomy carries a lower failure rate in terms of post-procedure pregnancy and there is less risk related to the procedure when compared with female sterilisation.
284. Patients should be told that the procedure is intended to be permanent, but should also be given the success rates of reversal procedures. They should be informed that the reversal operations of in vitro fertilisation (IVF) and intracytoplasmic sperm injection (ICSI) are rarely provided by the NHS.
285. People requesting sterilisation should be informed that tubal occlusion and vasectomy can be unsuccessful and that pregnancies can occur several years after the procedure.
286. Written consent must be obtained for vasectomy, and the man should be advised to take other contraceptive precautions until there have been two consecutive negative semen analyses. It is important that the possibility of late failure is explained to the patient and his partner before vasectomy, so they can make informed decision about additional contraceptive methods.
287. Non therapeutic sterilisation of someone who lacks the capacity to give their consent must be referred to the Court of Protection. The individual's capacity and best

interests must be thoroughly assessed in line with the Mental Capacity Act and legal advice should be sought at all times. (See chapter 8 and Appendix C).

## **Fertility**

288. It is a legal requirement under the HFEA 1990, as amended, that consent to the storage and use of gametes must be given in writing after the patient has received such relevant information as is proper and had an opportunity to receive counselling. Where these requirements are not satisfied, it is unlawful to store or use the patient's gametes. Healthcare professionals should ensure that written consent to storage exists before retrieving gametes.
289. Outside specialist infertility practice, these requirements may be relevant to healthcare professionals whose patients are about to undergo treatment which may render them sterile (such as chemotherapy or radiotherapy) where a patient may wish to have gametes, or ovarian or testicular tissue, stored prior to the procedure. Healthcare professionals may also receive requests to remove gametes from a patient unable to give consent.
290. The HFEA 1990 as amended makes provision to address cases where the taking of gametes is in the patient's best interests but the patient is unable to give written consent or lacks capacity to consent to the storage of the gametes.
291. Further guidance is available from the Human Fertilisation and Embryology Authority.

## **Termination of pregnancy**

292. The termination of a pregnancy may only take place with the informed consent of the pregnant woman. Prior to obtaining written consent, discussion must take place concerning the type of procedure (medical or surgical) and the risk of complications. Written information should be given to support verbal information. The husband or putative father's authority is not legally required.
293. If a woman opts for a medical termination of pregnancy then a realistic description should be given of the process, the number of visits necessary and the need for a health care professional to see products of conception or to perform a subsequent scan to ensure the termination is complete. It should be pointed out that there is a small risk of heavy bleeding at home before returning to hospital for the second part of the procedure, and that there is a high chance of miscarriage if the patient changes her mind between the first and second stages of the procedure.
294. If cervical ripening agents are to be used before surgical termination of pregnancy, the patient should understand that there is a high chance of miscarriage if she changes her mind before completing the procedure.
295. Prior to taking consent for termination of pregnancy, the senior doctor (Registrar or above) must sign Certificate A (Abortion Act, 1967) to indicate that he is in agreement with the need for the termination. The woman will receive counselling in advance of the procedure and will then be scanned to assess gestational age.

If the procedure is to be undertaken, Consent Form 1 must be used.

296. Clinicians are advised to seek legal advice (see Appendix C) where:

- a woman lacks the mental capacity to understand and appreciate the nature or consequences of a termination of her pregnancy; or
- a woman is in a state of continuous unconsciousness and there is no reasonable prospect that she will regain consciousness in time to request and to consent to the termination of her pregnancy
- a partner wishes to over-rule a decision to terminate a pregnancy

### **Histological examination and disposal of non-viable fetal products**

297. Consent should always be obtained with regard to the histological examination and disposal of non-viable fetal products up to the age of 24 weeks gestation.

## 18. Treatment in a Mental Health setting

### **S57 MHA: Treatment requiring capacity, consent and a second opinion**

298. Section 57 treatments include surgical operations that destroy brain tissue or destroy the functioning of brain tissue, and the surgical implantation of hormones for the purpose of reducing male sex drive. S57 applies to all patients, whether or not they are subject to the MHA.
299. Treatment under s57 can only be given if all three of the following requirements are met:
- the patient consents to the treatment,
  - a second opinion appointed doctor (SOAD) and two other people appointed by Healthcare Inspectorate Wales (HIW) certify the patient has the capacity to consent to the treatment and has done so, and
  - the SOAD also certifies that it is appropriate for the treatment to be given to the patient on form CO1.

