NHS Grampian

Supplementary Guidance For Controlled Drugs For Staff Working In Theatres And Other Interventional Areas Within NHS Grampian

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Policy Statement:

It is the responsibility of all staff to ensure that they are working to the most up to date and relevant guideline, policies, protocols and procedures.

Version 4

Executive Sign-Off

This document has been endorsed by the Controlled Drugs Accountable Officer, NHS Grampian

Signature: _____

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May 2025	New document template adopted.	Throughout document
May 2025	Inclusion of evidence base.	Page 3
May 2025	Stock lists introduced	Page 5
May 2025 May 2025	CD assurance checks reduced from three to two annually.	Page 7
May 2025	Links added to SOP template.	Appendix 2
May 2025	Contact details updated in SOP template.	Page 16
May 2025	Contact details updated.	Page 25

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Supplementary Guidance For Controlled Drugs For Staff Working In Theatres And Other Interventional Areas Within NHS Grampian

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Supplementary Guidance For Controlled Drugs For Staff Working In Theatres And Other Interventional Areas Within NHS Grampian

1. Introduction

The purpose of this document is to provide supplementary guidance on controlled drug management in addition to the information provided in NHS Grampian Policy and Procedure For The Safe Management Of Controlled Drugs In Hospitals. This guidance was developed to acknowledge that the above policy does not fully cover the specific variations encountered in operating departments and other interventional areas such as cardiac catheterisation laboratories, endoscopy and lithotripsy.

2. Evidence Base

Controlled drugs must be managed in compliance with relevant legislation, the overall legislative framework which applies to all Medicines is the Medicines Act 1968 and its associated legislation.

The Human Medicines Regulations 2012 are a result of the MHRA's consolidation and review of UK legislation. They replace nearly all UK medicines legislation – most of the Medicines Act 1968 and over 200 statutory instruments.

Controlled Drugs (CDs) are additionally defined and governed by the Misuse of Drugs Act 1971 and associated Regulations – principally the Misuse of Drugs Regulations 2001 which fall within the remit of the Home Office.

The Health and Social Care Act was implemented in April 2012. This resulted in a review of the associated regulations and the introduction of the Controlled Drugs (Supervision of Management and Use) Regulations 2013 which came into force in April 2013. This included a statutory requirement for all NHS Boards to appoint a Controlled Drug Accountable Officer (CDAO) with specific responsibility for the safe management and use of CDs within their Health Board. Within NHS Grampian the Director of Pharmacy and Medicines Management is the CDAO. The CDAO has in turn appointed a Controlled Drugs Team (CD team) to assist with the operational functions of the CDAO. These functions include governance, information sharing and co-operation between bodies, inspection, review of SOPs, monitoring prescribing of CDs, assessment of CD incidents and sharing lessons learnt.

Throughout this guidance, the terms **'must**' and '**should**' are used. The term 'must' relates to a legal requirement or a NHSG requirement. The term 'should' relates to recommendations of good practice.

There are a number of overarching principles that are used to underpin the safe management of CDs. These principles include:

- Patients should have timely access to medicines prescribed for them, including any CDs.

- Organisations and individuals must comply with the current legal requirements and local guidelines for the management of CDs.
- CDs must be used and managed safely and securely.
- There must be a clear audit trail for the movement and use of CDs.

Staff must consider this guidance relevant for any CDs stored in the CD cabinet and recorded in the Ward/Department Controlled Drug Record Book. Within NHSG all schedule 2 CDs and the schedule 3 CDs that require safe custody, i.e. temazepam and buprenorphine are stored in the CD cabinet and recorded in the CD record book. Temazepam and buprenorphine are treated in a stricter manner than legally required, this is NHS Grampian policy and must be adhered to.

This guidance must also be applied to any CD which is ordered using a Controlled Drug Order Book (schedule 2 and 3 CD) even where storage in CD cabinet and recording in the Controlled Drug Record Book (CDRB) are not mandatory, i.e. midazolam, tramadol, phenobarbital, gabapentin and pregabalin.

3. Process Document Main Components and Recommendations

3.1. Checks of Controlled Drugs (CDs)

The stock balance of all controlled drugs (CDs) entered in the Theatre Controlled Drug Record Book should be checked and reconciled with the amounts in the cabinet with sufficient frequency to ensure that discrepancies can be identified in a timely way.

Within the operating theatres and other interventional areas of NHS Grampian it is strongly recommended that checks of the actual quantities present against the balance recorded should be made at least daily, by a registered nurse, midwife, or an operating department practitioner (ODP) and a second appropriate person, e.g. registered nurse/midwife, ODP or a student nurse/midwife/ODP. Certain areas may choose to check the balance of controlled drugs more frequently, for example at the start and end of operating lists. For theatres/areas that are not operational on a daily basis checks should be carried out at least weekly. When theatres/areas are not operational for more than a few weeks, the CD team should be contacted for advice.

These checks must be recorded in the Theatre Controlled Drug Record Book. The dedicated stock check page(s) at the back of the Theatre Controlled Drug Record Book should be used to record these checks. Any local variations to this should be recorded within the specific area/theatre Standard Operating Procedures (SOPs) for CDs.

