

Guidelines on the management of controlled drugs (CD) in care homes

Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010¹ states: *'the registered person must protect service users against the risks associated with the unsafe use and management of medicines by means of the making of appropriate arrangements for the obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines used for the purposes of the regulated activity'*. This includes controlled drugs (CDs), which have more stringent regulations applied to them. This bulletin is intended to be a supporting guidance document for care home staff on the management of CDs in the care home setting. It can be adapted by care home staff to form a policy for use in individual care homes.

Recommendations

- Ensure supply, receipt, storage, administration and disposal of CDs meets regulatory requirements.
- Care homes should have policies in place to cover all processes relating to CDs.
- There should be procedures in place for identifying, reporting and reviewing incidents, errors and near misses involving CDs as well as sharing concerns about mishandling of CDs.
- See individual sections in this bulletin for further recommendations.

Access

- CDs are usually individually prescribed for residents in care homes.
- Care homes with nursing can purchase and use stocks of CDs for use in named residents against a written prescription that has been signed by the prescriber before the medicine is given, so long as they have a licence from the Home Office or are mainly maintained by charitable funds.² Further information on obtaining a Home Office licence can be found at www.homeoffice.gov.uk
- If a care home with nursing keeps stocks of schedule 2 CDs there should be a policy that details the agreed working practice. The local medicines management team should be involved in discussions.
- Care homes without nursing cannot purchase and keep stocks of CDs.² Any CDs in these care homes must be prescribed for individual patients by their doctor and dispensed by a pharmacy or dispensing practice.

Receipt

- It is important that there is a clear process for the safe handling of CDs when they are being delivered to the care home. CDs should be delivered separate to the main delivery of medicines and the package clearly marked that it contains a CD.
- The pharmacy or dispensing doctor may provide paperwork which lists the contents of the delivery and thus allows for an audit trail.

- If the CD is collected by a member of the care home staff from the pharmacy or dispensing doctor, there should be a procedure in place that provides an audit trail. It is good practice for the person collecting a schedule 2 or 3 CD from the community pharmacy/dispensary to be asked to sign for the CD (there is a space on the back of the prescription) and they may be asked for proof of identity.
- Check the product against the label (where it is practicable this check should be conducted with a witness):
 - » Drug name.
 - » Quantity, i.e. tablets, capsules, ampoules, patches, it is not expected that liquids are measured.
 - » Formulation.
 - » Strength.
- The expiry date should also be checked.
- The CD should be checked upon receipt to make sure that it is fit for use, i.e. not damaged.
- The CDs must be checked against any paperwork received or other relevant document, e.g. copy of prescription.
- The receipt of CDs by the care home should be recorded in a CD register (see appendix 1, page 7). The entry should be witnessed by a second suitably trained and competent member of staff. If there is a discrepancy between the product and the label, or what was ordered and the CD received, there should be a documented procedure for handling such an occurrence. See the section on discrepancies, page 4.
- It is important that staff know which medicines are CDs to ensure that they adhere to the safe keeping and recording requirements. See appendix 2, page 8, for examples of common CDs.

Storage

- Providers of adult care homes must comply with the Misuse of Drugs Act 1971 and associated regulations when storing CDs. Providers of children's homes should have robust processes for storing CDs.³
- If the CD requires safe custody and it has been provided in a monitored dosage system (MDS) the MDS should be stored in a CD safe or cabinet. If the resident self-administers their medication and a MDS is in use, this must be stored in a locked, non-portable cabinet or drawer in the resident's room.
- The CD safe or cabinet must comply with the requirements specified in the Safe Custody Regulations, see <http://www.legislation.gov.uk/ukxi/1973/798/made>
- When purchasing a safe or cabinet, assurance should be sought from the vendor or manufacturer that the product specifications comply with the requirements.
- Access to the CD cabinet should be restricted. The keys should be kept under the control of a designated person and there should be a clear audit trail of the holders of the key.

Administration

In accordance with Care Quality Commission (CQC) regulations, care home providers should have systems in place which comply with the requirements of the Misuse of Drugs Act 1971 and their associated regulations and the Safer Management of Controlled Drugs Regulations 2006 when administering CDs in care homes.