### **S58 MHA: Treatment requiring consent or a second opinion**

300. The approved clinician (AC) in charge of treatment must obtain the valid consent of any patient before the administration of medicine by any means after three months, unless such medicine is being administered under s62 (emergency treatment).
301. There can only be one 3 month period for s58 treatment in any continuous period the patient is subject to detention. This includes a patient detained under s2 which is immediately followed by detention under s3 and the patient is then discharged onto s17A (supervised community treatment) followed by the patient being recalled and having the Community Treatment Order (CTO) revoked and again discharged onto s17A.
302. When the patient has given valid consent to take s58 type treatment form CO2 must be completed by the AC in charge of the treatment. All medicines must be designated by their classes (as described in the BNF) rather than individually. Moreover, the doses may be entered as within BNF limits, but specific doses must be included when the BNF limit is being exceeded. Any new addition to the classes of drugs requires a Form CO2 to be completed by the AC in charge of the treatment. A contemporaneous entry must be made in the clinical record to document the discussion between the AC and the patient at which consent was given. A copy of the completed Form CO2 must be attached to the current prescription card.
303. The patient may at any time, subject to s62, withdraw consent before the completion of the treatment (see s60 MHA).

304. Where a detained patient withdraws consent or refuses consent to the proposed treatment with medication under s58 the AC must trigger the safeguards of a second opinion from a SOAD appointed by HIW. The same safeguard of a second opinion will apply to detained patients unable to consent to treatment under s58 of the Act.
305. It is the responsibility of the SOAD to arrange to examine the patient and consult a minimum of two 'statutory consultees' (i.e. one of who is a registered psychiatric nurse and the other who is someone who has been professionally involved in the medical treatment of the patient) prior to making a clinical decision about treatment.
306. The SOAD and the two statutory consultees must record the outcome of their assessment in the patient's clinical notes. The AC in charge of the treatment should inform the patient of the decision of the SOAD.
307. The SOAD, if he concurs with the AC's treatment plan, will complete the appropriate new Form CO3 authorising the proposed treatment plan.
308. In the case of medication, the SOAD's Form CO3 will specify the classes of drug/drugs dosage (mostly within BNF limits) and the route of administration. A copy of the Form CO3 must be attached to the current prescription card and the clinical records with the original to be sent to the MHA Administrator's Office.

#### **S58A: Electroconvulsive Therapy (ECT)**

309. Section 58A applies to ECT and medication administered as part of ECT. It applies to all detained patients and to all patients who are under 18 years whether or not they are a detained patient.
310. The written consent of all patients with capacity to consent to receiving ECT must be obtained, whether or not they are subject to s58A. A record of the discussion with the patient and of the steps taken to confirm that the patient has capacity to consent should be made.
311. Patients of all ages to be treated with ECT should be given written information before their treatment starts which helps them to understand and remember, both during and after the course of ECT, the advice given about its nature, purpose, and likely effects.
312. The key differences from s58 are that:
  - ECT cannot be given to an individual who has the capacity to consent to that treatment but refuses to do so unless it is immediately necessary to save the patient's life or to prevent a serious deterioration in the patient's condition (s58A(1)(a) and (2) and s62(1)(a) and (1A) MHA),
  - no patients under the age of 18 can be given ECT unless a SOAD has certified that the treatment is appropriate, and
  - Certification from SOAD is always required.

### **S58A (3) Detained adult patients with capacity to consent to ECT**

313. The AC in charge of treatment or a SOAD can certify on Form CO4 that the patient has attained the age of 18 and is capable of understanding the nature, purpose and likely effects of ECT and has consented to that treatment.
314. The original Form CO4 must be sent to the MHA administrator with a copy kept for the clinical record and one to go with the patient to the ECT department each time the patient is to receive the treatment. The patient may withdraw consent at any time. The certificate would not be valid if the patient subsequently lacks the capacity to make that decision during the course of treatment.

