East London
NHS Foundation Trust

Procedure for the Safe Management of 'Patient's Own' Controlled Drugs in the Domiciliary Setting

Version number :	5.0
Consultation Groups	Community Health Services, Clinical Policy Alignment Group and Senior Pharmacists Meeting Group, ELFT
Approved by (Sponsor Group)	Medicines Committee/CHS Directorate
Ratified by:	Medicines Committee
Date ratified:	November 2018
Name and Job Title of authors:	Charity Okoli, Lead Directorate Pharmacist, CHN
Executive Director lead :	Chief Medical Director (Paul Gilluley)
Implementation Date :	November 2018
Last Review Date	November 2018
Next Review date:	November 2021

Services	**Applicable to**
Trustwide	
Mental Health and LD	
Community Health Services, ELFT	√

Version Control Summary

Version	Description of Change(s)	Reason for Change	Author	Date
5.0	Title changed. Policy updated to include all CHS ELFT. Introduction updated. The section for definition was updated with key terms. RIO changed to electronic records. Nurse changed to healthcare practitioner. Legislations involved in CDs controls added. The appendix for CD schedule classification and lists of CD deleted. Other minor additions and corrections were also made. References updated.	Policy due for review. Policy was updated in order to incorporate all Community health Services across ELFT.	Charity Okoli	November 2018
4.1	Adjustment of last and next review date		Manpreet Saini	July 2015
4.0	Included the various points when documentation is required in the patient's paper and Rio notes. Notes added about the role of a Registered Nurse and a Health Care Assistant and the differences between assistance, prompting and	Clarity regarding the administration of Controlled Drugs from a Health Care Assistant	Manpreet Saini	September 2014

	administration. Minor adjustments to the Patient's CD Log Sheet			
3.0	Alteration of policy following reclassification of tramadol, lisdexamfetamine, zopiclone and zaleplon following change in legislation	Reclassification of tramadol, lisdexamfetamine, zopiclone and zaleplon	Manpreet Saini	July 2014
2.3	Rationalisation of policy. Replacement of 'Standard Operating Procedure' with 'policy'	Review of best practice.	Manpreet Saini	January 2012
2.2	Extra reference added to appendix 1		Manpreet Saini	May 2011
2.1	Removal of DCW reference		Manpreet Saini	May 2011
2.0	Rationalisation of policy	Review of best practice	Manpreet Saini	April 2011

Contents

INTRODUCTION

Controlled drugs (CDs) are drugs with restrictions on their use, including administration, prescribing, ordering, record keeping and storage. These drugs are subject to the misuse of Drugs Act 1971, and the other associated regulations such as the misuse of Drugs Regulations 2001 (in England, Wales and Scotland).
Additional statutory measures for the management of CDs are laid down in the Health Act (2006) and other associated Regulations.
See Appendix A of this document and Appendix 1 of the Trust CD policy for more information on legislation and regulations for controlled drugs.

CDs are important for the management of many clinical conditions but they are placed under special legislative controls due to the possibility of being abused or diverted which could lead to harm as well.

1.1 PURPOSE

To establish safe and consistent practice for the management of Controlled Drugs (CDs) in the domiciliary setting once the CD has been prescribed and dispensed within Community Health Services, East London NHS Foundation Trust (ELFT).

This procedure is to be adopted by all health care professionals who are involved with the handling of “patients own” controlled drugs (CDs) in the “patients own” home setting.

1.2 SCOPE

This procedure should be read in conjunction with the Trust Controlled Drugs Policy. It covers:

- The collection of CDs from the pharmacy by a healthcare practitioner on behalf of the patient.
- The transport of CDs from the pharmacy to the patient’s home by a healthcare practitioner on behalf of the patient.
- The administration of CDs.
- The storage of CDs in the patient home.
- The return of CDs to the pharmacy for disposal
- The prescribing of CDs by a non-medical prescriber

NOTE: The scope of this resource does not include policy relating to general medicine handling, staff training, procedures and /or protocols in relation to other clinical or continuity of care planning aspects of managing patients in their homes.

1.3 DEFINITION

For the purpose of this procedure the term:

NURSE: The term ‘Nurse’ is used in its generic form and applies to all Registered Nurses employed by the Community Health Services directorate, part of East London Foundation NHS Trust and within general practice.