3.2. Recording in the Theatre Controlled Drug Record Book

All drugs supplied, administered and discarded must be recorded in the appropriate sections of the Theatre Controlled Drug Record Book according to their strength, e.g. morphine sulphate should be recorded in milligrams (mg), fentanyl and alfentanil in micrograms (mcg) (see Appendix 1a - 1b for examples). The exception to this is remifentanil which is reconstituted in saline. When stating the amount supplied for remifentanil the volume of diluent that the drug has been reconstituted in must also be recorded in the Theatre Controlled Drug Record Book, e.g. 2mg/40mL, quantities of remifentanil administered and discarded should be recorded in millilitres (see Appendix 1c - Example).

The responsible person at the time of supply is the registered nurse/midwife or ODP in possession of the CD keys. For every CD supplied, the anaesthetist requesting the drug must sign in the witness box at the point when they take ownership of the controlled drug.

In theatres at the point of administration it is only the anaesthetist who is required to sign. In recovery the administration of CDs should be witnessed by a second registered nurse/midwife/ODP and both should sign the Theatre Controlled Drug Record Book accordingly.

At the point of destruction the responsible person can be either the anaesthetist or the nurse/midwife or ODP. For witnesses to the destruction of a CD it is desirable that they were involved in the CD preparation however, it is recognised that this is not always practicable, therefore the witness to the destruction of a CD can be any registered nurse/midwife or ODP from the theatre team.

3.3. Controlled Drugs Administered as Titrated Doses

There are several departments/areas across NHS Grampian where it may be appropriate to manage pain through individual patient assessment and the use of CDs administered as titrated doses. Such departments/areas would include recovery departments and other interventional areas.

There is a requirement for clarity regarding the prescribing, preparation, administration and destruction of CDs administered as titrated doses. This is necessary to ensure the prompt and appropriate treatment of pain with adequate patient safety, controls and a clear audit trail.

The responsibilities for signing the Controlled Drug Record Book are as stated in section 3.2. With titrated doses, the total amount of incremental doses administered must be recorded as the amount administered and any reminder which is not required must be recorded as destroyed in the Controlled Drug Record Book.

3.4. Storage and Recording of Midazolam within the Operating Department

Midazolam is a Schedule 3 CD and is not subject to safe custody requirements for storage. Midazolam is however a CD subject to abuse and midazolam is stored in the CD cabinet in theatres, recovery and other interventional areas. Midazolam does not need to be recorded in the Theatre Controlled Drug Record Book but in some areas there are local agreements to record midazolam in the Theatre Controlled Drug Record Book. Midazolam storage and recording requirements should be documented within the specific area/theatre Standard Operating Procedures (SOPs) for CDs.

3.5. Transfer of Stock CDs in Exceptional Circumstances

Areas should hold sufficient stocks to avoid the need to obtain supplies from other areas when they cannot be obtained from the pharmacy service. Each area/department should have a CD stock list generated in agreement with pharmacy staff and this should be reviewed annually.

In exceptional circumstances only, it may be necessary to transfer CDs between theatres/areas within the same department:

- When transferring stock the registered nurse/midwife or ODP from the requesting area must take their Theatre Controlled Drug Record Book with them to the supplying area.
- A nurse/midwife or ODP responsible for each area concerned in the transfer must make an entry in the supplying area's Theatre Controlled Drug Record Book stating clearly the amount of drug(s) being transferred and to which area they are going to. The entry in the supplying Theatre Controlled Drug Record Book must be dated and signed and the running balance of the stock should be altered accordingly.
- The balance of stock of the supplying area should be confirmed to be correct by checking the current physical stock holding for the drug concerned in the transfer.

Following the transfer of stock from another theatre the drugs received must be recorded in the Theatre Controlled Drug Record Book. The following details must be recorded:

- Date of transfer/receipt.
- The area that the drug(s) has been supplied from, i.e. Theatre 2 or Recovery 1 must be recorded in the "serial number of requisition" section of the Theatre Controlled Drug Record Book.
- Amount received – this must be recorded in words not numbers, i.e. "ten" rather than 10.
- Signature of the nurse/midwife or ODP receiving the CDs.
- Signature of the nurse/midwife or ODP supplying the CDs.
- Balance in stock – this should be confirmed to be correct by checking the current stock holding.

(See Appendices 1d and 1e Transfer examples).

For transfers to other areas (e.g. wards) outside the department the normal NHS Grampian policy for the transfer of CDs should be followed as per the NHS Grampian Policy and Procedure for the Safe Management of Controlled Drugs in Hospitals and Clinics.

3.6. Multiple Use of Single Use Injectable Medicines

Containers whose contents are designed to be used for more than one patient are labelled in such a way as to indicate that they are intended for multiple use. The contents of any other type of ampoule, whatever the size, must not be shared between patients. To do so would be out with the product license. Individual ampoules of opioids must be used for each individual patient and it is the responsibility of the healthcare professional who signed for receipt of the ampoule from the registered nurse/midwife/ODP to document the disposal of the discarded CD.

3.7. Cocaine Nasal Drops 10%

The manufacturer's recommendation for these drops is that they may be used for multiple patients within the same session. If there are patients on the list for the morning and the afternoon that require cocaine drops to be administered, then one bottle can be used, but must be discarded at the end of the day.

One bottle should be used for one day only and then discarded (see Appendix 1f for example of cocaine nasal drop documentation).

3.8. Monitoring and Inspection

A programme of external CD assurance checks is undertaken jointly every six months by pharmacy staff and a senior nurse/midwife/ODP from the area/department. Results are shared with Theatre Managers together with an action plan stating any recommendations for change in practice/improvement.

