Controlled Drugs Procedures

Contents

Purpose of this procedure

The purpose of this procedure is to provide details and guidance in relation to all activities concerning Controlled Drugs (CDs) e.g. requisitioning, receipt, administration. The information contained in this procedure is in relation to Schedule 2 and 3 CDs, unless stated otherwise. The CD status of a medicine can be found in the BNF (BNF (British National Formulary) | NICE) and on the Controlled Drugs List on the Government website (Controlled drugs list - GOV.UK (www.gov.uk).

If any additional procedures are required, to cover ward, theatre or department specific activities, they must be approved by the Controlled Drug Accountable Officer via the Controlled Drug Governance Team.

For the purposes of this procedure the Ward/Department Controlled Drug Record Book (Register) is referred to as Controlled Drug Record Book (Register).

All incidents and concerns involving CDs must be reported to the Controlled Drug Accountable Officer via DATIX.

General Practitioners (non-dispensing) Procedure

Guidance for Safer Management of Controlled Drugs including procedure template for General Practitioners (non-dispensing):
Guidance for Safer Management of Controlled Drugs including Standard Operating Procedure template for General Practitioners (non-dispensing)

Scottish Prison Service – HMP Edinburgh and HMP Addiewell

Procedures for the Safer Management of Controlled Drugs in the Prison Service (HMP Edinburgh and HMP Addiewell) is available from the Healthcare Managers within HMP Edinburgh and HMP Addiewell.

Lothian Unscheduled Care Service (LUCS) Procedure

Procedure for Management of Controlled Drugs in Lothian Unscheduled Care Service.
Policies and Procedures (scot.nhs.uk)
Management of Controlled Drugs in LUCS

Staff Group Definitions

Staff	Definition
Professional Lead	Registered nurse, midwife, or operating department practitioner (ODP) responsible for the ward, theatre or department.
Registered nurse, midwife or ODP	Nurse, midwife or ODP registered with their professional body.
Authorised member of staff	Member of staff who has been given delegated authority to undertake a task e.g. professional lead (registered nurse, midwife or ODP) in charge of a ward delegating tasks to a registered nurse, midwife or ODP, or Lead Pharmacist delegating tasks to a registered pharmacy technician or pharmacist.
Competent Student Nurse or Midwife	Student nurse or midwife who has received the relevant theoretical preparation at university and on placement and be assessed by their mentor/s to ensure they have the necessary competence.
Registered Pharmacist/Pharmacy Technician	Pharmacist or Pharmacy Technician registered with their professional body.

1 Management of Controlled Drugs in Wards, Theatres and Departments

1.1 Accountable individuals

The professional lead (registered nurse, midwife, or ODP) in charge of a ward, theatre or department is responsible for the safe and appropriate management of CDs in that area.

The professional lead in charge can delegate control of access (i.e. key-holding) to the CD cabinet to another, such as a registered nurse, midwife or ODP. However, legal responsibility remains with the professional lead in charge. Whilst the task can be delegated, the responsibility cannot.

Staff to which tasks have been delegated will be referred to as authorised members of staff. These are members of staff who have been delegated authority to undertake a task e.g. professional lead (registered nurse, midwife or ODP) in charge of a ward delegating tasks to a registered nurse, midwife or ODP, or Lead Pharmacist delegating tasks to a registered pharmacy technician or registered pharmacist.

Student nurses or midwives may take part in activities appropriate to their stage of learning, as agreed by their course tutors, local managers, and professional lead in charge of the ward, and as defined in these procedures. The student nurse or midwife must have received the relevant theoretical preparation at university and on placement and be assessed by their mentor/s to ensure they have the necessary competence. The professional lead in charge of the ward is responsible for ensuring the necessary competence is approved prior to them undertaking the activities defined in these procedures. The student nurse or midwife can only undertake these activities whilst working as a student nurse or midwife. Please refer to the 'Involvement of Pre-registration Nursing (except child) and Midwifery Students in Medicine Administration Guide'

Healthcare support workers (HCSW) cannot take part in any tasks relating to Controlled Drugs i.e. all Schedules. Individual area requests may be considered on a case-by-case basis after submission to the HCSW Medicine Approval Group. Refer to NHS Lothian Framework for Health Care Support Workers (Clinical) to support people with their medication.

Authorised Framework for HCSW supporting people with medication September 23.pdf (scot.nhs.uk)

Complete HCSW medicine request proforma (see appendix 3 within NHS Lothian Framework for Health Care Support Workers (Clinical) to support people with their medication) and submit along with risk assessment to HCSW Medicine Approval Group.

The Controlled Drug Accountable Officer remains finally accountable for systems for the safe management and use of CDs. The Controlled Drug Governance Team support the Controlled Drug Accountable Officer with this role. Tasks they undertake include audit, inspection, and monitoring all processes related to CDs.

1.2 Storage of Controlled Drugs

1.2.1 The Misuse of Drugs (Safe Custody) Regulations 1973 covers the safe custody of CDs in certain specified premises. The Regulations also set out certain standards for safes and cabinets used to store CDs.

1.2.2 Ward, theatre, and department CD cabinets should conform to the British Standard reference BS2881. NHS Lothian Estates department must install or relocate CD cabinets to ensure the fittings meet the requirements.

1.2.3 All CDs must be stored in a locked receptacle which can only be opened by a person who can lawfully be in possession, such as a registered pharmacist or the registered nurse, midwife or ODP in charge, or a person working under their authority.

1.2.4 If CD discharge/pass/short term leave prescriptions are received onto the ward before the patient is discharged, the CD discharge/pass/short term leave prescription may be stored in the CD cabinet. There is no requirement to record CD discharge/pass/short term leave prescriptions in the Patients' Own CD Record Book unless the medicines are remaining on the ward overnight. In this instance an entry should be made in the Patients' Own CD Record Book and the record updated when the patient is discharged.

1.2.5 General measures for the storage of CDs include the following:

- CD cabinets must be kept locked when not in use.
- The CD cabinet lock must not be common to any other lock in the hospital.
- CD keys must only be available to authorised members of staff and at any time the key-holder must be readily identifiable.
- The CD cabinet should be dedicated to the storage of Schedule 2 and Schedule 3 CDs subject to safe custody regulations.
- No other medicines or items should normally be stored in the CD cabinet unless this has been agreed to by the Controlled Drug Accountable Officer.
- CDs must be locked away when not in use.
- Nothing must be displayed on the outside of the CD cabinet to indicate that drugs are kept inside it.
- Expired stock must be segregated from in date ward stock.
- Patient's Own Controlled Drugs must be segregated from ward stock.
- For areas such as day surgery units and five-day wards that are not operational at all times, there must be a local procedure for the security of the CD keys. The local procedure must be approved by pharmacy.

1.3 Management and Security of Controlled Drug Keys

The professional lead (registered nurse, midwife or ODP) in charge is responsible for the CD key and must ensure only authorised members of staff have access to CDs.

1.3.1 Management and Security of Controlled Drug Keys

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1.3.1.2 The professional lead (registered nurse, midwife or ODP) is responsible for the safekeeping of, and for controlling access to, all medicines stored in their area of control. The professional lead must normally hold the keys for the CD cabinets, medicine cupboards and the master keys for patient lockable medicine cabinets. In circumstances where holding the keys personally would cause delays or difficulties in making medicines available, key-holding may be delegated to other suitably trained registered healthcare professionals, but the legal responsibility remains with the professional lead.

1.3.1.3 The key for CD cabinets must be kept separate from other keys and only given to other authorised members of staff when access to CDs is required.

1.3.1.4 On occasion, for the purpose of stock checking, the CD key may be handed to a registered member of the pharmacy staff (e.g. the pharmacy technician responsible for stock control of medicines on the ward), following an identity check.

1.3.1.5 The CD key should be returned to the registered nurse, midwife or ODP in charge, or who has been delegated responsibility, immediately after use by another registered member of staff. If this is not practical, the registered nurse, midwife or ODP in charge, or who has been delegated responsibility, must know, at all times, who has the CD key.

1.3.1.6 The professional lead (registered nurse, midwife or ODP) in charge is responsible for ensuring that the spare CD key is secure at all times, separate from the in-use CD key, and can only be accessed by authorised members of staff. Authorised members of staff should be aware of who to contact to access the spare CD key. Records of access to duplicate keys must be maintained.

If the spare CD key is held by a 3rd party a risk assessment must be undertaken and documented.

1.3.1.7 The CD key must be available in the ward/department at all times and must not be removed from the ward/department. Unless in situations where there is only one authorised keyholder in a ward / department and that person must leave the ward. The CD key must remain in their possession.

1.3.1.8 In the event of a missing CD key please refer to section 1.3.2 'Missing Controlled Drug Cabinet Keys'.

1.3.2 Missing Controlled Drug Cabinet Keys

1.3.2.1 If the CD key cannot be located, the registered nurse, midwife or ODP in charge of the ward, or the clinical nurse manager/duty nurse or midwife manager, must be informed as soon as possible. They are then responsible for ensuring the following steps are undertaken.

1.3.2.2 Ask all staff on duty to check if they have the CD key on their person.

1.3.2.3 If the CD key is still missing, conduct a thorough search of the environment.

1.3.2.4 If the CD key is still missing, contact staff that have left the premises. If one of them has the CD key, they must return it immediately. The spare CD key can be used until the CD key is returned. If a spare CD key is not available and CD stock is required immediately for a patient, refer to section 1.20 'Transferring Schedule 2 Controlled Drugs between Wards, Theatres and Departments'.

1.3.2.5 Inform the Lead Pharmacist or clinical pharmacist for the ward as soon as possible i.e. during working hours inform the Lead Pharmacist for the site or, out with working hours inform the on-call pharmacist.

1.3.2.6 Arrangements for preserving the security of CD stocks and for ensuring that patient care is not impeded must be implemented. Refer to section 1.20 'Transferring Schedule 2 Controlled Drugs between Wards, Theatres and Departments'.

1.3.2.7 A DATIX must be completed and submitted to the Controlled Drug Accountable Officer, even if the CD key is subsequently found.

1.3.2.8 If the CD key remains missing contact Estates to request the lock is changed urgently.

1.3.2.9 If the lock must be replaced, ensure that the CD stock is kept secure until this has been completed. The following points must be considered:

- The likelihood of detection of an intruder, the deterrents in place and the particular medicines being stored.
- Systems for ensuring access by authorised staff only
- Arrangements for the removal and temporary storage of CDs by pharmacy, if appropriate.
- Arrangements for the return of CDs to the pharmacy for re-use, if appropriate.
- Arrangements for the destruction of CDs, by pharmacy, if applicable.
- Arrangements for the secure storage of CD stationery.
- Arrangements for the secure storage of CDs
- Arrangements for the return of CDs to ward, theatre or department, including reconciliation with list of CDs removed, if appropriate.
- Arrangement for restocking, if appropriate.

Further advice can be obtained from the Controlled Drug Governance Team.

1.3.2.10 Carry out a full inventory check of the CD stock against the Controlled Drug Record Book (Register) and Patients' Own Controlled Drug Record Book (if applicable).

1.3.2.11 Complete a DATIX recording all relevant details and actions taken as soon as possible.

1.3.2.12 If there is evidence or suspicion of criminal activity, the senior nurse for the site e.g. clinical nurse manager/ duty nurse must inform the police and record on DATIX.

1.4 Controlled Drug Stationery

The professional lead (registered nurse, midwife or ODP) in charge of a ward, theatre or department, is responsible for:

- Ensuring the appropriate requisitioning of CD stationery for use in that area
- Ensuring that all CD stationery used to order, return, or distribute CDs is stored securely
- Ensuring that access to the CD stationery is restricted to authorised members of staff to order CDs.

CD stationery includes:

- Controlled Drug Order Book
- Controlled Drug Record Book (Register)
- Patients' Own Controlled Drug Record Book
- Record of Schedule 3 and 4 (part I) Destruction Ward Department Form
- Local CD documents such as CD returns advice notes, pharmacy distribution documents, Midwives Supply Orders etc.

1.4.1 Secure Storage of Controlled Drug Stationery

1.4.1.1 CD stationery which is kept in wards, theatres or departments must be kept in a locked cupboard or drawer to which access is restricted to authorised staff. Controlled Drug Order Books, Controlled Drug Record Books (Register) and Patients' Own Controlled Drug Record Books can be stored in the CD cabinet.

1.4.2 Supply, Receipt, Storage and Retention of Controlled Drug stationery

1.4.2.1 CD stationery must be transported securely at all times and handed to a registered nurse, midwife or ODP. The registered nurse, midwife or ODP must sign for the receipt of the sealed package, confirming it was received intact.

1.4.2.2 CD stationery must be issued from the pharmacy against a written requisition, on the existing Controlled Drug Order Book, signed by a registered nurse, midwife or ODP.

1.4.2.3 The ward must provide pharmacy with signed confirmation that the CD stationery has been received.

1.4.2.4 The authorised member of staff receiving CD stationery in the ward, theatre or department is responsible for its security.

1.4.2.5 Only one Controlled Drug Order book should be held on a ward at any time, except when otherwise agreed locally with the site Lead Pharmacist to meet exceptional circumstances, for example, community hospitals.

1.4.2.6 Any unused stationery must be returned to pharmacy and the supply record updated to record the return.

1.4.2.7 Records of the receipt and issue of CD stationery must be retained for two years.

1.4.2.8 Loss or theft of any CD stationery must be reported immediately to the professional lead (registered nurse, midwife or ODP) in charge of the ward, or department manager, who is responsible for investigating and reporting the incident in accordance with the procedure for incidents. The Controlled Drug Accountable Officer must be informed. Refer to section 1.4.4 'Missing Controlled Drug Stationery'.

1.4.2.9 The loss or theft of CD stationery must be reported on DATIX.

1.4.2.10 Controlled Drug Record Books (Register) and Patients' Own Controlled Drug Record Books must be retained securely for two years from date of last entry, or seven years if containing details of CD destructions. Refer to section 1.4.2 'Supply, Receipt, Storage and Retention of Controlled Drug Stationery'.

1.4.2.11 Controlled Drug Order Books must be retained securely for two years from date of last entry. Refer to section 1.4.2 'Supply, Receipt, Storage and Retention of Controlled Drug Stationery'.

1.4.3 Record Keeping - Controlled Drug Record Book (Register) and Patients' Own Controlled Drug Record Book

The following sections provide specific guidance in relation to certain tasks:

- Section 1.7 'Receipt of Controlled Drugs in Wards, Theatres and Departments'.
- Section 1.9 'Administration of Controlled Drugs'
- Section 1.12 'Ward, Theatre and Department Controlled Drug Stock Checks'

1.4.3.1 Each ward, theatre or department that holds stocks of CDs must keep a record of CDs received and administered in the Controlled Drug Record Book (Register) or Patients' Own Controlled Drug Record Book.

1.4.3.2 Where an area accepts patient's own CDs, a Patients' Own Controlled Drug Record Book must be used for this purpose.

1.4.3.3 The professional lead (registered nurse, midwife or ODP) in charge is responsible for keeping the Controlled Drug Record Book (Register) and Patients' Own Controlled Drug Record Book up to date and accurate.

1.4.3.4 The Controlled Drug Record Book (Register) or Patients' Own Record Book must be bound (not loose-leaf) with sequentially numbered pages. Only one Controlled Drug Record Book (Register) and one Patients' Own Record Book per ward or department should be in use at one time, except when otherwise agreed locally with the site Lead Pharmacist to meet exceptional circumstances, for example, liquid preparations in one, and all other preparations in another one Controlled Drug Record Book (Register).

1.4.3.5 There must be a separate page for each drug, form, brand (if applicable) and strength, so that a running balance can be kept easily. It is good practice to complete the index in the Ward/Department Stock Controlled Drug Record Book and the Patients' Own Record Book to allow staff to identify the correct page quickly.

Example – Ward/Department Stock Controlled Drug Record Book Index

Page 001

INDEX

Drug Name	Brand Name (if applicable)	Strength/ concentration	Form e.g. amp, tab, MR tab, cap	Ampoule/vial size (if applicable)	Page Numbers
Fentanyl		20mg	Injection	2ml	~~1~~ ~~2~~ ~~3~~ 6
Oxycodone	Longtec	5mg	MR Tab		4
Fentanyl		12mcg	Patch		~~10~~ 11

Example – Patients' Own Controlled Drug Record Book Index

Index

Date	Patient Name	CHI	Drug Name	Page No.	Date Page Closed
01/10/23	Joe White	24123566	Morphine 10mg Tab	1	04/10/23
03/10/23	Pauline Brown	45369043	Fentanyl 12mcg Patch	2	
			Oxycodone 10mg MR Tab	3	
07/10/23	Ruth Watt	74510235	Morphine Sulphate 10mg/ml Inj	4	09/10/23
09/10/2023	Suzanne Leitch	42119506	Methadone 50mg Tab	5	

1.4.3.6 The generic drug name, brand name (if applicable), strength/concentration, form and ampoule/vial size (if applicable) must be written clearly and legibly.

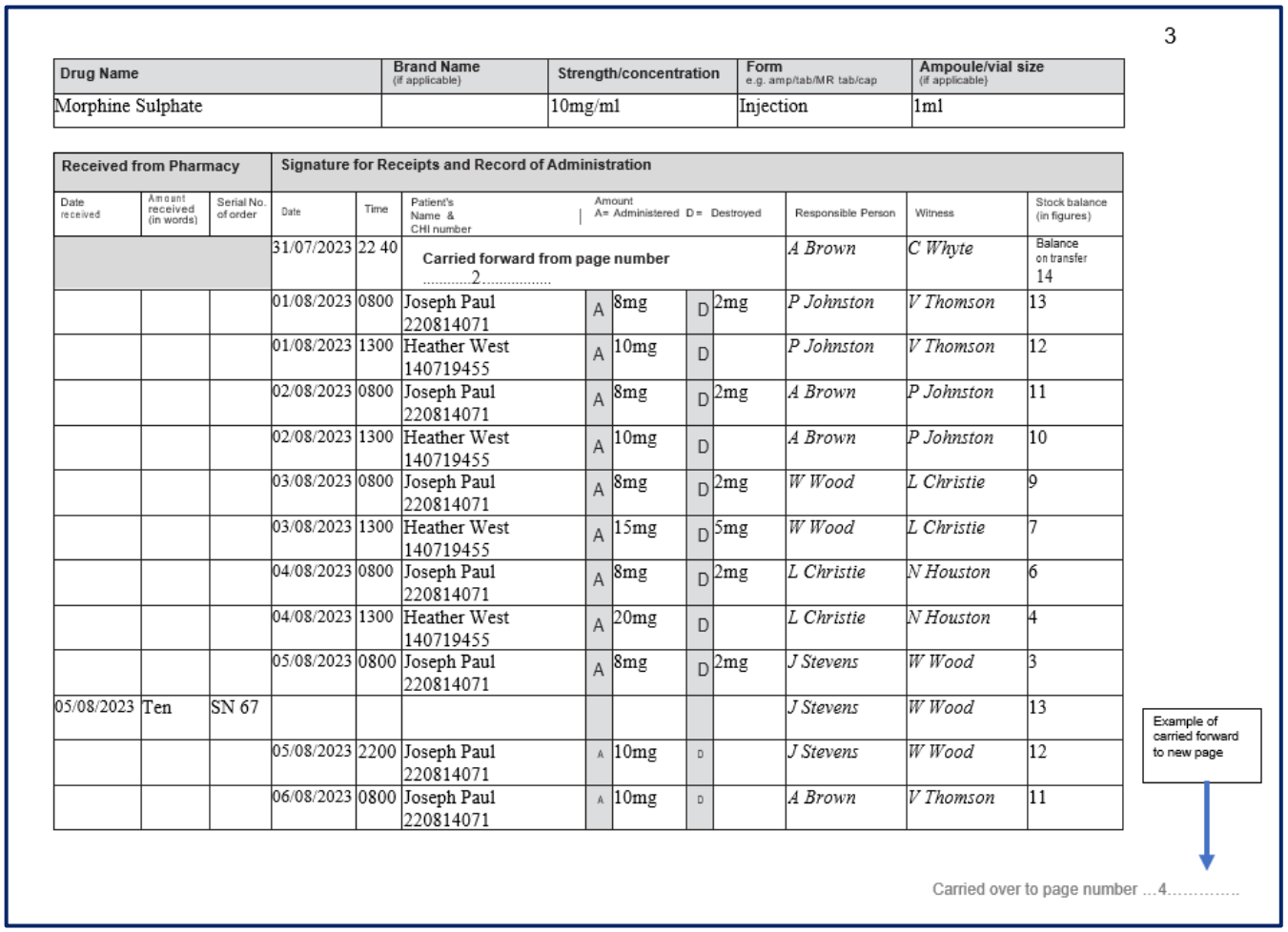
1.4.3.7 Entries must be made in consecutive, chronological order, with no blank lines in between.

1.4.3.8 Entries must be made in black ink; the entry must be indelible.

1.4.3.9 All entries must be signed by a registered nurse, midwife or ODP and must be witnessed by a second registered nurse, midwife or ODP.

1.4.3.10 On reaching the end of a page in the Controlled Drug Record Book (Register), the balance must be transferred to another page. The new page number must be added to the bottom of the finished page and the index updated. This transfer must be witnessed as specified in 1.4.3.9.

Example of transferred/carried forward to a new page:



3

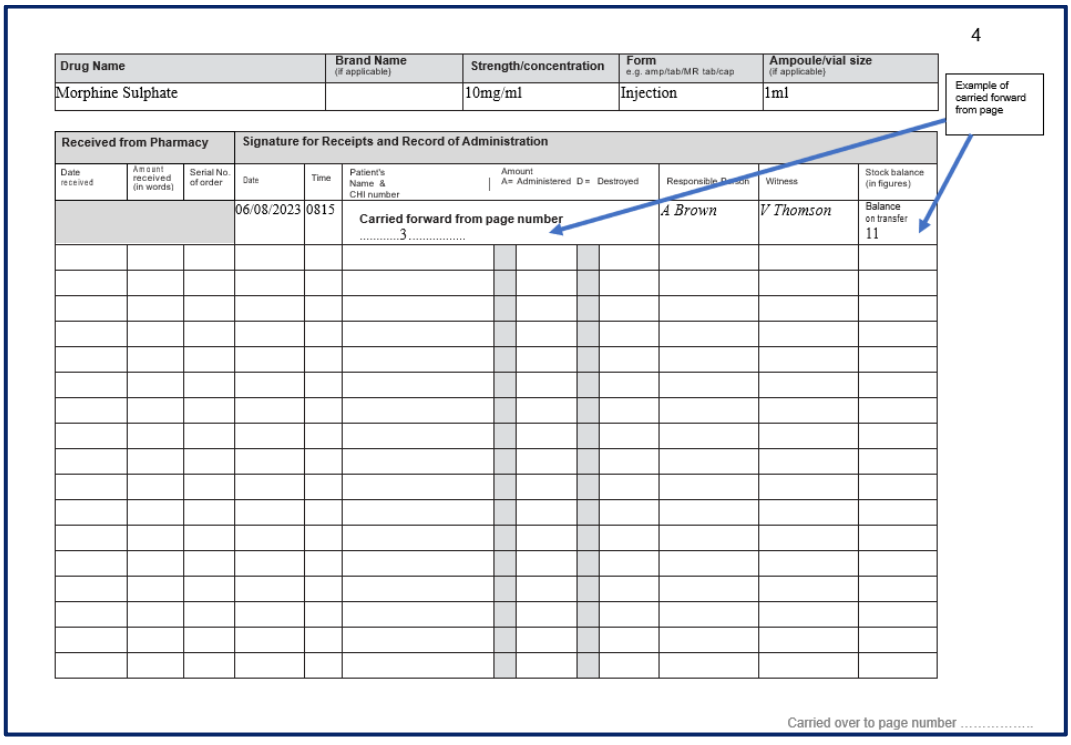
Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Morphine Sulphate		10mg/ml	Injection	1ml

Received from Pharmacy			Signature for Receipts and Record of Administration									
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered		D = Destroyed		Responsible Person	Witness	Stock balance (in figures)
			31/07/2023	22 40	Carried forward from page number .....2.....					*A Brown*	*C Whyte*	Balance on transfer 14
			01/08/2023	0800	Joseph Paul 220814071	A	8mg	D	2mg	*P Johnston*	*V Thomson*	13
			01/08/2023	1300	Heather West 140719455	A	10mg	D		*P Johnston*	*V Thomson*	12
			02/08/2023	0800	Joseph Paul 220814071	A	8mg	D	2mg	*A Brown*	*P Johnston*	11
			02/08/2023	1300	Heather West 140719455	A	10mg	D		*A Brown*	*P Johnston*	10
			03/08/2023	0800	Joseph Paul 220814071	A	8mg	D	2mg	*W Wood*	*L Christie*	9
			03/08/2023	1300	Heather West 140719455	A	15mg	D	5mg	*W Wood*	*L Christie*	7
			04/08/2023	0800	Joseph Paul 220814071	A	8mg	D	2mg	*L Christie*	*N Houston*	6
			04/08/2023	1300	Heather West 140719455	A	20mg	D		*L Christie*	*N Houston*	4
			05/08/2023	0800	Joseph Paul 220814071	A	8mg	D	2mg	*J Stevens*	*W Wood*	3
05/08/2023	Ten	SN 67								*J Stevens*	*W Wood*	13
			05/08/2023	2200	Joseph Paul 220814071	A	10mg	D		*J Stevens*	*W Wood*	12
			06/08/2023	0800	Joseph Paul 220814071	A	10mg	D		*A Brown*	*V Thomson*	11

Example of carried forward to new page

Carried over to page number ...4.....

Example of transferred/carried forward from page:



4

Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Morphine Sulphate		10mg/ml	Injection	1ml

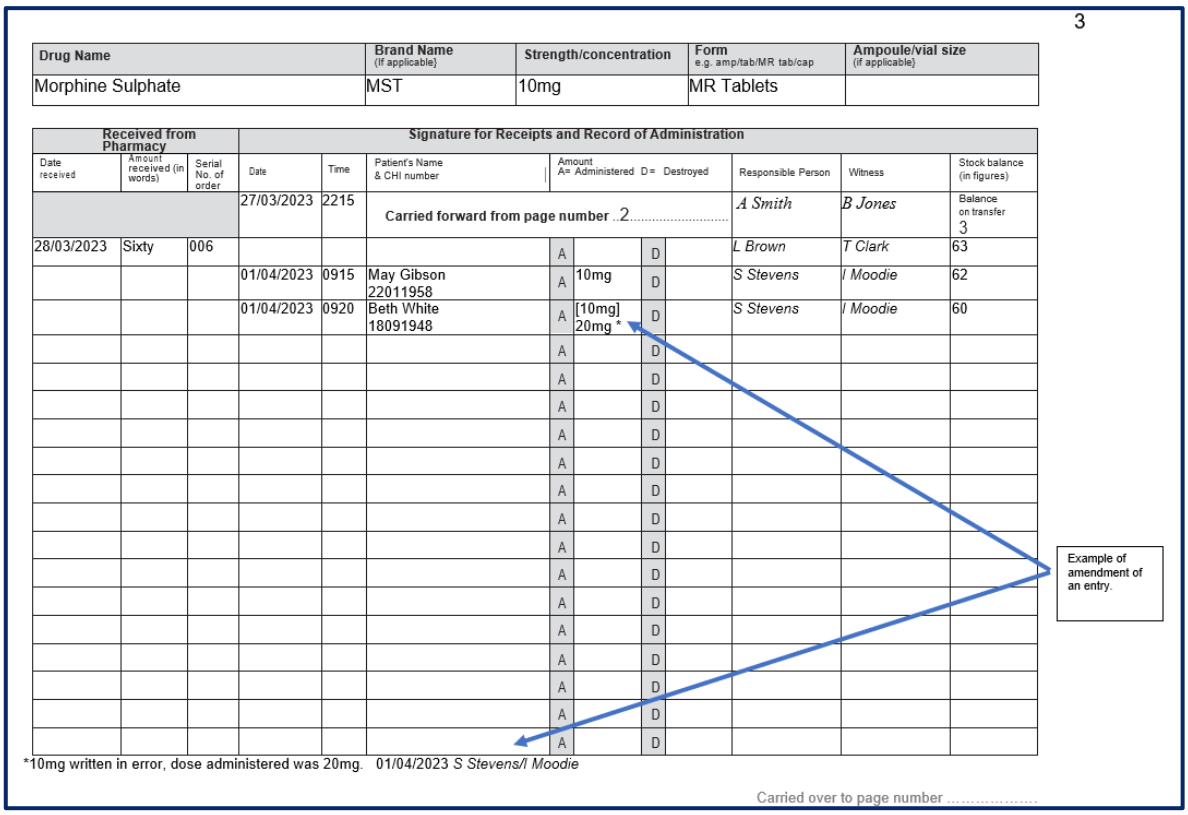
Received from Pharmacy			Signature for Receipts and Record of Administration									
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered		D = Destroyed		Responsible Person	Witness	Stock balance (in figures)
			06/08/2023	0815	Carried forward from page number .....3.....					*A Brown*	*V Thomson*	Balance on transfer 11

Example of carried forward from page

Carried over to page number .....

1.4.3.11 If an incorrect entry is made it must be bracketed, annotated with the nature of the error and in such a way that the original entry is still clearly legible. This must be signed and dated by the registered nurse, midwife or ODP, making the amendment and witnessed by a second e.g. registered nurse, midwife, ODP or other registered professional. The witness must agree with and sign the correction.

Example of an amendment to an entry:



3

Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Morphine Sulphate	MST	10mg	MR Tablets	

Received from Pharmacy			Signature for Receipts and Record of Administration									
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number		Amount A= Administered D= Destroyed		Responsible Person	Witness	Stock balance (in figures)
			27/03/2023	2215	Carried forward from page number ..2.....				*A Smith*	*B Jones*	Balance on transfer 3
28/03/2023	Sixty	006				A		D	*L Brown*	*T Clark*	63
			01/04/2023	0915	May Gibson 22011958	A	10mg	D	*S Stevens*	*I Moodie*	62
			01/04/2023	0920	Beth White 18091948	A	[10mg] 20mg *	D	*S Stevens*	*I Moodie*	60
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			

Example of amendment of an entry.