### **S58A (4) Detained or informal children and young people with capacity to consent to ECT**

315. For children and young people ECT may be given if the patient has consented and a SOAD has certified, on Form CO5, in writing:
- that the patient is capable of understanding the nature, purpose and likely effects of the treatment and has consented to it; and
  - that it is appropriate for the treatment to be given.

### **S58A (5) and (6) Patients who lack capacity to consent to ECT**

316. Patients who lack capacity to consent to treatment may be given ECT if a SOAD has certified in writing:
- that the patient is not capable of understanding the nature, purpose and likely effects of the treatment; but
  - that it is appropriate for the treatment to be given; and
  - that giving the patient the treatment would not conflict with:
    - an advance decision which the SOAD is satisfied is valid and applicable, in accordance with s25 of the MCA; or
    - a decision made by a donee or deputy or by the Court of Protection.
317. The SOAD must complete form CO6.
318. The SOAD shall consult a minimum of two other persons who have been professionally concerned with the patient's medical treatment. One shall be a nurse and the other shall be neither a nurse nor a registered medical practitioner. Furthermore, neither shall be the responsible clinician (if there is one) or the approved clinician in charge of the treatment in question.

## **S60 Withdrawal of consent**

319. Patients treated in accordance with s57, s58 or s58A may withdraw their consent to that treatment at any time. Fresh consent for the implementing of procedures as required by those sections will then be required before further treatment can be carried out or reinstated, except as provided for under the urgent treatment provisions within s62.
320. Where the patient withdraws consent he or she should receive a clear explanation:
- of the likely consequences of not receiving the treatment;
  - and in the case of s58 treatments that a second medical opinion under Part 4 of the Act may or will be sought, if applicable, in order to authorise treatment in the continuing absence of the patient's consent; and
  - of the power of the approved clinician in charge of the treatment to begin or continue urgent treatment under s62, if applicable.
321. The patient's withdrawal of consent and explanations given to the patient in light of that withdrawal of consent must be clearly documented in the patient's case notes.

## **S62 Treatment not requiring consent**

322. The consent of a patient subject to s56 i.e. most detained patients subject to the exceptions described in para 9(a) is not required for the administration of urgent treatment under s62. The forms of treatment are expected to include only those authorised under s58 and s58A. In urgent situations, such treatments can be administered without a second opinion. Whenever s58 or s58A type treatment is administered under s62, a simultaneous request must be made for a second opinion.
323. The same principle applies to a patient who has consented to take medication and then withdraws his consent after the three month period. HIW will be requested to arrange for the visit of a SOAD. Where the treatment is urgent, s62(2) may be used to continue with the treatment plan if the AC in charge of the treatment considers that discontinuance of the treatment or treatment under the plan would cause serious suffering to the patient.
324. There is no statutory prescribed form to record the use of treatment under s62, but a local record form should be completed each time s62 is used to treat a patient.

## **S63 Treatment not requiring consent**

325. Section 63 authorises medical treatment for mental disorder without consent and includes treatments that may alleviate the underlying causes of mental disorder, but not including treatments covered by s57, s58 or s58A, provided the treatment is given by or under the supervision of the AC in charge of treatment.

## **Advance Decisions to Refuse Treatment**

326. A patient with a mental disorder is able to make a valid and applicable ADRT, as long as they have mental capacity at the time the advance decision is made. The fact that a patient was/is detained under the Mental Health Act when the ADRT advance decision was made does not render him/her incapable.
327. If a patient has made a valid and applicable ADRT but that treatment is for a mental disorder a healthcare professional may still give that treatment to the patient if he or she has authority to do so under Part 4 or 4A of the Mental Health Act 1983 and consent is not required. An ADRT can override the provisions in s57 of the Act, but not those contained in s58, s62 and s63. In respect of ECT (s58A), a valid and applicable ADRT would prevent a SOAD from issuing a certificate but would not necessarily prevent the AC in charge of the treatment from giving urgent ECT treatment as described in s62.
328. Chapter 8 of this document provides more information in relation to advance decisions.