3.9. Standard Operating Procedures

There is a legal requirement for all areas of healthcare services that hold stocks of Controlled Drugs to have Standard Operating Procedures (SOPs) in place for their management and use. For full details see HDL (2007):12 and CEL (2007):14

Guidance on procedures can be found in NHS Grampian Policy and Procedure for the Safe Management of Controlled Drugs in Hospitals.

There should be standard operating procedures covering each of the activities concerned with CDs such as requisitioning, receipt, administration, etc. SOPs should be kept up-to-date, reflecting current legal and good practice requirements for CDs, and each should be clearly marked with the date of issue and review date. SOPs should be discussed with and reviewed by the CD Team. SOPs must comply with local policies and systems and be approved by area/departmental manager.

Refer to Appendix 2 and for a template for CD SOPs for Operating Theatre and training accountability record.

- The SOP contains a number of headed sections which outline the activities to be carried out by theatre staff to manage CDs safely.
- The left hand column describes the area of the SOP being addressed.
- The right hand column currently largely contains advice or an indication of the type of information (in bold) which should be entered in this section.
- In the majority of sections this right hand column should be updated with the relevant local information, describing the activity and its procedures applicable in the operating department.
- In some cases this may be used as the example but in other cases this may require more detailed local information, i.e. where a cabinet is located, who has the key, etc.
- Once updated with local information and processes the document can be saved as the operating department SOP with dates of completion.

3.10. Local Variation to Guidance

Where local circumstances prohibit adherence to this policy, local agreements may be made but only after discussion and agreement with the Accountable Officer/CD Team and the Theatre Manager. The agreement (variation) must be in writing, dated and signed by the relevant personnel and filed with the department copy of the NHS Grampian Policy and Procedure for the Safe Management of Controlled Drugs in Hospitals and Clinics. A copy of the agreement must also be held by the Accountable Officer/Controlled Drugs Team.

4. References

- NHS Grampian Policy and Procedure for the Safe Management of Controlled Drugs in Hospitals
- Safer Management of Controlled Drugs Standard Operating Procedures (Scotland) CEL 14 (2007)
- Storage of Drugs in Anaesthetic Rooms, Guidance on best practice from the RCoA

5. Responsibilities for implementation

Organisational:	Chief Executive and Management Teams
Corporate:	Senior Managers
Departmental:	Heads of Service/Clinical Leads
Area:	Line Managers
Hospital/Interface services:	Group Clinical Directors
Operational Management Unit:	Unit Operational Managers

Appendix 1a

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Drug name	Form	Strength/Concentration	Ampoule/vial size (if applicable)	Proprietary name (if applicable)
MORPHINE SULPHATE	INJECTION	10 mg /ml	1 ml	

Received from Pharmacy			Signatures for Receipts AND Record of Issues							
Date received	Amount received in words	Serial no. of requisition	Date	Patient's name & NHS Number	Amount S = Supplied A = Administered D = Destroyed (state if transferred)		Time	Responsible Person (Please Print & Sign)	Witness (Please Print & Sign)	Stock Balance (in numbers)
			Carried forward from page number 16					NURSE A Nurse A	NURSE B Nurse B	11 Balance on transfer
			3/4/24	DAISY DUCK 1703921626	S	10mg	08 10	NURSE A Nurse A	ANAESTHETIST C Anaesthetist C	10
					A	6 mg		ANAESTHETIST C Anaes C		
					D	4 mg	11 20	ANAESTHETIST C Anaes C	NURSE A Nurse A	
			3/4/24	MINNIE MOUSE 1901239291	S	10 mg	11 30	NURSE A Nurse A	ANAESTHETIST C Anaesthetist C	9
					A	9 mg		ANAESTHETIST C Anaes C		
					D	1 mg	15 10	ANAESTHETIST C Anaes C	NURSE A Nurse A	
*	WRITTEN IN ERROR WRONG SECTION NM VA 3/4/24		3/4/24	*ROGER RABBIT	S					
					A					
					D					
			4/4/24	DONALD DUCK 2703781619	S	10 mg	09 15	NURSE A Nurse A	ANAESTHETIST C Anaes C	8
					A	10 mg		ANAESTHETIST C Anaes C		
					D	0 mg				
			4/4/24	MICKEY MOUSE 1412954178	S	20 mg	11 50	NURSE A Nurse A	ANAESTHETIST C Anaes C	6
					A	17 mg		ANAESTHETIST C Anaes C		
					D	3 mg	14 10	ANAESTHETIST C Anaes C	NURSE A Nurse A	
4/4/24	TWENTY	BOOK 15 ORDER 9			S		15:00	NURSE A Nurse A	NURSE B Nurse B	26
					A					
					D					
			4/4/24	PIGLET PINK 1802994279	S	10 mg	15:30	NURSE A Nurse A	ANAESTHETIST C Anaes C	25
					A	10 mg		ANAESTHETIST C Anaes C		
					D	0 mg				
			4/4/24	WINNIE BEAR 6104983251	S	10mg	16:45	NURSE A Nurse A	ANAESTHETIST C Anaes C	24
					A	10 mg		ANAESTHETIST C Anaes C		
					D	0 mg				

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Appendix 1b

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Drug name	Form	Strength/Concentration	Ampoule/vial size (If applicable)	Proprietary name (If applicable)
FENTANYL	INJECTION	50 mcg /ml	10 ml	