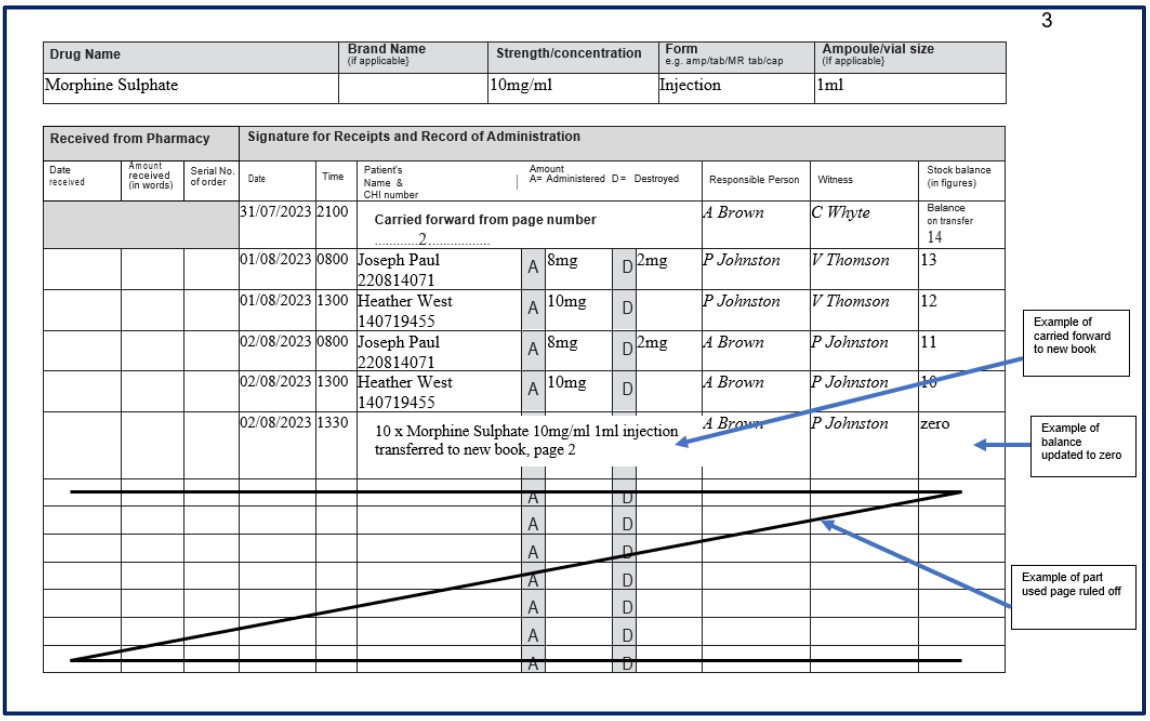
*10mg written in error, dose administered was 20mg. 01/04/2023 *S Stevens/I Moodie*

Carried over to page number .....

1.4.3.12 When a new Controlled Drug Record Book (Register) is started, the balance of all CDs in stock must be transferred to the new Controlled Drug Record Book (Register) at the same time. The transfer must be carried out by a registered nurse, midwife or ODP, and witnessed by a second registered nurse, midwife or ODP, registered member of pharmacy staff, or suitably competent student nurse or midwife. (The student nurse or midwife must have received the relevant theoretical preparation at university and on placement and be assessed by their mentor/s to ensure they have the necessary competence. Refer to section 1.1 'Accountable individuals' for information relating to competencies for student nurses or midwives.)

1.4.3.13 When transferring the physical balance, the Controlled Drug Record Book (Register) balance must be checked. The balance in the old Controlled Drug Record Book (Register) should be made 'zero' stating, the date, quantity transferred, and page number transferred to, in the new Controlled Drug Record Book (Register). This must be signed by both members of staff. Any part used pages in the old Controlled Drug Record Book (Register) should have the blank lines ruled off.

Example of transferring/carried forward balance to a new Controlled Drug Record Book (Register):



3

Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Morphine Sulphate		10mg/ml	Injection	1ml

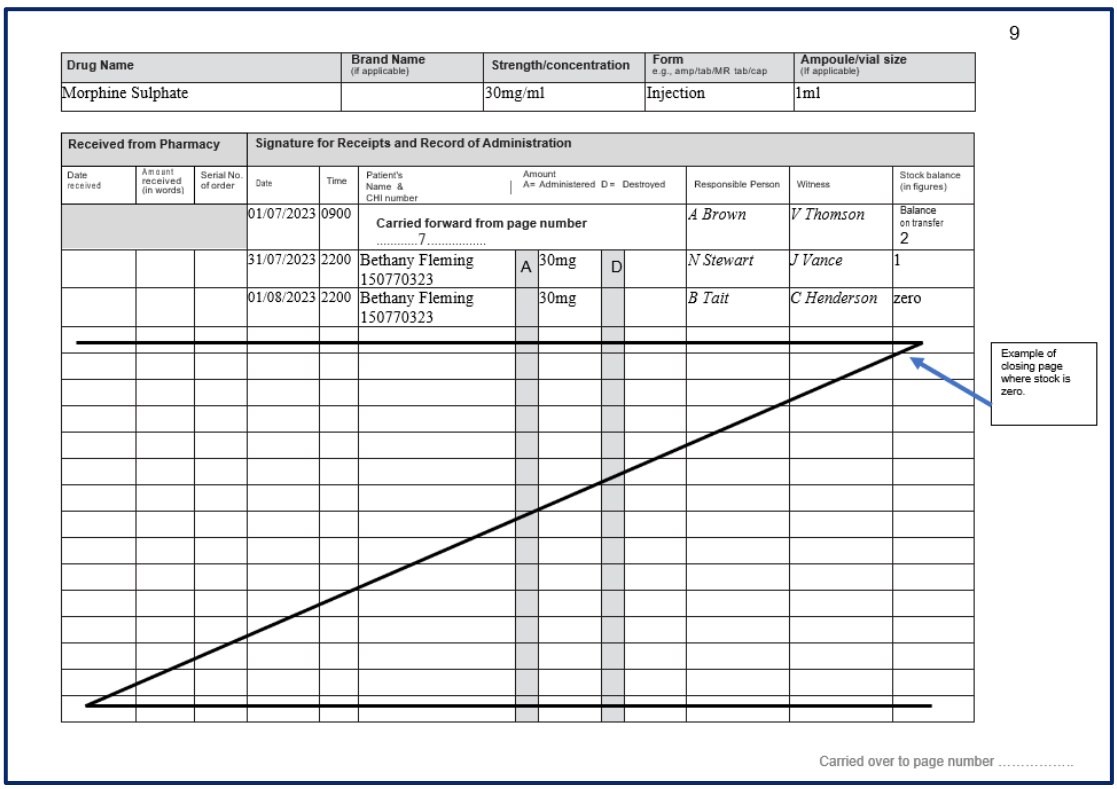
Received from Pharmacy			Signature for Receipts and Record of Administration									
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number		Amount A= Administered D= Destroyed		Responsible Person	Witness	Stock balance (in figures)
			31/07/2023	2100	Carried forward from page number ..2..				*A Brown*	*C Whyte*	Balance on transfer 14
			01/08/2023	0800	Joseph Paul 220814071	A	8mg	D 2mg	*P Johnston*	*V Thomson*	13
			01/08/2023	1300	Heather West 140719455	A	10mg	D	*P Johnston*	*V Thomson*	12
			02/08/2023	0800	Joseph Paul 220814071	A	8mg	D 2mg	*A Brown*	*P Johnston*	11
			02/08/2023	1300	Heather West 140719455	A	10mg	D	*A Brown*	*P Johnston*	10
			02/08/2023	1330	10 x Morphine Sulphate 10mg/ml 1ml injection transferred to new book, page 2				*A Brown*	*P Johnston*	zero
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			

Example of carried forward to new book

Example of balance updated to zero

Example of part used page ruled off

Example of closing page in Controlled Drug Record Book (Register) when the stock is at zero:



9

Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g., amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Morphine Sulphate		30mg/ml	Injection	1ml

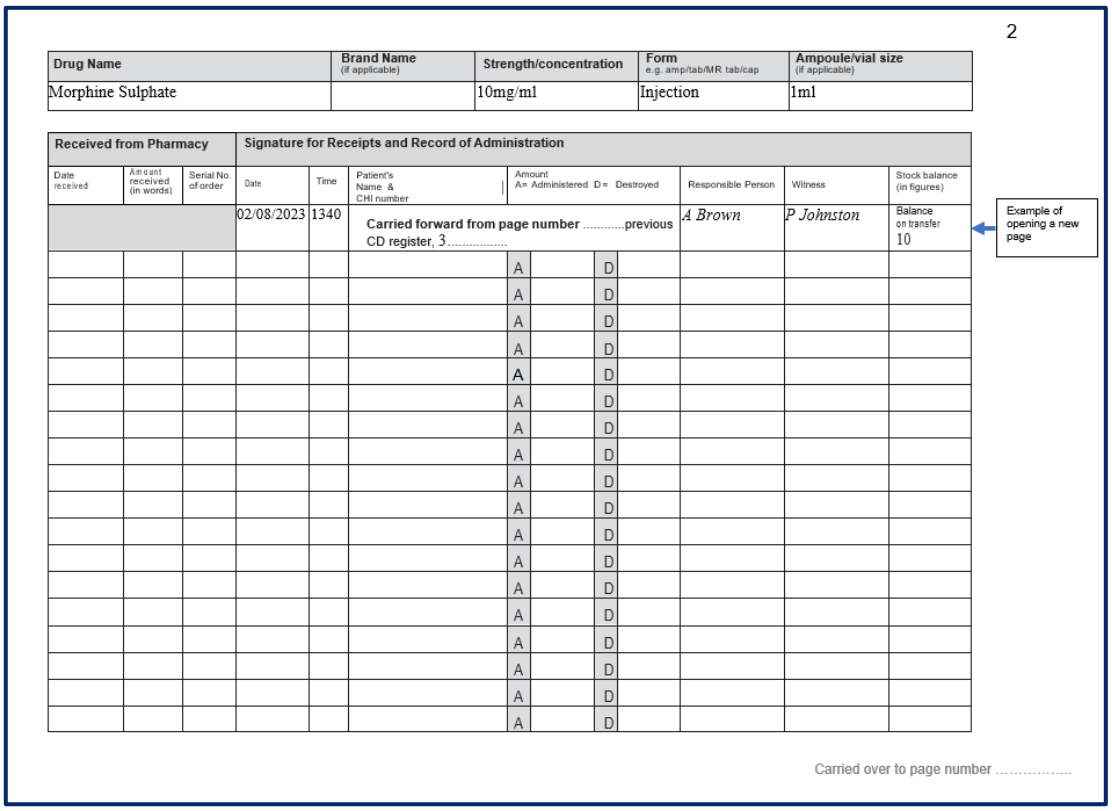
Received from Pharmacy			Signature for Receipts and Record of Administration								
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number		Amount A= Administered D= Destroyed		Responsible Person	Witness	Stock balance (in figures)
			01/07/2023	0900	Carried forward from page number ..7..				*A Brown*	*V Thomson*	Balance on transfer 2
			31/07/2023	2200	Bethany Fleming 150770323	A	30mg	D	*N Stewart*	*J Vance*	1
			01/08/2023	2200	Bethany Fleming 150770323		30mg		*B Tait*	*C Henderson*	zero

Example of closing page where stock is zero.

Carried over to page number .....

The new Controlled Drug Record Book (Register) should have an entry on the appropriately titled page stating, the date that the balance was transferred and the page of old Controlled Drug Record Book (Register) from which the information was transferred. This must be signed by both members of staff. The index should be updated.

Example of opening a new page in a Controlled Drug Record Book (Register):



2

Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Morphine Sulphate		10mg/ml	Injection	1ml

Received from Pharmacy			Signature for Receipts and Record of Administration							
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered D= Destroyed			Responsible Person	Witness	Stock balance (in figures)
			02/08/2023	1340	Carried forward from page number .....previous CD register, 3.....				*A Brown*	*P Johnston*	Balance on transfer 10
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			

Example of opening a new page

Carried over to page number .....

1.4.3.14 The front cover of the old Controlled Drug Record Book (Register) should be dated to show when the CDs were transferred, and the book closed.

1.4.3.15 The front cover of the new Controlled Drug Record Book (Register) should be dated to show when the book came into use.

1.4.3.16 Completed Controlled Drug Record Books (Register) and Patient's Own Controlled Drug Record Books must be retained securely in the ward or department for a minimum of two years from the date of closure or seven years if they contain details of a CD destruction. Refer to section 1.4.2 'Supply, Receipt, Storage and Retention of Controlled Drug Stationery'.

1.4.3.17 Refer to section 1.17 'Management of Patients' Own Controlled Drugs', for further information on completing Patients' Own Controlled Drug Record Book.

1.4.4 Missing Controlled Drug Stationery

1.4.4.1 Loss or theft of any CD stationery must be reported immediately to the professional lead (registered nurse, midwife or ODP) in charge of the ward, or department manager who is responsible for ensuring the following steps are undertaken.

1.4.4.2 Conduct a thorough search of the environment and check with all staff on duty.

1.4.4.3 A DATIX incident must be completed if the controlled stationery cannot be found.

1.4.4.4 Inform the Lead Pharmacist for the site if the controlled stationery cannot be found.

1.4.4.5 Order replacement stationery

1.5 Controlled Drug Stock Levels

1.5.1 There must be a list, and a minimum stock level, of ALL Schedules of CDs to be held in each ward, theatre, or department as stock items. The contents of the list must reflect current patterns of usage of CDs in the ward, theatre or department and must be agreed between the registered pharmacist or registered pharmacy technician responsible for stock control of medicines, and the lead professional (registered nurse, midwife or ODP) in charge. The stock list must be in line with agreed formularies.

1.5.2 The list must contain details of the name, strength, form and quantity of all the medicines required that must be held.

1.5.3 The list must be reviewed and modified to reflect practice changes and must be subject to annual review.

A blank stock list proforma for Schedule 2 and 3 Controlled Drugs is available on the Controlled Drug Governance Team Intranet page:

Controlled Drugs Governance Home (scot.nhs.uk)

1.5.4 The list should be used as a reference when ordering Schedule 2 and 3 Controlled Drugs.

1.5.5 Also refer to section 1.6.1.4 ‘Requisitioning/Ordering of Schedule 2 and 3 Controlled Drugs’.

1.6 Requisitioning/Ordering of Controlled Drugs

This section refers to the requisitioning/ordering of Schedule 2 and Schedule 3 Controlled Drugs. For ordering of non-Schedule 2 and 3 CDs refer to the NHS Lothian Medicines Procedures for 'Ordering and Receipt of Medicines'

NHS Lothian *Safe Use of Medicines Procedures* (scot.nhs.uk)

1.6.1 General Information - Requisitioning/Ordering of Controlled Drugs

1.6.1.1 The professional lead (registered nurse, midwife or ODP) in charge of a ward, theatre, or department, is responsible for ensuring the requisitioning of CDs for use in that area, is in line with procedure.

1.6.1.2 The professional lead (registered nurse, midwife or ODP) in charge can delegate the task of preparing a requisition to another registered nurse or midwife. However, legal responsibility remains with the professional lead in charge.

1.6.1.3 The professional lead (registered nurse, midwife or ODP) in charge of a ward, theatre, or department, is responsible for ensuring access to ordering stationery is restricted to authorised members of staff to order CDs.

1.6.1.4 Orders, for Schedule 2 and 3 CDs, must be written on a Controlled Drug Order Book with duplicate pages and must be signed by an authorised member of staff that is a registered nurse, midwife, or ODP.

1.6.1.5 Only one Controlled Drug Order book should be held on a ward at any time, except when otherwise agreed locally with the site Lead Pharmacist to meet exceptional circumstances, for example community hospitals.

1.6.1.6 The professional lead (registered nurse, midwife or ODP) in charge of a ward, theatre, or department, is responsible for carrying out a regular review of the Controlled Drug Order Book to ensure that all stock ordered is appropriate for the needs of the clinical area.

1.6.1.7 Controlled Drug Order Books must be retained securely for two years from date of last entry.

Refer to section 1.6.2 'Procedure for Requisitioning/Ordering of Drugs'.

1.6.2 Procedure for Requisitioning/Ordering of Controlled Drugs

1.6.2.1 The professional lead (registered nurse, midwife or ODP) must ensure that CDs are only ordered by registered nursing staff, midwife or OPD that they have authorised, and that authorised members of staff are trained and competent in the processes involved in ordering CDs.

1.6.2.2 Authorised staff must ensure that only required CDs are ordered, and that unnecessary medicines are not ordered. The stock list for CDs should be used as a reference. Refer to section 1.5 'Controlled Drug Stock Levels'. Patients should use their own medicines during the hospital stay where they are available, suitable for use, and where the patient consents to do so.

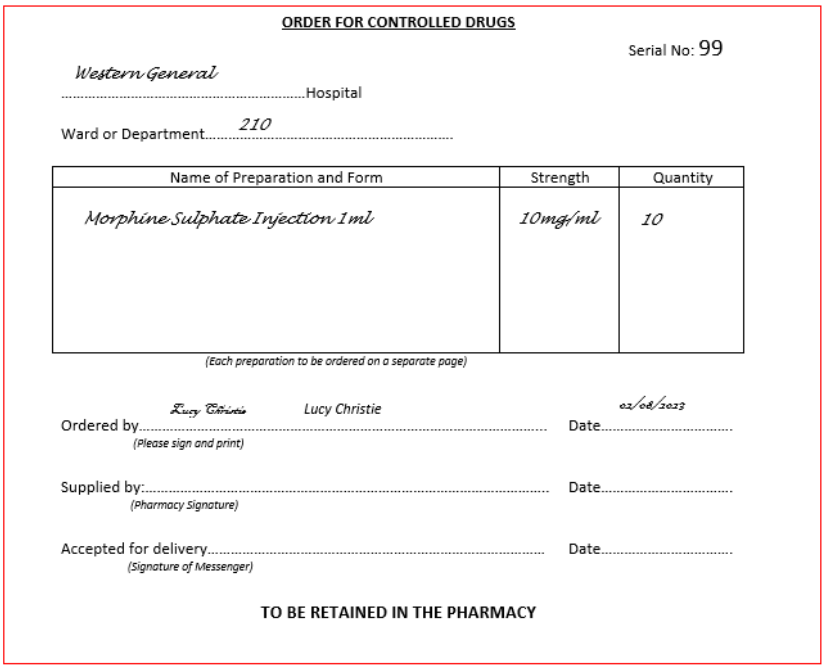
1.6.2.3 Schedule 2 and 3 CDs for stock must be ordered from the pharmacy using a bound Controlled Drug Order Book. A separate page must be used for each preparation ordered.

1.6.2.4 Only one Controlled Drug Order book should be held on a ward at any time, except when otherwise agreed locally with the site Lead Pharmacist to meet exceptional circumstances, for example community hospitals.

1.6.2.5 The order must be written clearly and contain the following:

- Name of hospital
- Ward/Department
- Drug name, brand (where applicable), form, strength, and ampoule size
- Total quantity
- Signature and printed name of the registered nurse, midwife or ODP authorised, by the professional lead, to order CDs for the ward/department/theatre
- Date

Example of completed order in the Controlled Drug Order Book:



ORDER FOR CONTROLLED DRUGS

Serial No: 99

Western General .....Hospital

Ward or Department..... 210 .....

Name of Preparation and Form	Strength	Quantity
Morphine Sulphate Injection 1ml	10mg/ml	10

(Each preparation to be ordered on a separate page)

Ordered by..... Lucy Christie Lucy Christie ..... Date..... 02/08/2023 .....
(Please sign and print)

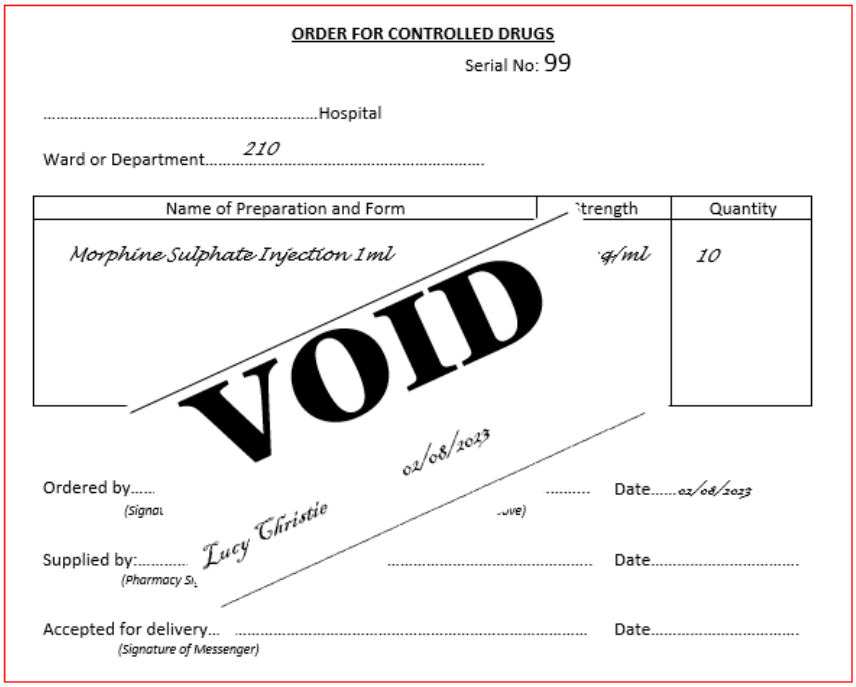
Supplied by:..... Date.....
(Pharmacy Signature)

Accepted for delivery..... Date.....
(Signature of Messenger)

TO BE RETAINED IN THE PHARMACY

1.6.2.6 If an order is no longer required, the page should be marked 'VOID' and both copies retained in the Controlled Drug Order Book.

Example of an order in the Controlled Drug Order Book that is no longer required:



ORDER FOR CONTROLLED DRUGS

Serial No: 99

.....Hospital

Ward or Department..... 210

Name of Preparation and Form	Strength	Quantity
Morphine Sulphate Injection 1ml	g/ml	10

VOID

02/08/2023

Ordered by..... (Signat...ove) ..... Date.....02/08/2023

Supplied by:..... Lucy Christie (Pharmacy Si...) ..... Date.....

Accepted for delivery... (Signature of Messenger) ..... Date.....

1.6.2.7 The Controlled Drug Order Book must be sent to pharmacy. It must be kept secure or under surveillance whilst awaiting collection or in transit between the ward, theatre or department and the pharmacy e.g. sealed box or bag.

1.6.2.8 On occasion it may be necessary for registered pharmacy staff to alter the quantity, strength or form supplied. Where this happens, the change must be altered, signed, and dated by the registered member of pharmacy staff on both copies on the requisition.

1.6.2.9 Controlled Drug Order Books must be retained securely for two years from date of last entry. Refer to section 1.4.2 'Supply, Receipt, Storage and Retention of Controlled Drug Stationery'.

1.6.2.10 All requests for CDs that require to be labelled with instructions for inpatient and/or discharge use, must comply with legal requirements.

1.7 Receipt of Controlled Drugs in Wards, Theatres and Departments

This section refers to receipt of Schedule 2 and 3 CDs.

Schedule 2 CDs – must be stored in the CD cabinet and entered into Controlled Drug Record Book (Register).

Schedule 3 (safe custody) CDs – must be stored in the CD cabinet. No requirement to record entries in the Controlled Drug Record Book (Register).

Schedule 3 (not subject to safe custody) CDs – no requirement to be stored in the CD cabinet or record entries in the Controlled Drug Record Book (Register).

1.7.1 General Information - Receipt of Controlled Drugs in Wards, Theatres and Departments

1.7.1.1 When CDs are delivered to a ward, theatre, or department they must be handed to a registered nurse, midwife, or ODP. The registered nurse, midwife or ODP must sign for receipt of the sealed package, confirming it was received intact. As a matter of good practice, where practical, the receiving person should not be the same person who ordered the CDs.

1.7.1.2 If the order cannot be checked immediately, the registered nurse, midwife, or ODP is responsible for ensuring that the package is stored in the conditions necessary to maintain security and quality (for example, in a locked area or under surveillance or in a locked refrigerator (refrigerated items). This should be for the minimal time possible.

1.7.1.3 The order must be unpacked, checked off, entered into Controlled Drug Record Book (Register) and placed into the CD cabinet.

Refer to section 1.7.2 '[Procedure for the Receipt of Controlled Drugs in Wards, Theatres and Departments]'.

1.7.2 Procedure for the receipt of Controlled Drugs in Wards, Theatres, and Departments

1.7.2.1 When CDs are delivered to a ward, theatre, or department they must be handed to a registered nurse, midwife, or ODP. The registered nurse, midwife or ODP must sign for receipt of the sealed package, confirming it was received intact. As a matter of good practice, where practical, the receiving person should not be the same person who ordered the CDs.

1.7.2.2 The registered nurse, midwife or ODP is responsible for ensuring that all CDs are placed in the CD cabinet immediately following the check on receipt.

1.7.2.3 If the order cannot be checked immediately, the registered nurse, midwife, or ODP is responsible for ensuring that the package is stored in the conditions necessary to maintain security and quality (for example, in a locked area or under surveillance or in a locked refrigerator (refrigerated items). This should be for the minimal time possible.

1.7.2.4 CDs must never be left unattended.

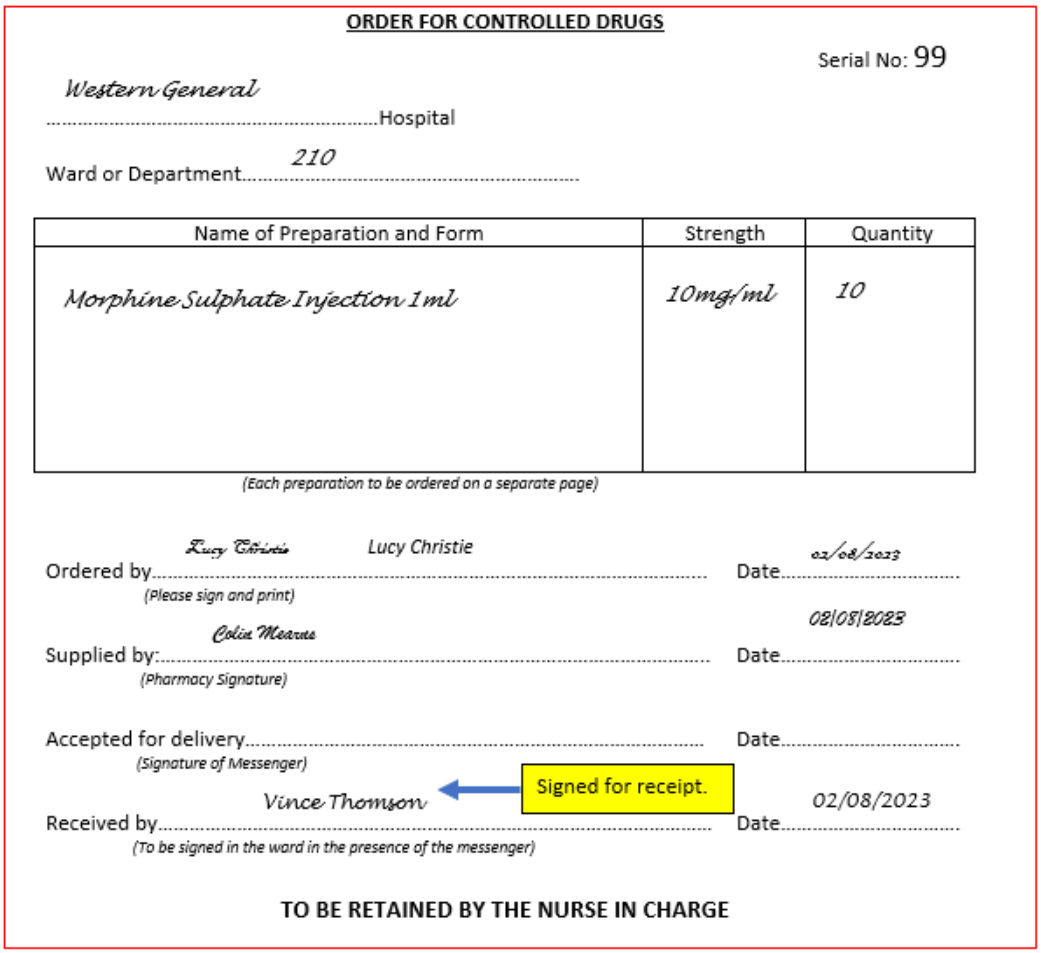
1.7.2.5 Checks on receipt of CDs and documenting in the Controlled Drug Record Book (Register) must be witnessed by a second registered nurse, midwife, ODP or suitably competent student nurse or midwife. (The student nurse or midwife must have received the relevant theoretical preparation at university and on placement and be assessed by their mentor/s to ensure they have the necessary competence. Refer to section 1.1 'Accountable individuals' for information relating to competencies for student nurses or midwives.) Both are responsible for checking that each detail required is entered correctly, and that the controlled drugs are immediately placed in the controlled drug cabinet.

If a second registered nurse, midwife, ODP or suitable competent student nurse or midwife is not available, a registered pharmacist or registered pharmacy technician can witness the receipt of CDs.

1.7.2.6 As soon as possible after delivery the registered nurse, midwife or ODP in charge must carry out the following checks:

- Check the package is sealed and has not been tampered with.
- Once the package has been opened the whole order must be checked and contents placed into the CD cabinet. (For Schedule 3 CDs with no safe custody requirements place into the appropriate medicines cabinet.)
- Check the CDs received against the order form, confirming:
  - The items listed on the note of what has been supplied match the items that were ordered, i.e. drug name, form, strength, quantity, and brand (where applicable).
  - The items listed on the note of what has been supplied match the items that have been received, i.e. drug name, form, strength, quantity, and brand (where applicable).
- Any tamper-evident seals on packs must be left intact when they are received from pharmacy. This will simplify and speed up routine checks on the ward. A seal must only be broken when the pack is required for administration. If, when the tamper evident seal is broken the contents do not match the expected amount stated on the pack, the person in charge must contact the pharmacy department immediately and make appropriate records in the Controlled Drug Record Book (Register) and all necessary action taken to resolve the discrepancy must be documented.
- Any discrepancies or concern with the integrity of the package must be reported immediately to the supplying pharmacy and reported in DATIX.
- If there are no discrepancies, the registered nurse, midwife or ODP, who received the CDs, must sign the "received by" section on the bottom (pink) copy of the ward Controlled Drug Order Book (which must be left in the Controlled Drug Order Book) and the delivery note. It is good practice that the receiving person is not the same as the person who ordered the CDs. The "received by" section in the Controlled Drug Order Book does not need to be completed in the presence of the messenger, as stated in the Controlled Drug Order Book.
- Place the Schedule 2 and 3 CDs, subject to safe custody, into the CD cabinet. For schedule 3 CDs with no safe custody requirements place into the appropriate medicine cabinet.

Example of completed "received by" section in the Controlled Drug Order Book:



ORDER FOR CONTROLLED DRUGS

Serial No: 99

Western General .....Hospital

Ward or Department..... 210

Name of Preparation and Form	Strength	Quantity
Morphine Sulphate Injection 1ml	10mg/ml	10

(Each preparation to be ordered on a separate page)

Ordered by..... Lucy Christie Date..... 02/08/2023
(Please sign and print)

Supplied by:..... Colin Mearns Date..... 02/08/2023
(Pharmacy Signature)

Accepted for delivery..... Date.....
(Signature of Messenger)

Received by..... Vince Thomson Date..... 02/08/2023
(To be signed in the ward in the presence of the messenger)

Signed for receipt.

TO BE RETAINED BY THE NURSE IN CHARGE

1.7.2.7 Receipt of CDs must be recorded in the Controlled Drugs Record Book (Register). A separate page must be dedicated to each individual product (that is, every different strength and form of a preparation requires a separate page), and all transactions recorded on that page.

