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Covert Medicines Guidance for Care Homes

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Covert Medicine

Covert medication occurs when pharmaceutical treatment for mental or physical health problems, is given disguised in food or drink to a service user without their knowledge as they lack the capacity to consent¹.

Covert administration of medication is controversial and has not always been specified in care plans. It should be a last resort limited to incapacitated service users where the treatment is necessary and in best interests under the Mental Capacity Act 2005² (MCA hereafter), or else authorised by mental health legislation or an appropriate court declaration. It is unethical, and may even be unlawful, to covertly administer medication to a person with mental capacity. This guidance does not apply to overt medication where a person has consented to medication given in food or drink due to difficulty swallowing or for the sole purpose of making it more palatable. Overt medication only applies to a person with capacity and implemented with full transparency and cooperation of the person. Clear documentation should be available in the person's care plan if medication is being administered overtly.

The National Institute for Clinical Excellence have produced guidance for managing medicines in care homes which explicitly refers to covert administration https://www.nice.org.uk/guidance/qs85/chapter/Quality-statement-6-Covert-medicines-administration stating:

'The covert administration of medicines should only be used in exceptional circumstances when such a means of administration is judged necessary, in accordance with the Mental Capacity Act 2005.'

Both the Nursing and Midwifery Council (http://www.nmc-uk.org/Nurses-and-midwives/Regulation-in-practice/Medicines-management-and-prescribing/Covert-administration-of-medicines) and the Royal College of Psychiatrists have produced guidance on issues to be considered when medicines are given covertly http://pb.rcpsych.org/content/28/10/385. The Care Quality Commission Regulation 12(2)(b) includes the use of covert medicines https://www.cqc.org.uk/content/regulation-12-safe-care-and-treatment#guidance

Scope of this Guidance

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This document is issued as **GUIDANCE ONLY** to care homes, Pharmacists and General Practitioners in Buckinghamshire. It is for service users aged 18 years or over only. It is not intended to replace or add to care homes own policies and procedures for medicines management, covert or otherwise but may be used to inform

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¹ https://www.sps.nhs.uk/articles/covert-administration-of-medicines-legal-issues/

² http://www.legislation.gov.uk/ukpga/2005/9/contents



decision making. All practitioners remain individually accountable for their actions under the law, and where applicable, to their Professional Body in general terms, if a resident has the mental capacity to refuse medical treatment, then this decision must be respected, and covert administration of medication would be unlawful.

It is necessary to distinguish between the concealing of medication in food or drink, and a co-operative process where consenting patients who find taking medication difficult have the medication delivered in food or drink for ease of ingestion/swallowing, in which case it is not necessary to consider that the medication has been given covertly.

Medication Non Concordance

Many people with or without a mental illness, do not wish to take medication or fail to comply with the treatment regime advised by health professionals. It is necessary to ask the question first why someone does not wish to take medication, is it a total refusal or for another reason? Studies into non-concordance have shown reasons such as:

- Lack of information about why a medication is prescribed/administered
- Because the person feels their symptoms are mild
- Because the treatment is preventative and the person does not feel it is essential
- Because the medication has unpleasant side effects
- The reputation of certain medications
- Concerns about dependency/addiction
- Difficulty swallowing consider offering liquids, creams, patches
- Cultural or spiritual beliefs about medication
- Relationship with the person prescribing or administering the medication
- Beliefs about medication in general
- Not remembering how to take the medication

By exploring the reasons for not taking medication with the person, every attempt is being made to support and encourage them to take the medication. Refusing to take a medicine should not be automatically seen as a lack of mental capacity or a part of mental illness. The World Health Organisation advises practitioners need to support people who do not wish to take their medication, rather than impose their own views and beliefs or blame them for not following advice (WHO, 2003)³

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³World Health Organisation. Adherence to long-term therapies. Evidence for action. Geneva: WHO; 2003.



The use of Covert Medication

The use of covert medication should be a last resort and not a routine measure. There are certain circumstances where covert medicine can be legally and ethically justified, provided that certain requirements, incorporated in to this guidance, have been met beginning with establishing whether a person has mental capacity.

Mental Capacity and Covert Medication

Every individual should be supported to make their own decisions about taking medication. If the person has a condition affecting the mind or brain that may also affect the ability to consent to, or refuse, treatment then an assessment of capacity in relation to this decision should be undertaken and the outcome documented.