Received from Pharmacy | **Signatures for Receipts AND Record of Issues**

Date received	Amount received in words	Serial no. of requisition	Date	Patient's name & NHS Number	Amount S = Supplied A = Administered D = Destroyed (state if transferred)		Time	Responsible Person (Please Print & Sign)	Witness (Please Print & Sign)	Stock Balance (in numbers)
			Carried forward from page number ..... 4 ⟹					NURSE A Num VA	NURSE B Num B	9 Balance on transfer
			30/5/24	ROGER RABBIT 1705781918	S	500mcg	08 10	NURSE A Num VA	ANAESTHETIST C A— C	8
					A	500mcg		ANAESTHETIST C A— C		
					D	0				
			30/5/24	PENNY PIG 1509735210	S	500mcg	09 30	NURSE A Num VA	ANAESTHETIST C A— C	7
					A	300mcg		ANAESTHETIST C A— C		
					D	200mcg	10 40	ANAESTHETIST C A— C	NURSE A Num VA	
			30/5/24	JOHN SMITH 1212845192	S	500mcg	11 30	NURSE A Num A	ANAESTHETIST C A— C	6
					A	150mcg		ANAESTHETIST C A— C		
					D	350 mcg	12 50	ANAESTHETIST C A— C	NURSE A Num VA	
					S					
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					

500 mcg = 10 ml
450 mcg = 9 ml
400 mcg = 8 ml
350 mcg = 7 ml
300 mcg = 6 ml
250 mcg = 5 ml
200 mcg = 4 ml
150 mcg = 3 ml
100 mcg = 2 ml
50 mcg = 1 ml

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Appendix 1c

Drug name	Form	Strength/Concentration	Ampoule/vial size (If applicable)	Proprietary name (If applicable)
REMIFENTANIL	INJECTION	2mg		

Received from Pharmacy — **Signatures for Receipts AND Record of Issues**

Date received	Amount received in words	Serial no. of requisition	Date	Patient's name & NHS Number	Amount (S = Supplied, A = Administered, D = Destroyed (state if transferred))		Time	Responsible Person (Please Print & Sign)	Witness (Please Print & Sign)	Stock Balance (in numbers)
			Carried forward from page number 26					NURSE A VA	NURSE B	16 Balance on transfer
			30/01/24	TIGGER THOMSON 1804497618	S	2mg/40ml	08:10	NURSE A VA	ANAESTHETIST C	15
					A	40ml		ANAESTHETIST C		
					D	0				
			30/01/24	KANGA ROO 2303394216	S	2mg/40ml	10:30	NURSE A VA	ANAESTHETIST C	14
					A	25ml		ANAESTHETIST C		
					D	15ml	11:40	ANAESTHETIST C	NURSE A VA	
			30/01/24	JOE BLOGGS 3007476152	S	2mg/40ml	11:55	NURSE A VA	ANAESTHETIST C	13
					A	30ml		ANAESTHETIST C		
					D	10ml	12:45	ANAESTHETIST C	NURSE A VA	
					S					
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					

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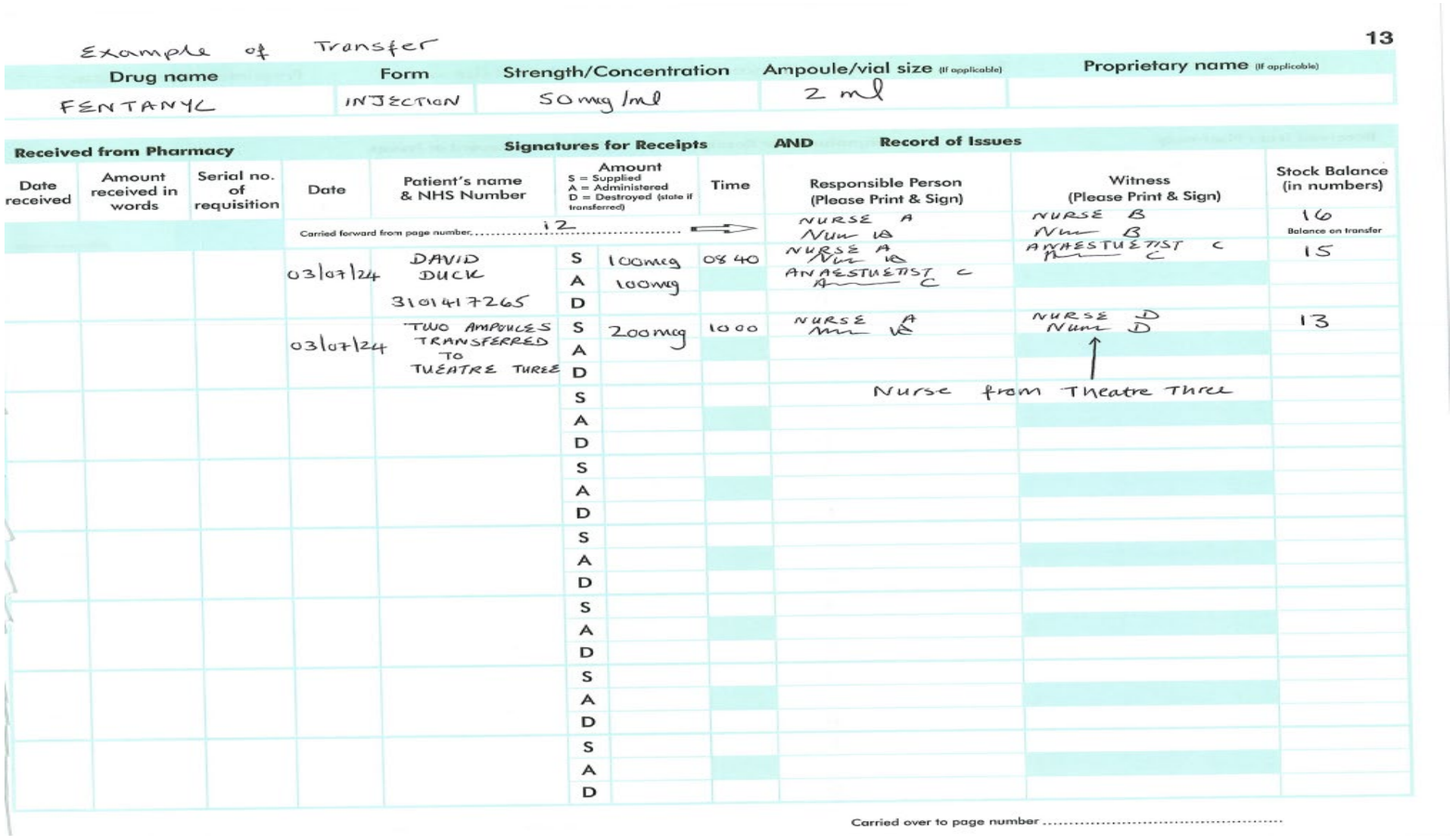
Appendix 1d