If the resident is not able to self-administer the controlled drug:

- **In a care home with nursing** a medical practitioner or a registered nurse should administer the CDs. In accordance with the Nursing and Midwifery Council (NMC) standards for medicines

management (standard 8) the registered nurse should obtain a secondary signatory from a witness who has been assessed as competent in relation to CDs.

- **In a care home without nursing** CDs should be administered by appropriately trained and competent care home staff, and this should be witnessed by another appropriately trained care home staff member. The use of a witness is intended to reduce the possibility of an error occurring. Therefore to be effective the witness must have the same level of training as the person administering the controlled drug.

It is good practice that the second signatory witnesses the whole administration process.

Documentation

- Administration of the CD should be documented on the medicines administration record (MAR) chart and the CD register.
- The care home staff responsible for administering the CD and an appropriately trained witness should sign the CD register. The staff member administering the CD should also sign the MAR (no signature is required on the MAR by the witness).
- The records should be completed immediately after the CD has been administered and not before.

If the medication has been administered by a visiting healthcare professional:³

- The care home staff should ask visiting healthcare professionals to make their record of administration available to the care home. The healthcare professional should also consider seeing the resident in the presence of care home staff responsible for administering medicines to the resident.
- Care home staff should keep a record of medicines administered by visiting health professionals on the resident's MAR.

If the CD is stored by the care home, appropriate records should be made in the CD register if it is then given to a visiting healthcare professional to administer. A second trained member of staff should witness the transfer.

If the CD is transferred out of the care home, e.g. when the resident is away from the home for a short period of time or is transferred to another care home, a record should be made in the CD register and witnessed by a second trained member of staff.

See appendix 3, page 9, for information regarding residents who keep and self-administer CDs.

See appendix 4, page 10, for information on the administration of transdermal opioids.

Disposal

Table 1: Disposal of CDs in care homes³

Type of care home	Arrangements	Records
Care home without nursing	CDs should be returned to the relevant pharmacist or dispensing doctor at the earliest opportunity for appropriate destruction.	Care homes should record the forms and quantities of CDs they are returning, and the pharmacist/dispensing doctor should sign for them on receipt. If pharmacy staff collects the CDs, they should sign for them in the CD register at the time of collection. Relevant details of any such transfer for disposal should be entered into the CD register and signed by a trained and competent member of staff, returning the drug.
Care home with nursing	The care home will need to make arrangements for the collection of waste medication with a Waste Management Regulations licensed waste disposal company. CDs must be denatured before being handed to the waste disposal company, e.g. in specially designed denaturing kits. A T28 exemption will be needed in order to comply with the legislation that is overseen by the Environment Agency.	For 'stock' CDs, a registered nurse and an authorised witness for destruction should sign the CD register. For CDs supplied to individual residents, a registered nurse and a suitably trained witness should sign the CD register. A record of the waste transfer note needs to be made by the appropriate nursing care home staff.

See appendix 6, page 13, for destruction of CDs.

Discrepancies

There should be a procedure for dealing with discrepancies, incidents and errors related to CDs. These should be reported immediately to the care home manager. Steps should be taken to establish what happened.

If a discrepancy is identified between what is expected and the supply received then the following guidance is provided:

- Enter the stock into the CD register indicating what was obtained, not what was requested.
- Contact the supplier as soon as possible to investigate and resolve the discrepancy.
- Store the CD separately in the CD cabinet awaiting collection.
- Arrange for the supplier to pick up the incorrect CD.
- When the stock is picked up, obtain a signed receipt from the person taking it away, and make an entry into the supplied section of the CD register.

If the CD received is deemed 'unfit' for use the following guidance is provided:

- Enter the medication received into the appropriate section of the CD register.
- Store the CD in the CD cabinet (ideally in a sealed bag marked 'Damaged Stock') until it is taken away.
- Inform the pharmacy that the stock received is 'unfit' for use, explaining the reason and arrange for the pharmacy to pick up the stock.
- When the stock is taken away, obtain a signed receipt from the person taking it away, and an entry must be made into the supplied section of the CD register.