All completed capacity assessments are time and decision specific and are only valid as such. The MCA states we are all assumed to have capacity where it has been assessed an individual lacks capacity relating to one decision does not automatically mean they lack capacity for other decisions. People who are unwell may experience fluctuating, or temporary loss of, capacity. In these cases, it must be established whether the decision can wait until the person regains capacity and decide for themselves. The free resource 'Assess Right' is available at www.assessright.co.uk for information and guidance regarding capacity assessments for professionals and the public.

A lack of capacity cannot be established merely by reference to –

- a) A person's age or appearance
- b) A condition of their, or an aspect of their behaviour, which might lead others to make unjustified assumptions about his capacity
- c) The making of an unwise decision

The Two Stage Functional Test

The MCA has a framework for assessing an individual's capacity where they have been unable to make a decision with support. To assess whether someone has the capacity to make a particular decision you must follow the two stages:

- 1. Is there a disturbance in the functioning of the person's mind or brain? If the answer to this question is yes, progress to stage two
- 2. Does the impairment or disturbance mean that the person is unable to make a specific decision when it needs to be made?

The Mental Capacity Act states that a person is unable to make their own decision if they **cannot** do one of the following:



- Understand the information provided and how this was assessed
- Retain the information and how this was assessed
- Weigh up the information to make a decision and how this was assessed
- Communicate their decision by any means they can and how this was assessed

If the person **can** do those four things with or without support, then they are assumed to have capacity to make the decision and this must be respected **even if it appears unwise.** This must be documented in the persons care plan and record.

Assent – Incapacitated Patients who Comply with Treatment

Compliant patients without capacity are perhaps the most vulnerable. Although they will not need medication to be administered covertly, they are not aware of the medications purpose and side effects and cannot give valid consent. The MCA must be followed to ensure lawful treatment for these patients.

Advance Decisions to Refuse Treatment

It is a general principle of law and medical practice that people have a right to consent to or refuse treatment. The courts have recognised that adults have the right to say in advance that they want to refuse treatment if they lose capacity in the future – even if this results in their death. A *valid and applicable* advance decision to refuse treatment has the same force as a contemporaneous decision. The MCA makes provision for this in Sections 24–26 of the Act setting out the when a person can make an advance decision to refuse treatment. Further guidance for Medical Professionals is available at: http://www.gmc-

uk.org/guidance/ethical_guidance/end_of_life_binding_advance_refusals.asp

Power of Attorney

A Lasting Power of Attorney (LPA hereafter) is created when a person with capacity appoints another person to act for them in the eventuality that they lose capacity at some point in the future. This is significant for healthcare workers because the MCA extends the decision making ability of people using services to a time when they lack capacity. Deputyships can be created by the court where a person lacks capacity to create an LPA. LPAs and Deputyships can be created separately for:

- Property and affairs LPA re financial and property matters
- Personal Welfare LPA re decisions about health and welfare, where you live day to day care or medical treatment.



This must be recorded in the person's file where there is knowledge of it. An LPA or Deputy can only act within the remit of their authority and must provide proof that their power is registered with the Office of the Public Guardian⁴.

Best Interests

The best interest's principle underpins the Mental Capacity Act. It is set out in section 1(5) of the Act.

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

A medicines review should be undertaken by the Prescriber to ensure all prescribed medicines are required. The medication must be established as essential for the person's health and well-being and considered so essential that the person needs to be deceived to receive it.

Medication must not be given to benefit others e.g. medication with controlling and sedative effects. If such medication needs to be given covertly, a discussion is required with the Local Authority Deprivation of Liberty Safeguards Team about whether authorisation from the Local Authority is required.

Alternatives to manage challenging behaviour or confusion in people with mental illness, Dementia or those with Learning Disabilities, must be explored and documented and the least restrictive option selected.

Establishing Best Interests

The best interests of the person must be paramount. Chapter 5 of the MCA Code of Practice sets out the principles be followed Best Interests to https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/49725 3/Mental-capacity-act-code-of-practice.pdf. There should be an open and inclusive discussion including members of the multi- disciplinary team, the care worker, family and friends, if the person has no one close to them then an Independent Mental Capacity Advocate or IMCA, should be consulted. When making a best interest decision on behalf of another then consideration must be given to the best interest Where there is a Power of Attorney over Personal check list (See Appendix 2). Welfare and there is conflict this will need to be referred to the Court of Protection to establish best interests if the dispute is significant and cannot be resolved.