Example of Transfer

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Drug name	Form	Strength/Concentration	Ampoule/vial size (If applicable)	Proprietary name (If applicable)
FENTANYL	INJECTION	50mcg/ml	2 ml	

Received from Pharmacy | **Signatures for Receipts AND Record of Issues**

Date received	Amount received in words	Serial no. of requisition	Date	Patient's name & NHS Number	Amount (S = Supplied, A = Administered, D = Destroyed (state if transferred))		Time	Responsible Person (Please Print & Sign)	Witness (Please Print & Sign)	Stock Balance (in numbers)
			Carried forward from page number 12							16 Balance on transfer
			03/07/24	DAVID DUCK 3101417265	S	100mcg	0840	NURSE A Num A	NURSE B Num B	
					A	100mcg		ANAESTHETIST C A C	ANAESTHETIST C C	15
					D					
			03/07/24	TWO AMPOULES TRANSFERRED TO THEATRE THREE	S	200mcg	1000	NURSE A Num A	NURSE D Num D	13
					A					
					D					
					S				Nurse from Theatre Three	
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					

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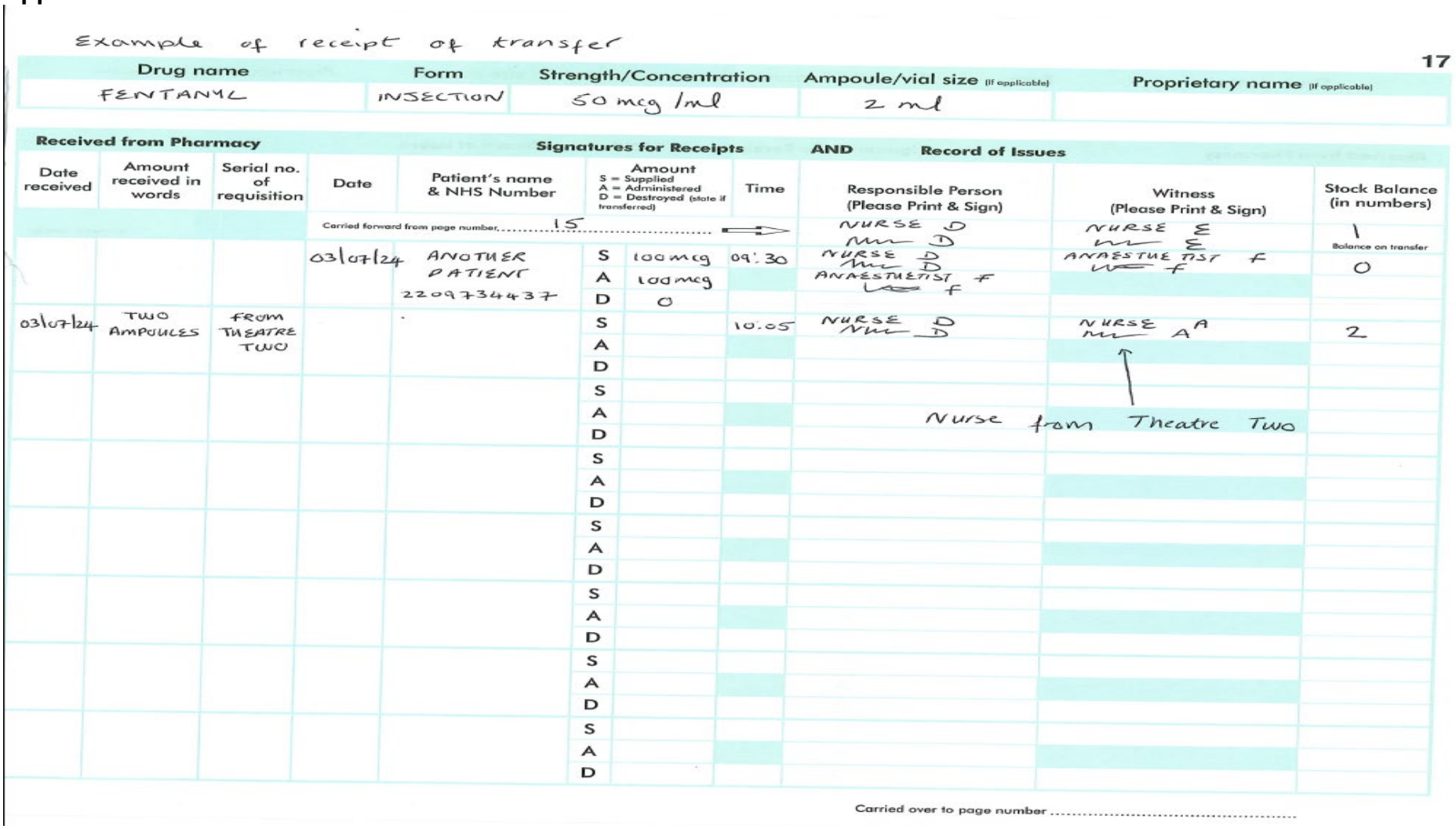
Appendix 1e