If a discrepancy is identified between calculated stock figures (running balances) and actual stock the following guidance is provided:

- Check back through the entries for that drug and ensure that there has not been a bookkeeping or numerical error.
- Check the MAR chart and also any records of disposed medicines.
- If the discrepancy **can** be identified, record the outcome and make any corrections to the CD register with a signed and dated entry (this a retrospective entry) in the margin or at the bottom of the relevant page making reference any supporting documentation that was used to resolve the discrepancy There must be no cancellation, obliteration or alteration of any entry in the CD register.
- If the discrepancy **cannot** be explained or rectified then the CQC should be informed and also the Area Team Controlled Drugs Accountable Officer and the police.

Safeguarding and medication

A safeguarding issue in relation to managing medicines could include: ³

- The deliberate withholding of a medicine(s) without a valid reason
- The incorrect use of a medicine(s) for reasons other than the benefit of a resident
- Deliberate attempt to harm through use of a medicine(s), or
- Accidental harm caused by incorrect administration or a medication error.

Reporting CD incidents

If there is a medication administration error involving a CD this should be reported in accordance with the care home policy (which should include informing the resident's GP) and local commissioning arrangements. It should also be reported to the CQC if the medication error met the notification criteria; as outlined in outcome 20 of the CQC guidance about compliance, *Essential standards of quality and safety*, see link below:

http://www.cqc.org.uk/sites/default/files/documents/gac_-_dec_2011_update.pdf

References

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10. Royal Pharmaceutical Society, Medicines, Ethics and Practice. The professional guide for Pharmacists. Edition 38, July 2014.

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Non-subscriber publication March 2015.

Additional PrescQIPP resources

Patch application record



ere: <http://www.prescqipp.info/resources/viewcategory/303-care-homes-controlled-drugs-practice-guide>

Appendix 1: The controlled drugs (CDs) register

- The CD register is a bound book with numbered pages. Electronic CD registers are permitted as an alternative. Legislation requires that computerised entries must be:
 - » Attributable to the person who created the record
 - » Secure
 - » Cannot be altered at a later time
 - » Capable of being audited
 - » Compliant with best practice
 - » Accessible from the care home and capable of being printed.
- The CD register must be used to record the receipt, administration, disposal and transfer of controlled drugs held by the care home.
- The entry must be made as soon as possible on the same day.
- The CD register should not be used for any other purpose.
- The CD register must be kept in a secure place when not in use.
- A separate page must be used for each form, strength of each medication and resident. The name, strength and form of each medication and the name of the resident should be recorded at the top of each page.
- It would be useful for an index page to be maintained in the CD register, indicating for individual residents, on which page of the CD register each CD can be found.
- Entries must be in chronological order.
- Entries should not be cancelled, altered or crossed out. Corrections must be made using marginal notes or footnotes which are signed and dated.
- All entries should be signed and dated by the member of staff making the entry and witnessed by a suitably trained member of care home staff (where practical to do so) who should also sign the entry .
- The administration of a CD should be recorded in the CD register indicating the name of the resident, the dose given and time administered.
- The running balance should be kept to ensure that irregularities or discrepancies are identified as quickly as possible. The balance should be updated each time an entry is made. It is good practice to check all stock (including zero balances where appropriate) regularly, e.g. weekly.
- The CD register should be kept for two years from the last entry. Good practice would be to retain the CD register for longer as cases can take several years to come to light or before they go to court.
- When transferring the drug record to a new page in the CD register the amount remaining should be identified with 'carried forward from page x' written clearly on the new page.

Appendix 2: Common controlled drugs (CDs)