## **PART 4A Treatment of patients on a Community Treatment Order (CTO) not recalled to hospital**

329. The purpose of a community treatment order (CTO) is to allow suitable patients to be safely treated in the community rather than under detention in hospital, and to provide a way to help prevent relapse and any harm to the patient or others.
330. Only patients who are detained in hospital for treatment under s3 of the MHA or are unrestricted part 3 patients (i.e. s37 without a s41) can be considered for a CTO.
331. Patients not recalled to hospital include patients on a CTO who are in hospital if they have been admitted informally.

## **CTO Patients (aged over 16 years) with capacity to consent to treatment**

332. Compulsory treatment cannot be given to a patient on a CTO who has not been recalled to hospital and who has capacity to consent or refuse treatment and is refusing. There are no exceptions to this rule, even in emergencies.
333. A Part 4A certificate is not required for the first month for s58 type treatment after a patient's discharge onto a CTO.
334. The Responsible Clinician completes form CO8 for s58 and s58a for patients with capacity to consent to treatment who are consenting to treatment.
335. A new CO8 form will need to be completed if there is a change of responsible clinician.

336. The Part 4A certification requirement does not apply if the treatment is immediately necessary and the patient has capacity to consent to it and does consent to it.

#### **S64D Adult CTO patients lacking capacity to consent to treatment**

337. A person is authorised to give medical treatment for mental disorder to a CTO patient who lacks capacity to consent to treatment if the following conditions are met:

- before giving the treatment, the person takes reasonable steps to establish whether the patient lacks capacity to consent to the treatment;
- when giving the treatment, he reasonably believes that the Supervised Community Treatment (SCT) Order patient lacks capacity;
- he has no reason to believe that the patient objects to be given the treatment; or he does have reasons to believe that the patient so objects, but it is not necessary to use force to give the treatment;
- he is the approved clinician in charge of the treatment, or the treatment is given under the direction of that clinician; and
- giving the treatment does not conflict with an advance decision which he is satisfied is valid and applicable, or a decision made by a donee or deputy of the CoP.

338. A Part 4A certificate is not required for the first month for s58 type treatment after a patient's discharge onto supervised community treatment.

339. The Responsible Clinician must request a SOAD, who completes form CO7, if a patient lacks capacity to consent to s58 or s58A treatment.

340. Before giving a Part 4A certificate, the SOAD shall consult a minimum of two other persons who have been professionally concerned with the patient's medical treatment. Of those persons s/he shall consult:

- at least one shall be a person who is not a registered medical practitioner; and
- neither shall be the patient's responsible clinician or the person in charge of the treatment in question.

341. The Part 4A certification requirements do not apply if the treatment is given in accordance with s64G (emergency treatment in patients lacking capacity), or the treatment is immediately necessary and a donee or deputy or the Court of Protection consents to the treatment on the patient's behalf.

#### **S64G Emergency treatment for CTO patients lacking capacity or competence**

342. A practitioner is authorised to give emergency treatment to a patient who lacks capacity to consent to treatment, and who is subject to a CTO, if the following conditions are met:

- the practitioner reasonably believes that the patient lacks capacity to decide or is not competent to consent to it;
- the treatment is immediately necessary; and
- if it is necessary to use force against the patient in order to give the treatment; the treatment needs to be given to prevent harm to the patient; and the use of such force is a proportionate response to the likelihood of the patient suffering harm, and to the seriousness of that harm.

343. The responsible clinician will fill in the appropriate form.

### **What does 'immediately necessary' mean?**

344. Treatment is immediately necessary if:

- It is immediately necessary to save the patient's life; or
- It is immediately necessary to prevent a serious deterioration of the patient's condition and is not irreversible; or
- It is immediately necessary to alleviate suffering by the patient and is not irreversible or hazardous; or
- It is immediately necessary, represents the minimum interference necessary to prevent the patient from behaving violently or being a danger to himself or others and is not irreversible or hazardous.

345. However, ECT may only be given in an emergency if it is immediately necessary to save the patient's life or to prevent a serious deterioration of the patient's condition.

### **S64E Child CTO Patients (aged under 16)**

346. Medical treatment may be given when there is authority to give it and the certificate requirements are met.

347. Certification is not needed for the first month after discharge onto the CTO or if it is immediately needed and the child is competent to consent to the treatment.