Please note, in the procedure there will be circumstances that require the patient’s consent or signature. If the patient’s mental state or a physical disability means that written or verbal

consent cannot be given, then a family member, carer or next of kin's consent should be sought. If this is not possible then it must be documented on the appropriate form to whichever stage it applies. The team manager must also be informed about this circumstance.

This procedure applies whilst the patient is using CDs as part of their therapy. The forms used from this procedure must be filed in the patient's paper notes and / or uploaded onto patient's electronic records.

If extra copies are made of any of the forms from this procedure and used for recording information, they must also be filed with the patient's paper notes and/or uploaded onto patients' electronic records.

PROMPTING: Prompting of medication is reminding a person of the time and asking if they have or are going to take their medicines. The person is still in control of their medicines, and may decide not to take them or to take them later. Prompting can be useful when a person knows what medicines to take and how to take them, but may simply forget the time.

ASSISTING: A person may be able to retain control of his or her medicines but need assistance with simple mechanical tasks. Assisting with medicines can include bringing packs of medicines to a person at their request so that the person can take the medicines; opening bottles or packaging, including Multi-Compartmental Compliance Aids at the request and direction of the person who is going to take the medicine; reading labels and checking the time at the request of the person who is going to take the medicine; ensuring the individual has a drink to take with his or her medication.

ADMINISTRATION: Administration of medication may include some or all of the following:

a) selecting and preparing medicines for immediate administration (including medicines in monitored dosage cassettes and liquid medicines)

b) applying creams and ointments

c) inserting drops to ear, nose or eye

d) assisting with the administration of inhaled medicines

For reference a list of some of the commonly used CDs has been provided under their schedules in appendix A (This is not the complete list of all existing CDs)

2. COLLECTION OF CONTROLLED DRUGS (CDs)

2.1 The healthcare practitioner involved in the delivery of patient care should **not routinely** transport a patient's own CD to and from that patient's home. This should **only** be undertaken in exceptional circumstances when all other options for obtaining the CD for the patient's use have been exhausted, including collection by patient, relatives, carers; and delivery by the community pharmacy. The practitioner should clearly document the reasons for any such decision taken in the patient's paper and/or electronic records. Where a healthcare practitioner, acting in his/her capacity as such, is collecting a CD on behalf of the patient they must:

- Provide the Pharmacist with their name, address and their work photo ID see appendix B for other ID that is considered suitable Sign the back of the prescription presented by the Pharmacist on receipt of the patient's CDs.

3. TRANSPORT OF CDs

3.1 Healthcare practitioners in legal possession of a CD have a professional duty of care to take all reasonable steps to maintain safe custody of that CD at all times. They must:

- Make a direct journey between collection and delivery points.
- Keep the CDs out of view during transit.
- Never leave the CDs unattended
- Never keep CDs overnight in the car or at their own home.

3.2 Once delivered to the patient's home, the healthcare practitioner must enter the details of the CD delivered onto the Patient Controlled Drug Log Sheet (PCDLS – yellow form on page 10) as CD collected from Pharmacy and annotated with a capital (P) in brackets. This will indicate that the quantity of the CD has increased due to a new supply being added. The entry must be signed accordingly. The healthcare practitioner should also record on the patient's electronic records that a new supply of the CD was delivered to the patient's home regardless of whether the healthcare practitioner collected it herself or whether or not it was collected by the patient, relative or carer themselves. Details such as the name of the drug, formulation (i.e. modified release if applicable); form (tablets, capsules, injections, solutions, suspensions etc.), strength and quantity must be recorded.

3.3 If a new CD (i.e. of a different drug name, strength, form, formulation) is added to the patient's supply, then a new PCDLS should be used for each CD. This is so that the running quantity of each different CD can be tracked and reconciled.

4. ADMINISTRATION OF CDs

4.1 Only a Registered Nurse may prompt, assist or administer a CD to a patient if the patient is not able to administer it to themselves. Other healthcare practitioners such as a Health Care Assistants (HCA) can only administer oral or topical CDs where they have been trained and assessed as competent to administer medicines. Otherwise, they can only prompt or assist but not administer CDs to a patient.

4.2 CDs may only be administered to a patient in accordance with the directions of a medical prescriber or another appropriate Independent Non-Medical Prescriber.

4.3 Non-medical Independent Prescribers should only prescribe CDs according to the Local Clinical Commissioning Group formulary and their own competency and remit.