Table 2: Examples of common controlled drugs

Schedule 2 CDs		
Controlled drug	Brand name	Legal requirements
Morphine	MST Continus®	<ul style="list-style-type: none"> Requires safe custody in a CD cabinet. Records need to be made in the CD register.
	Sevredol®	
	Zomorph®	
	MXL®	
	Oramorph® concentrated oral solution 100mg/5ml	
Oramorph® oral solution 10mg/5ml is not a CD. However it is good practice to store it in a CD cabinet and complete CD records		
Diamorphine	-	
Dexamphetamine	Dexedrine®	
Pethidine	-	
Oxycodone	Oxycontin®, Oxynorm®	
Methadone	Physeptone®	
Methylphenidate	Ritalin®, Concerta®	
Fentanyl	Durogesic DTrans®, Matrifen®, Tilofyl®, Fentalis® Fencino®	
Schedule 3 CDs		
Controlled drug	Brand name	Legal requirements
Buprenorphine	Subutex®, Temgesic® tablets	<ul style="list-style-type: none"> Buprenorphine and temazepam must be stored in the CD cabinet. Other CDs listed in schedule 3 do not need to be stored in the CD cabinet. Schedule 3 CDs do not need to be recorded in the CD register, however it is good practice to make records for buprenorphine and temazepam.
	Butrans®, Transtec® patches	
Midazolam	Hypnovel® injection	
	Buccolam® oromucosal solution	
Temazepam	-	
Phenobarbital	Fortral®	
Tramadol	Zydol® Zamadol®	
Schedule 4 CDs		
Controlled drug	Brand name	Legal requirements
Diazepam	Valium®	<ul style="list-style-type: none"> Safe custody is not required nor is it a requirement to make records in the CD register.
Clobazam	Frisium®	
Lorazepam	Ativan®	
Nitrazepam	Mogadon®	
Clonazepam	Rivotril®	
Chlordiazepoxide	Librium®	
Zaleplon	-	
Zolpidem	Stilnoct®	
Zopiclone	Zimovane LS® and Zimovane®	

This list is not exhaustive; therefore care home staff should seek advice for example from the pharmacist or dispensing doctor when unsure of the legal requirements for safety custody and recording of a CD.

Appendix 3: Guidelines if residents self-administer controlled drugs

NICE guidance on managing medicines in care homes³ advises that care home providers should ensure that their process for self-administration of CDs includes information about:

- Individual risk assessment
- Obtaining or ordering CDs
- Supplying CDs
- Storing CDs
- Recording supply of CDs to residents
- Reminding residents to take their medicines (including CDs)
- Disposal of unwanted CDs.

General points to note

Risk assessment

The ability of a resident to self-administer their medication must be reviewed periodically and if the resident's circumstances change.

The risk assessment should include whether the resident understands:

- Why the medicine is prescribed.
- How much and how often to take it.
- What may happen if they do not take the medicine or take too much.

Documentation

If the care home is ordering and receiving the CDs on behalf of the resident a record should be made of the receipt, supply and disposal of the CD in the CD register.

If the resident is solely responsible for the ordering and the receipt of the CD there isn't a requirement to document this in the CD register.

Storage

The CD must be stored in a locked non-portable cabinet or drawer in the resident's room.

Appendix 4: Transdermal opioids

The information outlined below has been compiled to highlight the differences between some of the various brands of transdermal opioids available. The list is not exhaustive and care home staff should refer to the patient information leaflets or speak to the pharmacist or dispensing doctor for further advice. It is good practice to keep the patient information leaflets where care home staff can access the information.

Table 3: Examples of transdermal buprenorphine preparations

Brand name	Strength	Duration	Administration
BuTrans® ⁴	5, 10, and 20 mcg/hr	The patch should be worn continuously for 7 days.	The patch may be applied to the upper outer arm, upper chest, upper back or side of chest, but not on any parts of skin that have large scars. It is recommended that no more than two patches are applied at the same time, regardless of the patch strength. A new patch should not be applied to the same skin site for the subsequent 3 - 4 weeks.
Transtec® ⁵	35, 52.5 and 70 mcg/hr	The patch should be worn continuously and replaced after 4 days (96 hours) at the latest. For convenience of use, the transdermal patch can be changed twice a week at regular intervals, e.g. always on Monday morning and Thursday evening.	The patch may be applied to the upper back or below the collar bone on the chest, but not on any parts of skin that have large scars. A new patch should be applied to a different skin site. At least one week should elapse before a new transdermal patch is applied to the same area of skin.
Hapoctasin® ⁶	35, 52.5 and 70 mcg/hr	Hapoctasin should be worn continuously for up to 3 days (72 hours)	Preferable sites on the upper body are: upper back or below the collar-bone on the chest. After removal of the previous transdermal patch a new Hapoctasin transdermal patch should be applied to a different skin site. At least one week should elapse before a new transdermal patch is applied to the same area of skin.