### **S64F Child CTO patients lacking competence to consent to treatment**

348. A person is authorised to give medical treatment for mental disorder to a patient subject to a CTO under the age of 16 years if the following conditions are met:

- the person takes reasonable steps to establish whether the patient lacks competence to consent to the treatment;

- he reasonably believes that the child lacks competence to consent to the treatment;
- he has no reason to believe that the patient objects to being given the treatment, or he does have reason to believe that the patient so objects, but it is not necessary to use force to give the treatment; and
- he is the approved clinician in charge of the treatment; or the treatment is given under the direction of that clinician.

### **CTO patients recalled to hospital**

349. CTO patients who are recalled to hospital are subject to s58 or s58A. Certification for s58 or s58A type of treatment is needed unless:
- less than one month has passed since the patient was discharged onto the CTO;
  - the s58 or s58A treatment is already explicitly authorised for administration on recall by the Part 4A certificate; or
  - if the AC in charge of the treatment considers that discontinuance will cause the patient serious suffering, he may continue with the treatment pending a fresh certificate.
350. For more detailed information regarding Community Treatment Orders, please refer to chapter 24 of the HA 1983 Code of Practice for Wales, 2016.

## **Appendix A - Link to current consent forms in use in this organisation**

[Insert links to new weblinks when available]

[All Wales Consent Forms: Patient Consent to Examination or Treatment - NHS Wales Shared Services Partnership](#)

## **Appendix B - Useful contact / link details**

[e.g. risk managers, training managers, clinical governance leads and clinical ethics committees]

## Appendix C – How to obtain legal advice

[e.g. details of how to contact the organisation's legal services, what information they will require etc.]

If you need to obtain legal advice or apply for a court ruling in relation to a complex consent issue you should [insert Health Board / Trust arrangements, including out of hours arrangements].

You should ensure that you have all the relevant information about the case to hand so that you can brief legal services / the solicitor appropriately. You should keep a clear record of the legal advice you have been given.

Where a decision is made to apply to a court, the lead clinician should, as soon as possible, inform the patient and his / her representative of the decision and of his or her right to be represented at the hearing. The patient's solicitor should be informed immediately and, if practicable, should have a proper opportunity to take instructions and apply for legal aid where necessary.

There may be occasions when the situation may be so urgent, and the consequences so desperate, that it is impractical to attempt to comply with these guidelines. Where delay may itself cause serious damage to the patient's health, or put their life at risk, then rigid compliance with these guidelines would be inappropriate.

The Court of Protection deals with serious decisions affecting personal welfare matters, including health care. Cases involving any of the following decisions should be regarded as serious medical treatment, and should be brought to the court:

- a) cases involving organ or bone marrow donation by a patient who lacks capacity to consent;
- b) cases involving non-therapeutic sterilisation of a patient who lacks capacity to consent;
- c) where it is proposed to withdraw / withhold nutrition and hydration from a patient with a prolonged disorder of consciousness (PDOC) and for example, the case seems 'finely balanced', or where there are differences of opinion between treating clinicians, or between treating clinicians and patients' families as to whether ongoing treatment is in the patient's best interests or where a dispute has arisen and cannot be resolved. The term PDOC encompasses both permanent vegetative state (PVS) and minimally conscious state (MCS)
- d) all other cases where there is dispute about whether a particular treatment will be in a patient's best interests (including cases involving ethical dilemmas in untested areas).

## **Appendix D - Assessing and documenting Gillick Competence in Under 16s**

Assessment of Gillick competence should document the following<sup>10</sup>:

- The age of the child
- The intervention being offered
- The child's ability to understand that there is a choice and that choices have consequences, both risks and benefits
- The child's understanding of the nature and purpose of the proposed intervention
- The child's understanding of the proposed intervention's risks and side effects, both in the short and long term
- The child's understanding of any alternatives to the proposed intervention, and the risks and benefits attached to them
- The child's ability to weigh the information and arrive at a decision
- The child's willingness to make a choice (including the choice that someone else should make the decision)
- An estimate of the child's freedom from undue pressure

<sup>10</sup> BMA - Children and Young People Toolkit

## **Appendix E - About the consent form: information for patients**

Before a doctor or other healthcare professional examines or treats you, they need your consent – in other words, your agreement. Sometimes you can simply tell them whether you agree with their suggestions. However, sometimes a written record of your decision is helpful – for example if your treatment involves sedation or general anaesthesia. In this case, you will then be asked to sign a consent form. If you later change your mind about having the treatment, you are entitled to withdraw consent – even after signing the form.