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⁴ https://www.gov.uk/government/organisations/office-of-the-public-guardian



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The pharmacist

Advice must be sought from the pharmacist when altering a medication or mixing it with another substance such as food or drink. This is to ensure the medication is safe to take in this way and to gain expert advice about alternative formulations or medications to improve the possibility of consent. Any addition or changes to a person's medication after the plan for covert medicine is put in place should be discussed in advance with the Pharmacist.

It is not safe practice to open capsules or crush tablets unless a Pharmacist has informed the practitioner that it is safe to do so.

The reasons for this are:

- Altering medicinal products (for example crushing tablets, opening capsules or adding to food/drink) is usually an unlicensed (off-label)⁵ activity.
- Medicines to be administered in this way must be authorised by a relevant prescriber.
- Authorising and prescribing medicines in this manner means that the medication will cease to be covered by the manufacturer's product license and it increases the prescriber's professional responsibility and liability.
- This should only be conducted if the prescriber can justify, and is confident in, the use of the medicine in this manner.

There are pharmaceutical issues to consider when administering medications.

Pharmaceutical Issues and Administration⁶

There may not be any information on the stability of a medicine when it is mixed with food or drink or crushed etc. The medicine may not be stable and may degrade. However it is important to assess the risk of not giving the medicine at all verses giving the medicine which may degrade when mixed with food and drink.

Factors to consider when giving medications covertly:

Mixing in food – the person may not receive the full dose if they do not finish
their food hence the medicine should be added to the first mouthful of food, so
that the full dose is received.

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⁵ Off-label use is the use of pharmaceutical drugs in unapproved age group, dosage, or form of administration

⁶https://www.sps.nhs.uk/articles/covert-administration-of-medicines-legal-issues/



- Unacceptable taste Crushing and mixing of some medicines can have a bitter taste and an anaesthetic effect on the tongue. Consider liquid formulations if available.
- Incompatibility with food and drink causing altered absorption Some medicines are required to be taken before food or after food as this may affect absorption. Some are incompatible with calcium, iron, magnesium and zinc and dairy products such as milk would need to be avoided.
- Safety of crushing tablets Crushing cytotoxics, hormonal and contraceptive medicines is not advised due to the potential risk to the administrator coming into direct contact with the crushed medicine or by the risk of inhalation of aerosolised dust.

It is important that the person administering the medication is able to do so safely and effectively and should receive the appropriate level of training and supervision to do so. The Care Quality Commission has Essential Standards for the management of medicines can be found at https://www.cqc.org.uk/guidance-providers/adult-social-care/medicines-management

Regular Reviews

As a person's mental capacity can change along with the need to continue a treatment so it is important to set regular review meetings for covertly administered medication to ensure it is still necessary. The timescales of reviews should reflect the person's condition and what medications are being administered, whether this is it for a short or long term condition. Initially reviews should be frequent e.g. weekly on commencement of a covert medication and evidence of on-going attempts to encourage compliance is essential. A change in medication or dosage should also prompt a structured medication review to assess the need for the medications, side effects, benefits and any ongoing monitoring needs as well as a review and a reassessment for any potential deprivation of liberty as a result.

Documentation

Each care provider should have a written policy for covert medication use, as part of their medicines policy.

The care plan and contemporaneous record of the person receiving a covert medication must contain all the information gathered during the decision making process including the mental capacity assessment, the pharmacy advice and the best interests decision making outcome, also if applicable, the paperwork relating to any deprivation of liberty request.



Any agreement for covert medication administration should be signed by all relevant parties involved in the decision. (See appendix 4)

Specifically to medications:

- The method of administration must be agreed with the pharmacist and prescriber and record must be kept with the Medication Administration Record (MAR) chart. (See Appendix 4)
- Prescriptions, MARs, and individual medication boxes should be clearly labelled and annotate with clear instructions on how each medication should be administered e.g., open capsule and sprinkle contents on specified amount of fruit puree, crush and add to 15ml of yoghurt or fruit puree.
- Care staff must ensure that the entire dose is administered and where practical given within the first mouthful.
- The covertly administered medication should always be "freshly" prepared and not made up previously.
- Residents receiving medication administered covertly must be supervised until the medication has been consumed by the carer/nurse responsible for administering the medication.