Table 4: Examples of transdermal fentanyl preparations

Brand name	Strength	Duration	Application
Durogesic DTrans® ⁷	12, 25, 50, 75, and 100 mcg/hr	The patch should be worn continuously for 3 days (72 hours).	The patch may be applied to the upper outer arm, upper chest, upper back or side of chest, but not on any parts of skin that have large scars. A new patch should be applied to a different skin site. Several days should elapse before a new patch is applied to the same area of skin.
Matrifen® ⁸			The patch may be applied on a flat surface of the upper torso or upper arm. A new transdermal patch should always be applied to a different site from the previous one. The same application site may be re-used only after an interval of at least 7 days.
Fentalis® ⁹			The patch may be applied on a flat surface of the upper torso or upper arm. A new transdermal patch should always be applied to a different site from the previous one. The same application site may be re-used only after an interval of at least 7 days.

Key points-transdermal opioid preparations

- The patches are usually prescribed by brand as there is some variation between manufacturers and different brands of product.
- The patch should be applied to a clean, dry area of skin which is non-hairy; the hair may be clipped with scissors but not shaved.
- Do not apply the patch to irritated, recently irradiated or shaven skin, or on lymphoedematous areas.
- Refer to the patient information leaflet (PIL) for information as to where the patch may be applied.
- Creams, ointments and talc should not be used on the area of skin that the patch is to be applied to. The skin should be completely dry before application of the patch.
- When applying the patch, remove it from the pack; press it firmly in place using the palm of the hand for at least 30 seconds, to ensure it is properly applied.
- If more than one patch is applied they should be applied at the same time and placed far enough apart so they do not overlap.
- The site of application should be rotated in accordance with the manufacturer guidance.
- Residents with fever should be observed for signs of toxicity, as heat increases the absorption of the drug from the patch.
- Do not apply the patch immediately after the resident has had a hot shower or bath.
- Heat sources such as hot water bottles and electric blankets should not be used.
- The patch should be checked each day to ensure that it is still in place.
- Generally a patch that has been cut, divided or damaged in any way should not be used. In practice matrix patches are sometimes cut however this is unlicensed, it is advisable to check with a pharmacist before using the patch.

Example of a Medicines Administration Record (MAR)

Month	Week	Week 3							Week 4							
		Date	26	27	28	29	30	31	1	2	3	4	5	6	7	8
BuTrans 10mcg/hr patch	8.00 am	EJ	/	/	/	/	/	/								
	12 noon															
	4.00 pm															
	8.00 pm															
Checked by: AB	Qty: 4	Upper left arm														

A record of the site application should be made; this can be on the MAR chart as shown or on a patch application record chart (see page 12).

The dates between patch changes should be crossed out

The day the patch should be changed can be highlighted on the MAR chart.

At the end of the cycle the new MAR chart should be annotated based on the information from the previous MAR chart. Therefore using the example above, the new MAR chart should be annotated to indicate the patch is next due to be changed on the 9th.

Appendix 5: The patch application record

An amendable version of this form is available as an attachment at:

<http://www.prescqipp.info/resources/viewcategory/303-care-homes-controlled-drugs-good-practice-guide>

Patch application record

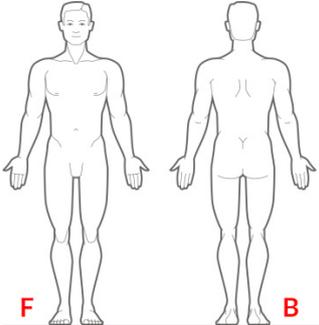
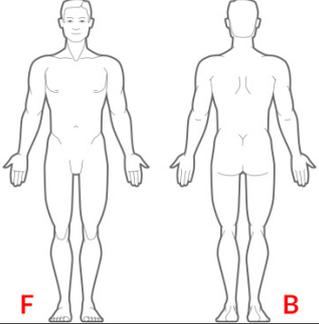
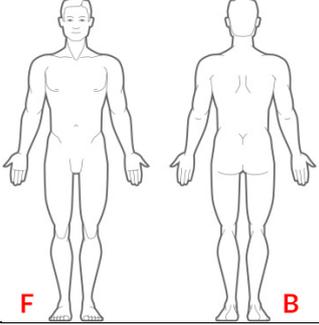
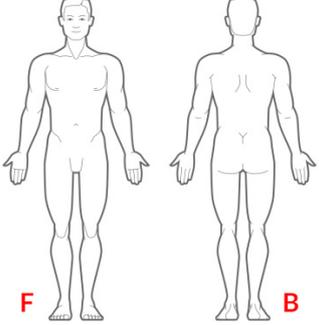
Name of resident			
Name of patch		Strength	