Example of receipt of transfer

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Drug name	Form	Strength/Concentration	Ampoule/vial size (If applicable)	Proprietary name (If applicable)
FENTANYL	INJECTION	50 mcg /ml	2 ml	

Received from Pharmacy | **Signatures for Receipts AND Record of Issues**

Date received	Amount received in words	Serial no. of requisition	Date	Patient's name & NHS Number	Amount (S = Supplied, A = Administered, D = Destroyed (state if transferred))		Time	Responsible Person (Please Print & Sign)	Witness (Please Print & Sign)	Stock Balance (in numbers)
			Carried forward from page number 15					NURSE D	NURSE E	1 Balance on transfer
			03/07/24	ANOTHER PATIENT 2209734437	S	100 mcg	09:30	NURSE D; ANAESTHETIST F	ANAESTHETIST F	0
					A	100 mcg				
					D	0				
03/07/24	TWO AMPOULES	FROM THEATRE TWO			S		10:05	NURSE D	NURSE A	2
					A					
					D					
					S					
					A			Nurse from Theatre Two		
					D					
					S					
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					

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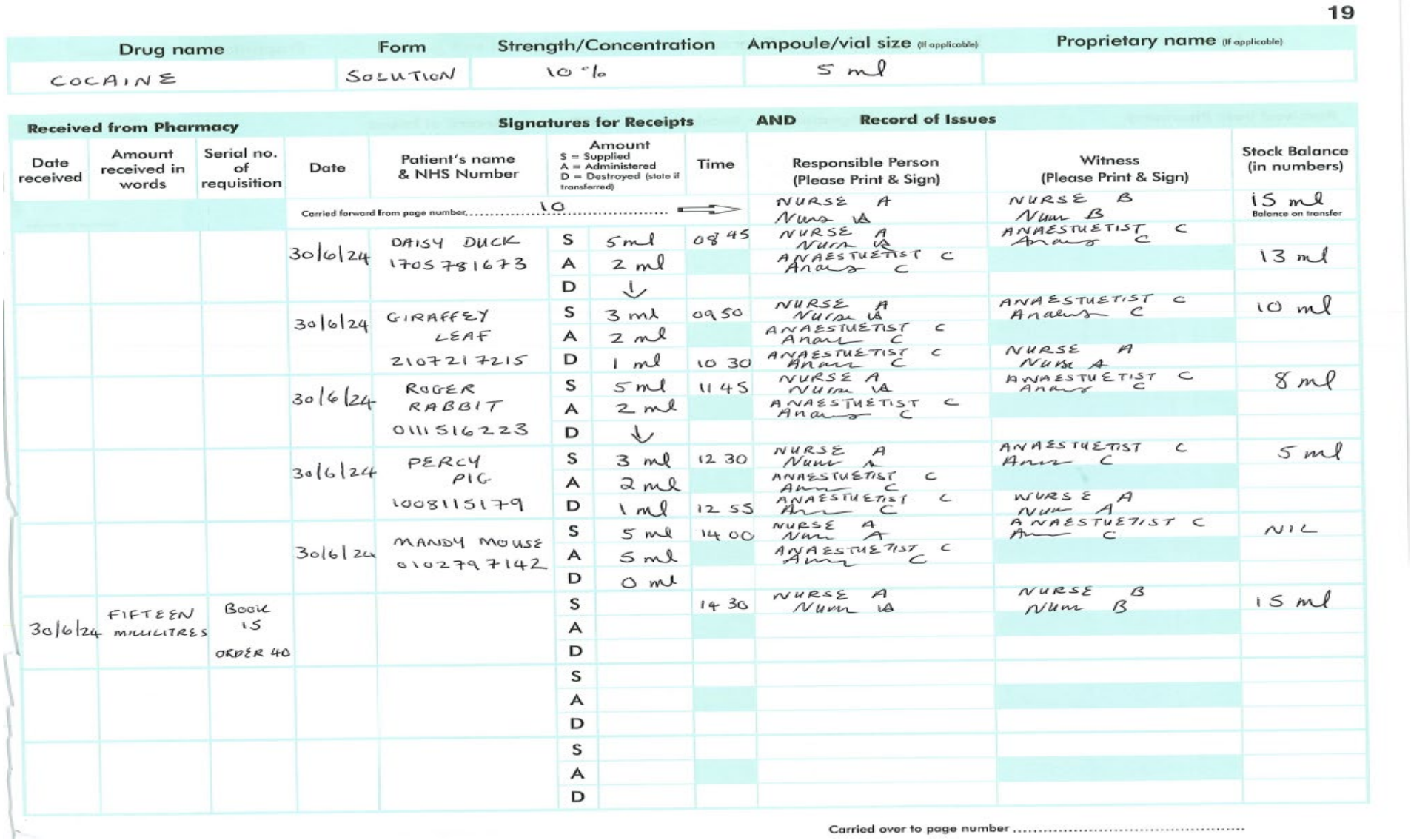
Appendix 1f



