

Manager's Guide: Consent

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Overview

Before administering medicines, it is vital to ensure that consent has been given by a person to have their medicines administered to them. Consent must not only be given **voluntarily**, but also must be given by a person who has **received sufficient information** to allow them to give valid consent.

This document applies to staff who administer medicines to people within their care organisation and covers identifying how to seek consent, what constitutes valid consent and safeguarding issues surrounding consent.

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Consent and the Law

Consent is governed by the Mental Capacity Act 2005 (MCA 2005) with additional guidance in the Mental Capacity Act Code of Practice. The rights set out under the Human Rights Act 1998 should also be borne in mind.

The Mental Capacity Act applies to all people involved in the care, treatment and support of those aged 16 or over who may lack the capacity to make decisions for themselves. It should be remembered that there is a different legal position surrounding consent and refusal of treatment for those under 18 years of age.

The NICE Guidance for Managing Medicines in Care Homes (2014) and the NICE Guidance for Managing Medicines in Adults Receiving Social Care in the Community (2017) also provide some guidance on how and when consent should be obtained in a care setting (NICE Guidance).

5 Underlying Statutory Principles under MCA 2005

These principles underpin all decisions and actions in relation to consent

1. The presumption of capacity - every adult has the right to make his or her own decisions and must be assumed to have capacity to do so unless it is proved otherwise
2. People must be given all appropriate help before anyone concludes that they cannot make their own decisions
3. Individuals retain the right to make what might be seen as eccentric or unwise decisions
4. Anything done for or on behalf of people without capacity must be in their best interests
5. Anything done for or on behalf of people without capacity should be an option that is the least restrictive of their basic rights and freedoms - as long as it is still in their best interests.

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When to Obtain Consent

Valid consent must be obtained before starting treatment or physical investigation, or providing personal care, for a person.

Individuals have a right to determine what happens to their own bodies, and is a fundamental part of good practice.

The NICE Guidance 2014 says that health and social care practitioners should 'ensure that care home residents have the same opportunities to be involved [in their decisions around consent] in care homes, and that residents get the support they need to help them to take a full part in making decisions.'

What is Valid Consent?

For consent to be valid it must:

- ✓ Be given voluntarily
- ✓ By an appropriately informed person
- ✓ With the capacity to consent to the intervention in question

N.B. for a person under 18, this person might be someone with parental responsibility, someone authorised to do so under a Lasting Power of Attorney or a court appointed deputy.

These elements are broken down further below:

1) Voluntary Consent

- Consent must be given voluntarily and freely without pressure or undue influence being exerted on the person to either accept or refuse treatment.
- Coercion invalidates consent.
- Acquiescence is NOT consent.

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2) Informed Person

- The person must understand the nature and purpose of the procedure
- Any misrepresentation of this information invalidates consent
- Information provided to the person should be enough to allow them to make an informed judgment on whether to give or withhold consent e.g. material or significant risks.

3) With Capacity

- The MCA 2005 states a person lacks capacity if they are a person who is unable to make a decision for themselves because of an impairment or disturbance in the functioning of their mind or brain.

The 2 stage test for capacity

A person lacks capacity if:

- 1) **They have an impairment or disturbance (for example a disability, condition or trauma or the effect of drugs or alcohol) that affects the way their mind or brain works; and**
- 2) **That impairment or disturbance means that they are unable to make a specific decision at the time it needs to be made**

Enabling a person to make a decision themselves

As part of the 2nd stage of the test, the MCA 2005 requires health and social care professionals to take appropriate steps to enable a person to make a decision themselves, including:

- ✓ Providing relevant information;
- ✓ Communicating in an appropriate way ;
- ✓ Making the person feel at ease; and
- ✓ Supporting the person

Assessment of capacity

Any assessment of a person's capacity must be based on their ability to make a **specific decision at the time it needs to be made** and not their ability to make decisions in general.

A person is deemed unable to make a decision if they cannot do one or more of the following things:

- Understand the information given to them that is relevant to the decision
- Retain that information long enough to be able to make the decision
- Use or weigh up the information as part of the decision-making process
- Communicate that decision- this could be by talking or using sign language and includes simple muscle movements such as blinking an eye or squeezing a hand.

Points to note:

- A person can have capacity at certain times, but not others. Where a person's capacity fluctuates, it is often helpful to establish (during a period where they have capacity) their views on clinical intervention and to record these views.
- A person must be assumed to have capacity unless it is established they lack capacity.
- Health and social care professionals should identify and record things that may hinder a person from giving informed consent (see recording below).
- Capacity should not be confused with a health or social care professional's assessment of the reasonableness of the decision.