The patch should be checked on a daily basis to make sure it is still in place.

The site of application should be rotated in accordance with the manufacturer guidance.

The old patch must be folded in half and stuck together before disposal, in accordance with the care home policy.

Please indicate where the patch has been applied using a cross (x). If more than one patch is in use please indicate with a separate symbol, e.g. o

	Old patch removal date		Time	
	Removed by			
	New patch applied date		Time	
	Applied by			
	Witnessed by			
	Old patch removal date		Time	
	Removed by			
	New patch applied date		Time	
	Applied by			
	Witnessed by			
	Old patch removal date		Time	
	Removed by			
	New patch applied date		Time	
	Applied by			
	Witnessed by			
	Old patch removal date		Time	
	Removed by			
	New patch applied date		Time	
	Applied by			
	Witnessed by			

Appendix 6: Destruction of controlled drugs (CDs) in care homes with nursing

The CDs should be denatured before they are disposed of using specially designed denaturing kits. Instructions for denaturing the different dosage forms may be provided by the manufacturer of the denaturing kit. If this has not been provided, the Royal Pharmaceutical Society guidance on the methods of destruction/denaturing CDs meets the requirements of the Misuse of Drugs Regulations 2001 and the health and safety needs of people undertaking the role.

Table 5: Methods of destroying CDs¹⁰

Dosage form	Method of destruction
Solid dosage forms, e.g. capsules and tablets	Grind or crush the solid dose formulation before adding to the controlled drug denaturing kit to ensure that whole tablets or capsules are not retrievable. The use of a small amount of water whilst grinding or crushing may assist in minimising particles of dust being released into the air. An alternative method of denaturing is to crush or grind the solid dose formulation and place it into a small amount of warm, soapy water stirring sufficiently to ensure the drug has been dissolved or dispersed. The resulting mixture may then be poured onto an appropriate amount of cat litter (or similar product) and added to an appropriate waste disposal bin supplied by the waste contractor.
Liquid dosage forms	Pour into an appropriately sized CD denaturing kit. Alternatively pour onto an appropriate amount of cat litter (or similar product) being careful so that the people destroying are protected from harm and the environment is protected from pollution.
Ampoules and vials	For liquid containing ampoules, open the ampoule and empty the contents into a CD denaturing kit, or dispose of in the same manner as liquid dose formulations above. Dispose of the ampoule as sharps pharmaceutical waste. For powder containing ampoules, open the ampoule and add water to dissolve the powder inside. The resulting mixture can be poured into the CD denaturing kit and the ampoule disposed of as sharps pharmaceutical waste. An alternative but less preferable, disposal method is where the ampoules are crushed with a pestle inside an empty plastic container. Once broken, a small quantity of warm soapy water (for powder ampoules) or cat litter (for liquid ampoules) is added. If these methods are used, care should be taken to ensure that the glass does not harm the person destroying the CD. The resulting liquid mixture should then be disposed of in a CD denaturing kit or in the bin that is used for disposal of liquid medicines.
Patches	Remove the backing and fold the patch over on itself. Place into a waste disposal bin or a CD denaturing kit.
Aerosol formulations	Expel into water and dispose of the resulting liquid in accordance with the guidance above on destroying liquid formulations. If this is not possible because of the nature of the formulation, expel into an absorbent material and dispose of this as pharmaceutical waste. Alternatively consider if it would be safe to open or to otherwise compromise the container to release the controlled drug safely. The resulting liquid mixture should then be disposed of in a CD denaturing kit or adsorbed onto cat litter and disposed of as pharmaceutical waste.