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Drug name	Form	Strength/Concentration	Ampoule/vial size (if applicable)	Proprietary name (if applicable)
COCAINE	SOLUTION	10 %	5 ml	

Received from Pharmacy — **Signatures for Receipts AND Record of Issues**

Date received	Amount received in words	Serial no. of requisition	Date	Patient's name & NHS Number	Amount (S = Supplied, A = Administered, D = Destroyed (state if transferred))		Time	Responsible Person (Please Print & Sign)	Witness (Please Print & Sign)	Stock Balance (in numbers)
			Carried forward from page number 10					NURSE A Num A	NURSE B Num B	15 ml Balance on transfer
			30/6/24	DAISY DUCK 1705781673	S	5ml	0845	NURSE A Num A	ANAESTHETIST C Anes C	
					A	2 ml		ANAESTHETIST C Anes C		13 ml
					D	↓				
			30/6/24	GIRAFFEY LEAF 2107217215	S	3 ml	0950	NURSE A Num A	ANAESTHETIST C Anes C	10 ml
					A	2 ml		ANAESTHETIST C Anes C		
					D	1 ml	1030	ANAESTHETIST C Anes C	NURSE A Num A	
			30/6/24	ROGER RABBIT 0111516223	S	5ml	1145	NURSE A Num A	ANAESTHETIST C Anes C	8 ml
					A	2 ml		ANAESTHETIST C Anes C		
					D	↓				
			30/6/24	PERCY PIG 1008115179	S	3 ml	1230	NURSE A Num A	ANAESTHETIST C Anes C	5 ml
					A	2 ml		ANAESTHETIST C Anes C		
					D	1 ml	1255	ANAESTHETIST C Anes C	NURSE A Num A	
			30/6/24	MANDY MOUSE 0102797142	S	5 ml	1400	NURSE A Num A	ANAESTHETIST C Anes C	NIL
					A	5 ml		ANAESTHETIST C Anes C		
					D	0 ml				
30/6/24	FIFTEEN MILLILITRES	BOOK 15 ORDER 40			S		1430	NURSE A Num A	NURSE B Num B	15 ml
					A					
					D					
					S					
					A					
					D					
					S					
					A					
					D					

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Appendix 2 - Standard Operating Procedure

CONTROLLED DRUGS	**Standard Operating Procedure For Controlled Drugs (CDs) In Operating Departments**				
	SOP No.		Version	Date	
NHS Grampian			Review Date		
	Superseded Version No and Date				
	Author		Approved by		

Revision Chronology		
Version No	Effective Date	Reason for Change

1. Purpose

Completion of this document with local practice information ensures that all legal and professional requirements relating to the use of Controlled Drugs (CDs) are satisfied.

There is a legal requirement for all areas of healthcare services that hold stocks of Controlled Drugs to have Standard Operating Procedures in place for their management and use. For full details see HDL (2007):12 and CEL (2007):14

Guidance on procedures can be found in NHS Grampian Policy and Procedure for the Safe Management of Controlled Drugs in Hospitals.

It is intended to provide advice on the minimum standards and does not preclude more stringent controls being in place.

2. Scope

This standard operating procedure covers all aspects of the management of controlled drugs (CDs) within the Operating Environment. These procedures apply to all individuals working within Operating Departments who deal with Schedules 2, 3 and 4 (part I) Controlled Drugs as part of their job role within the department.

3. Responsible Persons

Theatre management, all grades of Anaesthetist, Registered Nurses, Midwives and Operating Department Practitioners (ODPs).

4. Responsibilities

The registered nurse/midwife or ODP in charge of a department or theatre is legally responsible for the CDs in the theatre/department and is responsible for the safe and appropriate management of CDs in that area. It is their responsibility to ensure all staff is aware of and follow these SOPs in relation to CDs.

The following staff have been authorised to receive handle and dispense CDs and have access to safe storage facilities. Anaesthetists of all grades, Registered Nurses/Midwives and ODPs.

5. Information

The fourth report of the Shipman Inquiry "*The Regulation of Controlled Drugs in the Community*" made recommendations to strengthen and improve current systems for the management and use of controlled drugs. The UK Government's response to the report set out a programme of work to address the shortcomings identified by the Inquiry. The Health Act 2006 and Regulations made under the Act – the Controlled Drugs (Supervision of Management and Use) Regulations 2006 – introduced new governance arrangements for controlled drugs which includes a requirement that healthcare organisations holding stocks of controlled drugs must put in place and operate within SOPs. There is a legal requirement for all areas of healthcare services that hold stocks of Controlled Drugs to have Standard Operating Procedures in place for their management and use. For full details see HDL (2007):12 and CEL (2007):14

Guidance on procedures can be found in NHS Grampian Policy and Procedure for the Safe Management of Controlled Drugs in Hospitals.

It is intended to provide advice on the minimum standards and does not preclude more stringent controls being in place.