Refer to section 1.4.3 'Record Keeping - Controlled Drug Record Book (Register) and Patients' Own Controlled Drug Record Book' for information on how to transfer a balance when a page is full.

1.7.2.8 Enter the receipt of the Schedule 2 CDs into the relevant page in the Controlled Drug Record Book (Register). Enter the following:

- Date of receipt of stock
- Serial number of the requisition
- Quantity received
- Signature of authorised member of staff e.g. registered nurse, midwife or ODP making the entry
- Signature of witness i.e. authorised member of staff e.g. registered nurse, midwife, ODP
- Confirm and update the running balance
- Update the index, if required

Example of an entry in the Controlled Drug Record Book (Register) for the receipt of stock from pharmacy:

3

Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Morphine Sulphate	MST	10mg	MR Tablets	

Received from Pharmacy			Signature for Receipts and Record of Administration									
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered D= Destroyed				Responsible Person	Witness	Stock balance (in figures)
			22/03/2023	0830	Carried forward from page number ..2..........................					*A Smith*	*B Jones*	Balance on transfer 3
28/03/2023	Sixty	006				A		D		*L Brown*	*T Clark*	63
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				

Example entry for receipt of stock from pharmacy

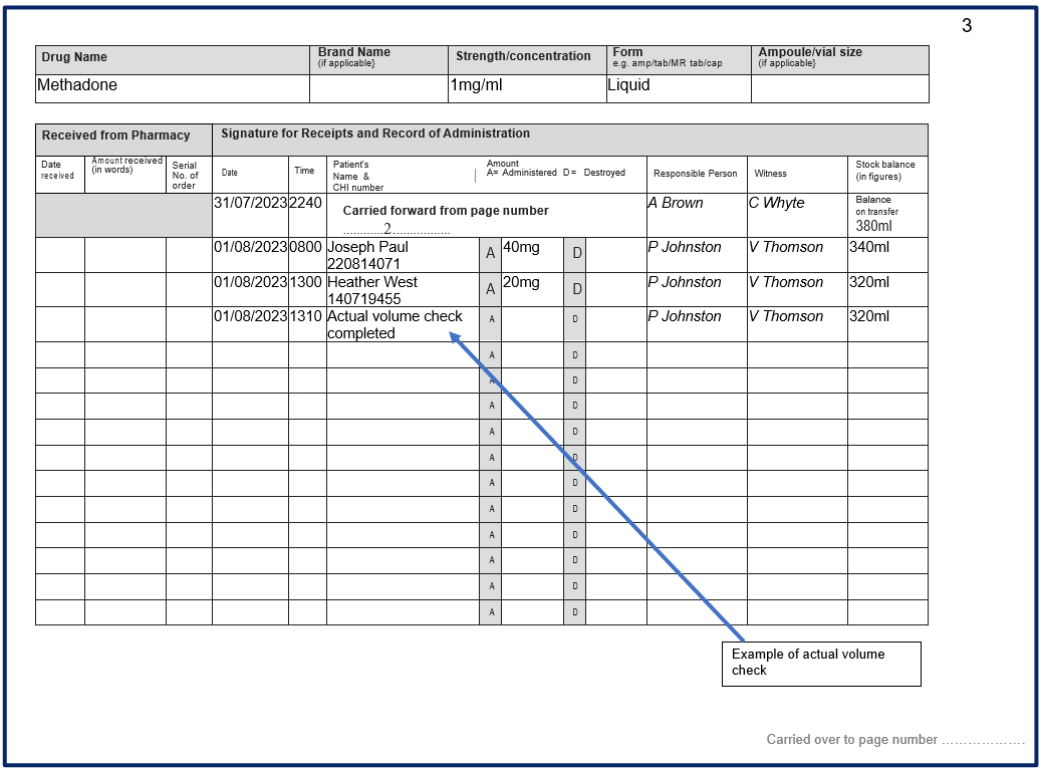
Carried over to page number ………………

1.7.2.9 Check that the balance tallies with the physical stock balance.

The actual stock level of liquid CDs must be recorded on completion of a bottle.

The record of the actual volume check must be recorded as an entry in the Controlled Drug Record Book (register). The entry must include, the date, time, details of entry i.e. date, “Actual volume check completed”, and signed by the registered nurse, midwife or ODP and the witness e.g. second registered nurse, midwife or ODP.

Example of an actual volume check in the Controlled Drug Record Book (Register):



3

Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Methadone		1mg/ml	Liquid	

Received from Pharmacy			Signature for Receipts and Record of Administration									
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered		D= Destroyed		Responsible Person	Witness	Stock balance (in figures)
			31/07/2023	2240	Carried forward from page number ..2..					*A Brown*	*C Whyte*	Balance on transfer 380ml
			01/08/2023	0800	Joseph Paul 220814071	A	40mg	D		*P Johnston*	*V Thomson*	340ml
			01/08/2023	1300	Heather West 140719455	A	20mg	D		*P Johnston*	*V Thomson*	320ml
			01/08/2023	1310	Actual volume check completed	A		D		*P Johnston*	*V Thomson*	320ml
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				

Example of actual volume check

Carried over to page number .....

Any discrepancies must be reported to the registered nurse, midwife or ODP in charge of the ward, or the clinical nurse manager/ duty nurse or midwife manager immediately, reported on DATIX and investigated. The DATIX reference must be recorded in the Controlled Drug Record Book (Register). Refer to section 1.14 'Discrepancies' for information of steps to be taken in the event of identifying a discrepancy.

1.7.2.10 Entries in the Controlled Drug Record Book (Register) must be completed by a registered nurse, midwife or ODP and witnessed by a second registered nurse, midwife, ODP or suitably competent student nurse or midwife. (The student nurse or midwife must have received the relevant theoretical preparation at university and on placement and be assessed by their mentor/s to ensure they have the necessary competence. Refer to section 1.1 'Accountable individuals' for information relating to competencies for student nurses.)

In the event that a second registered nurse, midwife, ODP or suitable competent student nurse or midwife is not available, a registered pharmacist or registered pharmacy technician can witness the receipt of CDs.

1.8 Prescribing Controlled Drugs

[Document in Development]

Medical doctors who have not achieved full registration with the GMC are permitted to prescribe CDs (and other POM medicines) on these prescription forms and administration charts so far as this is necessary for the purposes of their employment as defined in the Medical Act 1983. Further guidance is available from the GMC.

1.8.1 Prescribing Controlled Drugs - Inpatients

1.8.1.1 CDs can be prescribed on the prescription and administration record, or other approved prescription chart including electronic versions in line with local policies and procedures. CDs may only be prescribed by a suitably qualified practitioner who is recognised and authorised by the organisation to undertake this function.

1.8.1.2 The written requirements for CDs on the prescription and administration record is the same as for other medicines:

- Medicine name and form
- Route
- Dose
- Frequency (if prescribed “when required” e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours, and a maximum total quantity to be administered in 24 hours if applicable)
- Start date
- Finish date where appropriate
- Signature of prescriber and print name
- The patient’s name, CHI number and allergy status must also be written on the chart.

1.8.2 Prescribing Controlled Drugs - Discharge Patients

1.8.2.1 CD immediate discharge letters for patients who are going home (discharge medicines) must be written/generated on locally approved prescription forms for dispensing by the hospital pharmacy. These prescriptions must conform to all requirements of the Misuse of Drugs Regulations for a CD prescription.

1.8.2.2 A discharge prescription for Schedule 2 and 3 CDs must contain the following details written so as to be indelible, i.e. written by hand, typed or computer-generated:

- The patient’s full name, address and, where appropriate, age. (on all pages of the prescription)
- The name and form of the drug, even if only one form exists.
- The strength of the preparation, where appropriate.
- The dose to be taken.
- The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures.

In addition, the patient's CHI number must be included on the prescription.

1.8.2.3 Up to a maximum of 30 days' supply should be prescribed, as a matter of good practice. There may be circumstances where there is a genuine need to prescribe for more than 30 days. Where a prescriber considers it clinically appropriate to supply more than a 30-day quantity, and this does not pose an unacceptable risk to patient safety, the patient's notes should be annotated to that effect. Prescribers who prescribe more than a 30-day supply must justify their decision.

1.8.2.4 The prescription must be signed by the prescriber with their usual signature, in their own handwriting and dated (the date does not have to be handwritten).

1.8.2.5 CD prescriptions may be computer-generated. Only the signature must be in the prescriber's own handwriting. The prescriber is also required to sign any manual changes. If an electronic solution exists, local polices should describe how this operates within the supply system.

1.8.2.6 The use of pre-printed adhesive labels e.g. addressograph labels, on prescriptions is good practice to ensure that all required details are included in a legible form, and to reduce transcription errors. However, if they are used, such adhesive labels should be non-peelable and tamper-evident (so that it is obvious if an attempt has been made to remove them), and they must be fixed to all duplicate copies of the prescription. Prescribers must sign across the adhesive label and prescription (so that the signature is not entirely on the label). This is a further safeguard to ensure adhesive labels are not tampered with or another adhesive label is not placed on top of the one that the prescriber signed for.

1.8.3 Prescribing Controlled Drugs – Out Patients

1.8.3.1 CD prescriptions for outpatients must be written in accordance with the requirements of the Misuse of Drugs Regulations (regulation 15). The prescription must be written on the approved outpatient prescription for the hospital pharmacy to dispense or a hospital HBP for a community pharmacy to dispense.

Adhesive labels must not be used on CD prescriptions to be dispensed in the community. The scanning systems in use at Practitioner Services Division cannot process such prescriptions.

1.8.3.2 A prescription for Schedule 2 and 3 CDs must contain the following details written so as to be indelible, i.e. written by hand, typed or computer-generated:

- The patient's full name, address and, where appropriate, age i.e. under 12.
- The name and form of the drug, even if only one form exists.
- The strength of the preparation, where appropriate.
- The dose to be taken.
- The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures.

In addition, the patient's CHI number must be included on the prescription.

1.8.3.3 Up to a maximum of 30 days' supply should be prescribed, as a matter of good practice. There may be circumstances where there is a genuine need to prescribe for more than 30 days. Where a prescriber considers it clinically appropriate to supply more than a 30-day quantity, and this does not pose an unacceptable risk to patient safety, the patient's notes should be annotated to that effect. Prescribers who prescribe more than a 30-day supply must be prepared to justify their decision.

1.8.3.4 The prescription must be signed by the prescriber with their usual signature, in their own handwriting and dated (the date does not have to be handwritten).

1.8.3.5 The prescriber is also required to sign any manual changes. If an electronic solution exists, local polices should describe how this operates within the supply system.

1.8.3.6 The use of pre-printed adhesive labels e.g. addressograph labels, on prescriptions is good practice to ensure that all required details are included in a legible form, and to reduce transcription errors. However, if they are used, such adhesive labels should be non-peelable and tamper-evident (so that it is obvious if an attempt has been made to remove them), and they must be fixed to all duplicate copies of the prescription. Prescribers must sign across the adhesive label and prescription (so that the signature is not entirely on the label). This is a further safeguard to ensure adhesive labels are not tampered with or another adhesive label is not placed on top of the one that the prescriber signed for.

1.8.3.7 Adhesive labels must not be used on CD prescriptions to be dispensed in the community. The scanning systems in use at Practitioner Services Division cannot process such prescriptions.

1.8.4 Prescribing Controlled Drugs – Supplementary Prescribers

Refer to NHS Lothian Framework for Independent and Supplementary Prescribing:

Independent and Supplementary Prescribing Framework.pdf (nhslothian.scot)

Also refer to the NHS Lothian Medicines Procedures 'Prescribers that are not registered doctors, dentists or Foundation Year 1 (FY1) doctors':

NHS Lothian *Safe Use of Medicines Procedures* (scot.nhs.uk)

1.9 Administration of Controlled Drugs

Refer to NHS Lothian Medicines Procedures 'Practitioners Authorised to Administer Medicines'

Practitioners authorised to administer medicines (nhslothian.scot)

1.9.1 General Information - Administration of Controlled Drugs

1.9.1.1 The administration of CDs must comply with NHS Lothian Safe Use of Medicine Policy and associated procedures.

1.9.1.2 The professional lead (registered nurse, midwife or ODP) in charge of a ward, theatre or department must ensure that records of administration of CDs are properly maintained, and that stocks are reconciled.

1.9.1.3 The administration of Schedule 2 CDs within secondary care should be done via two-person administration process. Any departure from the double-check process should be considered exceptional and carry with it a specific risk assessment to support this practice.

1.9.1.4 Administration involving Schedule 2 CDs must be witnessed, except in circumstances where it is not possible, for example, administration takes place in the patient's home, or where it is not feasible for operational reasons, for example, in theatres. In such circumstances, a risk assessment must be undertaken, and the action taken to minimise the risk must be documented.

This risk assessment for hospital specialities must be approved by the Clinical Director for the service (for doctors) and the Clinical Nurse Manager (for nurses) and be submitted to the Medicines Policy Subcommittee for review. The chair of the Medicines Policy Subcommittee will present the document to the Area Drug and Therapeutics committee for final approval.

1.9.1.5 For the administration of Schedule 2 CDs, one of the practitioners should be a registered nurse, midwife or ODP. The administration must be witnessed by a registered professional who is authorised to administer the medicine.

1.9.1.6 A suitably competent student nurse or midwife (The student nurse or midwife must have received the relevant theoretical preparation at university and on placement and be assessed by their mentor/s to ensure they have the necessary competence. Refer to section 1.1 'Accountable individuals' for information relating to competencies for student nurses or midwives.), can administer a CD to the patient; the registered nurse/midwife witnesses the administration and is accountable for the whole process.

Both practitioners must be present during the whole of the administration procedure or, in the case of an infusion or patient-controlled analgesia device, for the set-up and start. They must both witness:

- Calculation of dose (independently)
- The preparation of the CD to be administered.
- The CD being administered to the patient.

- The destruction of any surplus drug (e.g. part of an ampoule or infusion not required). Refer to section 1.11 'Returns/Disposal/Destruction of Controlled Drugs'

1.9.2 Procedure for the Administration of Controlled Drugs

1.9.2.1 The administration of CDs must comply with all local policies and procedures for the administration of medicines.

1.9.2.2 The professional lead (registered nurse, midwife or ODP) in charge of a ward, theatre or department must ensure that records of administration of CDs are properly maintained, and that stocks are reconciled.

1.9.2.3 The administration of Schedule 2 CDs within secondary care should be done via two-person administration process. Any departure from the double-check process should be considered exceptional and carry with it a specific risk assessment to support this practice.

1.9.2.4 Administration involving Schedule 2 CDs must be witnessed, except in circumstances where it is not possible for example, administration takes place in the patient's home, or where it is not feasible for operational reasons, for example, in theatres. In such circumstances, a risk assessment must be undertaken, and the action taken to minimise the risk must be documented. In secondary care, the risk assessment for hospital specialities must be approved by the Clinical Director for the service (for doctors) and the Clinical Nurse Manager (for nurses) and be submitted to the Medicines Policy Committee.

1.9.2.5 For the administration of Schedule 2 CDs, one of the practitioners should be a registered nurse, midwife or ODP. The administration must be witnessed by a registered professional who is authorised to administer the medicine.

1.9.2.6 A suitably competent student nurse or midwife (The student nurse or midwife must have received the relevant theoretical preparation at university and on placement and be assessed by their mentor/s to ensure they have the necessary competence. Refer to section 1.1 'Accountable individuals' for information relating to competencies for student nurses or midwives.), can administer a CD to the patient; the registered nurse/midwife witnesses the administration and is accountable for the whole process.

1.9.2.7 If using an oral syringe to administer an oral liquid controlled drug, the bottle must be fitted with an appropriately sized 'bung' and an oral syringe suitable to the dose being measured must be used. Bungs are available via PECOS (bottle adaptor), and your local pharmacy department can advise on appropriate sizes.

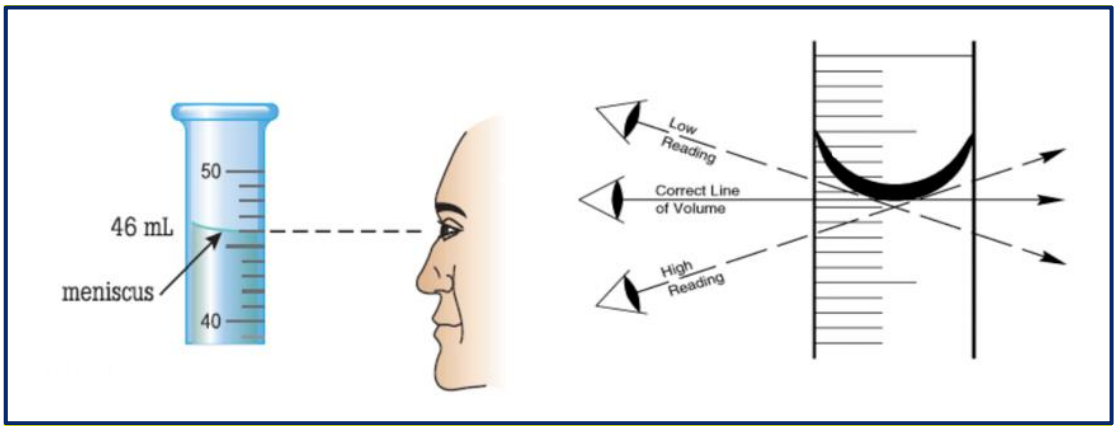
Larger doses e.g. Methadone must be measured using an appropriate size and marked conical measure. Marked conical measures are available via PECOS, and your local pharmacy department can advise on appropriate sizes.

Plastic medicine cups are not appropriate for accurately measuring controlled drugs.

When measuring liquid controlled drugs using a conical measure, ensure consistency by:

- Using a suitable appropriate size and marked conical measure i.e. smallest size to measure the required dose ensures an accurate volume.

- Placing the measure on a flat hard surface
- Ensure the sight line is at the same height as the bottom of the meniscus. The bottom of the meniscus is the accurate measurement.



After measuring, use a prolonged drainage period until there are no further drops (around 3 seconds).

1.9.2.8 Both practitioners must be present during the whole of the administration procedure or, in the case of an infusion or patient-controlled analgesia device, for the set-up and start. They must both witness:

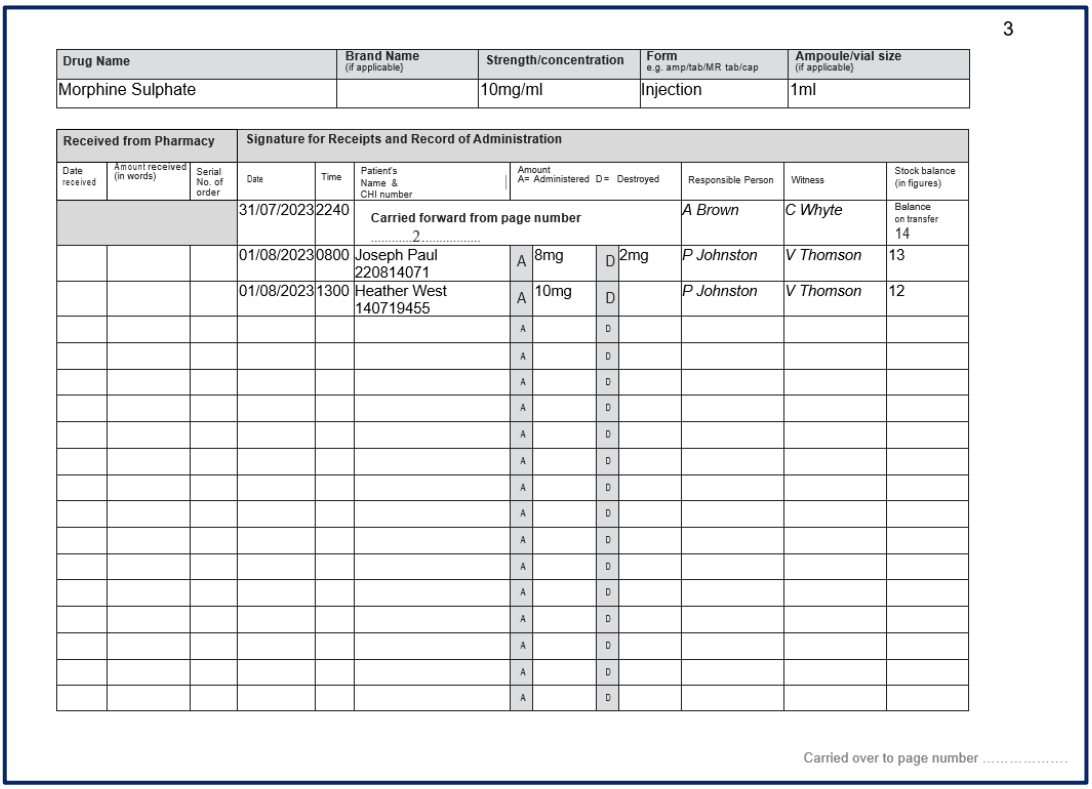
- The preparation of the CDs to be administered.
- The CD being administered to the patient (please refer to the NHS Lothian Medicine Procedures on the administration of medicines), or at the set up and start of administration for injections that are administered over a longer period than a few minutes.

The destruction of any surplus drug (e.g. part of an ampoule or infusion not required). Refer to section 1.11 'Returns/Disposal/Destruction of Controlled Drugs'

1.9.2.9 A record must be made in the ward, theatre, or department Controlled Drug Record Book (Register) or Patients' Own Controlled Drug Record Book when a Schedule 2 CD is removed from the CD cabinet for administration. The record must include:

- Date and time of administration
- Patient's full name
- Dose administered
- Amount discarded (if relevant)
- Signature of authorised member of staff e.g. registered nurse, midwife or ODP nurse, administering the dose
- Signature of witness i.e. authorised member of staff e.g. registered nurse, midwife, ODP
- Confirm and update the running balance

Example of an administration record in the Controlled Drug Record Book (Register):



3

Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Morphine Sulphate		10mg/ml	Injection	1ml

Received from Pharmacy			Signature for Receipts and Record of Administration										
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered D= Destroyed				Responsible Person	Witness	Stock balance (in figures)
			31/07/2023	2240	Carried forward from page number ..2..					*A Brown*	*C Whyte*	Balance on transfer 14
			01/08/2023	0800	Joseph Paul 220814071	A	8mg	D	2mg	*P Johnston*	*V Thomson*	13
			01/08/2023	1300	Heather West 140719455	A	10mg	D		*P Johnston*	*V Thomson*	12
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
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						A		D				
						A		D				

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1.9.2.10 If part of a vial is administered to the patient, the registered nurse, midwife or registered practitioner, and witness, should record the amount given and the amount discarded. For appropriate methods of destruction refer to section 1.11 '[Returns/Disposal/Destruction of Controlled Drugs]'.

1.9.2.11 Individual doses of CDs which have been prepared but not administered must be destroyed by a registered nurse, midwife or registered health professional on the ward or department in the presence of a witness i.e. a second competent person, such as a registered nurse, midwife or ODP. This must be recorded in the Controlled Drug Record Book (Register), including the reason, and signed by both practitioners. For appropriate methods of destruction refer to section 1.11 '[Returns/Disposal/Destruction of Controlled Drugs]'.

1.9.2.11 In theatres, the practice of issuing "active stock" to the anaesthetist and then returning the unused portion to stock, recording both issues and returns in the Theatre Controlled Drug Record Book (Register), must be avoided. An amount must be issued to the anaesthetist for a specific patient and any surplus drug must be destroyed and witnessed. For example, if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, "2.5mg given and 2.5mg discarded ". For appropriate methods of destruction refer to section 1.11 '[Returns/Disposal/Destruction of Controlled Drugs]'.

1.9.2.12 Injectables must be treated as intended for single use only unless the label specifically indicates that they are licensed and intended for use on more than one occasion or to provide more than a single dose on any one occasion.

1.9.2.13 If, when the tamper evident seal is broken the contents do not match the expected amount stated on the pack, the registered nurse or midwife in charge must contact the pharmacy department immediately, make appropriate records in the Controlled Drug Record Book (Register), document all necessary action taken to resolve the discrepancy, and report on DATIX. The entry in the Controlled Drug Record Book (Register) must be signed by both practitioners i.e. registered nurse, midwife or ODP, and witness i.e. a second competent person, such as a registered nurse, midwife or ODP. The DATIX reference must be recorded in the Controlled Drug Record Book (Register).

1.10 Management of Controlled Drugs when Patients are transferred to other Wards or Departments

Appropriate records, i.e. documentation and records of administration, must be maintained when patients are transferred between wards/departments with CDs physically attached to them, e.g. patient-controlled analgesia or patches etc, or the patient has their own CDs.

- Patients are transferred between wards/departments and have their own supply of CDs e.g. dispensed on a 'named patient' basis or patients own supply of CDs – refer to section 1.10.1 'Transfer of Patient's Own Controlled Drugs to another Hospital, Ward or Department'.
- Patients are transferred between wards/departments with CDs physically attached to them – refer to section 1.10.2 'Transferring Patients to another Clinical Area with Controlled Drugs in Progress'.

1.10.1 Transfer of Patient's Own Controlled Drugs to another Hospital (within NHS Lothian), Ward or Department

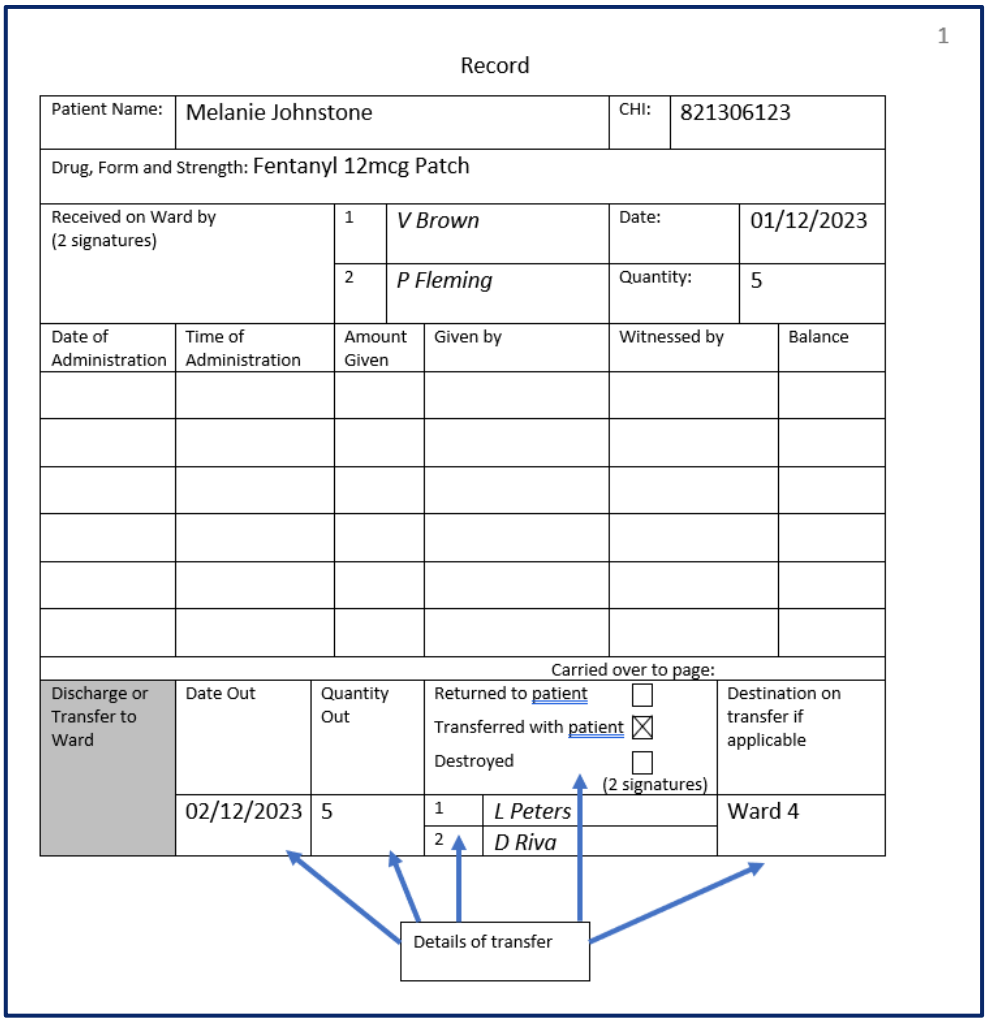
1.10.1.1 It may be necessary to transfer a patient from one hospital, ward or department to another hospital, ward, or department. Where the patient has their own CDs, where appropriate e.g. for ongoing treatment or required in the near future, these should be transferred with the patient.

It is the responsibility of the transferring ward to telephone the receiving ward to alert them that the patient being transferred has patient's own CDs in their possession.

1.10.1.2 When a patient is being transferred, the Patients' Own Controlled Drug Record Book must be updated with details of:

- Drug name, form, and strength
- Date patient transferred
- Quantity transferred
- Destination of new ward/hospital
- Signature of authorised member of staff e.g. registered nurse, midwife or ODP transferring the CDs
- Signature of witness i.e. authorised member of staff e.g. registered nurse, midwife, ODP

Example of transfer in the Patients' Own Controlled Drug Record Book:



1

Record

Patient Name:	Melanie Johnstone		CHI:	821306123	
Drug, Form and Strength: Fentanyl 12mcg Patch					
Received on Ward by (2 signatures)	1	*V Brown*	Date:	01/12/2023	
	2	*P Fleming*	Quantity:	5	

Date of Administration	Time of Administration	Amount Given	Given by	Witnessed by	Balance

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Discharge or Transfer to Ward	Date Out	Quantity Out	Returned to patient ☐ Transferred with patient ☒ Destroyed ☐ (2 signatures)		Destination on transfer if applicable
	02/12/2023	5	1	*L Peters*	Ward 4
			2	*D Riva*	

Details of transfer

1.10.1.3 Once on the new ward or department, two registered nurses, midwives or ODP's must confirm the drug and quantities received and record in the Patients' Own Controlled Drug Record Book. Both registered nurses, midwives or ODP's must sign the page in the Patients' Own Controlled Drug Record Book to confirm receipt.

1.10.1.4 Refer to section 1.17 'Management of Patients' Own Controlled Drugs' for further information.

1.10.2 Transferring Patients to another Clinical Area with Controlled Drugs in Progress

1.10.2.1 When a patient is transferred to another clinical area with CDs such as infusions, syringe drivers or patches, the current administration and monitoring chart must be transferred with them.

1.10.2.2 The registered nurse, midwife or ODP, in the clinical area the patient leaves, must check the administration system and volume/quantity remaining and sign, date and time the administration and monitoring chart to ensure that the record is accurate when the patient is handed over, and that the quantity remaining is accurate.

1.10.2.3 The registered nurse, midwife or ODP, in the clinical area to which the patient is transferred must check the administration system and volume/quantity remaining and

sign, date and time the administration and monitoring chart to confirm that the record is accurate.