Transfer of Care

It is essential that, should the person receiving covert medication, be transferred to another care facility or to Domiciliary Care, that the correct and relevant documentation accompanies them including a verbal handover to the person or persons who will be responsible for their care. On arrival at a new care venue, any covert medication should be reviewed and the necessary assessments, plans and documentation completed. Any existing Deprivation of Liberty authorisation is not transferable and will require re-application by the new care provider.

Legal and Ethical Considerations

Covert medication is a complex issue involving principles of service users' autonomy and consent to treatment, set in common law and statute, underpinned by the MCA and the Human Rights Act 1998.

Any adult with mental capacity has the right to consent to, or to decline treatment or nursing intervention.

Persons Detained Under Mental Health Act

For persons detained under the Mental Health Act (1983), the principles of consent still apply to conditions unrelated to the mental disorder they are being detained for. For medications related to the condition the person is detained for, these can be given



against a person's wishes during the first three months or afterwards if sanctioned by a Second Opinion Approved Doctor.

Deprivation of Liberty Safeguards – DoLS

The Deprivation of Liberty Safeguards (DoLS)⁷ are part of the Mental Capacity Act but were introduced at a later date coming into operation in April 2009. The safeguards apply to people who lack capacity to consent to their care and treatment in hospitals and homes (whether privately or publicly funded) and their purpose is to prevent arbitrary decisions that deprive vulnerable people of their liberty.

A Supreme Court Judgment known as 'Cheshire West' on 19 March 2014, made clear that liberty means the same for all, regardless of disabilities or conditions and the deprivation of that liberty, therefore, applies far wider than health and social care have previously recognised.

DoLS system is the current authorisation arrangement for adults either residing in a care home or hospital. The Court of Protection directly authorises all other care arrangements amounting to a deprivation of liberty that are not covered by DoLS, including those in community settings, as well as young people aged 16-17. The Liberty Protection Safeguards (LPS) will replace these existing processes to authorise a deprivation of liberty. The aim for full implementation of LPS is by April 2022.

Also, please note that the DHSC's MCA/DoLS COVID-19 guidance was updated on 15 October 2020, including, in particular, consideration of when face-to-face visits can take place in different tiers of the new alert system, and also thinking about the operation of the self-isolation regulations in the context of those with impaired decision-making capacity. Both the main and additional guidance can be found here https://www.gov.uk/government/publications/coronavirus-covid-19-looking-after-people-who-lack-mental-capacity

The 'Acid Test' was devised by the court to help identify a deprivation of liberty:

- Is this patients free to leave (whether they are compliant or not) AND
- Is this patient subject to continuous supervision and control?

To covertly administer medication that has controlling or sedative effects may amount to a deprivation of the person's liberty. A discussion with the DoLS Team at Buckinghamshire County Council is advised and the appropriate authorisation request

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⁷ https://www.scie.org.uk/mca/dols/at-a-glance/

⁸https://www.cqc.org.uk/sites/default/files/20140416%20Supreme%20Court%20judgment%20on%20deprivation%20of%20liberty%20Briefing%20FINAL.pdf



forms completed by the care provider e.g. care home. The DoLS team can be contacted at:

Buckinghamshire County Council DoLS Advice Line: 01296 382195

Email: dols@buckscc.gov.uk

Forms are available to download on the GOV.UK website

In the event of it being necessary to deprive a person of their liberty, the Safeguards give a person rights to representation, appeal and for any authorisation to be monitored and reviewed.

Developing case law regarding covert medication and DoLS offers further clarity: 'Covert medication is a serious interference with a person's autonomy and right to self-determination under Article 8. It is likely to be a contributory factor giving rise to the existing DOL. Safeguards by way of review are essential'

[taken from AG v BMBC & Anor [2016] EWCOP 37]

Covert Medication General Principles

- Mental Capacity Assessment establishing the person lacks capacity for this
 decision and all practicable steps taken to help the person make the decision
- Last Resort all other option should be explored
- **Best Interests** all decisions, based on a holistic assessment of the impact of covert medication on the person
- Inclusive decisions should not be made in isolation, evidence of a team decision involving those closest to the person and the person themselves where or as far possible
- **Transparent** the decision making process should be simple to follow and clearly documented
- Regularly reviewed the necessity must be reviewed formally
- Time limited for a short a time as possible



Appendix 1 - Covert Medication Flowchart

The flowchart must be used in conjunction with full covert administeration guidelines.