### **What should I know before deciding?**

Healthcare professionals must ensure you know enough to enable you to decide about treatment. They will write information on the consent form and offer you a copy to keep (in either Welsh, English or both languages) as well as discussing the choices of treatment with you. Although they may well recommend a particular option, you do not have to accept that option. People's attitudes vary on things like the amount of risk or pain they are prepared to accept. That goes for the amount of information, too. The person who is treating you will encourage you to listen to all of the information about your treatment but if you would rather not know about certain aspects, discuss your worries with them.

### **Should I ask questions?**

Healthcare professionals will encourage you to ask questions and you should always ask anything you want. As a reminder, you can write your questions down. The person you ask should do his or her best to answer, but if they don't know they should find someone else who is able to discuss your concerns. To support you and prompt questions, you might like to bring a friend or relative. Ask if you would like someone independent to speak up for you.

### **Is there anything I should tell people?**

If there is any procedure or treatment you **don't** want, you should tell the people treating you. It is also important for them to know about anything that is particularly important to you and any illnesses or allergies which you may have or have suffered from in the past.

### **Who is treating me?**

Amongst the healthcare professionals treating you may be a "doctor in training" – medically qualified, but now doing more specialist training. They range from recently qualified doctors to doctors almost ready to be consultants. They will only carry out procedures for which they have been appropriately trained. Someone senior will supervise – either in person accompanying a less experienced doctor in training or available to advise someone more experienced. Other healthcare professionals such as nurses and therapists may also provide you with treatment.

## **What about anaesthesia?**

If your treatment involves general or regional anaesthesia (where more than a small part of your body is being anaesthetised), you will be given general information about it in advance. You will also have an opportunity to talk with the anaesthetist when he or she assesses your state of health shortly before treatment. For some procedures you will be invited to a pre-assessment clinic which will provide you with the chance to discuss things a few weeks earlier.

## **Will samples be taken?**

Some kinds of operation involve removing a part of the body (such as a gall bladder or a tooth). You would always be told about this in advance. Other operations may mean taking samples as part of your care. These samples may be of blood or small sections of tissue, for example of an unexplained lump. Such samples may be further checked by other healthcare professionals to ensure the best possible standards. Again, you should be told in advance if samples are likely to be taken.

Sometimes samples taken during operations may also be used for teaching, research or public health monitoring in the future interests of all NHS patients. If a healthcare professional wishes to use your samples for research purposes they will ask for your written consent.

## **Students**

One of the ways that student doctors, nurses or other healthcare professionals learn is by watching care or treatment being given. If the healthcare professional treating you would like a student to watch your examination or treatment, then they have to ask your permission first. If you are having sedation or anaesthetic during your treatment, then they need your written consent for a student to watch your procedure. This is why there is a section on the consent form for you to say whether or not you agree to students being present. If you are happy for the student to be present, they will be supervised by a qualified member of staff at all times. Your care will not be affected in any way if you decide that you prefer not to have students in the room during your procedure.

## **Advance decisions to refuse treatment**

Some people chose to make "advance decisions" refusing certain care or treatment (sometimes referred to as "living wills" or "advance directives"). If you have made, or wish to make an advance decision refusing a treatment or procedure which may become necessary during the course of your care or treatment, then you must tell the healthcare professional caring for you. This will make sure that your decisions are followed, for example, whilst you are under anaesthetic. This is why there is a section on the consent form for you to say whether or not you have made a relevant advance decision.