1.10.2.4 If the patient is transferred with a CD transdermal patch in situ this must be recorded on the transfer/discharge summary and highlighted verbally to the registered nurse/healthcare professional in the receiving clinical area to which the patient is transferred. The information must include the name, strength, location of the transdermal patch, date and time of application and date and time of replacement. This must be recorded on the patient's medicine chart or monitoring chart.

1.10.2.5 Refer to section 1.23 'Patient Controlled Analgesia (PCA)' for more information.

1.11 Return/Disposal/Destruction of Controlled Drugs

Denaturing kits must be stored securely, in an area not accessible to patients, with restricted access for authorised members of staff only. Denaturing kits that do not require medicines to be crushed must be used.

Expired stock must be segregated from in-date ward stock.

1.11.1 Return of Controlled Drugs to Pharmacy

Contact the local pharmacy department, to obtain authorisation, before sending any returns to pharmacy.

1.11.1.1 Unused CD stock from wards or departments may be returned to the pharmacy for re-issue by the pharmacy, provided it was initially issued by that pharmacy and has at all times been under the control of that hospital. The pharmacy department must carry out a risk assessment of returned CDs to ensure they are fit for re-use.

1.11.1.2 The table below details the process for expired and unused CDs (all Schedules)

Schedule	Expired	Unused
2 (inc patients own*)	Destroyed, using a CD denaturing kit, on the ward/department by registered pharmacist or registered pharmacy technician and appropriately trained registered healthcare professional. Refer to section 1.11.3 'Disposal/Destruction of Schedule 2, 3 and 4 (part I) CDs in the ward/department'.	Contact local pharmacy for guidance and refer to section 1.11.2 'Record of Controlled Drugs returned to pharmacy'.
3 (inc patients own*)	Destroyed, using a CD denaturing kit, on the ward/department by two appropriately trained registered healthcare professionals. Refer to section 1.11.3 'Disposal/Destruction of Schedule 2, 3 and 4 (part I) CDs in the ward/department'.	Contact local pharmacy for guidance and refer to section 1.11.2 'Record of Controlled Drugs returned to pharmacy'.
4 (part I) (inc patients own*)	Destroyed, using a CD denaturing kit, on the ward/department by two appropriately trained registered healthcare professionals. Refer to section 1.11.3 'Disposal/Destruction of Schedule 2, 3 and 4 (part I) CDs in the ward/department'.	Contact local pharmacy for guidance and refer to NHS Lothian *Safe Use of Medicines Procedures* – 'Return and Disposal of Medicines in Hospital'
4 (part II) and 5 (inc patients own*)	Refer *to* NHS Lothian *Safe Use of Medicines Procedures 'Return of Medicines to Pharmacy'.*	Contact local pharmacy for guidance and refer to NHS Lothian *Safe Use of Medicines Procedures - 'Return and Disposal of Medicines in Hospital'*

*refer to section 1.17 'Management of Patients' Own Controlled Drugs'.

1.11.1.3 All CDs returned to pharmacy must be transported in a safe and secure way, e.g. tamper-evident packaging.

1.11.2 Records of Controlled Drugs returned to pharmacy

Please refer to NHS Lothian *Safe Use of Medicines Procedures*- *'Return and Disposal of Medicines in Hospital'* for the process for the return of Schedule 3 (not subject to safe custody), Schedule 4 and Schedule 5 CDs.

1.11.2.1 An itemised list containing the name, strength, form, and quantity of the medicine, must accompany all Schedule 2 and Schedule 3 CDs subject to safe custody regulations being returned to pharmacy. This must be signed by the registered pharmacist, or registered pharmacy technician, and the registered nurse, midwife or ODP.

1.11.2.2 The ward or department must keep a record of Schedule 2 CDs returned to the pharmacy in the Controlled Drug Record Book (Register). The entry must be made on the relevant page of the Controlled Drug Record Book (Register) and must show:

- Date
- Signatures of the registered nurse, midwife or ODP and the registered pharmacist/pharmacy technician
- Quantity removed
- Name, form, and strength of drug
- Balance remaining.

Example of return to pharmacy entry in the Controlled Drug Record Book (Register):

3

Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g., amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Morphine Sulphate		10mg/ml	Injection	1ml

Received from Pharmacy			Signature for Receipts and Record of Administration									
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered D= Destroyed				Responsible Person	Witness	Stock balance (in figures)
			31/07/2023	2240	Carried forward from page number ..2..					*A Brown*	*C Whyte*	Balance on transfer 11
			01/08/2023	0800	Joseph Paul 220814071	A	8mg	D	2mg	*P Johnston*	*V Thomson*	10
			11/08/2023	1300	10 x 10mg returned to pharmacy	A		D		*L Wyhyte* (pharmacist)	*V Thomson*	zero
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
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						A		D				
						A		D				

Example of return to pharmacy

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1.11.2.3 The ward/department must receive confirmation from the pharmacy confirming receipt of the CDs listed on the itemised list. Any anomalies must be highlighted to pharmacy

immediately and reported on DATIX. Where applicable, the DATIX reference must be recorded in the Controlled Drug Record Book (Register).

1.11.3 Disposal/Destruction of Schedule 2, 3 and 4 (part I) Controlled Drugs in the Ward/Department

This section refers to expired stock and patients' own CDs destroyed on the ward/department. The table below details requirements for each Schedule.

Schedule	Destroyed by	Denature before disposal	Entry in CD Register	Record retained on ward
2	Registered pharmacist or registered pharmacy technician and appropriately trained registered healthcare professional.	Yes	Yes	Yes – record will be in Controlled Drug Record Book (Register)
3	Two appropriately trained registered healthcare professionals.	Yes	No*	Yes – items recorded on the 'Record of Schedule 3 and 4 (part I) CD Destruction Ward Department' form***
4 (part I)	Two appropriately trained registered healthcare professionals. **	Yes	No**	Yes – items recorded on the 'Record of Schedule 3 and 4 (part I) CD Destruction Ward Department' form***
4 (part II)	Two appropriately trained registered healthcare professionals.	No	No	No
5	Two appropriately trained registered healthcare professionals.	No	No	No

*with exception of Buprenorphine in Scottish Prison Service whereby Buprenorphine is recorded in the Controlled Drug Record Book (Register).

**Sativex is required to be recorded in the Controlled Drug Record Book (Register) and requires a registered pharmacist or registered pharmacy technician to witness the destruction.

*** Proforma available on the Controlled Drug Governance Team Intranet page: Controlled Drugs Governance Home (scot.nhs.uk)

Schedule 2, 3 and 4 (part I) CDs must be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or re-used. NHS Lothian considers the following methods to render the drug irretrievable.

Schedule 2 CDs must be destroyed by a registered pharmacist or registered pharmacy technician and a registered healthcare professional.

Denaturing kits that do not require crushing must be used. When disposing of CDs into a denaturing kit, dry CDs should be added first, and then liquid CDs can follow.

Medication Form	Method of Destruction
Ampoules and vials	– **Liquid** - Open ampoule/vial and empty contents into denaturing kit. The empty ampoule/vial should also be placed into the denaturing kit. There is no need to crush the ampoule/vial. – **Powders** - Add water to the powder and empty contents into the denaturing kit. The empty ampoule should be placed into the denaturing kit. If space is a problem, the empty ampoules can be placed in a blue lidded pharmaceutical waste bin.
Tablets and capsules	Remove from outer packaging and from blister strip, where applicable, and place into denaturing kit. There is no need to crush tablets or open capsules.
Oral liquids/drops	Empty contents into the denaturing kit. Rinse the bottle and measure, if used, and empty the rinsings into the denaturing kit.
Patches	Remove from outer packaging, remove backing strip, fold patch over on itself and place the patch and the plastic backing into the denaturing kit.

All packaging that has been in direct contact with the drug e.g., foil packaging, should be disposed of in the blue lidded pharmaceutical waste bin.

Please contact pharmacy for methods of destruction for any medication form not listed above.

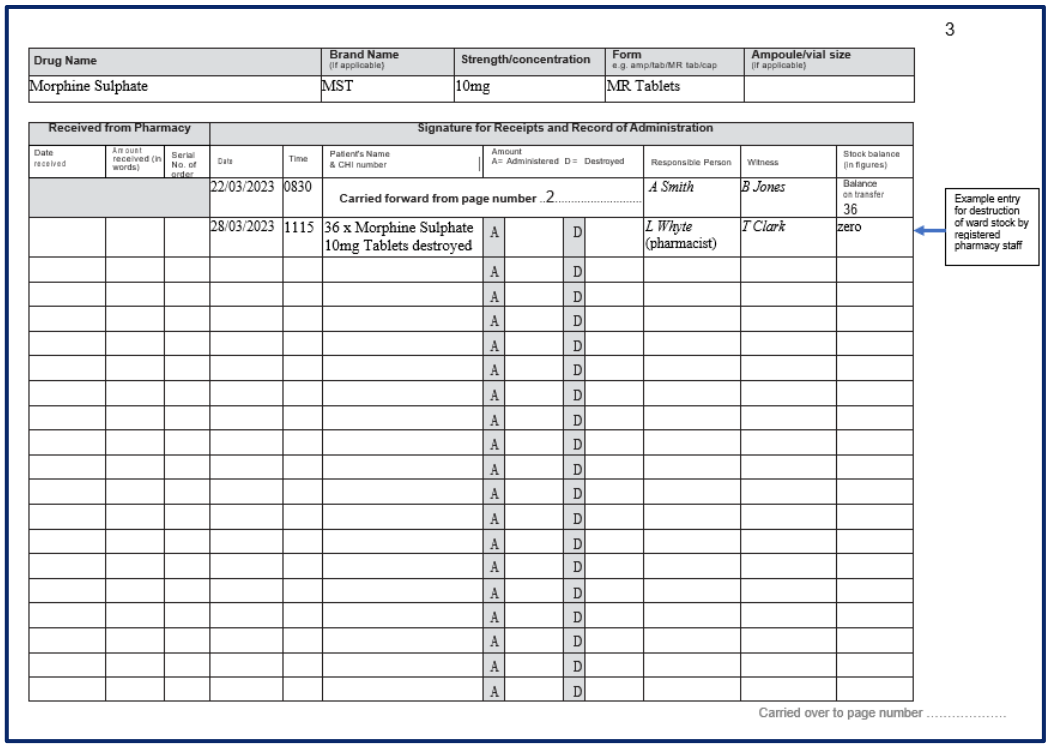
Schedule 4 (part II) and Schedule 5 CDs can be placed directly into a blue lidded pharmaceutical waste bin.

1.11.3.1 Activated denaturing kits, containing Schedule 2 CDs and Schedule 3 CDs safe custody, must be stored in the CD cabinet as per the directions on the denaturing kit e.g. store in CD cabinet for 24 hours after activation. Activated denaturing kits, containing Schedule 3 CDs (not safe custody) and Schedule 4 (Part I), can be stored in a secure medicine cupboard. Activated denaturing kits e.g. 24 hours after activation or as per directions on the denaturing kit, can be placed in a blue lidded pharmaceutical waste bin or returned to pharmacy. In the event that a denaturing kit does not solidify, contact pharmacy.

1.11.3.2 The ward or department must keep a record of Schedule 2 CDs destroyed in the Controlled Drug Record Book (Register). The entry must be made on the relevant page of the Controlled Drug Record Book (Register) and must show:

- Date
- Signatures of the registered nurse, midwife or ODP and the registered pharmacist/pharmacy technician
- Quantity destroyed
- Name, form, and strength of drug
- Balance remaining.

Example of destruction entry in the Controlled Drug Record Book (Register):



3

Drug Name	Brand Name (If applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (If applicable)
Morphine Sulphate	MST	10mg	MR Tablets	

Received from Pharmacy			Signature for Receipts and Record of Administration								
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered D= Destroyed			Responsible Person	Witness	Stock balance (in figures)
			22/03/2023	0830	Carried forward from page number 2				A Smith	B Jones	Balance on transfer 36
			28/03/2023	1115	36 x Morphine Sulphate 10mg Tablets destroyed	A		D	L Whyte (pharmacist)	T Clark	zero
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
						A		D			
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						A		D			
						A		D			
						A		D			

Example entry for destruction of ward stock by registered pharmacy staff

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1.11.3.3 Schedule 3 and 4 (part I) destroyed in a CD denaturing kit at ward level by two appropriately trained registered healthcare professionals, must be recorded on a Record of Schedule 3 and 4 (part I) CD Destruction Form*.

* Proforma available on the Controlled Drug Governance Team Intranet page:

Controlled Drugs Governance Home (scot.nhs.uk)

There is no requirement to complete paperwork for the unused part of a CD dose. Refer to section 1.11.4 'Disposal of small amounts of Controlled Drugs'.

1.11.4 Disposal of Small Amounts of Controlled Drugs

1.11.4.1 This applies only to CD doses that are to be discarded after being prepared for administration to a patient, e.g. patient refused dose, or surplus amount when the dose required is smaller than the total dose unit of a preparation, or spillages/breakages. Discarded part of CD doses should be rendered irretrievable on disposal.

- Liquids up to about 10mL, including part-used ampoules, syringes etc, should be soaked onto either a tissue or other absorbent material, and placed into a blue lidded pharmaceutical waste bin.
- Solid doses should be dropped directly into a blue lidded pharmaceutical waste bin in a way that prevents the drug being recovered.
- Patches should be folder over on themselves and place the patch and the plastic backing directly into a blue lidded pharmaceutical waste bin.

1.11.4.2 All destructions/disposals of small amounts of Schedule 2 CDs, as defined in 1.11.4.1, must be witnessed by a second competent person, such as a registered nurse, midwife or

ODP and documented in the Controlled Drug Record Book (Register) to include the following:

- Date
- Signatures of the two authorised members of staff e.g. registered nurse, midwife or ODP
- Quantity destroyed
- Balance remaining.

Example of part dose/disposal in the Controlled Drug Record Book (Register):

3

Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Morphine Sulphate		10mg/ml	Injection	1ml

Received from Pharmacy			Signature for Receipts and Record of Administration									
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered		D= Destroyed		Responsible Person	Witness	Stock balance (in figures)
			31/07/2023	2240	Carried forward from page number ..2..					*A Brown*	*C Whyte*	Balance on transfer 14
			01/08/2023	0800	Joseph Paul 220814071	A	8mg	D	2mg	*P Johnston*	*V Thomson*	13
			01/08/2023	1300	Heather West 140719455	A	10mg	D		*P Johnston*	*V Thomson*	12
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				

Example of part dose/disposal

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1.12 Ward, Theatre and Department Controlled Drug Stock Checks

1.12.1 General Information - Ward, Theatre and Department Controlled Drug Stock Checks

1.12.1.1 The professional lead (registered nurse, midwife or ODP) in charge is responsible for ensuring that the regular CD stock check is carried out by authorised staff in the ward, theatre, or department.

1.12.1.2 The stock balance of all CDs entered in the Controlled Drug Record Book (Register), including patients' own CDs and suspicious substances must be checked and reconciled with the amounts in the CD cabinet at least once each day, on days that the ward, theatre or department is open, at a change of shift, where possible, by a registered nurse, midwife or ODP from each shift. If this is not possible two registered nurses, midwifes or ODP's from the same shift may undertake the stock balance check.

It is also necessary to ensure that all CDs in the CD cabinet have been recorded in the Controlled Drug Record Book (Register) or Patients' Own Controlled Drug Record Book.

1.12.1.3 Where possible the staff undertaking this check should be rotated periodically.

1.12.1.4 In exceptional circumstances, if a second nurse is unavailable then another appropriately trained registered healthcare professional e.g. registered pharmacist or registered pharmacy technician, can assist with the daily check at the discretion of the registered nurse, midwife or ODP in charge.

1.12.1.5 A registered pharmacist or registered trained pharmacy technician must check the Controlled Drug Record Book (Register) and reconcile stock at least once every 4 months. This must be carried out with a registered nurse, midwife or ODP from the ward/department. The registered pharmacist or registered pharmacy technician must provide a written report of the check to the professional lead (registered nurse, midwife or ODP) in charge. This report must be retained by the professional lead in charge for two years.

The stock check must be carried out in accordance with pharmacy procedures.

1.12.1.6 All discrepancies involving CDs must be reported on DATIX. The DATIX reference must be recorded in the Controlled Drug Record Book (Register).

1.12.1.7 Refer to section 1.12.2 'Procedure for Ward, Theatre and Department Controlled Drug Stock Checks'.

1.12.2 Procedure for Ward, Theatre and Department Controlled Drug Stock Check

1.12.2.1 The professional lead (registered nurse, midwife or ODP) in charge is responsible for ensuring that the regular CD stock check is carried out by authorised staff in the ward, theatre, or department.

1.12.2.2 The stock balance of all CDs entered in the Controlled Drug Record Book (Register), including patients' own CDs and suspicious substances must be checked and reconciled with the amounts in the CD cabinet at least once each day, on days that the ward, theatre

or department is open, at a change of shift, where possible, by a registered nurse, midwife or ODP from each shift. If this is not possible two registered nurses, midwives or ODP's from the same shift may undertake the stock balance check.

It is also necessary to ensure that all CDs in the CD cabinet have been recorded in the Controlled Drug Record Book (Register) or Patients' Own Controlled Drug Record Book.

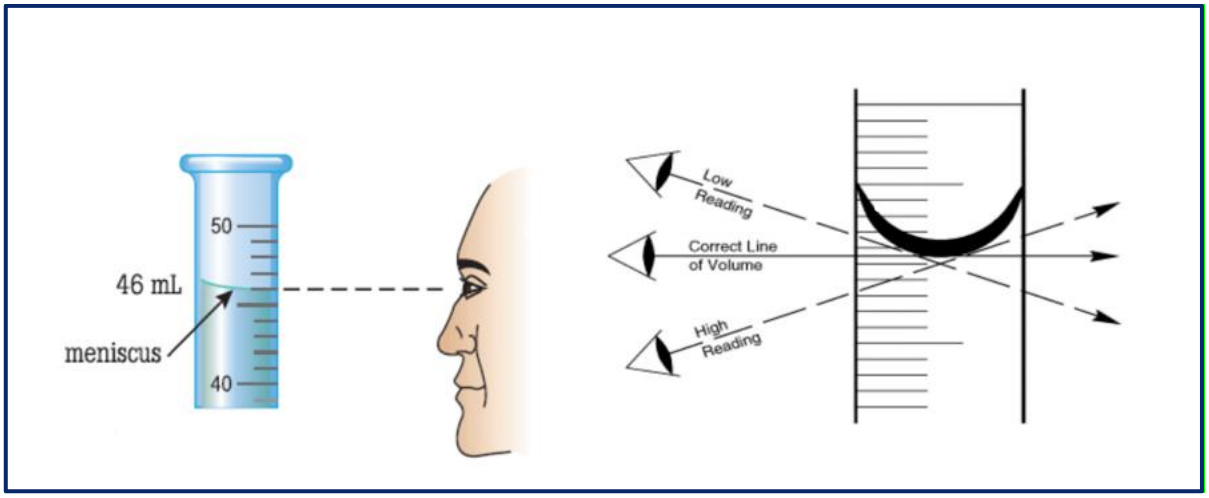
1.12.2.3 Where possible the staff undertaking this check should be rotated periodically.

1.12.2.4 The stock check must take account of the following points:

- The balance in the Controlled Drug Record Book (Register) must be checked against the contents of the CD cabinet, not the reverse, to ensure all balances are checked.
- The balance in the Patients' Own Controlled Drug Record Book must be checked against the contents of the CD cabinet, not the reverse, to ensure all balances are checked.
- It is also necessary to ensure that all CDs in the CD cabinet have been recorded in the Controlled Drug Record Book (Register) or Patients' Own Controlled Drug Record Book.
- It is not necessary to open packs with intact tamper-evident seals for stock checking purposes, e.g. manufacturer's complete sealed packs.
- The suspicious substance(s) must be checked daily as part of the daily CD check to ensure the sealed package is intact. Refer to section 1.24 'Suspicious Substances'.
- Check that each order in the Controlled Drug Order Book, and any CDs returned to pharmacy, since the last daily check, have been entered in the Controlled Drug Record Book (Register).
- Stock balances of liquid medicines should generally be checked by visual inspection, but an actual volume check, i.e. measured using a conical measure, must be carried out a minimum of once per month, or if there is a discrepancy identified when performing a visual check. The record of the actual volume check must be recorded as an entry in the Controlled Drug Record Book (Register). The entry must include, the date, time, details of entry i.e. date, "Actual volume check completed", and signed by the registered nurse, midwife or ODP and the witness e.g. registered nurse, midwife or ODP.

When measuring liquid controlled drugs, ensure consistency by:

- Using a suitable appropriately size and marked conical measure i.e. smallest size to measure the required dose ensures an accurate volume.
- Placing the measure on a flat hard surface
- Ensuring the sight line is at the same height as the bottom of the meniscus. The bottom of the meniscus is the accurate measurement.

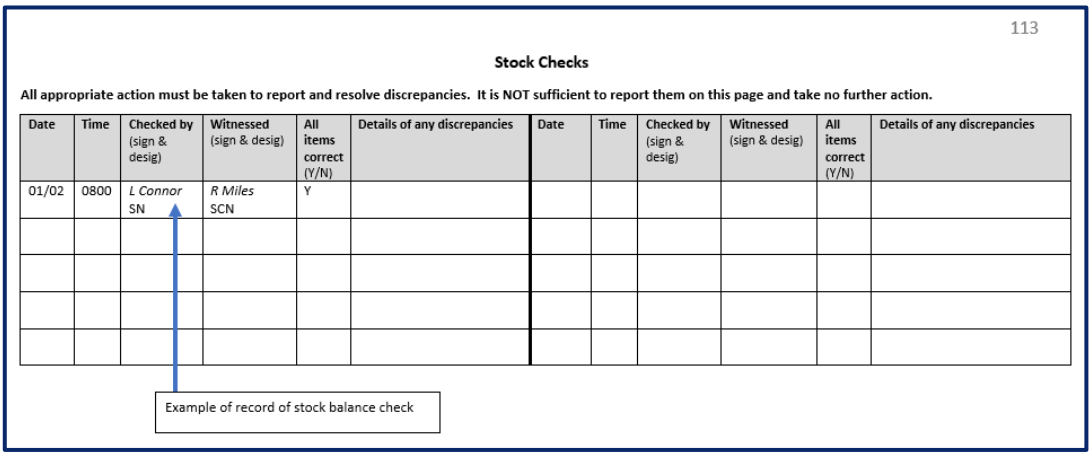


After measuring, use a prolonged drainage period until there are no further drops (around 3 seconds).

- The actual stock level must be recorded on completion of a bottle of liquid. The record of the actual volume check must be recorded as an entry in the Controlled Drug Record Book (Register). The entry must include, the date, time, details of entry i.e. date, "Actual volume check completed", and signed by the registered nurse, midwife or ODP and the witness e.g. registered nurse, midwife or ODP.
- When a bottle of liquid CD expires, the actual stock level should be written in the Controlled Drug Record Book (Register) e.g. 500mL + 137mL expired. The expired bottle must be sealed and left in the CD cabinet. Pharmacy should be contacted to arrange the destruction of the expired stock with a registered nurse, midwife or ODP.
- In the event of a spillage or breakage, a second authorised staff member must verify that it has occurred and countersign the Controlled Drug Record Book (Register). This should be recorded on DATIX and the DATIX reference recorded in the Controlled Drug Record Book (Register). Refer to section 1.13 'Breakages and Spillages of Controlled Drugs'.
- In the event of any discrepancies, inform the registered nurse, midwife or ODP in charge of the ward, or the clinical nurse manager/ duty nurse or midwife manager and report on DATIX. The DATIX reference must be recorded in the Controlled Drug Record Book (Register). Please refer to section 1.14 'Discrepancies'
- Activated denaturing kits e.g. 24 hours after activation or as per directions on the denaturing kit, can be placed in a blue lidded pharmaceutical waste bin or returned to pharmacy. An itemised list e.g. entry in the Medicines Returns Book, must be sent with the denaturing kit and a copy retained on the ward. **If** a denaturing kit does not solidify, contact pharmacy.

1.12.2.5 A record indicating that this reconciliation/stock balance check has been carried out and confirming the stock is correct must be kept. This record must include as a minimum the date and time of the reconciliation check, and be signed by the registered nurse, midwife or ODP and the witness.

Example of record of a stock balance check in the Controlled Drug Record Book (Register):



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Stock Checks

All appropriate action must be taken to report and resolve discrepancies. It is NOT sufficient to report them on this page and take no further action.

Date	Time	Checked by (sign & desig)	Witnessed (sign & desig)	All items correct (Y/N)	Details of any discrepancies	Date	Time	Checked by (sign & desig)	Witnessed (sign & desig)	All items correct (Y/N)	Details of any discrepancies
01/02	0800	*L Connor* SN	*R Miles* SCN	Y							

Example of record of stock balance check

Additional blank stock check record sheets for the Ward/Department Stock Controlled Drug Record Book (Register) can be added if required. Template is available on the Controlled Drug Governance Team Intranet page:

Controlled Drugs Governance Home (scot.nhs.uk)

1.12.2.6 If an error or omission has been traced during this check, the registered nurse, midwife or ODP must make an entry in the Controlled Drug Record Book (Register) clearly stating the reason for the entry and the correct balance. This entry must be witnessed by the second registered nurse, midwife or ODP, and both persons must sign the Controlled Drug Record Book (Register). Any discrepancy must be reported immediately to the registered nurse, midwife or ODP in charge of the ward, or the clinical nurse manager/ duty nurse or midwife manager and reported on DATIX. The DATIX reference must be recorded in the Controlled Drug Record Book (Register).

1.12.2.7 Any discrepancy which cannot be accounted for by an error or omission must be reported to the Lead Pharmacist for the hospital. Liquid discrepancies within permitted levels do not need to be reported (refer to section 1.14.1 Liquid Volume Discrepancies). If the discrepancy cannot be resolved it must be reported to the Controlled Drug Accountable Officer and the police as soon as possible, within 48 hours.

1.12.2.8 Please refer to section 1.14 'Discrepancies'.

1.12.2.9 All discrepancies involving CDs must be reported on DATIX. The DATIX reference must be recorded in the Controlled Drug Record Book (Register).

1.13 Breakages and Spillages of Controlled Drugs

1.13.1.1 All breakages, spillages, including dropped tablets, must be reported to the registered nurse, midwife or ODP in charge as soon as possible, an entry made in the Controlled Drug Record Book (Register) and reported via DATIX. The DATIX reference must be recorded in the Controlled Drug Record Book (Register).

An entry must be made in the Controlled Drug Record Book (Register) for any doses refused by a patient. These do not need to be recorded on DATIX. *Refer to NHS Lothian Medicines Procedure 'Administration of Medicines in Hospital and NHS Lothian Healthcare Premises' for details on actions to be taken when a patient refuses a dose.*

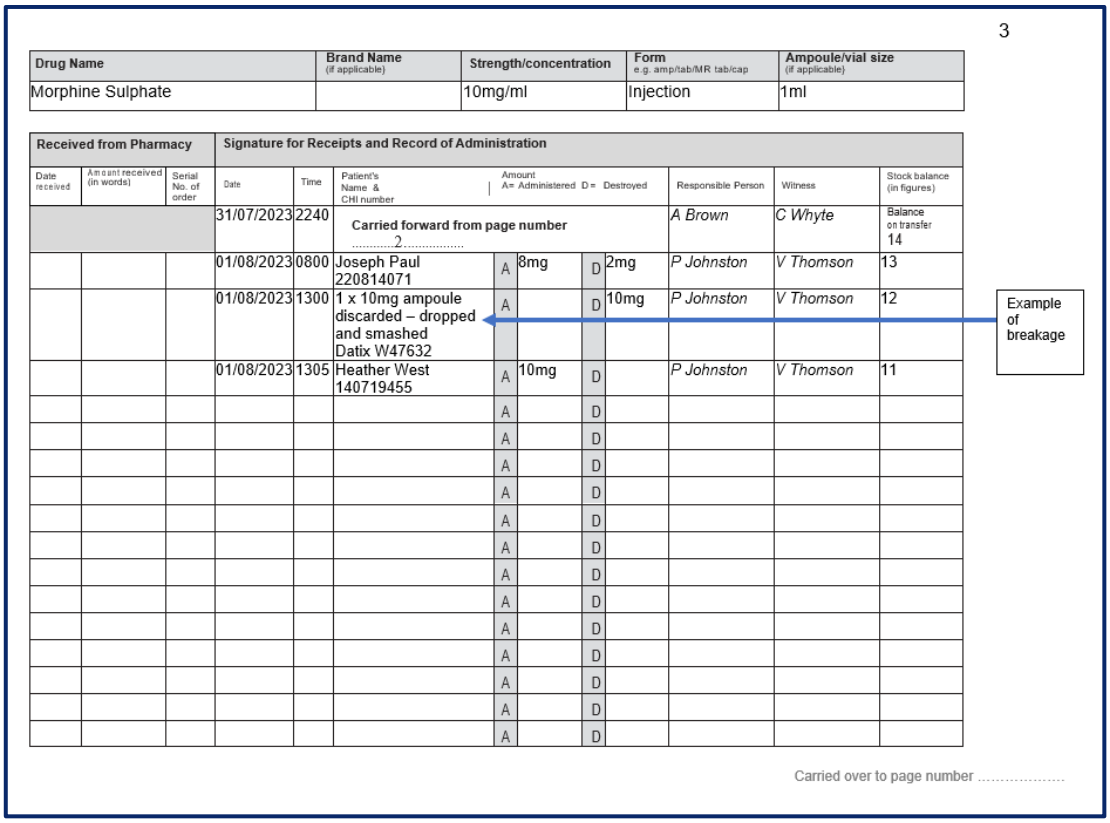
These must be disposed of in accordance with section 1.11.4 'Disposal of Small Amounts of Controlled Drugs'.

1.13.1.2 When liquid spillages occur, the two registered nurses, midwives or ODP's present should make an entry in the Controlled Drug Record Book (Register).

1.13.1.3 Breakages, spillages, dropped tablets and patient refusals must be entered in the Controlled Drug Record Book (Register) and include the following detail:

- Date
- Reason e.g. dropped tablet, patient refused etc.
- Signatures of the two authorised members of staff e.g. registered nurse, midwife or ODP
- Quantity destroyed
- Balance remaining
- Datix reference, where applicable.

Example of breakage entry in the Controlled Drug Record Book (Register):



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Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Morphine Sulphate		10mg/ml	Injection	1ml

Received from Pharmacy			Signature for Receipts and Record of Administration									
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered		D= Destroyed		Responsible Person	Witness	Stock balance (in figures)
			31/07/2023	2240	Carried forward from page number ..2..					*A Brown*	*C Whyte*	Balance on transfer 14
			01/08/2023	0800	Joseph Paul 220814071	A	8mg	D	2mg	*P Johnston*	*V Thomson*	13
			01/08/2023	1300	1 x 10mg ampoule discarded – dropped and smashed Datix W47632	A		D	10mg	*P Johnston*	*V Thomson*	12
			01/08/2023	1305	Heather West 140719455	A	10mg	D		*P Johnston*	*V Thomson*	11
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				

Example of breakage

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1.13.1.4 All breakages and spillages, including dropped tablets, must be reported on DATIX. The DATIX reference must be recorded in the Controlled Drug Record Book (Register). There is no requirement to report on Datix if a patient refuses a dose.