For more information on Nurse Independent Prescribing and the assessment process prior to prescribing please refer to the Trust 'Non- Medical Prescribing Policy' available from the ELFT intranet

4.4 The drug name, form, strength, route, frequency and dose as authorised by the prescriber must be recorded accurately onto the patient's Medicines Administration Record Chart (MARC). In order to maximise patient safety, the prescriber should provide clear and full directions on how to administer the medication. 'PRN' labelled instructions e.g. 'as directed', 'as required', are of no value to the patient or carer. The dose and frequency should be clearly stated. For administration recording purposes, competent Nurses are able to copy Controlled Drugs onto the patient's MARC but must pay particular attention to details such as the form, formulation and strengths of the CD being written e.g. morphine sulphate 10mg tablets (Sevredol® 10mg tablets) and morphine sulphate 10mg m/r tablets (MST® CONTINUS® 10 mg prolonged release tablets) are not the same thing. The MARC is an East London NHS Foundation Trust (ELFT) record of what is administered by Community Nurses and Health Care professionals trained and qualified to administer medications. The current prescription is what should be used to ascertain what has been prescribed. Further information about the MARC can be found in the Medicines Policy on the intranet or by clicking the link below:

http://elftintranet/sites/common/Private/Community_View.aspx?id=408&keyword=medicines policy

4.5 Any CD that has been prescribed and is to be administered must be recorded on the patient's MARC. The following information has to be documented using black ink only and clearly written in CAPTIALS

- Date and time of administration
- Name, form and strength of drug administered
- Route of administration
- Dose of drug administered
- Signature of the healthcare practitioner administering it.

Any alteration to the dosage, by the patient's prescriber, must be recorded promptly on the patient's MARC with the original entry deleted. The original entry must NOT be amended but deleted and the new dose rewritten. The prescriber must contact the health professional concerned of the changes immediately to enable them to do this

4.6 A continuous record of CDs received and administered, including a running balance of stocks, must be held at the place of residence where the patient is receiving care. This must be recorded on the Patient Controlled Drugs Log Sheet (PCDLS). A separate PCDLS must be used for each different CD used by the patient. The only exception to this is where the CD is contained in a MCA.

4.7 It is important to monitor the use of CDs. The patient's stock of CDs should be checked, counted, reconciled and clearly recorded at the time of every administration onto the PCDLS. Medication counters if available should be used when counting tablets in bottles. Quantities of liquids should be estimated. If a discrepancy is suspected the volume should be measured with a measuring cylinder or an alternative measuring utensil. Any errors,

discrepancies should be logged in the patient's notes and reported to the manager and the Accountable Officer immediately. A Datix incident form must also be completed.

4.8 Where CDs are present, then a balance check should be made on every occasion that a healthcare practitioner, who administers medicines to the patient, attends to the patient. This is a safety measure for the Nurse and this action would provide a much quicker awareness of any unaccounted for CDs. This will involve:

- Physical count of CDs against the amount recorded (including any spoilt doses that have not been returned to pharmacy).
- Assessing for any anomalies in the volume of patient's refused CDs, spoilt doses etc. Once the healthcare practitioner is satisfied with the check they must sign off on the PCDLS.

4.9 Any omissions of medication must be recorded, with the reason(s), on the patient's MARC, PCDLS and in the patient's notes with a written record of the action taken following refusal. Regular refusal to take the CD by the patient must be reported to the patient's GP or the Independent Prescriber. In the event that the GP is not the prescriber, they should still be informed of the situation promptly with the aim to review the therapy and for any other remedial action to be taken.

4.10 Spoilt doses of CDs (e.g. spat out, dropped, ripped off etc.) which are still recoverable but not fit for consumption or re-use should be disposed of immediately and recorded in the PCDLS.

- Solid dose formulation must be ground or crushed and placed in a small amount of hot, soapy water and stirred sufficiently until dissolved or dispersed before being placed into a waste container, once the mixture has cooled.
- The Home Office has advised that all Controlled Drugs in Schedules 2, 3 and 4 (part 1) should be denatured and, therefore, rendered irretrievable before disposal.
- The active ingredient in CD patches can be rendered irretrievable by removing the backing and folding the patch over on itself and then placing it in a waste disposal bin. Gloves must be worn by the person destroying the patch to prevent absorption via the skin.