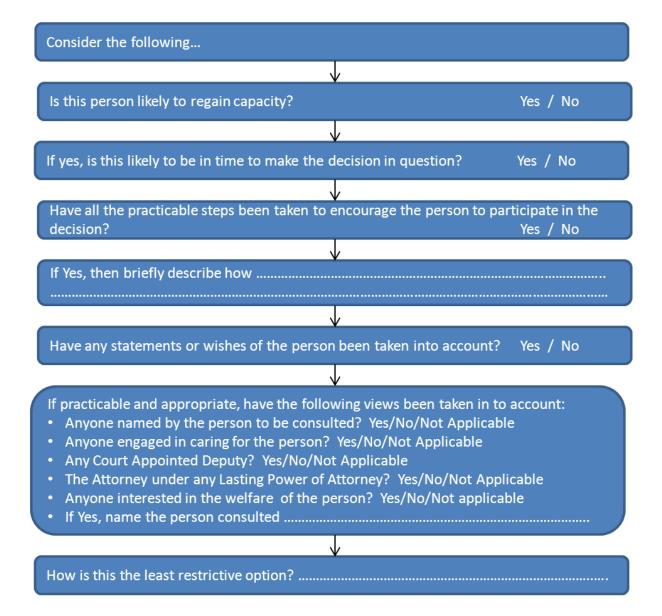


Appendix 2 - Best Interests Checklist

The Mental Capacity Act 2005 Section 4 sets out principles to make best interests decisions. The list is not exhaustive.

The best interest of a person must not be based merely on:

- The persons age or appearance
- A condition of his, or an aspect of his behaviour which may lead others to make unjustified assumptions about what might be in his best interests



Note:

If decisions are being made about treatment that is needed to keep a person alive, people are not allowed to be motivated by a desire to bring about their death, and they must not make assumptions about the quality of their life



Appendix 3 - Human Rights Act

The following articles of the Human Rights Act seem particularly relevant.

Article 2 'Everyone's right to life shall be protected by law'

Article 3 'No one shall be subject to torture or inhuman or degrading treatment or punishment'

Article 5 'Everyone has the right to liberty and security of person'

Article 6 'Everyone is entitled to a fair and public hearing within a reasonable period of time by an independent and impartial tribunal established by law'

Article 8 'Everyone has the right to respect for his private and family life, his home, and his correspondence'.

Article 2 Where covert medication enables the provision of effective treatment to someone who would otherwise reject it, this article might be used to justify such a practice. Clearly no treatment may be given covertly that is not specifically indicated for the treatment of illness or alleviation of distress (although such treatments may, sometimes, shorten life as a secondary result of their administration). Administration of treatments whose purpose is to shorten life is illegal.

Article 3 In an incapacitated individual, repeated restraint and injection of treatment (with attendant risk to life as well) may be more degrading and inhuman than the covert administration of medication.

Article 5 To justify the invasion of privacy which covert medication entails, it must be clear that this invasion is justified by the need for effective treatment.

Article 6 It is essential that, if medication is administered covertly this is done following discussion and with clear clinical records, so that a fair and public hearing may be obtained when required.

Article 8 See comment to Article 5 above.



Appendix 4

Covert Medication Risk Assessment

Risk assessment to be completed and held with the resident's medication chart and a copy in their care plan.

Residents Name:		Date of	Birtn:
Named Carer/Nurse:		Date:	
		1	
Members of the Multidisciplina	ary Team/relatives/care	rs involve	ed in decision making:
<u>Name</u> :	Designation:		<u>Date:</u>
Summary of problems encount	ered with administratio	n of med	ication:
What other alternative medica considered?	tion options/methods o	f adminis	stration have been
Has a capacity and Best interes	sts assessment been com	npleted: \	res/No
Date completed:			
Has a DOLs notification/application Date completed:	ation been completed: Y	es/No	



Covert Administration Medication Guidance from Pharmacist

Medication	Formulation	Administration information and advice from pharmacist	Date	Pharmacist signature
Example xxxxxxxxx	Capsules	Open capsule and give contents with first spoonful of yogurt		

Name of GP:	Date:	Signature:
lamed Carer/Nurse:	Date:	Signature:
Name of Pharmacist: :	Date:	Signature:
Discussed with Next of Kin/Advocate	:	Date:
ignature of next of kin where possib	le:	
ame of Next of Kin/Advocate		
eview date:		
are Home Manager signature:		
lame:	Date:	

 $(Acknowledged\ and\ adapted\ from\ Herts\ Valley\ CCG-Covert\ Administration\ of\ medication\ guideline\ for\ care\ home)$