1.14 Discrepancies

The professional lead (registered nurse, midwife or ODP) in charge is responsible for ensuring discrepancies are investigated.

1.14.1 Liquid Volume Discrepancies

Discrepancies in liquid volumes may arise due to manufacturer overage or underage or due to regular small losses when measuring small volumes. Discrepancies also occur due to incorrect bungs and syringes being used. If using an oral syringe to administer an oral CD liquid the bottle must be fitted with an appropriately sized 'bung' and an oral syringe suitable to the dose being measured must be used. Bungs are available via PECOS (bottle adaptor), and your local pharmacy department can advise on appropriate sizes.

On completion of a bottle the actual stock level should be annotated in the Controlled Drug Record Book (Register). The record of the actual volume check must be recorded as an entry in the Controlled Drug Record Book (register). The entry must include, the date, time, details of entry i.e. date, "Actual volume check completed", and signed by the registered nurse, midwife or ODP and the witness e.g. registered nurse, midwife or ODP.

1.14.1.1 Overage Discrepancy

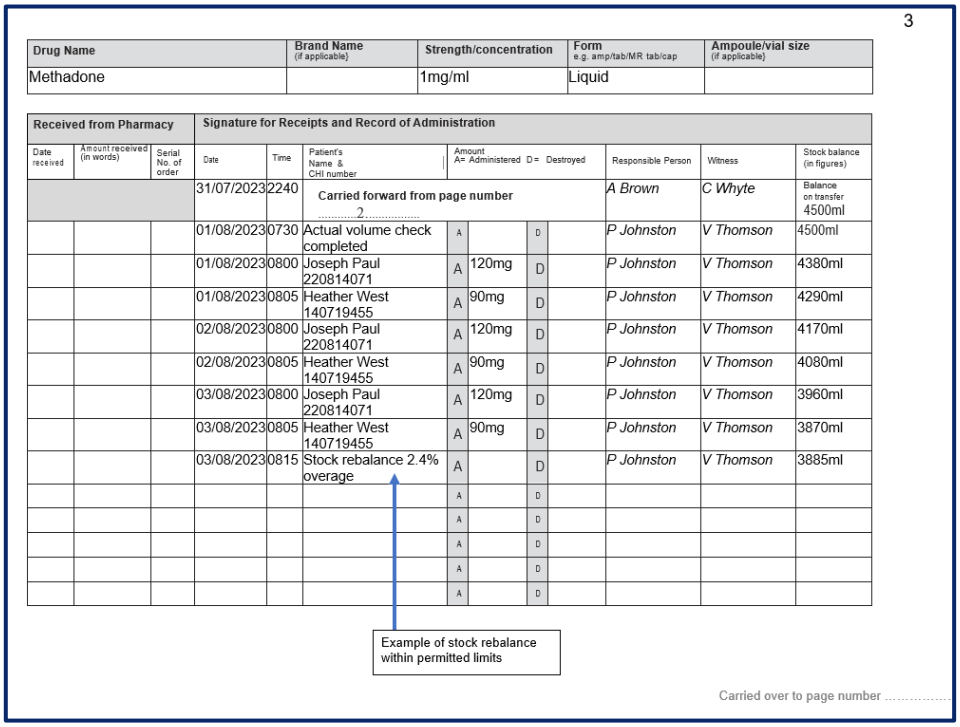
- If the discrepancy is an overage of **less than or equal to 5%** i.e. % difference between the discrepancy volume and the quantity administered since the last recorded **actual volume check**, two members of authorised registered healthcare staff must rebalance the stock in the Controlled Drug Record Book (Register). This must be annotated in the Controlled Drug Record Book (Register) as:
  - 'stock rebalance X% overage'
  - The entry signed by the two members of authorised registered healthcare staff.
  - A DATIX is not required for an overage discrepancy less than or equal to 5% for liquid preparations.
- If the discrepancy is **over 5%** difference between the discrepancy volume and the quantity administered since the last actual volume check refer to section 1.14.2 'Investigating Discrepancies'.

  A DATIX entry is required for an overage discrepancy **over** 5%. The DATIX reference must be recorded in the Controlled Drug Record Book (Register).

Example 1 (discrepancy is less than or equal to 5%):

Current balance in Controlled Drug Record Book (Register)	3870mL
Current physical balance	3885mL
Discrepancy between balance in Controlled Drug Record Book (Register) and physical balance	+15mL
Quantity administered since last actual balance check	630mL
Calculation i.e. disc volume divided by qty administered	15mL divided by 630mL, multiplied by 100. = 2.4%
Action to be taken:	Two members of authorised registered healthcare staff must rebalance the stock in the Controlled Drug Record Book (Register) DATIX entry in NOT required

Example of stock rebalance, within permitted limits, in the Controlled Drug Record Book (Register):



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Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Methadone		1mg/ml	Liquid	

Received from Pharmacy			Signature for Receipts and Record of Administration									
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered		D = Destroyed		Responsible Person	Witness	Stock balance (in figures)
			31/07/2023	2240	Carried forward from page number ……2……					*A Brown*	*C Whyte*	Balance on transfer 4500ml
			01/08/2023	0730	Actual volume check completed	A		D		*P Johnston*	*V Thomson*	4500ml
			01/08/2023	0800	Joseph Paul 220814071	A	120mg	D		*P Johnston*	*V Thomson*	4380ml
			01/08/2023	0805	Heather West 140719455	A	90mg	D		*P Johnston*	*V Thomson*	4290ml
			02/08/2023	0800	Joseph Paul 220814071	A	120mg	D		*P Johnston*	*V Thomson*	4170ml
			02/08/2023	0805	Heather West 140719455	A	90mg	D		*P Johnston*	*V Thomson*	4080ml
			03/08/2023	0800	Joseph Paul 220814071	A	120mg	D		*P Johnston*	*V Thomson*	3960ml
			03/08/2023	0805	Heather West 140719455	A	90mg	D		*P Johnston*	*V Thomson*	3870ml
			03/08/2023	0815	Stock rebalance 2.4% overage	A		D		*P Johnston*	*V Thomson*	3885ml
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				

Example of stock rebalance within permitted limits

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Example 2 (discrepancy is more than 5%):

Current balance in Controlled Drug Record Book (Register)	2400mL
Current physical balance	2704mL
Discrepancy between balance in Controlled Drug Record Book (Register)and physical balance	+304mL
Quantity administered since last recorded actual balance check	2100ml
Calculation i.e. disc volume divided by qty administered	304mL divided by 2100mL, multiplied by 100. = 14.5%
Action to be taken:	Follow investigating discrepancy process 1.14.2. Record discrepancy on DATIX.

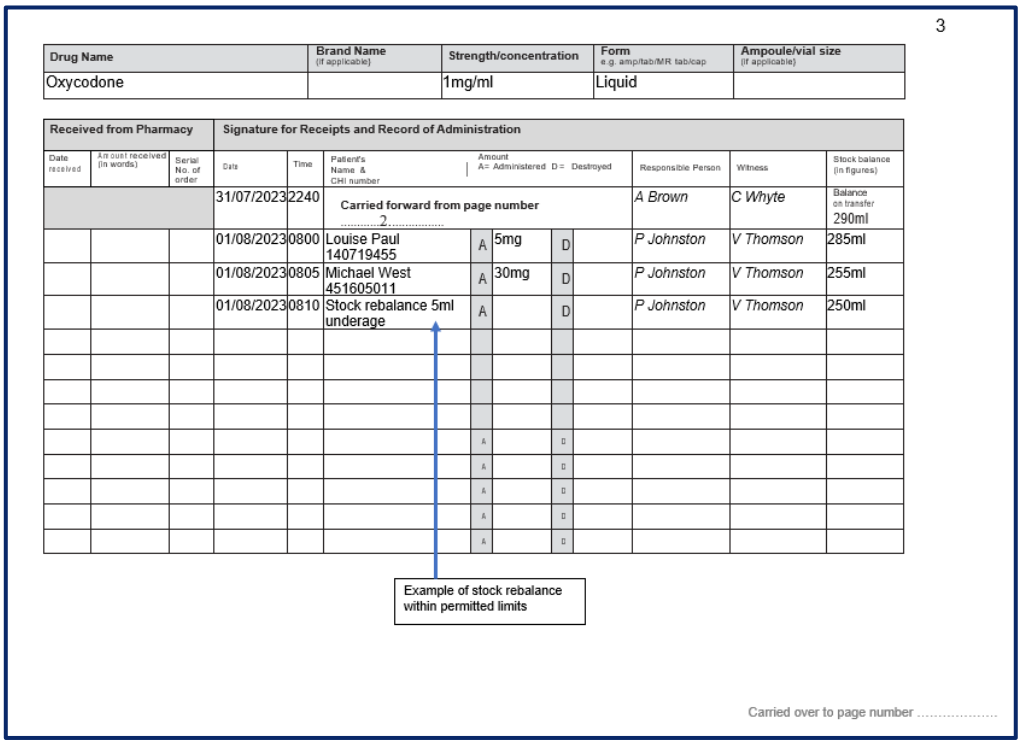
1.14.1.2 **Underage Discrepancy**

- **Oxycodone 1mg/mL Liquid**

  Oxycodone liquid is a very viscous liquid therefore if the discrepancy is an underage of **less than or equal to 10mL** i.e. the difference between the Controlled Drug Record Book (Register) balance and the physical balance, two members of authorised registered healthcare staff must rebalance the stock in the Controlled Drug Record Book (Register). This must be annotated in the Controlled Drug Record Book (Register) as:

  - 'Stock rebalance Xml underage'
  - The entry signed by the two members of authorised registered healthcare staff.
  - A DATIX is not required for an underage discrepancy less than 10mL for Oxycodone mg/mL liquid

Example of stock rebalance, within permitted limits, in the Controlled Drug Record Book (Register):



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Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Oxycodone		1mg/ml	Liquid	

Received from Pharmacy			Signature for Receipts and Record of Administration									
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered		D = Destroyed		Responsible Person	Witness	Stock balance (in figures)
			31/07/2023	2240	Carried forward from page number ..2..					A Brown	C Whyte	Balance on transfer 290ml
			01/08/2023	0800	Louise Paul 140719455	A	5mg	D		P Johnston	V Thomson	285ml
			01/08/2023	0805	Michael West 451605011	A	30mg	D		P Johnston	V Thomson	255ml
			01/08/2023	0810	Stock rebalance 5ml underage	A		D		P Johnston	V Thomson	250ml

Example of stock rebalance within permitted limits

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If the discrepancy is **over 10mL** refer to section 1.14.2 '[Investigating Discrepancies]'. A DATIX entry is required and the DATIX reference must be recorded in the Controlled Drug Record Book (Register).

- **All other Liquid Controlled Drug Preparations**

  Underage discrepancies in all other liquid CD preparation must be investigated, refer to section 1.14.2 '[Investigating Discrepancies]'. A DATIX entry is required and the DATIX reference must be recorded in the Controlled Drug Record Book (Register).

1.14.2 Investigating Discrepancies

1.14.2.1 If a Schedule 2 CD discrepancy is identified it must be reported and investigated immediately. The Schedule 2 Controlled Drug stock Discrepancy (Ward) Flow Chart must be followed. This is available on the Controlled Drug Governance Team Intranet page:

Controlled Drugs Governance Home (scot.nhs.uk)

1.14.2.2 The registered nurse, midwife and ODP must complete steps 1 and 2 of the Schedule 2 Controlled Drug Discrepancy (Ward) Identified Checklist – Preliminary Checks. This is available on the Controlled Drug Governance Team Intranet page:

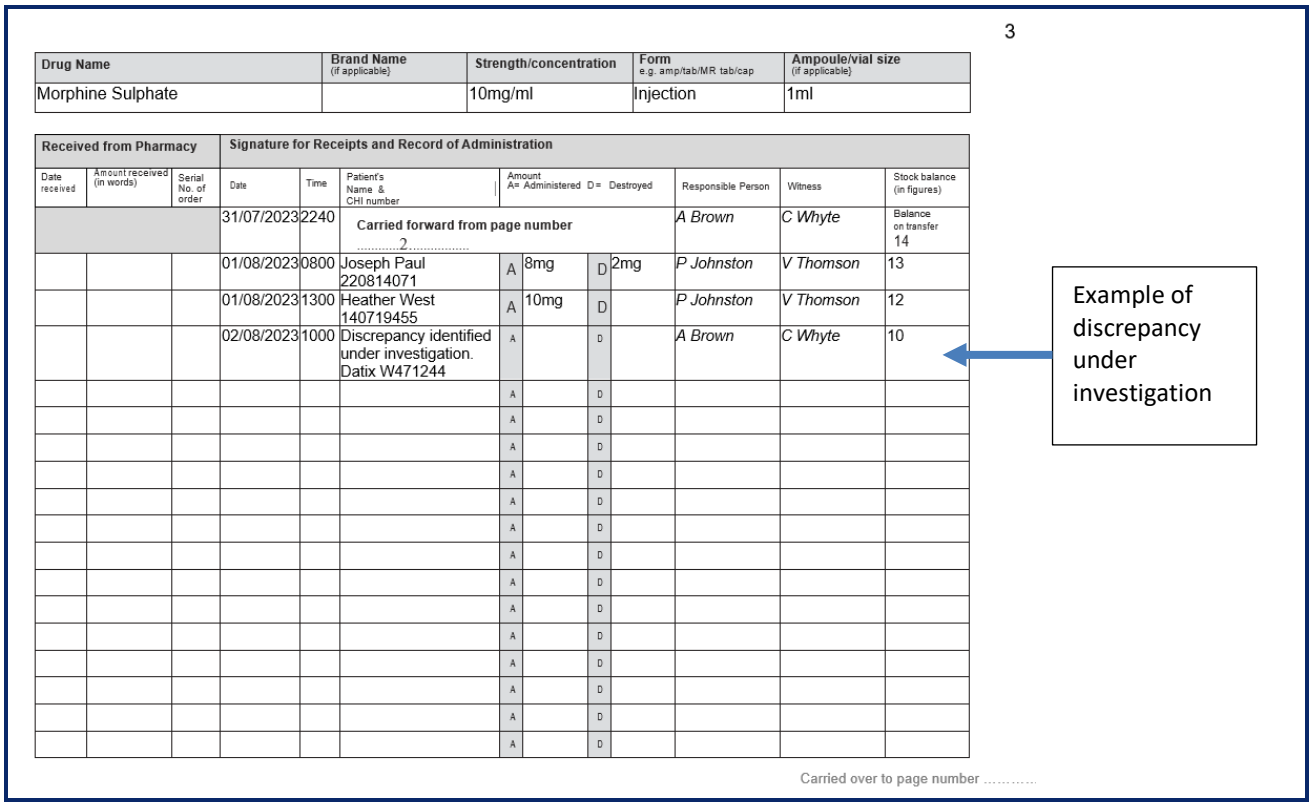
Controlled Drugs Governance Home (scot.nhs.uk)

This includes the following:

- Record details of the discrepancy
- Record of reporting the discrepancy
- Report on Datix

- Update the Controlled Drug Record Book (Register) with current balance, Datix reference, and endorse the entry: “Discrepancy identified, under investigation”. This must be signed by two authorised staff members e.g. registered nurse, midwife or ODP
- Inform ward nurse in charge (senior charge nurse / charge nurse / shift coordinating nurse) of the discrepancy
- Inform the registered nurse, midwife, ODP in charge and forward the completed (step 1 and 2) Schedule 2 Controlled Drug Discrepancy (Ward) Identified Checklist

Example of stock discrepancy under investigation in the Controlled Drug Record Book (Register):



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Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Morphine Sulphate		10mg/ml	Injection	1ml

Received from Pharmacy			Signature for Receipts and Record of Administration									
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered		D= Destroyed		Responsible Person	Witness	Stock balance (in figures)
			31/07/2023	2240	Carried forward from page number 2					A Brown	C Whyte	Balance on transfer 14
			01/08/2023	0800	Joseph Paul 220814071	A	8mg	D	2mg	P Johnston	V Thomson	13
			01/08/2023	1300	Heather West 140719455	A	10mg	D		P Johnston	V Thomson	12
			02/08/2023	1000	Discrepancy identified under investigation. Datix W471244	A		D		A Brown	C Whyte	10
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				

Example of discrepancy under investigation

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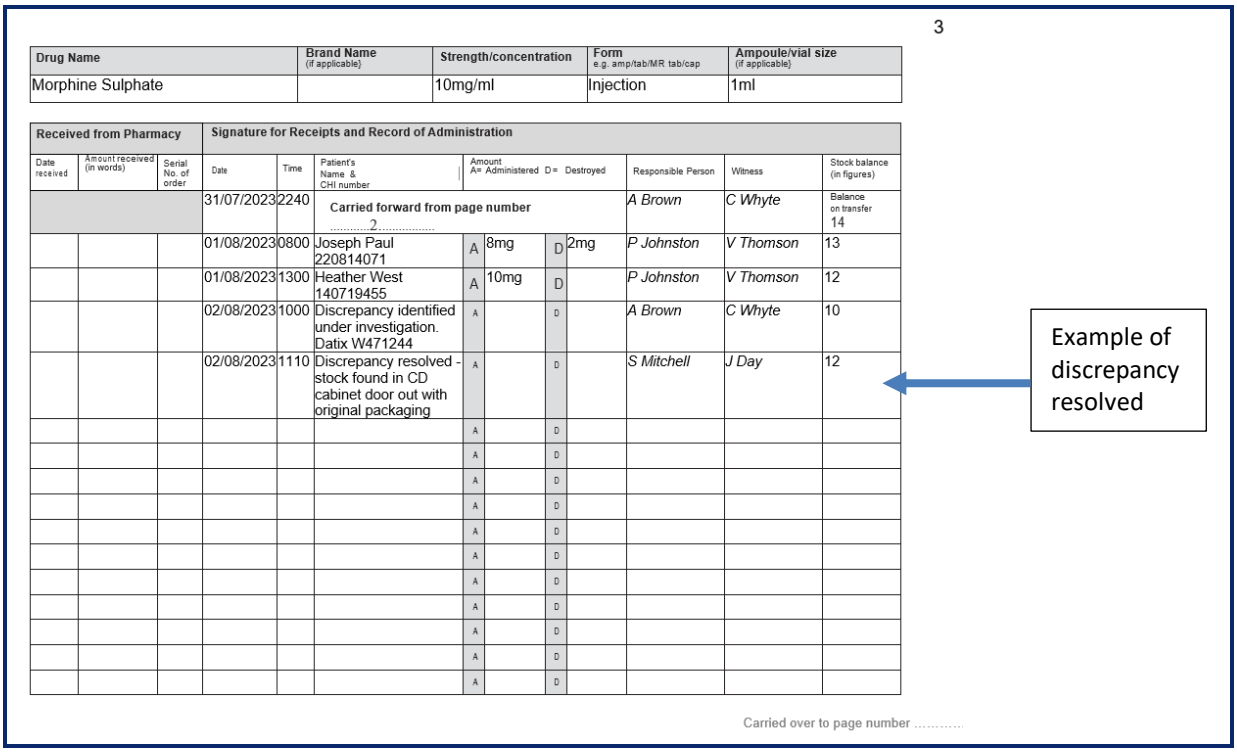
1.14.2.3 The registered nurse, midwife, ODP in charge, or registered nurse delegated by the nurse in charge must complete steps 3 -7 of the Schedule 2 Controlled Drug Discrepancy (Ward) Identified Checklist – Preliminary Checks. This includes the following:

- Complete the preliminary checks
- Update Datix entry

1.14.2.4 If the discrepancy is resolved following completion of the preliminary checklist the registered nurse, midwife, ODP in charge, or registered nurse delegated by the nurse in charge must:

- Update entry in Controlled Drug Record Book (Register), if applicable (the entry must be signed by the witness e.g. registered nurse, midwife or ODP.
- Pass the completed Schedule 2 Controlled Drug Discrepancy (Ward) Identified Checklist – Preliminary Checks to the Senior Charge Nurse to review

Example of discrepancy resolved in the Controlled Drug Record Book (Register):



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Drug Name	Brand Name (if applicable)	Strength/concentration	Form e.g. amp/tab/MR tab/cap	Ampoule/vial size (if applicable)
Morphine Sulphate		10mg/ml	Injection	1ml

Received from Pharmacy			Signature for Receipts and Record of Administration									
Date received	Amount received (in words)	Serial No. of order	Date	Time	Patient's Name & CHI number	Amount A= Administered		D= Destroyed		Responsible Person	Witness	Stock balance (in figures)
			31/07/2023	2240	Carried forward from page number ..2..					A Brown	C Whyte	Balance on transfer 14
			01/08/2023	0800	Joseph Paul 220814071	A	8mg	D	2mg	P Johnston	V Thomson	13
			01/08/2023	1300	Heather West 140719455	A	10mg	D		P Johnston	V Thomson	12
			02/08/2023	1000	Discrepancy identified under investigation. Datix W471244	A		D		A Brown	C Whyte	10
			02/08/2023	1110	Discrepancy resolved - stock found in CD cabinet door out with original packaging	A		D		S Mitchell	J Day	12
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				
						A		D				

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1.14.2.5 If the Schedule 2 CD discrepancy is not resolved by completing the preliminary checklist the registered nurse, midwife, ODP in charge, or registered nurse delegated by the nurse in charge must inform the professional nurse lead (Clinical Nurse Manager and/or Senior Charge Nurse and/or Charge Nurse and/or Co-ordinating Charge Nurse)

1.14.2.6 The professional nurse lead (Clinical Nurse Manager and/or Senior Charge Nurse and/or Charge Nurse and/or Co-ordinating Charge Nurse) must complete the Schedule 2 Controlled Drug Discrepancy (Ward) Identified Checklist – Investigation Checklist. This is available on the Controlled Drug Governance Team Intranet page:

Controlled Drugs Governance Home (scot.nhs.uk)

This includes the following:

- Review of preliminary checks
- Escalate to nurse management for the site (for unresolved discrepancies)
- Inform pharmacy (for unresolved discrepancies)
- Inform Police Scotland (for unresolved discrepancies)
- Data gathering and review (for unresolved discrepancies)
- Meeting with nurse management, professional nurse lead and pharmacy (for unresolved discrepancies)
- Identify further actions required (for unresolved discrepancies)
- Update Datix

1.14.2.7 All completed checklists and data gathered should be uploaded to the Datix entry.

1.15 Movement/Distribution of Controlled Drugs within and outside the hospital

Movement/distribution of CDs is likely to involve the following situations:

- Collection by ward staff from the pharmacy.
- Collection by porters from the pharmacy.
- Delivery by pharmacy staff to wards, departments, theatres.
- Collection by patient or representative for outpatient items only.
- Delivery by hospital porter/driver.
- Delivery by commercial courier (for example, taxi out-of-hours).

1.15.1 Methods of Transfer

1.15.1.1 CDs must be transferred or conveyed in a secure, sealed, tamper-evident container.

1.15.1.2 CDs must not be transported in pneumatic tubes or posted.

1.15.2 Records of Transfer

1.15.2.1 At each point where a CD moves from the authorised possession of one person to another, a signature for receipt must be obtained.

1.15.3 Messengers

1.15.3.1 The person who conveys the CD acts as a messenger, that is to say they carry a sealed or tamper-evident container and is responsible for delivering the container intact.

1.15.3.2 The person acting as the messenger must:

- Ensure destination is known.
- Be aware of safe storage and security, the importance of handing over the item to an authorised person, as instructed when collecting the package, and obtaining a signature for delivery on the delivery document.
- Have a valid ID badge.

1.15.3.3 CDs must only be handed to members of staff who are wearing valid NHS ID badges.

1.15.3.4 CDs should be transported using NHS transport whenever possible. Where a commercial courier or taxi driver is responsible for conveying a CD, they must be asked to show their valid company ID.

1.15.3.5 Taxi drivers or commercial couriers should not be made aware that CDs are being transported as this may increase the potential for diversion or may discourage taxi drivers from carrying CDs. As a matter of good practice, the taxi driver identity number should be recorded. Contract taxi companies should be informed that taxi driver proof of identity will be routinely requested.

1.15.4 Transfer of Controlled Drugs from Ward to Ward or Theatre to Ward

1.15.4.1 The three situations in which this is most likely to arise are:

- When a patient is receiving a CD by means of syringe pump (PCA pump) or infusion.
- When a patient has their own CDs for administration.
- When a CD has been dispensed on a "named patient" basis.

Refer to section 1.10 'Management of Controlled Drugs when Patients are transferred to other Wards or Departments'.

1.16 Clinical Trials

Please refer to NHS Lothian *Safe Use of Medicines Procedures* 'Medicines used for Research and Clinical Trials'

1.16.1 General Information - Clinical trials

1.16.1.1 The procedures for the use of CDs in clinical trials must comply with the Misuse of Drugs Regulations and with local policies governing the management of clinical trial medicines, in addition to clinical trials legislation and MHRA guidance on clinical trials.

1.16.1.2 All clinical trial CDs must be stored in the CD cabinet, segregated from stock CDs. They do not necessarily need to be stored in a separate CD cabinet. A separate page in the Controlled Drug Record Book (Register) must be used to record receipt and issues in addition to clinical trial documentation so that a running balance of trial stock can be kept.

1.16.1.3 If a discrepancy is identified, then it must be reported on DATIX in accordance with local procedures. A note in the file should be stored with all the clinical trials documentation. The sponsor and investigator should be informed as well as the Lead Pharmacist for the hospital site, the pharmacy clinical trials team and the Controlled Drug Accountable Officer.

1.16.1.4 For double blind trials in which only one arm involves a CD, pharmacy staff may be unaware which packs contain CDs. In this situation, all supplies must be treated as CDs until the end of trial.

1.16.1.5 For trials that involve the use of Schedule 1 CDs, such as cannabinoids, a license from the Home Office must be obtained before the item is received into stock or supplied. The licence should normally be held by the Lead Pharmacist for the hospital site and/or the Controlled Drug Accountable Officer. A copy must be kept with the trial protocol.

1.16.2 Labelling - Clinical Trials

1.16.2.1 All clinical trial CDs must be labelled and dispensed in accordance with the specific trial protocol in addition to the Misuse of Drugs Regulations requirements.

1.16.3 Disposal – Clinical Trials

1.16.3.1 The clinical trial protocol must stipulate requirements for disposal of CDs. Clinical trial CDs must be destroyed in the same way as other CDs (refer to section 1.11 'Returns/Disposal/Destruction of CDs'). However, this destruction may need to be carried out following the monitoring instructions with the trial sponsor. For example, the sponsor may wish to carry out an independent reconciliation (in addition to the check and reconciliation carried out by the pharmacy department) prior to any destruction.

1.16.4 Clinical trial Controlled Drugs Returned by Patients

1.16.4.1 The clinical trial protocol must be approved by NHS Lothian and stipulate requirements for handling of CDs returned by patients. The pharmacy must establish secure arrangements for the storage (and destruction) of CD clinical trial medicines returned by

patients. Drug accountability records must be completed promptly when a patient returns the CD clinical trial medicine and opportunities for diversion should be minimised.

1.16.5 Arrangements for research departments

1.16.5.1 If a hospital pharmacy supplies CDs to a research department, then the same governance arrangements for safe use must apply as for elsewhere in the organisation. All the activities must be covered by procedures which comply with NHS Lothian Medicines Policy and Procedures, and the processes should be robust and auditable.

1.17 Management of Patients' Own Controlled Drugs

Also refer to and follow NHS Lothian *Safe Use of Medicines Procedures* *'Use of Patient's Own Medicines'*.

1.17.1 If a patient brings their own CDs i.e. Schedule 2 and Schedule 3 CDs subject to safe custody regulations, into hospital on admission, these must be stored in the CD cabinet and entered in the Patients' Own Controlled Drug Record Book.

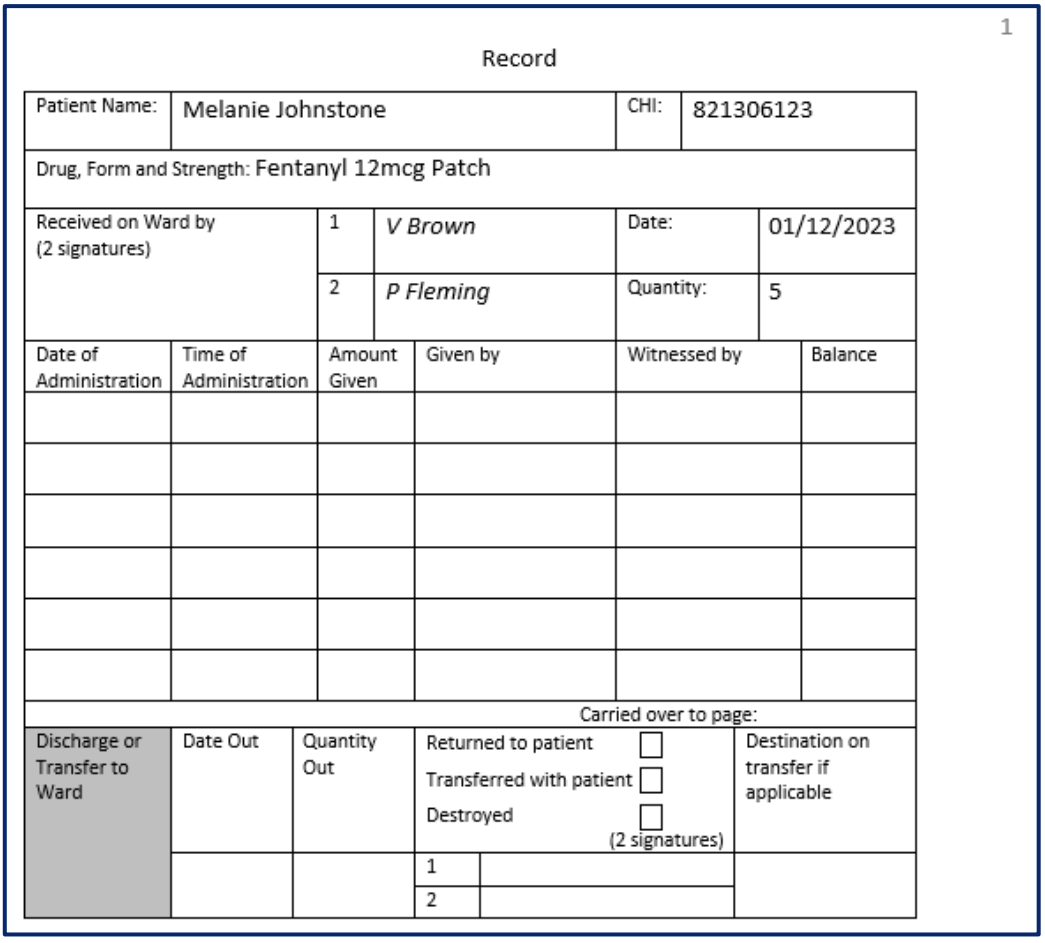
1.17.2 It may be appropriate to use patient's own CDs whilst they are in hospital. They must be checked for suitability according to the NHS Lothian *Safe Use of Medicines Procedures* *'Use of Patients' Own Medicines*', to ensure that they are fit for purpose.