Form of Consent

- Valid consent does not depend on the form in which it is given.
- Written consent merely serves as evidence of consent. It is important to confirm the person has capacity to consent before asking them to sign anything.
- If the person has capacity but is unable to read or write, they may be able to make a mark on the form to indicate consent.
- Consent may be verbal or non-verbal e.g. a person holds out their arm for their blood pressure to be taken having received all the appropriate information.

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Recording of Consent

- Care home staff should record a resident's informed consent in the resident's care record.
- Consent does not need to be recorded every time the medicine is given but record of the administration should be made on the MAR sheet each time.
- Care home staff (registered nurses and social care practitioners working in care homes) should record the circumstances and reasons why a resident refuses a medicine in the resident's care record and MAR chart, unless there is already an agreed plan of what to do when that resident refuses their medicines. If the resident agrees, care home staff should tell the health professional who prescribed the medicine about any ongoing refusal and inform the supplying pharmacy, to prevent further supply to the care home.
- Health and social care practitioners should identify and record anything that may hinder a person giving informed consent. Things to look out for include mental health problems, lack of (mental) capacity to make decisions, health problems (such as problems with vision and hearing), difficulties with reading, speaking or understanding English and cultural differences. These should be taken into account when seeking informed consent and should be regularly reviewed.

Refusal or Withdrawal of Consent

- If an adult with capacity, who is fully informed makes a voluntary decision to refuse treatment, this decision must be respected.
- Refusal of treatment by a person under the age of 18 is covered below.
- A person with capacity is entitled to withdraw consent at any time, including during the performance of a procedure.
- A person can make an advance decision to refuse treatment. A valid and applicable advance decision to refuse treatment has the same force as one made at the time of treatment and must be followed by health and social care professionals.

Best Interests

As set out above, the MCA 2005 requires that any act for or on behalf of people without capacity must be in their best interests.

- When determining a person's best interests, no judgment should be made on account of the person's age, appearance, condition or any aspect of their behaviour.
- All relevant circumstances relating to the decision in question must be considered.

Considering relevant circumstances

In considering relevant circumstances, health and social care professionals must:

- Consider whether the person is likely to regain capacity and, if so, whether the decision can wait
- Involve the person as fully as possible in the decision that is being made on their behalf
- As far as possible consider:
 - The person's past and present wishes and feelings
 - Any beliefs and values likely to influence the decision in question
 - The other factors a person is likely to consider if they were able to do so
- As far as possible, consult other people if appropriate to do so and take into account their views as to what would be in the best interests of the person lacking capacity

Health and social care professionals should demonstrate in their records that all relevant evidence has been considered prior to making any best interests decision.

Even where similar actions are taken repeatedly, the considerations above should be taken into account separately each time.

Other sources to consider

When making a best interests decision, health and social care professionals should also consider any or all of the following:

- Statements of preferences and wishes
- Lasting Power of Attorney
- Court of Protection orders or any court appointed deputy
- Appointment of an Independent Mental Capacity Advocate

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Consent for People under 18 Years of Age

1. Young People (age 16-17)

- Young people aged 16 or 17 are presumed capable of consenting to their own medical treatment.
- As with adults, valid consent must be given voluntarily by an informed person with capacity.
- If a young person is deemed to lack capacity, the MCA 2005 will apply in the same way as with adults (set out above).
- If a 16/17 year old is capable of giving valid consent there is no legal requirement to obtain consent from a person with parental responsibility but it would be good practice to involve them in the decision-making process, where appropriate and with the young person's agreement.

2. Children (under 16)

Gillick competence

- Where a child of under 16 years of age has the understanding and intelligence to enable them to fully understand what is involved in a proposed medical intervention, they may be considered to have the capacity to consent to that intervention (known as being "Gillick competent"), provided such consent is voluntary (see below) and they have capacity.
- A child's capacity to consent should be assessed carefully in relation to each decision that needs to be made.
- If a child's consent is valid then it is not necessary to get consent from a person with parental responsibility, but it may be best practice to involve them in the decision-making process, with the agreement of the child.

Children without capacity

- Where a child lacks capacity to consent, consent can be given on their behalf by any one person with parental responsibility or by the court.
- Those giving consent on behalf of the child must have the capacity to consent themselves by acting voluntarily and being appropriately informed.
- The power to consent must be exercised according to the 'welfare principle' where the child's welfare or best interests must be paramount.
- The Children's Act 1989 sets out persons who may have parental responsibility¹.
- Consent given by one person with parental responsibility is valid, even if another with parental responsibility withholds consent. Where two people with parental responsibility disagree, it is often best to refer the decision to the courts.

Voluntary Consent

Consent by a child or young person is only valid if it is given voluntarily. Health and social care professionals should be careful to ensure a child or young person is not being unduly influenced by their parents.

Refusal

Refusal to accept treatment by a young person or child may be overridden in certain circumstances by a person with parental responsibility or a court, namely where such refusal would in all probability lead to the death of the young person/ child or to severe permanent injury.