4.11 All disposal actions must be clearly documented at the time of the destruction and the quantity disposed must be clearly stated, with the remaining balance recorded in the CDLS. There are more information regarding the handling and destruction of CDs in Misuse of drugs regulations 2001. http://www.legislation.gov.uk/uksi/2001/3998/regulation/27/made and also on the recommendations of NICE guideline (NG46), see link below. https://www.nice.org.uk/guidance/ng46/chapter/recommendations#handling-controlled-drugs.

4.12 CD doses which have been rendered irretrievable (or not recoverable) through vomiting or in the case of liquids spat out must be documented, including the quantity:

- On the PCDLS with '(W)' annotated next to it where 'W' stands for 'wasted'.

PATIENT CONTROLLED DRUG LOG SHEET

Transferred from Form No.:

Patient Name: NHS No.: Form No:

CD Name: Form:

Quantity: Date Received:

Name & signature of persons who collected CD:

Date	Quantity Administered (A) Quantity Wasted (W) Quantity supplied by Pharmacy (P)	Balance Remaining	Entered by (Name & Sign.)
Transferred to Form No.:			

- After each quantity recorded please annotate in brackets whether this quantity was (A) administered or (W) wasted. If a further supply of the CD was obtained from the Pharmacy thereby increasing the quantity of the CD, then this should be entered as well and annotated with a (P).

5.0 STORAGE OF CDs IN PATIENT'S HOME

5.1 Patients and/or their relatives should be educated about the need to keep CDs as securely as possible. The Nurse should perform a risk assessment with regards to the potential for misuse of CDs in the domiciliary setting. This should be uploaded onto the patient's electronic notes and/or clearly documented in the patient's paper records. Where concerns are identified the prescriber should be informed of these and a plan agreed for managing the issues raised.

5.2 Patients and relatives should be encouraged to store CDs in the original dispensed labelled boxes, keeping different strengths physically separated, especially injectable morphine and diamorphine, to minimise risk of accidental preparation and administration of a wrong dose

5.3 Keep all medicines in one location to avoid them being mislaid.

5.4 Store them in a location which is cool and dry – i.e. not adjacent to a radiator or other source of heat, or in a location subject to steam or moisture e.g. bathrooms.

5.5 The healthcare practitioner should explain that CDs are potentially dangerous and vulnerable to misuse, and that a drug which is appropriate to the particular needs of a patient might be a temptation or a danger to others, and that it should be looked after accordingly. Any such discussions or conversations must be documented clearly in the patient's paper notes and/or uploaded onto the patient's electronic notes.

6.0 DISPOSAL / DESTRUCTION OF 'PATIENT'S OWN' CDs

6.1 Prescribed drugs including CDs are the property of the patient and remain so even after death. It is illegal to possess CDs that have not been prescribed for you. Relatives/carers should be advised that it is illegal to possess the CDs and that all CDs should be returned to a community pharmacy for safe destruction; whether that is because of discontinuation of the CD or due to the death of the patient. Ideally this should be carried out by the carer/relative but in exceptional circumstances may be returned back by the healthcare practitioner. It would be good practice for the healthcare practitioner to also take the yellow log sheet with them to the pharmacy as extra proof of the quantity and the different CDs that are being surrendered to them for disposal. Any decision that the Nurse make for returning the CDs must be clearly documented in the patient's paper and/or patient's electronic notes with reasoning.

6.2 If return by relatives or next of kin is not practical or possible then it would be appropriate for the healthcare practitioner to return the unwanted CDs to the pharmacy as long as consent has been obtained. A signature is required on the 'Return of Patient CDs to Pharmacy for Disposal' form either by the patient or next of kin as evidence of consent. If the patient or next of kin is refusing consent then the reason for this must be enquired and the healthcare practitioner must try to ascertain as fully as they can of the family's intentions regarding the CDs (i.e. if and when they will be returned to the pharmacy for destruction). This must be documented on the PCDLS as 'consent to return CDs refused' and signed and dated by the healthcare practitioner. A Datix incident report must then be filled out to document that the Nurse was unable to return the CDs to the pharmacy as the family's consent was not obtained.