1.17.3 Patients' Own CDs must be appropriately segregated from ward stock CDs.

1.17.4 Each CD per patient must be recorded on a separate page in the Patients' Own Controlled Drug Record Book. Refer to section 1.4.3 'Record Keeping - Controlled Drug Record Book (Register) and Patients' Own Controlled Drug Record Book'.

1.17.5 On receipt of patients' own CDs two registered nurses or midwives must confirm the drugs and quantities received and record in the Patients Own Controlled Drug Record Book. Both registered nurses or midwives must sign the page in the Patients' Own Controlled Drug Record Book to confirm the receipt.

Example of receipt of patient's own CDs in the Patients' Own Controlled Drug Record Book:



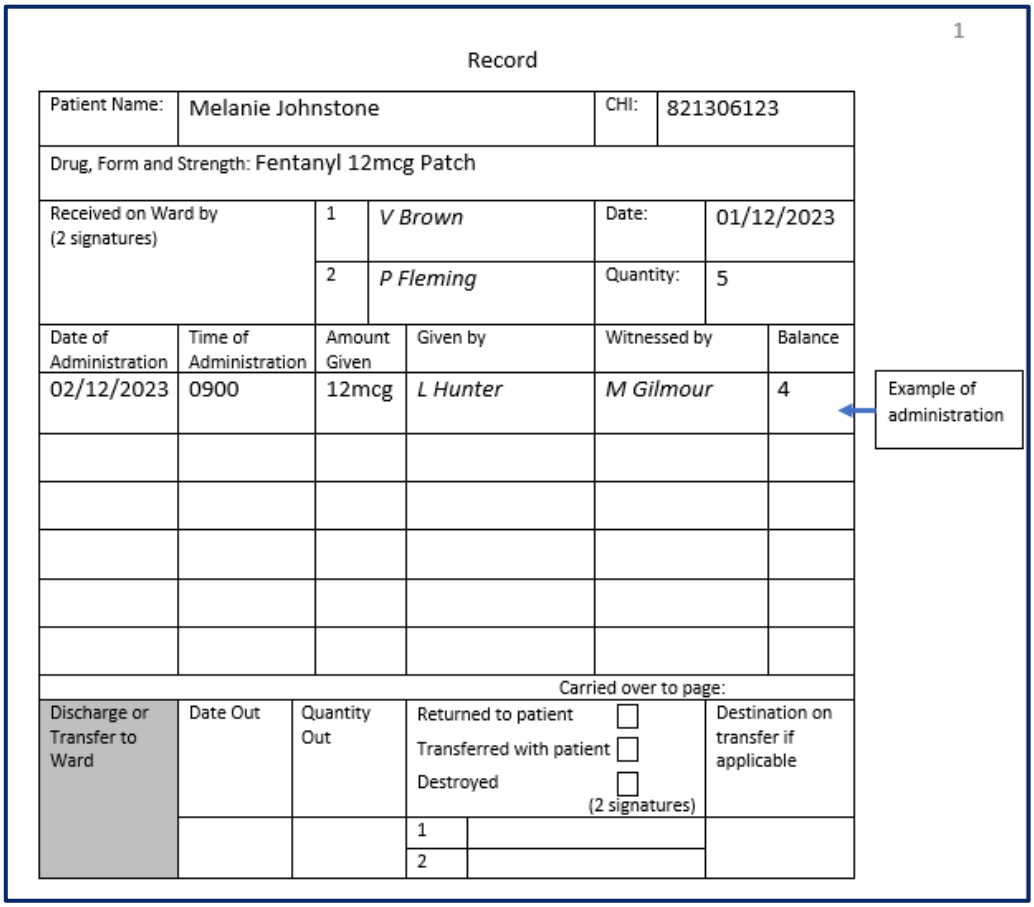
1

Record

Patient Name:	Melanie Johnstone			CHI:	821306123	
Drug, Form and Strength: Fentanyl 12mcg Patch						
Received on Ward by (2 signatures)		1	*V Brown*	Date:	01/12/2023	
		2	*P Fleming*	Quantity:	5	
Date of Administration	Time of Administration	Amount Given	Given by	Witnessed by		Balance
Carried over to page:						
Discharge or Transfer to Ward	Date Out	Quantity Out	Returned to patient ☐ Transferred with patient ☐ Destroyed ☐ (2 signatures)			Destination on transfer if applicable
			1			
			2			

1.17.6 If doses are administered to a patient using the patients' own CD stock, the administration record must be recorded in the Patients' Own Controlled Drug Record Book. Refer to section 1.9 '[Administration of Controlled Drugs]'.

Example of an administration entry in the Patients' Own Controlled Drug Record Book



1

Record

Patient Name:	Melanie Johnstone			CHI:	821306123
Drug, Form and Strength: Fentanyl 12mcg Patch					
Received on Ward by (2 signatures)	1	*V Brown*		Date:	01/12/2023
	2	*P Fleming*		Quantity:	5

Date of Administration	Time of Administration	Amount Given	Given by	Witnessed by	Balance
02/12/2023	0900	12mcg	*L Hunter*	*M Gilmour*	4

Example of administration

Carried over to page:

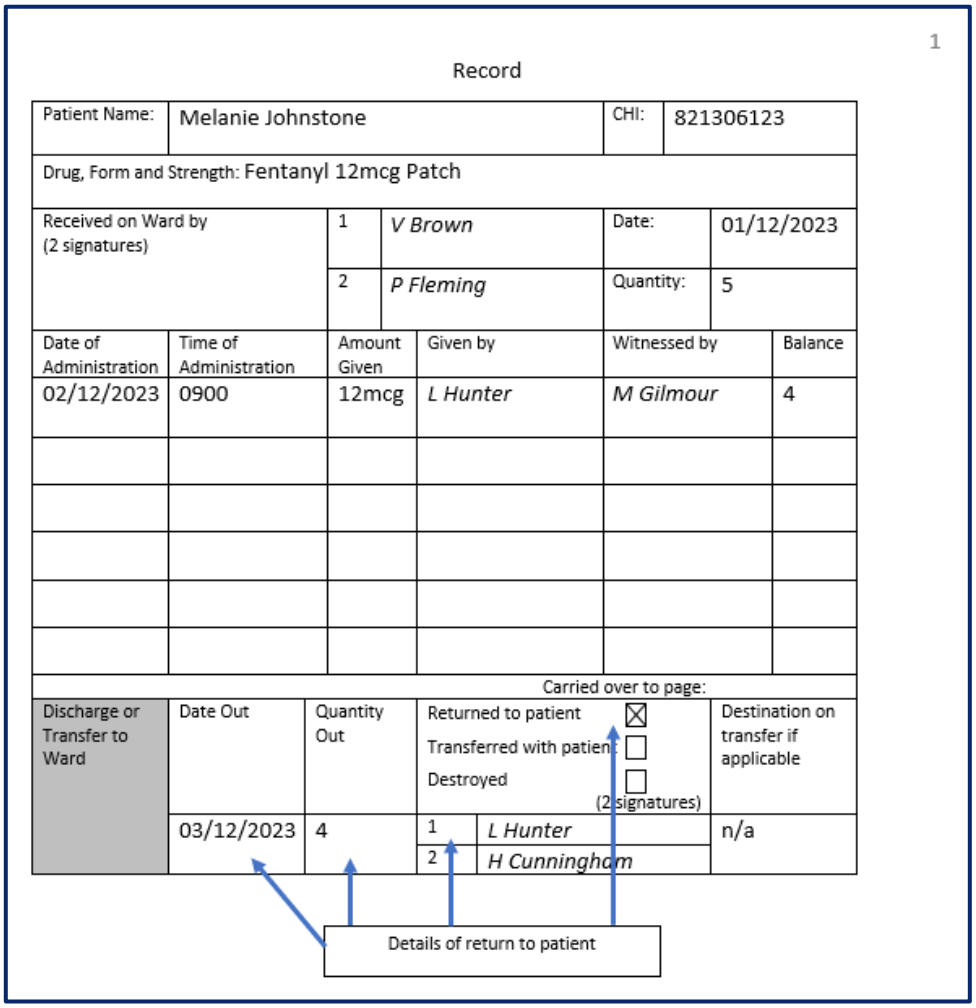
Discharge or Transfer to Ward	Date Out	Quantity Out	Returned to patient ☐ Transferred with patient ☐ Destroyed ☐ (2 signatures)		Destination on transfer if applicable
			1		
			2		

1.17.7 The balance of all patients' own CD stock must be checked daily as part of the daily stock check. Refer to section 1.12 '[Ward, Theatre and Department Controlled Drug Stock Checks]'.

1.17.8 In the event the patient is transferred to another ward, the patient's own CDs must be transferred with them. Refer to section 1.10.1 '[Transfer of Patient's Own Controlled Drugs to another Hospital, Ward or Department]'.

1.17.9 If patients own medicine is returned to the patient on discharge, their CDs must be written out of the Patients' Own Controlled Drug Record Book. The quantity returned to the patient, date returned to patient and destination i.e. returned to patient, must be completed in the Patients' Own Controlled Drug Record Book. The entry must be signed by two registered nurses or midwives.

Example of patient's own CDs returned to the patient in the Patients' Own Controlled Drug Record Book:



1

Record

Patient Name:	Melanie Johnstone			CHI:	821306123
Drug, Form and Strength: Fentanyl 12mcg Patch					
Received on Ward by (2 signatures)	1	*V Brown*		Date:	01/12/2023
	2	*P Fleming*		Quantity:	5

Date of Administration	Time of Administration	Amount Given	Given by	Witnessed by	Balance
02/12/2023	0900	12mcg	*L Hunter*	*M Gilmour*	4

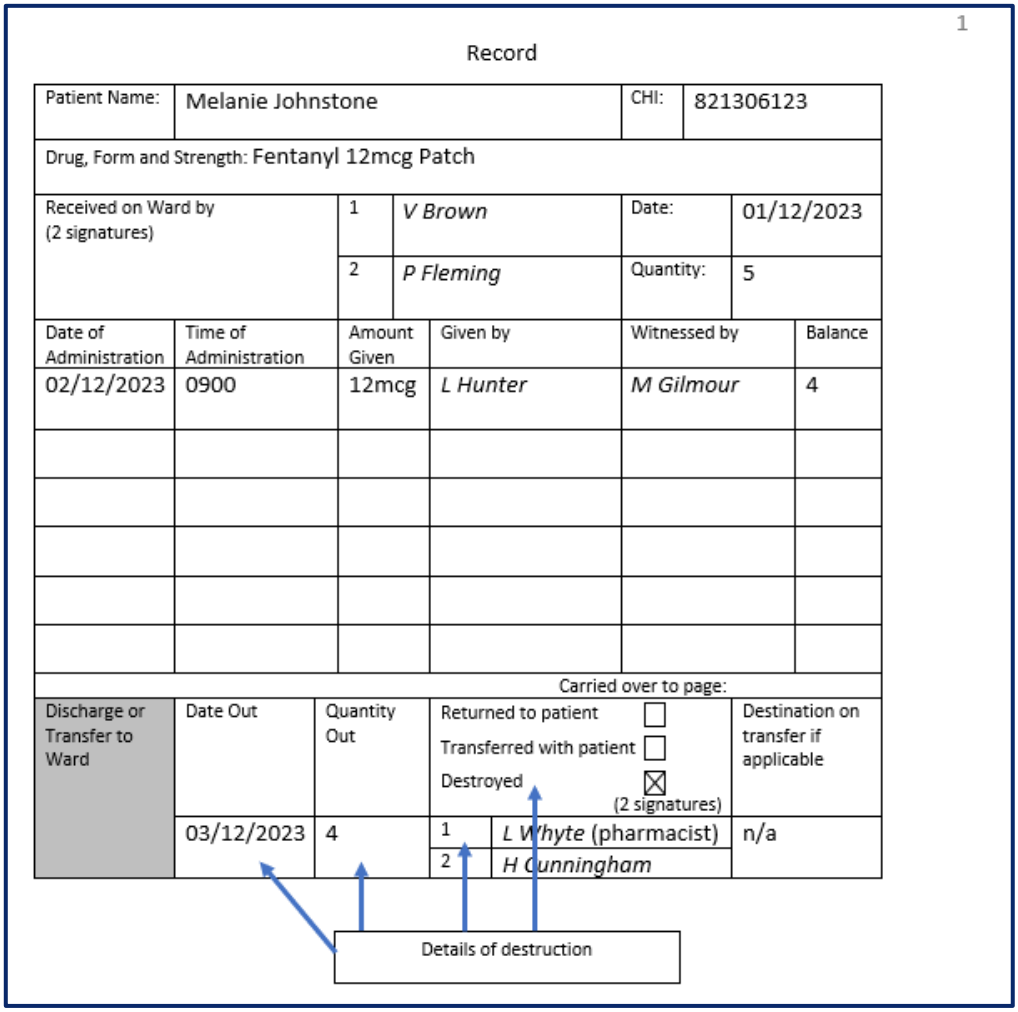
Carried over to page:

Discharge or Transfer to Ward	Date Out	Quantity Out	Returned to patient ☒ / Transferred with patient ☐ / Destroyed ☐ (2 signatures)		Destination on transfer if applicable
	03/12/2023	4	1	*L Hunter*	n/a
			2	*H Cunningham*	

Details of return to patient

1.17.10 All CDs brought into hospital by patients remain their own property. They may be destroyed on the ward if they are no longer required. They must only be disposed of with the consent of the patient. This must be destroyed by a registered pharmacist or registered pharmacy technician and a registered nurse. A record of the destruction i.e. quantity, date, destination i.e. 'destroyed', must be completed in the Patients' Own Controlled Drug Record Book. The entry must be signed by the registered pharmacist or registered pharmacy technician and the registered nurse involved in the destruction. Refer to section 1.11 'Return/Disposal/Destruction of Controlled Drugs'.

Example of patient's own CDs destroyed in the Patients' Own Controlled Drug Record Book:



1

Record

Patient Name:	Melanie Johnstone			CHI:	821306123
Drug, Form and Strength: Fentanyl 12mcg Patch					
Received on Ward by (2 signatures)	1	*V Brown*		Date:	01/12/2023
	2	*P Fleming*		Quantity:	5

Date of Administration	Time of Administration	Amount Given	Given by	Witnessed by	Balance
02/12/2023	0900	12mcg	*L Hunter*	*M Gilmour*	4

Carried over to page:

Discharge or Transfer to Ward	Date Out	Quantity Out	Returned to patient ☐ Transferred with patient ☐ Destroyed ☒ (2 signatures)		Destination on transfer if applicable
	03/12/2023	4	1	*L Whyte* (pharmacist)	n/a
			2	*H Cunningham*	

Details of destruction

1.18 Self-Administration of Controlled Drugs

The procedure for self-administration of medicines must be followed for the self-administration of CDs.

1.19 Out-of-Hours Supply of Controlled Drugs

1.19.1 The professional lead (registered nurse, midwife or ODP) in charge of a ward, theatre, or department, is responsible for ensuring that adequate stocks of CDs are available to ensure that doses are not missed or delayed. There must be a system in place to ensure that adequate supplies of required medicines are ordered during the pharmacy opening hours.

1.19.2 If supplies of CDs are required when the pharmacy is closed, the procedure for out-of-hours supply must be followed.

1.19.3 Schedule 2 CDs may only be transferred between wards, theatres, and departments to support the administration of a patient with an immediate need when the pharmacy is closed, unless under emergency situations, and following consultation with the ward or on-call pharmacist. Refer to section 1.20 'Transferring Schedule 2 Controlled Drugs between Wards, Theatres and Departments'.

1.20 Transferring Schedule 2 Controlled Drugs between Wards, Theatres and Departments

1.20.1 The professional lead (registered nurse, midwife or ODP) in charge of a ward, theatre, or department, is responsible for ensuring that adequate stocks of CDs are available to ensure that doses are not missed or delayed. There must be a system in place to ensure that adequate supplies of required medicines are ordered during the pharmacy opening hours.

1.20.2 Schedule 2 CDs may only be transferred between wards, theatres, and departments to support the administration to a patient with an immediate need when the pharmacy is closed unless and following consultation with the on-call pharmacist. Schedule 2 CDs may be transferred within pharmacy working hours under emergency situations and following consultation with the ward pharmacist. The approval from the pharmacist can be verbal approval, and a record of the pharmacist's name, and GPhC number should be annotated in the Controlled Drug Record Book (Register).

Registered nurses, midwives or ODPs cannot legally transfer Schedule 2 CDs, therefore the transfer must be approved by a pharmacist.

1.20.3 Schedule 2 CDs may be transferred under the following circumstances:

- The registered nurse, midwife or ODP in charge from the supplying ward and transferring ward agree.
- The ward, theatre or department that holds the stock is nearby to the transferring ward, theatre, or department (stock must be transferred from the nearest ward that holds stock)

1.20.4 A single dose must be transferred at the time it is required. If further doses are required stock must be obtained from the pharmacy, or when the pharmacy is closed arrangements agreed with the on-call pharmacist regarding obtaining further supplies.

1.20.5 Stock i.e. more than one dose, must not be transferred between the two Controlled Drug Record Books (Registers).

1.20.6 If the patient cannot be moved to the supplying ward, the registered nurse or midwife in charge of the ward, theatre, or department, from which the dose is being supplied from, must securely take the original pack of the CD medicine and the Controlled Drug Record Book (Register) to the requiring ward.

1.20.7 The registered nurse, midwife or ODP in charge from both the supplying and receiving ward must check the prescription and administration record, administer, and witness the administration, and update the supplying ward's Controlled Drug Record Book (Register) of the supplying ward with details of the administration. This should be signed by both registered nurses, midwives or ODP in charge.

If the CD is not recorded in the Controlled Drug Record Book (Register) i.e. non-Schedule 2 CDs, the medicines transfer book must be used for the transfer of single doses.

1.20.8 The registered nurse, midwife or ODP in charge, from the supplying ward, will return the remaining CD medicine stock and Controlled Drug Record Book (Register) to the

supplying ward stock. A stock balance check must be completed by two registered nurses, midwifes or ODP's on return to the supplying ward, and recorded in the Controlled Drug Record Book (Register).

1.21 Ward, Theatre or Department Closure/Relocation

1.21.1 Ward, Theatre or Department Closure – Permanent

1.21.1.1 In the event of a permanent ward closure the professional lead (nurse, midwife or ODP) in charge of the ward, theatre or department must liaise with pharmacy to make arrangements for the return or destruction of CDs. Refer to section 1.11 'Return/Disposal/Destruction of Controlled Drugs'.

1.21.1.2 The professional lead (nurse, midwife or ODP) in charge of the ward, theatre or department must ensure the controlled stationery for the ward, theatre or department is retained securely as per section 1.4.2 'Supply, Receipt, Storage and Retention of Controlled Drug Stationery'.

1.21.1.3 Minimal stock must be kept where possible prior to closure with any excess being returned to pharmacy or destroyed.

1.21.2 Ward, Theatre or Department Closure - Temporary

1.21.2.1 In the event of a temporary ward closure the professional lead (nurse, midwife or ODP) in charge of the ward, theatre or department must liaise with pharmacy to undertake a risk assessment. The risk assessment must include:

- The likelihood of detection of an intruder, the deterrents in place and the particular medicines being stored.
- Arrangements for the removal and temporary storage of CDs by pharmacy, if appropriate.
- Arrangements for the return of CDs to the pharmacy for re-use, if appropriate.
- Arrangements for the destruction of CDs, by pharmacy, if applicable.
- Arrangements for the secure storage of CD stationery.
- Arrangements for the secure storage of CDs during temporary closure.
- Arrangements for the return of CDs to ward, theatre or department, including reconciliation with list of CDs removed, if appropriate.
- Arrangement for restocking, if appropriate.

1.21.3 Ward, Theatre, or Department Relocation

1.21.3.1 Where a ward/department moves to another location, a decision must be made by the professional lead (nurse, midwife or ODP) in charge of the ward, theatre or department and a member of the pharmacy team as to whether its CDs and CD stationery may be transferred.

1.21.3.2 The professional lead (nurse, midwife or ODP) in charge of the ward, theatre or department and a member of the pharmacy team must carry out a risk assessment for the management and security of CDs during ward moves. This must include:

- The likelihood of detection of an intruder, the deterrents in place and the particular medicines being stored.

- Arrangements for the removal and temporary storage of CDs by pharmacy, if appropriate.
- Arrangements for the return of CDs to the pharmacy for re-use, if appropriate.
- Arrangements for the destruction of CDs, by pharmacy, if appropriate.
- Arrangements for the transfer of CDs and CD stationery.
- Arrangement for restocking, if appropriate.
- Arrangement for the movement of CD stock, if appropriate.

1.21.3.3 Minimal stock must be kept where possible prior to the relocation with any excess being returned to pharmacy or destroyed.

1.21.3.4 CDs and CD stationery must be transferred in a secure, sealed, tamper evident container.

1.21.3.5 Two registered healthcare professionals, (one may be a registered pharmacist/ pharmacy technician) must check the stock against the Controlled Drug Record Book (Register) when packing the CDs into a tamper evident container. The sealed container must be transferred by authorised staff i.e., valid NHS Lothian ID badge, to the new location. Appropriate documentation must be used to record who has possession of the CD container at all times.

1.21.3.6 On arrival at new location:

- The container must be signed for by the registered nurse, midwife or ODP in charge.
- Two registered healthcare professionals (one may be a registered pharmacist/ pharmacy technician) must check/witness the contents of the container and record this in the Controlled Drug Record Book (Register) when transferring the CDs to the CD cabinet.
- Any discrepancies must be reported in accordance with this policy. Refer to NHS Lothian *Safe Use of Medicines Procedures* - Medication Incidents.
- Alter ward name on the Controlled Drug Order Book.

1.22 Patients on Dispensing Instalments e.g. Methadone, Admitted or Discharged to/from Hospital

1.22.1.1 Patients who are receiving their medication e.g. Methadone, in instalments in the community may be dispensed their medication by instalments e.g. daily, weekly etc. Consumption of the dose may be supervised by the community pharmacist. Frequency of dispensing takes into account the individual patient's dose, stability, and personal circumstances.

1.22.1.2 If a patient receiving their medication by instalments is admitted to hospital, it is essential that hospital and community colleagues work together to ensure that the supply arrangements are modified appropriately during the period of the hospital stay and at discharge.

1.22.1.3 On admission (person dealing with patient's admission)

- Contact the prescriber and the community pharmacist to confirm that the patient is prescribed the medication, and to inform them of the admission. Obtain the following information:
  - Current dose
  - Frequency of supply and whether suspended or not
  - When last dose was dispensed/supervised
  - Number of days supply given (if not daily dispensing)
- Advise the community pharmacist that no further supplies should be given and ask the prescriber to cancel or suspend the prescription, as appropriate. Remove any of the medicine that is in the patient's possession and obtain consent for use during the hospital stay if suitable, or destruction if not suitable. Document all these details in the patients' healthcare record. Maintain a record in the Patients' Own Controlled Drug Record Book, where applicable i.e. Schedule 2 CDs.

1.22.1.4 On discharge (person dealing with patient's discharge)

- Contact the prescriber and community pharmacist in the community to
  - Inform them of the agreed discharge date and time.
  - Confirm the current dose and when the last dose will be administered before discharge.
  - Confirm that the usual prescriber in the community will make the necessary arrangements with the community pharmacist to either provide a new prescription or re-instate the suspended prescription if appropriate.
  - Confirm if any unused supplies that were brought in on admission can be returned to the patient or if these should be destroyed.
- Make sure that suitable arrangements have been made to allow the patient to collect the next due dose following discharge.
- Administer the daily dose on the ward before the patient is discharged unless alternative arrangements have been made.

- Inform the patient of the arrangements for the next dose.
- Do not provide a discharge supply unless a dose, or doses are required until the regular arrangement in the community is put in place.

1.23 Patient Controlled Analgesia (PCA)

The local procedure for PCA must be followed at all times.

1.23.1 CDs for administration via a PCA device should be prescribed on the relevant PCA infusion chart stating the drug, concentration, bolus dose, lock out time and rate of background infusion as appropriate, and as a placeholder drug on electronic prescription and administration record chart, or relevant paper prescription and administration record chart in areas where HEPMA is not in use.

1.23.2 Two registered practitioners that have been trained and assessed as competent must be present during the set up and start of the device. One must prepare the CD to be administered and attach the device to the patient, the other must check each step. They must both verify the programme against the written prescription and must sign the administration monitoring chart, as a record of this check. Both practitioners are equally accountable for the process.

1.23.3 The following details should be recorded in the Controlled Drug Record Book (Register):

- Date and time when PCA commenced
- Name of patient
- Quantity in syringe
- Form (name, form, and strength) in which administered
- Name/signature of practitioners who set up the PCA
- Name of the prescriber
- Balance in stock

1.23.4 When the PCA is discontinued, the time, date, and the residual amount of drug in milligrams should be recorded on the PCA chart together with the signatures of the two practitioners involved. The residual CD must be disposed of, and a record made on the administration monitoring chart. The residual CD must be disposed of as per section 1.11.4 'Disposal of Small Amounts of Controlled Drugs'.

1.24 Suspicious Substances

1.24.1 The NHS does not permit the use, possession, or supply of illegal substances on its premises. For the purposes of this procedure, a substance is suspicious if the person in possession cannot reasonably explain why they have it, or there is any doubt about its nature. This includes Novel Psychoactive Substances (NPS) or “Legal Highs” as these may contain CDs.

1.24.2 Schedule 1 CDs include the hallucinogenic drugs, for example, LSD, ecstasy, cannabis. The class of persons who may lawfully possess them is strictly limited, and does not include registered pharmacists or other clinicians, except under licence granted by the Home Office.

1.24.3 A nurse may only take possession of a Schedule 1 CD for the purpose of handing it to a police officer, or to a person authorised to destroy it. The nurse is not authorised to supply; therefore, it is illegal for the nurse to return it to the patient or patient representative.

1.24.4 A registered pharmacist is authorised to take possession of a Schedule 1 CD in order to destroy it, or to hand it to a police officer or to another person authorised to destroy it.

1.24.5 When a member of staff takes possession of a suspicious substance, it is important that all actions related to the taking into safe custody or destruction of such substances are fully and correctly documented and witnessed. Also, accurate records may be required for evidence if matters proceed to a court case.

1.24.6 If a patient is found in possession of a suspicious substance, the nurse or other member of staff should inform the patient that the substance is to be removed for destruction. Unless large quantities of drugs are involved, the main aim is to ensure that the drugs are handled and destroyed in a safe and legal manner.

1.24.7 Where large quantities of unauthorised drugs or other substances are found on a patient’s person, the police should always be informed and fully assisted in their enquiries. It is recommended that in these circumstances the local police station is contacted directly. The police may attend the ward and initiate enquiries. In these circumstances, public interest overrides that of confidentiality.

1.24.8 Discovery in the hospital setting of quantities of unauthorised drugs consistent with the patient’s own personal use rarely leads to successful prosecution. Furthermore, a heavy-handed response can compromise patient care and cause considerable disruption of ward routines and the waste of much time and effort. The police are aware of this and do not wish to compromise patient care and recognise that the delicacy of the circumstances demands a balanced and sensitive approach. Therefore, the decision to contact the police or dispose lawfully of the substance should be taken jointly by the lead nurse/midwife in conjunction with the consultant or senior doctor with clinical responsibility for the patient.

1.24.9 If the patient refuses to hand over the suspicious substance, the police should be informed, and they will remove the suspicious substance when they attend in these circumstances.

1.24.10 The member of staff finding the substance should immediately inform the registered nurse, midwife or ODP, in charge of the ward or department.

1.24.11 The nurse in charge/lead midwife or manager in charge of the ward or department should contact the clinical nurse manager/duty nurse or midwife manager, and the consultant or senior doctor in charge of the patient and request their attendance.

1.24.12 The person finding the suspicious substance, the nurse in charge/lead midwife or department manager and the clinical nurse manager/duty nurse or midwife manager should complete Part A of the form 'The removal and destruction of suspicious substances' (see link below for form).

'The Removal and Destruction of Suspicious Substances' form is available on the NHS Lothian Intranet: Form for the removal or destruction of suspicious substances (scot.nhs.uk)

1.24.13 An entry should also be made in a separate page in the back of the Controlled Drug Record Book (Register) or Patients' Own Controlled Drugs Record Book, headed "Suspicious Substances" stating 'received one sealed package of a suspicious substance from patient, CHI number', witnessed and signed by two registered nurses. The sealed package can be an envelope signed across the seal by two registered nurses. This ensures the sealed package is tamper evident.

1.24.14 Where it is agreed by the clinical nurse manager/ duty nurse or midwife manager and the patient's consultant or senior doctor that the quantity of the substance found is consistent with patient's own personal use, then the ward/clinical registered pharmacist should be requested to attend to destroy the substance. In this case, Parts B and C of the form 'The removal and destruction of suspicious substances' (see link below for form) should be completed as indicated, by the clinical nurse manager/ duty nurse or midwife manager, consultant/senior doctor, registered pharmacist, and witness. An entry must be made in the Controlled Drug Record Book (Register) or Patients' Own Controlled Drug Record Book with details of the destruction i.e. date, quantity destroyed, signature of registered pharmacist and witness, and balance updated. If the patient objects to this course of action, the local police must be contacted.

1.24.15 The suspicious substance and form must be stored securely in the CD cabinet until a registered pharmacist can attend. The suspicious substance must be checked daily as part of the daily CD check to ensure the sealed package is intact. All destructions should be undertaken using a denaturing kit.

1.24.16 The original copy of the form should be filed in the patient's medical notes and one copy retained by the pharmacy department in a designated folder for 2 years.

1.24.17 Where either the clinical nurse manager/duty nurse or midwife manager or the consultant or senior doctor in charge, or both, consider that the quantity of the substance found is greater than is consistent with the patient's own personal use the local police must be alerted.

1.24.18 Contact the police to arrange for the substance to be collected by a police officer.

1.24.19 The suspicious substance and form should be stored securely in the CD cabinet until police officers can attend. The suspicious substance must be checked daily as part of the daily CD check to ensure the sealed package is intact.

1.24.20 When the police attend, ward and pharmacy staff should cooperate fully. In some cases, the police may not need to know the identity of the patient. However, if this information is required it should be disclosed by the clinical nurse manager/duty nurse or midwife manager or consultant. In the investigation of an alleged criminal offence, confidentiality is unlikely to be a sufficient defence in law against disclosure.

1.24.21 Each case will be treated on its own merits, and it is therefore not possible to indicate the precise action the police will take. However, the patient will never be questioned or removed from the ward or department if it is considered by the consultant or senior doctor in charge to be inappropriate on clinical grounds.