## **Photographs, videos and audio recordings**

As part of your treatment it is sometimes helpful for a photographic, video or audio recording to be made – for example to record changes to a skin lesion. You will always

be told if this is going to happen. The use of photographs and recordings is also extremely important for other NHS work, such as teaching or medical research. If the healthcare professional would like to take photographs, video or audio recordings, then you will be asked to sign a consent form giving your permission. The photograph / video / audio recording will be kept with your notes and will be held in confidence as part of your medical record. This means that it will normally be seen only by those involved in providing you with care or those who need to check the quality of care you have received, unless you have given permission for it to be used in other ways e.g. teaching, publication, research. We will not use the photograph / recording in a way that might allow you to be identified or recognised without your express permission.

### **What if things don't go as expected?**

Amongst the 25,000 operations taking place every day, sometimes things don't go as they should. Although the doctor involved should inform you and your family, often the patient is the first to notice something amiss. If you are worried – for example about the after-effects of an operation continuing much longer than you were told to expect – tell a healthcare professional right away. Speak to your GP, or contact your clinic - the phone number should be on your appointment card, letter or consent form copy.

### **What do I need to know?**

You should be aware of all of the significant risks (including important (material) risks to you), benefits and alternative treatments (including no treatment) so that you can make an informed decision

### **What are the key things to remember?**

It's your decision! It is up to you to choose whether or not to consent to what is being proposed. Ask as many questions as you like, and remember to tell the team about anything that concerns you or about any medication, allergies or past history which might affect your general health.

### **Can I find out more about giving consent?**

[xxxxxxx Health Board / Trust] has a policy on patient consent to examination or treatment, which will be made available to you on request. The Welsh Government has also issued a *Guide to Consent for Examination or Treatment* which can be accessed at: <http://www.wales.nhs.uk/governance-emanual/patient-consent/>

### **Questions to ask healthcare professionals**

As well as giving you information healthcare professionals must listen and do their best to answer your questions. Before your next appointment, you can write some down.

You may want to ask questions about the **treatment itself**, for example:

- What are the main treatment options?

- What are the benefits of each of the options?
- What are the risks, if any, of each option?
- What are the success rates for different options (nationally, for this unit or for the surgeon)?
- Why do you think an operation (if suggested) is necessary?
- What are the risks if I decide to do nothing for the time being?
- How can I expect to feel after the procedure?
- When am I likely to be able to get back to work?

You may also want to ask questions about how the treatment might affect your future state of health or style of life, for example:

- Will I need long-term care?
- Will my mobility be affected?
- Will I still be able to drive?
- Will it affect the kind of work I do?
- Will it affect my personal/sexual relationships?
- Will I be able to take part in my favourite sport/exercises?
- Will I be able to follow my usual diet?

Health care professionals should welcome your views and discuss any issues so they can work in partnership with you for the best outcome.

### **Unacceptable behaviour**

Our staff deserve the right to do their jobs without being verbally or physically abused. Most of our patients and visitors respect this right. Thank you for being one of them. We will work with the police to prosecute those who abuse our staff.

### **Complaints and compliments**

We would like to hear your views about your experience of our services. Our aim is to provide you with the highest standards of care at all times, but we recognise that things can sometimes go wrong. If you have any concerns, speak to the ward sister or senior therapist who will be able to assist and, hopefully, resolve matters to your satisfaction.

Where this is not successful, ask for our leaflet “[insert the local title for the concerns information leaflet]”. This advises you how to make a formal complaint and the various stages of the procedure.

In making a complaint, advice and assistance is available to you from your local Community Health Council, which represents the interests of patients and the public in the NHS. The Community Health Councils are skilled in handling complaints. Their Complaints Advocates can provide a range of support during the process of your complaint.

[Health Board/Trust] Community Health Council can be contacted as follows:  
[Insert local details and address of the Community Health Council]

### **Data Protection Act/General Data Protection Regulations (2016) or any subsequent legislation having the same effect**

Under current Data Protection Legislation, we are committed to protecting the privacy of patient information. If you require an explanation of why information is needed, or how you can access information or your health records, please contact [insert details of the local process]. You are entitled to receive a copy but should note that a charge will usually be made. You should also be aware that in certain circumstances your right to see some details in your health records may be limited in your own interest or for other reasons.

If you require further electronic copies of this publication please access the NHS Wales Governance E-Manual at: <http://www.wales.nhs.uk/governance-emanual/patient-consent/>

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