6.3 A record of the CDs returned to the pharmacy for destruction by the h must be made on the 'Return of Patient CDs to Pharmacy for Disposal' form prior to returning the unwanted

CDs. CDs can be returned to any community pharmacy regardless of where they were originally dispensed. After the CDs have been returned, the pharmacy stamped form should then form part of the patient's paper notes and/or uploaded onto the patient's electronic notes.

7.0 RETURN OF PATIENT CONTROLLED DRUGS TO PHARMACY FOR DISPOSAL

I, the patient / patient representative hereby consent to the return of the unused controlled drugs prescribed for (insert name of patient) to the pharmacy by:

(Insert name of Nurse): _____

Name of Patient / Patient representative:
Signature of Patient / patient representative:

Name of Chemist:

Pharmacy Stamp:

Date	Controlled Drug Item	Quantity	Name & Signature	
			Returner	Pharmacist

Appendix A:

Misuse of Drugs Regulations 2001 (MDR)

The use of CDs in medicine is permitted by the Misuse of Drug Regulations (MDR). The MDR classify the drugs in five schedules according to the different levels of control required.
Schedule 1 CDs are subject to the highest level of control, whereas Schedule 5 CDs are subject to a much lower level of control.
The main groups of CDs are summarised in Appendix B. Schedule 1 drugs have been omitted from the table in Appendix B as drugs in this group have virtually no therapeutic use and a licence is generally required for their production, possession or supply. Although Sativex© (a cannabis based product) is currently being supplied on a named-patient basis.

For practical purposes, health care staff need to be aware of the current Regulations. The MDR are periodically amended and revised. The MDR currently in force and its amendments can be found using this link (http://www.legislation.gov.uk/uksi/2001/3998/contents/made) or check the website for the Office of Public Information (www.opsi.gov.uk).

Schedule 1 (CD Licence)

Schedule 1 drugs include hallucinogenic drugs such as coca leaf, lysergide and mescaline, ecstacy-type substances, raw opium and cannabis.
Production, possession and supply of drugs in this Schedule 1 are limited, in the public interest, to research or other special purposes. Only certain persons can be licensed by the Home Office to possess them for research purposes. Practitioners (e.g. doctors, dentists and veterinary surgeons) and pharmacists may not lawfully possess Schedule 1 drugs except under licence from the Home Office.

Medicines Act 1968

This Act, and Regulations made under the Act, sets out the requirements for the legal sale, supply and administration of medicines. It also allows certain exemptions from the general restrictions on the sale, supply and administration of medicines which, for example, enable midwives to supply and/or administer diamorphine, morphine, pethidine or pentazocine. A number of health care professionals are permitted to supply and/or administer medicines generally in accordance with a Patient Group Direction (PGD). Some of these professional groups, but not all, are permitted to possess, supply or administer CDs in accordance with a PGD under Misuse of Drugs legislation

Health Act 2006

One of the key provisions of the Act is that, all designated bodies such as healthcare organisations and independent hospitals are required to appoint an Accountable Officer.

The accountable officer for East London NHS Foundation Trust (ELFT) is the Chief Pharmacist.
For more information on the responsibilities of the accountable officer for ELFT and any other relevant legislation for controlled drugs see the trust main CD policy on the intranet following this link below

http://elftintranet/sites/common/Private/Community_View.aspx?id=408&keyword=controlled%20drug%20policy

References

- Medicines, Ethics and Practice guide: Number 42 (July 2018). Available at: https://www.rpharms.com/resources/publications/medicines-ethics-and-practice-mep

- Pharmaceutical Services Negotiating Committee, Controlled Drugs / Misuse of Drugs Regulations. Available at: https://psnc.org.uk/contract-it/pharmacy-regulation/controlled-drug-regulations

- National Prescribing Centre, Controlled Drugs. Available at: https://www.gov.uk/government/publications/national-prescribing-centre-reports-on-safe-management-and-use-of-controlled-drugs

- Safer Management of Controlled drugs: The Government's response to the fourth Report of the Shipman Inquiry. December 2004

- https://www.rqia.org.uk/reviews/review-reports/2012-2015/2013-14/independent-review-of-the-management-of-controlled

- NICE guideline (NG46), April 2016 https://www.nice.org.uk/guidance/ng46/chapter/recommendations#handling-controlled-drugs

- The East London NHS Foundation Trust policy for Controlled drugs, can be accessed by this link below

  http://elftintranet/sites/common/Private/Community_View.aspx?id=408&keyword=controlled%20drug%20policy