1.24.22 Following enquiries, the police will remove the suspicious substance directly from the ward. Part D of the form 'The removal and destruction of suspicious substances' should be signed by the police officer and the nurse/midwife or registered pharmacist witnessing the transfer. One copy should be given to the police, one copy retained by the pharmacy department in a designated folder for 2 years and the original copy filed in the patient's medical records. An entry must be made in the Controlled Drug Record Book (Register) or Patients' Own Controlled Drug Record Book with details of the destruction i.e. date, quantity destroyed, signature of registered nurse and police officer, and balance updated.

1.25 Controlled Drugs for Midwives

A registered midwife may possess, administer, and supply diamorphine, morphine, pethidine and pentazocine in their own right so far as is necessary for the practice of their profession.

1.25.1 Supplies of Controlled Drugs for Home Confinements

1.25.1.1 In NHS Lothian, for a home confinement, it is important to plan in advance for any requirement for opioids. Women that wish to have diamorphine, morphine, pethidine and pentazocine available to them in labour must obtain a prescription from either their GP or hospital consultant.

1.25.1.2 The medicine dispensed is the property of the mother and may be administered by the midwife providing her care during labour.

1.25.1.3 If a woman booked for a home confinement has not obtained a supply of opioids prior to the onset of labour, and subsequently requests an opioid during labour, she should be transferred to hospital. If a prescription has been obtained but the supply has not yet been dispensed, if feasible, arrangements should be made for the prescription to be dispensed to avoid hospital admission.

1.25.2 Records for Home Confinements

1.25.2.1 Administration of CDs by midwives must be in accordance with locally agreed procedures.

1.25.2.2 A record of administration of the CDs must be kept in the woman's maternity record.

1.25.2.3 Maternity records must be returned to the hospital medical records department when post-natal care is complete.

1.25.3 Returns and Disposal of Controlled Drugs for Home Confinements

1.25.3.1 When a CD has been drawn up but not administered, it should be destroyed by the midwife in the presence of a witness, where possible. A member of the family may act as the witness. Record of disposal must be recorded in the woman's maternity record. Refer to section 1.11 Return/disposal/destruction of Controlled Drugs for methods of disposal.

1.25.3.2 Following confinement, the midwife should advise the woman to destroy opioids that are no longer required, preferably in the presence of the midwife. Alternatively, the woman should be advised to return them to a community pharmacy for disposal.

1.25.3.3 CDs should not normally be removed by the midwife, but if this is necessary for safety and security, the midwife should obtain the woman's agreement in writing in the maternity record before removing the CD from her home and returning it to a community pharmacy for safe disposal.

1.25.4 Use of Opioids by Midwives for Hospital Births

1.25.4.1 Procedures for ordering, receipt, storage and disposal of CDs for use by midwives within the hospital must be the same as those for all wards, theatres and departments.

1.25.4.2 Midwives may administer diamorphine, morphine, pethidine and pentazocine without a prescription written by a registered prescriber, or a Patient Group Direction, provided it is part of their professional practice.

1.25.4.3 There should be a protocol agreed by the multi-professional team for the administration of diamorphine, morphine, pethidine and pentazocine during labour. Opioids required for the relief of pain out with labour should be prescribed by a registered prescriber.

1.25.4.4 Administration must be recorded on the woman's prescription and administration record, in the maternity record and in the Controlled Drug Record Book (Register).

2 Management of Controlled Drugs in Hospital Pharmacies

2.1 Accountability and Responsibility – Hospital Pharmacies

2.1.1 The Lead Pharmacist for the hospital is responsible for the safe and appropriate management of CDs in the pharmacy. Day-to-day management of CDs (for example, receipt into and issue from dispensary stock) in the pharmacy will normally be delegated to a suitably trained, competent registered pharmacy technician or registered pharmacist. However, legal responsibility for CDs remains with the Lead Pharmacist for the hospital.

2.2 Management of Controlled Drugs – Hospital Pharmacies

2.2.1 The pharmacy must have procedures covering all aspects of the safe management of CDs such as ordering, receipt, record-keeping, stock checks, destructions, spillages, discrepancies etc.

2.2.2 Procedures must be kept up to date, reflecting current legal and good practice requirements for CDs, and there must be a system of document control to ensure that the correct version is used.

2.2.3 Procedures must be approved by the Controlled Drug Accountable Officer or by the person to whom they have delegated this task. The Controlled Drug Accountable Officer is accountable for all the systems for the safe management of CDs.

2.3 Ordering of Controlled Drugs– Hospital Pharmacies

2.3.1 Ordering of CDs from wholesalers and manufacturers and receipt of CDs must follow the principles of good procurement. Local procedures should ensure that there is a robust audit trail and that the opportunities for diversion are minimised.

2.3.2 The stock level of all CDs must reflect usage and practice change and is subject to annual review.

2.4 Receipt of Controlled Drugs– Hospital Pharmacies

2.4.1 There must be a local procedure for the receipt of CDs into the pharmacy department. The procedure must ensure the security of CDs and should be auditable. It must include:

- Who is authorised to sign for receipt.
- How the goods must be checked (e.g. matching of the details on the delivery note to the goods) and appropriate stock control documentation completed.
- An instruction that any tamper-evident seals on packs must be left intact when they are received from the supplier. This will simplify and speed up routine balance checks.
- An instruction that if, when the tamper-evident seal is broken the contents do not match the expected amount stated on the pack, the pharmacy must contact the supplier.
- The action to be taken if the item received is incorrect.
- Arrangements for storage of incorrect items for return.
- Specifications of the entry required in the Controlled Drug Record Book (Register), including who may make the Controlled Drug Record Book (Register) entry and whether a witness is required.
- Balance checks required i.e. physical, Controlled Drug Record Book (Register) and pharmacy stock control system.
- CD invoices retention period i.e. 6 years
- CD delivery notes retention period i.e. 2 years

2.4.2 Receipt of CDs must be recorded immediately, and no later than 24 hours after receipt. A procedure is required defining the procedure for safe storage and records of stock when receipt is not recorded immediately.

- The balance in stock must be checked and recorded as correct by the person making the entry.
- The stock balance in the Controlled Drug Record Book (Register) should be checked against both the quantity in the CD cabinet and the balance shown in the pharmacy stock control system at each transaction.
- The stock must be put away into the appropriate section of the CD cabinet promptly.

Refer to section 2.9 ‘Controlled Drug Record Book (Register) – Hospital Pharmacies’, for details of entry requirements.

2.5 Storage and Security of Controlled Drugs – Hospital Pharmacies

2.5.1 Pharmacy CD cabinets must comply with the Misuse of Drugs (Safe Custody) Regulations. A risk assessment must be undertaken to determine whether additional security arrangements are required, for example when the pharmacy is unmanned.

2.6 Issuing of Controlled Drugs to Wards, Theatres and Departments - Hospital Pharmacies

2.6.1 There must be a procedure for the issuing of CDs to wards, theatres and departments. The procedure must ensure the security of the CDs and must be auditable. It must include:

- The procedure for checking that the requisition is valid and complete.
- The process for correcting an incomplete or inaccurate requisition i.e. The registered pharmacist or registered pharmacy technician supplying the controlled drugs can make the following amendments:
  - If the carbonated copy is not clear or there is no record on the pink copy within the signed order book, the registered pharmacist/pharmacy technician can go over the requisition, to ensure a copy goes through to the pink page.
  - The **quantity** required must be clearly specified. If an order has been placed for 1 x OP the exact quantity supplied must be documented. The registered pharmacist/pharmacy technician can amend the quantities supplied, for example, to that of a part pack or blisters strip or a complete pack.
  - Clarify the **formulation** supplied and document this on the requisition.
  - All amendments made must be altered, signed, name printed, GPhC number added and dated by the registered pharmacist/pharmacy technician on both copies of the CD requisition. Pharmacy staff must contact the ward/department that has placed the order to discuss any changes, where applicable e.g. off-site locations, to their order before it is assembled in pharmacy.
  - If any other aspects are incorrect, the ward must be contacted to correct the order.
- Details required on pack supplied, additional labels may be required (Refer to section 2.8 'Labelling of Controlled Drugs for Ward, Theatre or Department Use – Hospital Pharmacies'.
- Details of entry required in the Controlled Drug Record Book (Register), including who is authorised to record entries in the Controlled Drug Record Book (Register).
- Whether a check by a second person is required. The decision as to whether a check by a second person is required or not must be made following a risk assessment.
- Arrangements for the transfer of the CDs to the ward, theatre, or department.

Refer to section 2.8 'Labelling of Controlled Drugs for Ward, Theatre or Department Use – Hospital Pharmacies', for details of labelling requirements.

Refer to section 2.9 'Controlled Drug Record Books (Registers) – Hospital Pharmacies', for details of Controlled Drug Record Book (Register) entries.

2.6.2 The messenger or porter who collects the completed order from the pharmacy must sign for receipt of the sealed package.

2.6.3 The details of any person that collects a CD from the pharmacy must be recorded in the pharmacy Controlled Drug Record Book (Register). If the person collecting the CD is a

registered healthcare professional, then the name and address e.g. ward number must be recorded. If the person that collects the CD is a non-registered healthcare worker, patient, or patient's representative, then a description of the person must be recorded e.g. hospital porter.

2.7 Electronic Systems – Hospital Pharmacies

2.7.1 Where approved electronic systems for the requisitioning of CDs are introduced, safeguards in the software must be put in place to ensure that:

- Only individuals who are authorised members of staff to requisition CDs from the pharmacy can do so.
- Entries cannot be altered at a later date.
- A log of all data entered is kept and can be recalled for audit purposes.

2.8 Labelling of Controlled Drugs for Ward, Theatre or Department Use – Hospital Pharmacies

2.8.1 There must be a procedure for labelling CDs issued from the pharmacy. Each individual pack issued much contain the following information:

- Drug name, form, and strength.
- Quantity.
- Store in CD cabinet.
- Expiry date if packed down from bulk. (NB: Certain preparations have a reduced expiry once opened, e.g. oral methadone solution).
- Keep out of reach and sight of children.
- Address of the pharmacy.
- The batch number of a product that has been packed down from bulk.

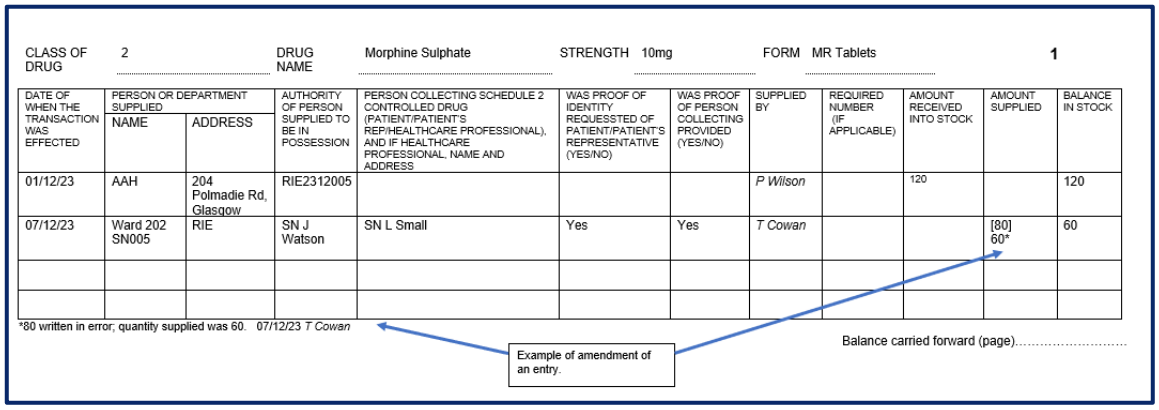
2.9 Controlled Drug Record Book (Register) – Hospital Pharmacies

2.9.1 Pharmacy departments are required to keep a Controlled Drug Record Book (Register) of receipts and supplies of Schedule 2 CDs. The Controlled Drug Record Book (Register) must be bound (not loose-leaf) with sequentially numbered pages.

2.9.2 Controlled Drug Record Book (Register) entries must be made in consecutive, chronological order. The entry must be made no later than 24 hours after the CD is received, and immediately when it is supplied. Entries must be in black ink or be otherwise indelible.

2.9.3 If an incorrect entry is made it must be bracketed, and annotated with the nature of the error, in such a way that the original entry is still clearly legible. This must be signed and dated. A footnote must be added to explain the alteration.

Example of amendment to an entry:



CLASS OF DRUG 2 DRUG NAME Morphine Sulphate STRENGTH 10mg FORM MR Tablets 1

DATE OF WHEN THE TRANSACTION WAS EFFECTED	PERSON OR DEPARTMENT SUPPLIED NAME	ADDRESS	AUTHORITY OF PERSON SUPPLIED TO BE IN POSSESSION	PERSON COLLECTING SCHEDULE 2 CONTROLLED DRUG (PATIENT/PATIENT'S REP/HEALTHCARE PROFESSIONAL), AND IF HEALTHCARE PROFESSIONAL, NAME AND ADDRESS	WAS PROOF OF IDENTITY REQUESSTED OF PATIENT/PATIENT'S REPRESENTATIVE (YES/NO)	WAS PROOF OF PERSON COLLECTING PROVIDED (YES/NO)	SUPPLIED BY	REQUIRED NUMBER (IF APPLICABLE)	AMOUNT RECEIVED INTO STOCK	AMOUNT SUPPLIED	BALANCE IN STOCK
01/12/23	AAH	204 Polmadie Rd, Glasgow	RIE2312005				*P Wilson*		120		120
07/12/23	Ward 202 SN005	RIE	SN J Watson	SN L Small	Yes	Yes	*T Cowan*			[80] 60*	60

*80 written in error; quantity supplied was 60. 07/12/23 *T Cowan*

Balance carried forward (page).....

Example of amendment of an entry.

2.9.4 The following staff may complete the Controlled Drug Record Book (Register):

- Any competent member of pharmacy staff as assessed and approved by the Lead Pharmacist for the hospital.
- Any person who is being trained, if a competent member of pharmacy staff, countersigns the entry.

2.9.5 The Controlled Drug Record Book (Register) must contain:

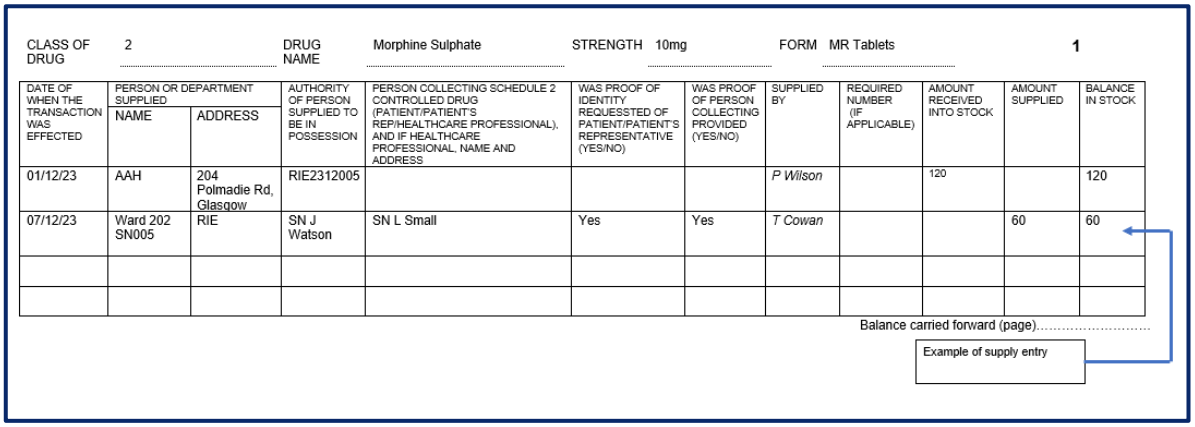
- Separate page for each drug form and strength.
- Drug name, brand name (if applicable), strength/concentration, form, and ampoule/via size (if applicable) must be written clearly and legibly.
- An index must be kept at the front of the Controlled Drug Record Book (Register).

2.9.6 For CDs supplied the Controlled Drug Record Book (Register) entry must also include:

- Date of transaction
- Name and address of patient/department supplied
- Licence or authority of person/department supplied
- Amount supplied

- Form in which supplied
- Name of patient, if individually dispensed
- Serial number of order.

Example of a supply entry in the Controlled Drug Record Book (Register):



CLASS OF DRUG 2 DRUG NAME Morphine Sulphate STRENGTH 10mg FORM MR Tablets 1

DATE OF WHEN THE TRANSACTION WAS EFFECTED	PERSON OR DEPARTMENT SUPPLIED		AUTHORITY OF PERSON SUPPLIED TO BE IN POSSESSION	PERSON COLLECTING SCHEDULE 2 CONTROLLED DRUG (PATIENT/PATIENT'S REP/HEALTHCARE PROFESSIONAL), AND IF HEALTHCARE PROFESSIONAL, NAME AND ADDRESS	WAS PROOF OF IDENTITY REQUESSTED OF PATIENT/PATIENT'S REPRESENTATIVE (YES/NO)	WAS PROOF OF PERSON COLLECTING PROVIDED (YES/NO)	SUPPLIED BY	REQUIRED NUMBER (IF APPLICABLE)	AMOUNT RECEIVED INTO STOCK	AMOUNT SUPPLIED	BALANCE IN STOCK
	NAME	ADDRESS									
01/12/23	AAH	204 Polmadie Rd, Glasgow	RIE2312005				*P Wilson*		120		120
07/12/23	Ward 202 SN005	RIE	SN J Watson	SN L Small	Yes	Yes	*T Cowan*			60	60

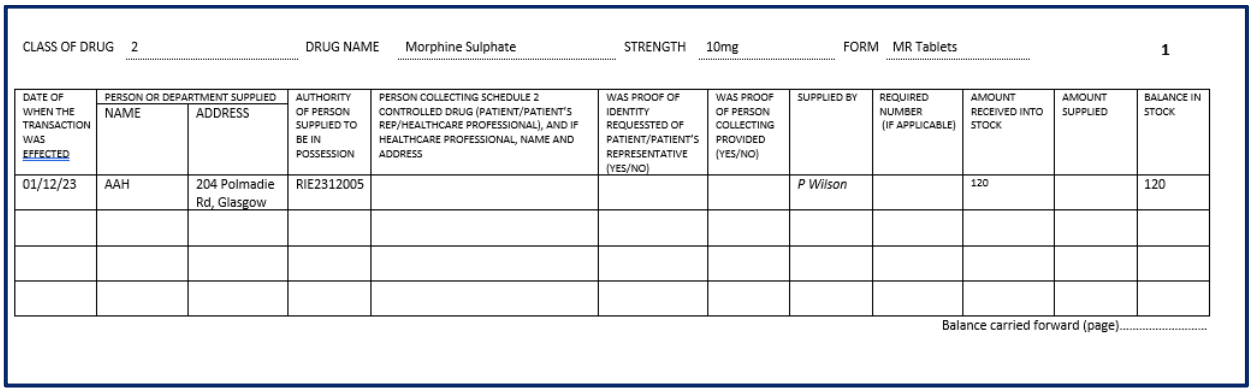
Balance carried forward (page).....

Example of supply entry

2.9.7 For CDs received into stock the following details must be recorded in the Controlled Drug Record Book (Register):

- The date on which the CD was received.
- The name and address of the supplier e.g. wholesaler, pharmacy, ward
- The quantity received.
- The drug name, brand name (if applicable), form, and strength of the CD.

Example of a receipt entry in the Controlled Drug Record Book (Register):



CLASS OF DRUG 2 DRUG NAME Morphine Sulphate STRENGTH 10mg FORM MR Tablets 1

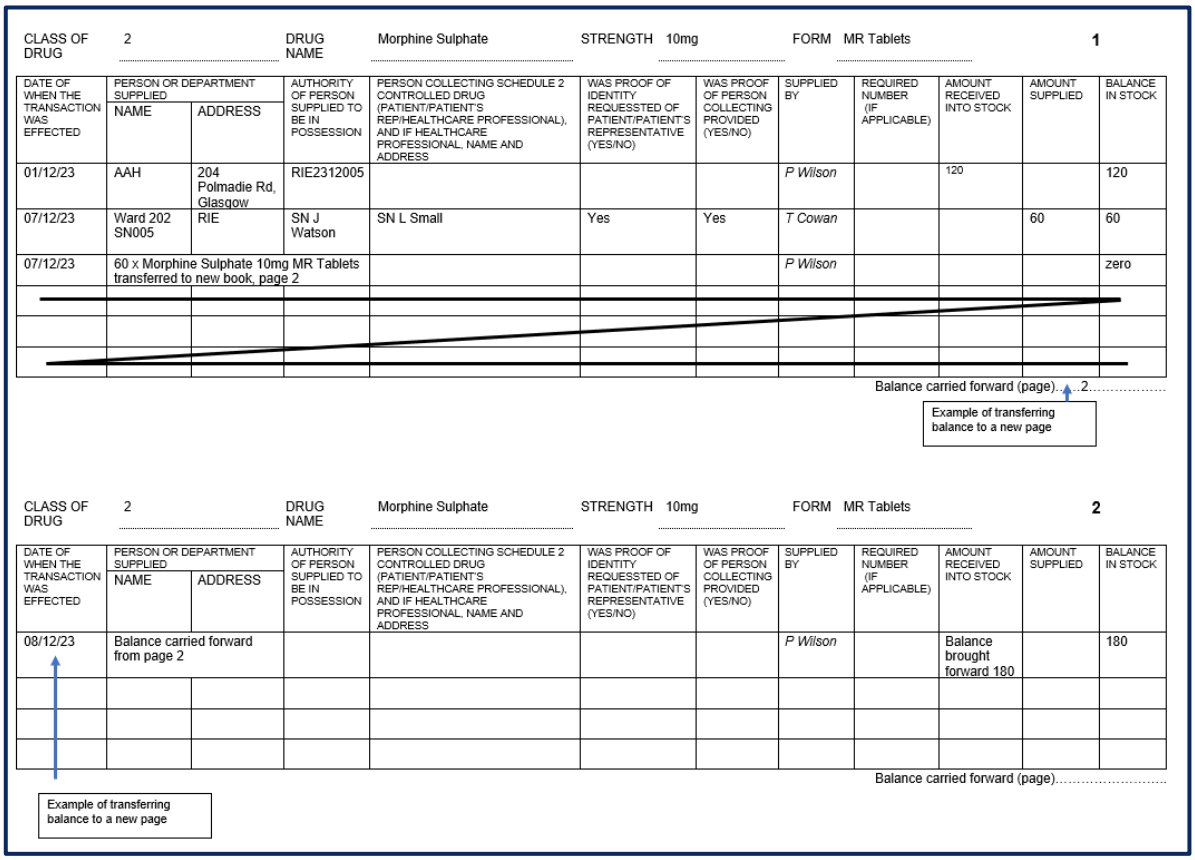
DATE OF WHEN THE TRANSACTION WAS EFFECTED	PERSON OR DEPARTMENT SUPPLIED		AUTHORITY OF PERSON SUPPLIED TO BE IN POSSESSION	PERSON COLLECTING SCHEDULE 2 CONTROLLED DRUG (PATIENT/PATIENT'S REP/HEALTHCARE PROFESSIONAL), AND IF HEALTHCARE PROFESSIONAL, NAME AND ADDRESS	WAS PROOF OF IDENTITY REQUESSTED OF PATIENT/PATIENT'S REPRESENTATIVE (YES/NO)	WAS PROOF OF PERSON COLLECTING PROVIDED (YES/NO)	SUPPLIED BY	REQUIRED NUMBER (IF APPLICABLE)	AMOUNT RECEIVED INTO STOCK	AMOUNT SUPPLIED	BALANCE IN STOCK
	NAME	ADDRESS									
01/12/23	AAH	204 Polmadie Rd, Glasgow	RIE2312005				*P Wilson*		120		120

Balance carried forward (page).....

2.9.8 The stock balance in the Controlled Drug Record Book (Register) should be checked against both the quantity in the CD cabinet and the balance shown in the pharmacy stock control system at each transaction.

2.9.9 On reaching the end of a page in the Controlled Drug Record Book (Register), the balance must be transferred to another page. The new page number must be added to the bottom of the finished page and the index updated.

Example of transferring a balance in the Controlled Drug Record Book (Register):



CLASS OF DRUG 2 DRUG NAME Morphine Sulphate STRENGTH 10mg FORM MR Tablets 1

DATE OF WHEN THE TRANSACTION WAS EFFECTED	PERSON OR DEPARTMENT SUPPLIED NAME	ADDRESS	AUTHORITY OF PERSON SUPPLIED TO BE IN POSSESSION	PERSON COLLECTING SCHEDULE 2 CONTROLLED DRUG (PATIENT/PATIENT'S REP/HEALTHCARE PROFESSIONAL), AND IF HEALTHCARE PROFESSIONAL, NAME AND ADDRESS	WAS PROOF OF IDENTITY REQUESSTED OF PATIENT/PATIENT'S REPRESENTATIVE (YES/NO)	WAS PROOF OF PERSON COLLECTING PROVIDED (YES/NO)	SUPPLIED BY	REQUIRED NUMBER (IF APPLICABLE)	AMOUNT RECEIVED INTO STOCK	AMOUNT SUPPLIED	BALANCE IN STOCK
01/12/23	AAH	204 Polmadie Rd, Glasgow	RIE2312005				*P Wilson*		120		120
07/12/23	Ward 202 SN005	RIE	SN J Watson	SN L Small	Yes	Yes	*T Cowan*			60	60
07/12/23	60 x Morphine Sulphate 10mg MR Tablets transferred to new book, page 2						*P Wilson*				zero

Balance carried forward (page) 2

Example of transferring balance to a new page

CLASS OF DRUG 2 DRUG NAME Morphine Sulphate STRENGTH 10mg FORM MR Tablets 2

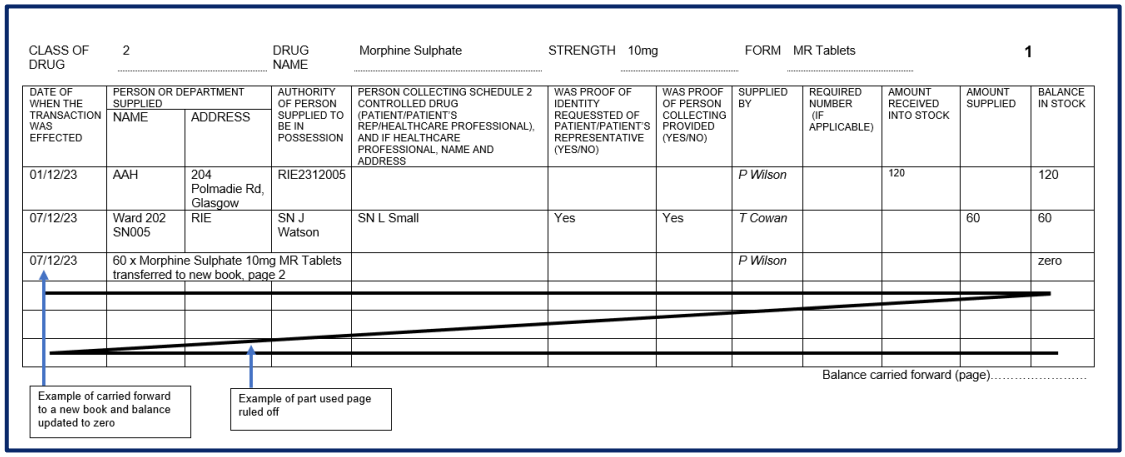
DATE OF WHEN THE TRANSACTION WAS EFFECTED	PERSON OR DEPARTMENT SUPPLIED NAME	ADDRESS	AUTHORITY OF PERSON SUPPLIED TO BE IN POSSESSION	PERSON COLLECTING SCHEDULE 2 CONTROLLED DRUG (PATIENT/PATIENT'S REP/HEALTHCARE PROFESSIONAL), AND IF HEALTHCARE PROFESSIONAL, NAME AND ADDRESS	WAS PROOF OF IDENTITY REQUESSTED OF PATIENT/PATIENT'S REPRESENTATIVE (YES/NO)	WAS PROOF OF PERSON COLLECTING PROVIDED (YES/NO)	SUPPLIED BY	REQUIRED NUMBER (IF APPLICABLE)	AMOUNT RECEIVED INTO STOCK	AMOUNT SUPPLIED	BALANCE IN STOCK
08/12/23	Balance carried forward from page 2						*P Wilson*		Balance brought forward 180		180

Balance carried forward (page)

Example of transferring balance to a new page

2.9.10 When a new Controlled Drug Record Book (Register) is started, the balance of CDs in stock must be written into the new book immediately. All CDs must be transferred to the new Controlled Drug Record Book (Register) at the same time. The balance in the old Controlled Drug Record Book (Register) should be made 'zero' stating the date and the quantity transferred to the new Controlled Drug Record Book (Register). Any part used pages in the old Controlled Drug Record Book (Register) should have the blank lines ruled off.

Example of transferring a balance to a new Controlled Drug Record Book (Register):



CLASS OF DRUG 2 DRUG NAME Morphine Sulphate STRENGTH 10mg FORM MR Tablets 1

DATE OF WHEN THE TRANSACTION WAS EFFECTED	PERSON OR DEPARTMENT SUPPLIED NAME	ADDRESS	AUTHORITY OF PERSON SUPPLIED TO BE IN POSSESSION	PERSON COLLECTING SCHEDULE 2 CONTROLLED DRUG (PATIENT/PATIENT'S REP/HEALTHCARE PROFESSIONAL), AND IF HEALTHCARE PROFESSIONAL, NAME AND ADDRESS	WAS PROOF OF IDENTITY REQUESSTED OF PATIENT/PATIENT'S REPRESENTATIVE (YES/NO)	WAS PROOF OF PERSON COLLECTING PROVIDED (YES/NO)	SUPPLIED BY	REQUIRED NUMBER (IF APPLICABLE)	AMOUNT RECEIVED INTO STOCK	AMOUNT SUPPLIED	BALANCE IN STOCK
01/12/23	AAH	204 Polmadie Rd, Glasgow	RIE2312005				*P Wilson*		120		120
07/12/23	Ward 202 SN005	RIE	SN J Watson	SN L Small	Yes	Yes	*T Cowan*			60	60
07/12/23	60 x Morphine Sulphate 10mg MR Tablets transferred to new book, page 2						*P Wilson*				zero

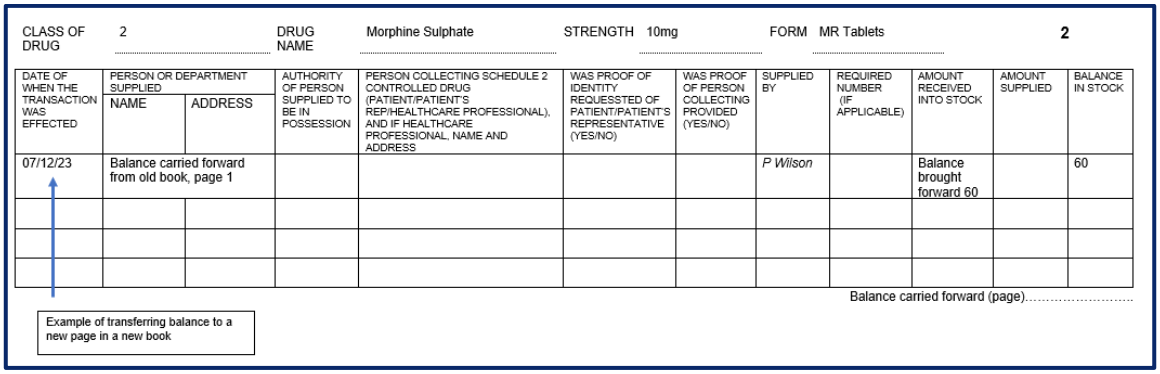
Balance carried forward (page)

Example of carried forward to a new book and balance updated to zero

Example of part used page ruled off

2.9.11 The new Controlled Drug Record Book (Register) should have an entry on the appropriately titled page stating the balance that was transferred and the page of old Controlled Drug Record Book (Register) from which the information was transferred.