This note does not go into detail about withdrawing and withholding life-sustaining treatment. For further information on this topic, please see 2nd edition of the Department of Health "Reference guide to consent for examination or treatment", July 2009.

¹ For further information on Parental Responsibility, see the House of Commons Briefing Paper entitled "Children: parental responsibility - what is it and how is it gained and lost (England and Wales)", August 2017.

Covert Administration and Consent

Covert administration (as defined by the CQC) is the ‘term used when medicines are administered in a disguised format e.g. in food, drink or via a feeding tube **without the knowledge or consent of the person receiving them**’.

Covert administration must only take place where there is clear authorisation or clear instructions to do so, in accordance with the MCA 2005 and the person’s care plan.

The NICE Guidance 2017 requires that care organisations “ensure that the process for covert administration clearly defines who should be involved in, and responsible for, decision-making, including:

- assessing a person's mental capacity to make a specific decision about their medicines
- seeking advice from the prescriber about other options, for example, whether the medicine could be stopped
- holding a best interests meeting to agree whether giving medicines covertly is in the person's best interests
- recording any decisions and who was involved in decision-making
- agreeing where records of the decision are kept and who has access
- planning how medicines will be given covertly, for example, by seeking advice from a pharmacist
- providing authorisation and clear instructions for care workers in the provider's care plan
- ensuring care workers are trained and assessed as competent to give the medicine covertly
- when the decision to give medicines covertly will be reviewed.”

Consideration should also be given to any **Deprivation of Liberty Safeguards** required when medicines, such as sedatives, are given covertly (see Safeguarding below for more detail).

Whilst there may be appropriate circumstances for medicines to be administered covertly, this should be regularly reviewed within specified timescales as should the person’s capacity to consent.

Best Practice Principles for Covert Administration

The following best practice principles must be followed, in accordance with the CQC recommendations:

- ✓ **Policy-** There should be a clear explanation of the covert medicine administration process in the setting's medicines policy, which should be specific to the setting, in date, read and followed by staff.
- ✓ **Best Interest-** all decisions must be in the person's best interest with due consideration to the holistic impact on the person's health and well-being.
- ✓ **Last Resort-** covert administration is the least restrictive option when all other options have been tried.
- ✓ **Medicine Specific-** the need for covert administration must be identified for each medicine prescribed, including when new medicines are added. This usually includes specific input from a pharmacist.
- ✓ **Time Limited-** it should be used for as short a period of time as possible, with consideration of fluctuating capacity (see below).
- ✓ **Regularly Reviewed-** the continued need for covert administration must be regularly reviewed within specified timescales as should the person's capacity to consent.
- ✓ **Transparent-** the decision-making process must be easy to follow and clearly documented.
- ✓ **Inclusive-** the decision-making process must involve discussion and consultation with appropriate advocates for the person. It must not be a decision taken alone; it must be a multi-disciplinary team decision.
- ✓ **Records-** need a clear record of which medicines are administered covertly and when. This is particularly important in people with fluctuating capacity.

Safeguarding

The primary purpose of the MCA is to promote and safeguard decision-making within a legal framework. It does this in two ways:

- by empowering people to make decisions for themselves wherever possible, and by protecting people who lack capacity by providing a flexible framework that places individuals at the heart of the decision-making process; and
- by allowing people to plan ahead for a time in the future when they might lack the capacity, for any number of reasons.

Safeguarding issues in relation to consent and medicines could include:

- giving medicines to a person who has declined them;
- the incorrect use of a medicine(s) for reasons other than the benefit of a resident; and
- situations where the person does not have the capacity to understand and make decisions about any abuse or neglect-related risks and any immediate safety actions required.

Deprivation of Liberty Safeguards

Deprivation of Liberty Safeguards are additional safeguards that work in conjunction with the powers of the MCA 2005 “to protect the rights of people who are deprived of their liberty in their own best interests to protect their health and safety.²”

The CQC further advises that “DoLS should not be one-size-fits-all – good practice in person-centred care is at the heart of ensuring decisions made around the Mental Capacity Act and DoLS are in the person’s best interests.”

² “The state of health care and adult social care in England”, CQC, 2016/17

Failure to Follow Rules on Consent

A health or social care professional who does not obtain consent and respect the principle can be liable to both legal action by the patient as well as action by their professional body.

Claims for negligence as well as battery (where a patient was touched without consent) are also a possibility.

It is therefore imperative that consent is sought before any treatment is given to a person.

References

Department of Health- Reference guide to consent for examination and treatment, July 2009

Mental Capacity Act 2005 and associated Code of Practice

NICE Guidance on Managing Medicines in Care Homes, 2014

NICE Guidance on Managing medicines for adults receiving social care in the community, March 2017

CQC FAQ on Covert Administration, 2018

“The State of Health Care and Adult Social Care in England”, CQC, 2016/17