Example of transferring/carrying forward a balance to a new Controlled Drug Record Book (Register):



CLASS OF DRUG 2 DRUG NAME Morphine Sulphate STRENGTH 10mg FORM MR Tablets **2**

DATE OF WHEN THE TRANSACTION WAS EFFECTED	PERSON OR DEPARTMENT SUPPLIED		AUTHORITY OF PERSON SUPPLIED TO BE IN POSSESSION	PERSON COLLECTING SCHEDULE 2 CONTROLLED DRUG (PATIENT/PATIENT'S REP/HEALTHCARE PROFESSIONAL), AND IF HEALTHCARE PROFESSIONAL, NAME AND ADDRESS	WAS PROOF OF IDENTITY REQUESSTED OF PATIENT/PATIENT'S REPRESENTATIVE (YES/NO)	WAS PROOF OF PERSON COLLECTING PROVIDED (YES/NO)	SUPPLIED BY	REQUIRED NUMBER (IF APPLICABLE)	AMOUNT RECEIVED INTO STOCK	AMOUNT SUPPLIED	BALANCE IN STOCK
	NAME	ADDRESS									
07/12/23	Balance carried forward from old book, page 1						*P Wilson*		Balance brought forward 60		60

Balance carried forward (page).....

Example of transferring balance to a new page in a new book

2.9.12 The front page of the old Controlled Drug Record Book (Register) should be dated to show when the CDs were transferred, and the book closed.

2.9.13 The front cover of the new Controlled Drug Record Book (Register) should be dated to show when the book came into use.

2.9.14 Completed Controlled Drug Record Books (Register) must be retained securely for a minimum of two years from the date of closure, or seven years if they contain details of a CD destruction. Refer to section 1.4.2 'Supply, Receipt, Storage and Retention of Controlled Drug Stationery'.

2.10 Computerised Record Books (Register) – Hospital Pharmacies

2.10.1 Entries in computerised registers must be attributable and auditable.

2.10.2 If the Controlled Drug Record Book (Register) is held in computerised form, the following safeguards in the software must be put in place to ensure that:

- Author of each entry is identifiable.
- Entries cannot be altered at a later date.
- All entries are attributable to the individual making the entry.
- A log of all data entered is kept and can be recalled for audit purposes.
- Adequate backups are made.
- Systems are in place to minimise the risk of unauthorized access to the data.

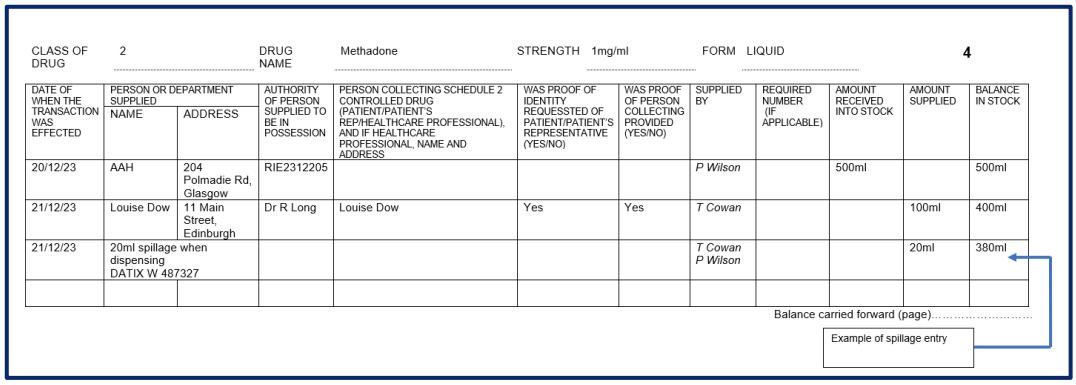
2.11 Spillages and Breakages – Hospital Pharmacies

2.11.1 In the event of a breakage or spillage, a second authorised member of staff must verify that it has occurred and countersign the Controlled Drug Record Book (Register). A DATIX entry must be made. The DATIX reference must be recorded in the Controlled Drug Record Book (Register).

2.11.2 If breakages, spillages or dropped tablets occur an entry must be made in the Controlled Drug Record Book (Register) to include the following detail:

- Date.
- Reason e.g. dropped tablet etc.
- Signatures of the registered pharmacist/pharmacy technician and witness.
- Quantity destroyed.
- Balance remaining.

Example of spillage entry in the Controlled Drug Record Book (Register):



CLASS OF DRUG 2 DRUG NAME Methadone STRENGTH 1mg/ml FORM LIQUID 4

DATE OF WHEN THE TRANSACTION WAS EFFECTED	PERSON OR DEPARTMENT SUPPLIED		AUTHORITY OF PERSON SUPPLIED TO BE IN POSSESSION	PERSON COLLECTING SCHEDULE 2 CONTROLLED DRUG (PATIENT/PATIENT'S REP/HEALTHCARE PROFESSIONAL), AND IF HEALTHCARE PROFESSIONAL, NAME AND ADDRESS	WAS PROOF OF IDENTITY REQUESSTED OF PATIENT/PATIENT'S REPRESENTATIVE (YES/NO)	WAS PROOF OF PERSON COLLECTING PROVIDED (YES/NO)	SUPPLIED BY	REQUIRED NUMBER (IF APPLICABLE)	AMOUNT RECEIVED INTO STOCK	AMOUNT SUPPLIED	BALANCE IN STOCK
	NAME	ADDRESS									
20/12/23	AAH	204 Polmadie Rd, Glasgow	RIE2312205				*P Wilson*		500ml		500ml
21/12/23	Louise Dow	11 Main Street, Edinburgh	Dr R Long	Louise Dow	Yes	Yes	*T Cowan*			100ml	400ml
21/12/23	20ml spillage when dispensing DATIX W 487327						*T Cowan* *P Wilson*			20ml	380ml

Balance carried forward (page).....

Example of spillage entry

2.11.3 Refer to section 2.17.3 'Methods of Disposal of Controlled Drugs', for information regarding destruction of spillage, breakage etc.

2.12 Pharmacy Controlled Drug Stock Checks – Hospital Pharmacies

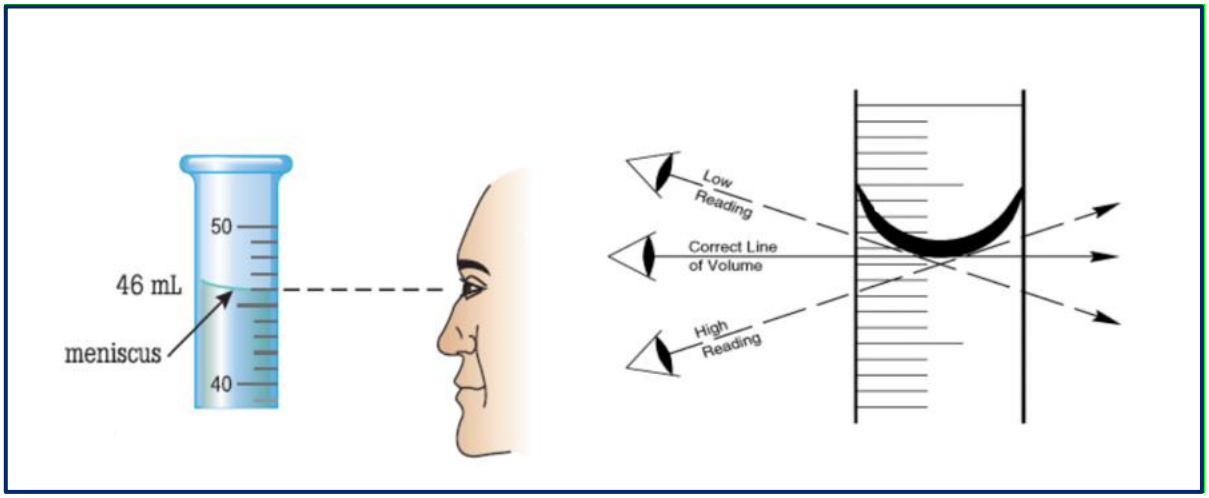
2.12.1 All CDs in the pharmacy must be checked periodically, as specified in the local procedure as agreed by the Lead Pharmacist. This must include a physical check of stock against the Controlled Drug Record Book (Register) and against the stock levels on the pharmacy computer system. CDs that are awaiting destruction must be included in the Controlled Drug Record Book (Register) running balance and segregated from in-date stock. A separate Controlled Drug Record Book (Register) for out-of-date stock must not be kept. Following a risk assessment, the frequency of such checks should be determined by the pharmacist with operational responsibility for managing CDs.

2.12.2 The check may be undertaken by any authorised competent person approved by the Lead Pharmacist for the hospital. The system must enable the Controlled Drug Record Book (Register) to be reconciled with issues to wards/departments. The routine check must include sample reconciliations of the Controlled Drug Record Book (Register) against requisitions received in the pharmacy, plus checks of any exceptional ordering which should be queried.

2.12.3 Stock balance of liquid medicines should be checked by visual inspection but periodic actual volume checks, as specified in a procedure (minimum of once per month), must be carried out. The actual stock balance must be recorded on completion of a bottle.

When measuring liquid controlled drugs, ensure consistency by:

- Using a suitable appropriately sized and marked conical measure i.e. smallest size to measure the required dose ensures an accurate volume.
- Placing the measure on a flat hard surface
- Ensuring the sight line is at the same height as the bottom of the meniscus. The bottom of the meniscus is the accurate measurement.

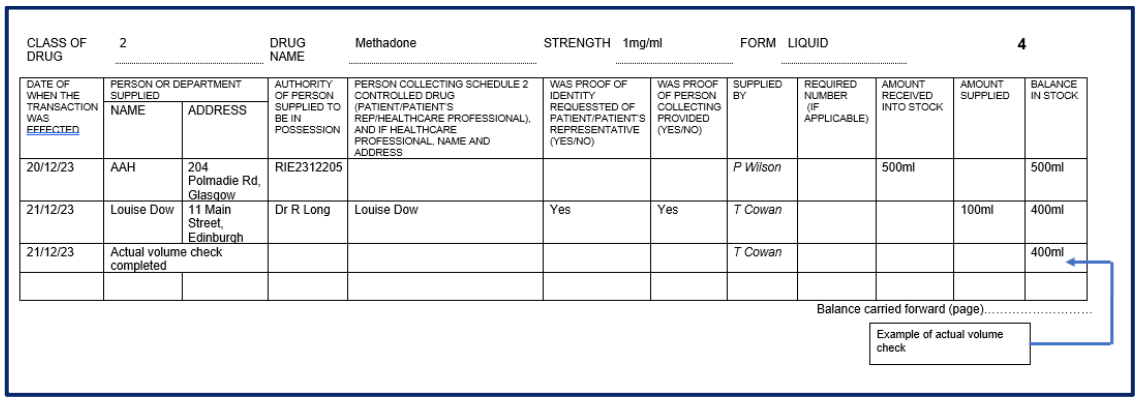


After measuring, use a prolonged drainage period until there are no further drops (around 3 seconds).

2.12.4 The check should be recorded in the Controlled Drug Record Book (Register) by means of a signature, date, and an appropriate entry, for example, “Stock checked. Balance

correct". Entries for an actual volume check must also include "Actual volume check completed".

Example of actual volume check in the Controlled Drug Record Book (Register):



CLASS OF DRUG 2 DRUG NAME Methadone STRENGTH 1mg/ml FORM LIQUID 4

DATE OF WHEN THE TRANSACTION WAS EFFECTED	PERSON OR DEPARTMENT SUPPLIED		AUTHORITY OF PERSON SUPPLIED TO BE IN POSSESSION	PERSON COLLECTING SCHEDULE 2 CONTROLLED DRUG (PATIENT/PATIENT'S REP/HEALTHCARE PROFESSIONAL), AND IF HEALTHCARE PROFESSIONAL, NAME AND ADDRESS	WAS PROOF OF IDENTITY REQUESSTED OF PATIENT/PATIENT'S REPRESENTATIVE (YES/NO)	WAS PROOF OF PERSON COLLECTING PROVIDED (YES/NO)	SUPPLIED BY	REQUIRED NUMBER (IF APPLICABLE)	AMOUNT RECEIVED INTO STOCK	AMOUNT SUPPLIED	BALANCE IN STOCK
	NAME	ADDRESS									
20/12/23	AAH	204 Polmadie Rd, Glasgow	RIE2312205				*P Wilson*		500ml		500ml
21/12/23	Louise Dow	11 Main Street, Edinburgh	Dr R Long	Louise Dow	Yes	Yes	*T Cowan*			100ml	400ml
21/12/23	Actual volume check completed						*T Cowan*				400ml

Balance carried forward (page).....

Example of actual volume check

2.13 Discrepancies – Hospital Pharmacies

2.13.1 The balance recorded in the Controlled Drug Record Book (Register) and/or, where relevant, the electronic Controlled Drug Record Book (Register)/pharmacy stock control system must be reconciled against the stock of every product in the CD cabinet. If one or more of these levels does not tally, the discrepancy must be investigated and resolved without delay. It is important to remember that a discrepancy may indicate diversion of stock.

A Schedule 2 Controlled Drug Discrepancy Investigation form is available. This is available on the Controlled Drug Governance Team Intranet page: Controlled Drugs Governance Home (scot.nhs.uk)

2.13.2 Discrepancies can arise with liquid CDs as a result of e.g. manufacturer's overage, the measurement process or spillage. Such overage or losses of liquid preparations should be recorded, and the running balance adjusted.

Overage Discrepancy

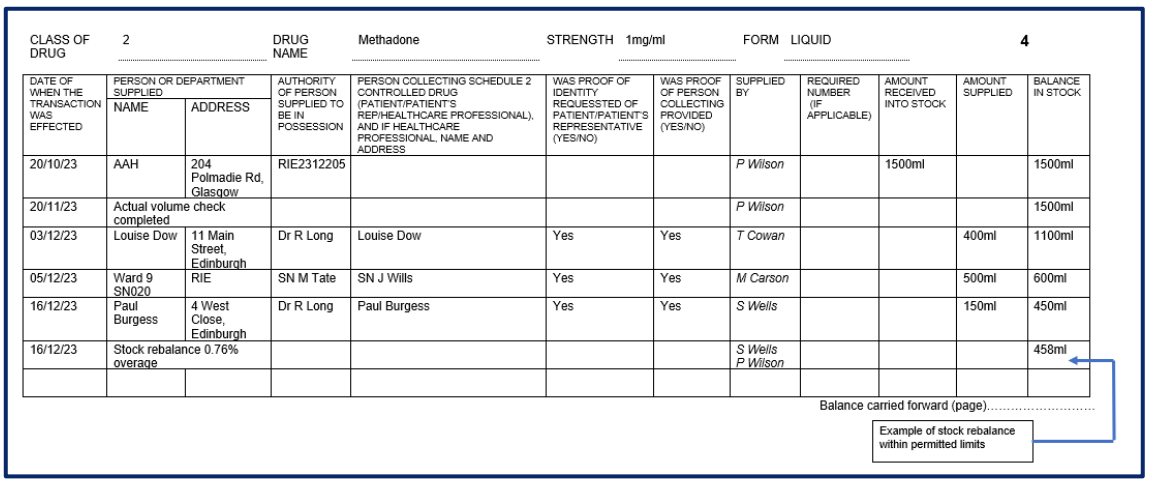
- If the discrepancy is an overage of **less than or equal to 5%** i.e. % difference between the discrepancy volume and the quantity supplied since the last recorded **actual volume check**, two members of authorised registered healthcare staff must rebalance the stock in the Controlled Drug Record Book (Register). This must be annotated in the Controlled Drug Record Book (Register) as:
  - 'stock rebalance X% overage'
  - The entry signed by the two members of authorised registered healthcare staff.
  - A DATIX is not required for an overage discrepancy less than or equal to 5% for liquid preparations.
- If the discrepancy is **over 5%** difference between the discrepancy volume and the quantity supplied since the last actual volume check refer to section 1.14.2 'Investigating Discrepancies'.

  A DATIX entry is required for an overage discrepancy **over** 5%. The DATIX reference must be recorded in the Controlled Drug Record Book (Register).

Example 1 (discrepancy is less than or equal to 5%):

Current balance in Controlled Drug Record Book (Register)	450mL
Current physical balance	458mL
Discrepancy between balance in Controlled Drug Record Book (Register) and physical balance	+8mL
Quantity supplied since last actual balance check	1050mL
Calculation i.e. disc volume divided by qty administered	8mL divided by 1050mL, multiplied by 100. = 0.76%
Action to be taken:	Two members of authorised registered healthcare staff must rebalance the stock in the Controlled Drug Record Book (Register) DATIX entry in NOT required

Example of stock rebalance, within permitted limits, in the Controlled Drug Record Book (Register):



CLASS OF DRUG 2 DRUG NAME Methadone STRENGTH 1mg/ml FORM LIQUID 4

DATE OF WHEN THE TRANSACTION WAS EFFECTED	PERSON OR DEPARTMENT SUPPLIED		AUTHORITY OF PERSON SUPPLIED TO BE IN POSSESSION	PERSON COLLECTING SCHEDULE 2 CONTROLLED DRUG (PATIENT/PATIENT'S REP/HEALTHCARE PROFESSIONAL), AND IF HEALTHCARE PROFESSIONAL, NAME AND ADDRESS	WAS PROOF OF IDENTITY REQUESSTED OF PATIENT/PATIENT'S REPRESENTATIVE (YES/NO)	WAS PROOF OF PERSON COLLECTING PROVIDED (YES/NO)	SUPPLIED BY	REQUIRED NUMBER (IF APPLICABLE)	AMOUNT RECEIVED INTO STOCK	AMOUNT SUPPLIED	BALANCE IN STOCK
	NAME	ADDRESS									
20/10/23	AAH	204 Polmadie Rd, Glasgow	RIE2312205				*P Wilson*		1500ml		1500ml
20/11/23	Actual volume check completed						*P Wilson*				1500ml
03/12/23	Louise Dow	11 Main Street, Edinburgh	Dr R Long	Louise Dow	Yes	Yes	*T Cowan*			400ml	1100ml
05/12/23	Ward 9 SN020	RIE	SN M Tate	SN J Wills	Yes	Yes	*M Carson*			500ml	600ml
16/12/23	Paul Burgess	4 West Close, Edinburgh	Dr R Long	Paul Burgess	Yes	Yes	*S Wells*			150ml	450ml
16/12/23	Stock rebalance 0.76% overage						*S Wells* *P Wilson*				458ml

Balance carried forward (page).....

Example of stock rebalance within permitted limits

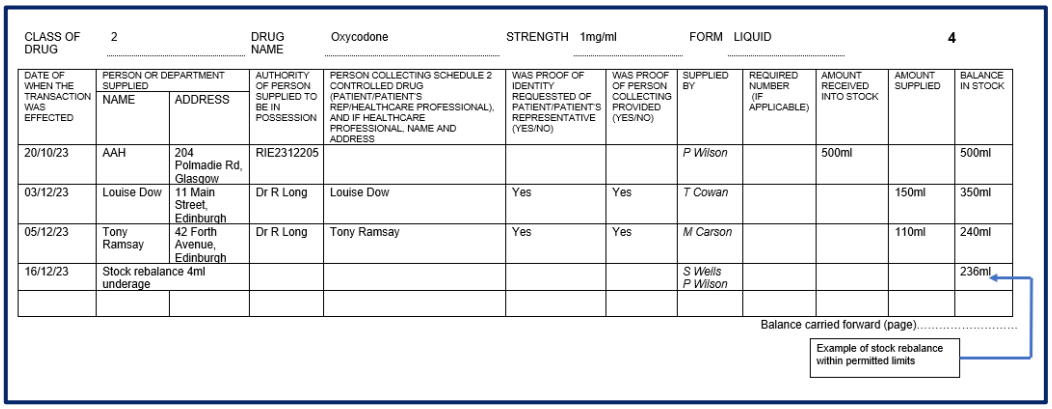
Underage Discrepancy

- Oxycodone 1mg/mL Liquid

  Oxycodone 1mg/ml liquid has a very thick viscosity therefore if the discrepancy is an underage of **less than or equal to 10mL** i.e. the difference between the Controlled Drug Record Book (Register) balance and the physical balance, two members of authorised registered healthcare staff must rebalance the stock in the Controlled Drug Record Book (Register). This must be annotated in the Controlled Drug Record Book (Register) as:

  - 'Stock rebalance Xml underage'
  - The entry signed by the two members of authorised registered healthcare staff.
  - A DATIX is not required for an underage discrepancy less than 10mL for Oxycodone 1mg/mL liquid

Example of stock rebalance, within permitted limits, in the Controlled Drug Record Book (Register):



CLASS OF DRUG 2 DRUG NAME Oxycodone STRENGTH 1mg/ml FORM LIQUID 4

DATE OF WHEN THE TRANSACTION WAS EFFECTED	PERSON OR DEPARTMENT SUPPLIED		AUTHORITY OF PERSON SUPPLIED TO BE IN POSSESSION	PERSON COLLECTING SCHEDULE 2 CONTROLLED DRUG (PATIENT/PATIENT'S REP/HEALTHCARE PROFESSIONAL), AND IF HEALTHCARE PROFESSIONAL, NAME AND ADDRESS	WAS PROOF OF IDENTITY REQUESSTED OF PATIENT/PATIENT'S REPRESENTATIVE (YES/NO)	WAS PROOF OF PERSON COLLECTING PROVIDED (YES/NO)	SUPPLIED BY	REQUIRED NUMBER (IF APPLICABLE)	AMOUNT RECEIVED INTO STOCK	AMOUNT SUPPLIED	BALANCE IN STOCK
	NAME	ADDRESS									
20/10/23	AAH	204 Polmadie Rd, Glasgow	RIE2312205				*P Wilson*		500ml		500ml
03/12/23	Louise Dow	11 Main Street, Edinburgh	Dr R Long	Louise Dow	Yes	Yes	*T Cowan*			150ml	350ml
05/12/23	Tony Ramsay	42 Forth Avenue, Edinburgh	Dr R Long	Tony Ramsay	Yes	Yes	*M Carson*			110ml	240ml
16/12/23	Stock rebalance 4ml underage						*S Wells* *P Wilson*				236ml

Balance carried forward (page).....

Example of stock rebalance within permitted limits

All other Liquid Controlled Drug Preparations

Underage discrepancies in all other liquid CD preparation must be investigated, refer to section 1.14.2 '[Investigating Discrepancies]'. A DATIX entry is required and the DATIX reference must be recorded in the Controlled Drug Record Book (Register).

2.13.3 There must be a careful check of transactions in the Controlled Drug Record Book (Register) and in the stock control system to trace an error or omission.

2.13.4 If an error is traced then an entry must be made in the Controlled Drug Record Book (Register), clearly stating the reason for the entry, the reference of the error or the omission, the date of the error or omission and the signature of both the registered pharmacy staff carrying out the amendment and the second person who checks the whole process.

2.13.5 All CD discrepancies, unless the discrepancy is within permitted limits i.e. liquids, must be reported on DATIX. The DATIX reference must be recorded in the Controlled Drug Record Book (Register).

2.13.6 If no errors or omissions are detected, then the discrepancy must be reported to the Lead Pharmacist for the hospital. If the discrepancy cannot be resolved it must be reported to the Controlled Drug Accountable Officer and the police as soon as possible, within 48 hours.

2.14 Archiving of Controlled Drug Records – Hospital Pharmacies

2.14.1 Every requisition, order, or prescription on which a CD is supplied must be retained by the Pharmacy department for a minimum period of two years from the date on which the last delivery or supply was made i.e. from the requisition, order, or private prescription.

2.14.2 The time periods for archiving CD documentation are:

Requisitions	2 years
Controlled Drug Record Book (Register)	2 years from last entry
Controlled Drug Record Book (Register) containing details of CD destructions	7 years from last entry
CD invoices	6 years
CD delivery notes	2 years

2.15 Supply to Outpatients and Discharge patients – Hospital Pharmacies

2.15.1 For collection of CD prescriptions pharmacy staff must establish whether the person collecting the medicine is the patient, their representative e.g. porter, taxi or courier, or a healthcare professional acting in their professional capacity on behalf of the patient.

2.15.2 When outpatient prescriptions are being given directly to patients or their representatives, the patients or their representatives may be asked to provide evidence of identity when collecting Schedule 2 CDs. The requirement allows discretion not to ask patients or patient representatives for proof of identity if for example they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicine dispensed.

2.15.3 The following information must be recorded in the Controlled Drug Record Book (Register) for Schedule 2 CDs supplied on prescription:

- If the person who collected the drug was the patient, the patient's representative e.g. porter, taxi or courier, or a healthcare professional acting on behalf of the patient.
- If the person who collected the drug was a healthcare professional acting on behalf of the patient, that person's name and address.
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the member of pharmacy staff did not ask may be included but this is not mandatory); and
- If evidence of identity was provided by the person collecting the medicine.

2.15.4 The patient's date of birth and address may be used as a second check if necessary.

2.16 Supply to External Units or Other Health and Social Care bodies in Exceptional Circumstances – Hospital Pharmacies

2.16.1 A hospital pharmacy can no longer supply CDs to an external organisation unless for a named individual and not routine practice.

2.17 Destruction/Disposal of Controlled Drugs – Hospital pharmacies

2.17.1 Destruction of Stock Controlled Drugs – Hospital Pharmacies

There must be a local procedure in place for the destruction of stock CDs. The table below details requirements for each Schedule.

Denaturing kits that do not require crushing must be used.

Schedule	Destroyed by	Denature before disposal	Entry in Controlled Drug Record Book (Register)	Record retained in pharmacy
2	Registered pharmacist or registered pharmacy technician and authorised witness.	Yes	Yes	Yes (Controlled Drug Record Book (Register)
3	One member of registered pharmacy staff and pharmacy staff member, as defined in procedure.	Yes	No*	Yes
4 (part I)	Defined in procedure	Yes	No**	Yes
4 (part II)	Defined in procedure	No	No	Yes
5	Defined in procedure	No	No	Yes

*unless stock is recorded in Controlled Drug Record Book (Register)

** Sativex is required to be recorded in the Controlled Drug Record Book (Register)

2.17.1.1 Any pharmacy held stock of obsolete, expired, or unwanted Schedule 2 CDs must be recorded in a timely manner. Destruction can only take place in the presence of an authorised witness appointed by the Controlled Drug Accountable Officer.

2.17.1.2 Obsolete, expired, and unwanted stock CDs requiring safe custody, must be kept segregated from other CDs in the CD cabinet, but continue to be included in the running balance. CDs awaiting destruction must be clearly marked to minimise the risk of errors and inadvertent supply.

2.17.1.3 When stock Schedule 2 CDs are destroyed, the following details must be entered into the Controlled Drug Record Book (Register):

- Drug name
- Drug form
- Drug strength
- Quantity of drug being destroyed.
- Date of destruction
- Signature of the authorised witness in whose presence the drug was destroyed.
- Signature of the authorised member of staff carrying out the destruction
- Confirm and update the running balance.

2.17.2 Destruction of Controlled Drugs Returned by Patients – Hospital Pharmacies

Patients' Own CDs no longer required should be destroyed on the ward. Refer to section 1.17 '[Management of Patients' Own Controlled Drugs]'. If patients' own CDs are returned to pharmacy the following guidance should be followed:

2.17.2.1 CDs that have been prescribed for, and dispensed to, a named patient and then returned unused or part-used by the patient or their representative to the pharmacy must be kept securely and separately from pharmacy stock. When destroyed their destruction must be recorded appropriately.

2.17.2.2 A record of CDs returned by patients must be kept and a record of destruction must be made in a timely manner.

2.17.2.3 The record of CDs returned by patients and of their destruction must be made in the Patients' Own Controlled Drug Record Book (Register) including the following:

- Date of return of the CDs.
- Name, quantity, strength, and form of the CDs.
- Role of the person who returned the CDs (if known).
- Name and signature of the person who received the CDs.
- Patient's name and address (if known).
- Names, positions, and signatures of the person destroying the CDs and the witness.
- Date of destruction.
- Comments, for example, expiry date, name of patient and ward.

2.17.2.4 CDs returned by patients awaiting destruction must be stored in the CD cabinet separately from pharmacy stock CDs.

2.17.2.5 Destruction of CDs returned by patients should occur with sufficient frequency to ensure that excessive quantities are not stored awaiting destruction. The frequency should be determined locally following a risk assessment but be no less then every three months.

2.17.3 Methods of Disposal of Controlled Drugs – Hospital Pharmacies

2.17.3.1 The pharmacy procedure for disposal of CDs must be followed.

2.18 Storage and Supply of Controlled Drug Stationery – Hospital Pharmacies

CD stationery must be transported securely at all times.

2.18.1 Stocks of CD stationery held in the pharmacy department must be kept in a secure area that is locked when there is no one present.

2.18.2 CD stationery must be issued from the pharmacy against a written requisition in the existing Controlled Drug Order Book signed by a registered nurse, midwife or ODP.

2.18.3 A record must be kept of the supply of CD stationery. It should include:

- Date.
- Ward/Department.
- Name of person ordering the stationery.
- Type of stationery issued.
- Quantity.
- The serial numbers of the stationery.
- Name and signature of the member of authorised pharmacy staff making the supply.
- Name and signature of the registered nurse or midwife receiving the stationery.

A system must be in place to receive signed confirmation, from the ward/department, of receipt of CD stationery.

2.18.4 Only one Controlled Drug Order Book should be held on a ward at any time, except when otherwise agreed locally with the Lead Pharmacist to meet exceptional circumstances, for example, community hospitals. Pharmacy must have a system in place to ensure only one Controlled Drug Order Book is in use at one time.

2.18.5 Records of the receipt and issue of CD stationery must be retained for two years.

2.18.6 Loss or theft of any CD stationery must be reported immediately to the Lead Pharmacist who is responsible for investigating and reporting the incident in accordance with the procedure for incidents. The Controlled Drug Accountable Officer must be informed.

2.18.7 The loss or theft of CD stationery must be reported on DATIX.

2.19 Pharmacy Staff Training for the Management of Controlled Drugs – Hospital Pharmacies

2.19.1 Pharmacy staff must receive appropriate training on local procedures for CDs when they first become involved in supplying, administering, or disposing of CDs and then regularly thereafter. The frequency of training should be determined locally.

2.19.2 Pharmacy staff must be informed and, if necessary, receive additional training when procedures are revised or amended and when new CD products or systems are introduced.