6. Responsible Persons

Controlled Drug Accountable Officer (CDAO) A person nominated by the NHS Board to be responsible for a range of measures relating to the monitoring of the safe use and management of CDs in accordance with the Health Act 2006 and the CD Regulations.	**CDAO Team Contact details :** gram.directorofpharmacy@nhs.scot gram.cdteam@nhs.scot
Anaesthetic Staff Anaesthetic staff should ensure that they are aware of the procedures contained within the CD SOP and are expected to follow these procedures. Anaesthetists are responsible for the signing for CDs they have received in the operating Theatre Controlled Drug Record Book, and for recording in the patient's notes (or anaesthetic	**All anaesthetic staff currently employed within NHSG are authorised to be involved with all stages of CD preparation, administration and disposal unless deemed otherwise by the GMC or the Director of Anaesthetics NHSG.** **All locum anaesthetists working within NHSG operating departments are subject to the same authority in regard**

record) the amount of drugs administered. Anaesthetists must return any unopened ampoules and are responsible for the safe disposal of any unused controlled drugs that remain in an open ampoule or syringe.	**to CDs as those directly employed by the trust unless they are subject to restrictions imposed by the GMC.**
Theatre Managers Theatre Managers will ensure the procedures contained within the CD SOP are introduced and followed by all their staff. They will ensure that all staff expected to deal with CDs are aware of how to access the SOP. They will identify any areas of significant risk and take action to control this risk. They will promote and demonstrate good practice associated with CD use.	**Insert names of theatre managers**
Registered Nurses/Midwives and ODPs All staff dealing with CDs will ensure they are familiar with the SOP and will follow the correct procedure when undertaking any task involving CDs. They will report any concerns relating to the risks associated with CDs to their line manager or pharmacist so action can be taken.	**All registered nurses/midwives and ODPs employed by NHSG are authorised to order, receive, handle and discard of CDs within the operating department.** **Registered agency and bank staff are subject to the same authority as NHSG staff in regard to CDs provided they have been deemed competent by management to handle CDs.**

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Theatre Controlled Drug Record Book, Ordering, Receipt, Collection, Transfer and Return of CDs (SOP) 1

Theatre Controlled Drug Record Book Entries of all CDs received, supplied, administered and destroyed must be made in the Theatre Controlled Drug Record Book.	**Detail who is responsible for ensuring that the Theatre Controlled Drug Record Book is kept up to date and in good order.** **Detail who should complete entries within the Theatre Controlled Drug Record Book and which parts of the record book should be completed and how.** **Detail what to do on reaching the last line of a page in the Theatre Controlled Drug Record Book.**
Errors made when writing in the Theatre Controlled Drug Record Book must be corrected in accordance with NHSG policy.	**Detail what to do when an entry is written in error or a mistake is made in the Theatre Controlled Drug Record Book.**
The Theatre Controlled Drug Record Book must be stored securely.	**Detail where the Theatre Controlled Drug Record Book is kept.**
When the Theatre Controlled Drug Record Book is full a new record book should be started. Completed Theatre Controlled Drug Record Books must be retained for two years from the date of the last entry.	**Detail how and where to obtain a new Theatre Controlled Drug Record Book from.** **Detail the process for transferring stock from the old Theatre Controlled Drug Record Book to the new one.** **Detail where completed Theatre Controlled Drug Record Books should be stored.**

Ordering Each theatre should hold a CD stock list. The list should be agreed with the area pharmacist, anaesthetists and theatre manager. The list should be kept up to date and modified as required.	**Detail where the CD stock list is kept and the procedure to follow should the list require to be altered in any way.**
Format of requisitions including descriptions of all forms and stationery to be used.	**Detail how you place an order for CDs, list the processes involved, i.e. The registered nurse/midwife or ODP orders CDs by completing the requisition in the CD order book etc.**

The CD order book must be stored securely. New CD order books will be issued automatically by the Senior Pharmacy Technician for CDs as the current book nears the end. There is no action required from theatre staff to order a replacement. The completed CD order book must be retained for 2 years from the date of last entry.	**Detail where the CD order book is kept.** **Detail where completed books are to be kept and what you will do with them at the end of the 2 year period. Describe the actions to be taken following the loss or theft of an order book.**
CD orders can only be carried out by authorised signatories.	**Detail where the theatres authorised signatories list is kept and how often it should be reviewed.**
There are two pages to each order. The white original is removed by the pharmacist/technician who supplies the drugs and is retained in the Pharmacy Department. The pink copy remains in the Theatre/Department CD Order Book. Mistakes made at the time of ordering must be clearly annotated.	**Describe what to do if you make a mistake when completing an order.**
Designated CD order day(s)	**Detail the order days for all theatres and recoveries within the department.**
CDs required out of hours or in an emergency.	**Detail the procedures that must be followed to obtain CDs out with the regular order time. (Emergency theatres – out of hours supplies).**
CD orders that have been placed and not received in the expected timescale	**Describe who to contact in this instance and what action you would take locally, i.e. Datix reporting.**
Receipt Personnel authorised to receive CDs	**All registered nurses/midwives and ODPs employed by NHSG are authorised to receive CDs.**

	All agency and bank staff working within the operating department can receive CDs provided they have been authorised to do so by management.
All CD orders received must be reconciled against the original order.	**Detail exactly the process that is followed once CDs have been delivered from pharmacy.**
An entry is made in the Theatre Controlled Drug Record Book by the recipient at the time of receipt.	**Specify what details should be recorded in the record book at the time of receipt and who should be recording.**
Collection of CDs from Pharmacy The "Accepted for delivery" section of the theatre CD order book will only be filled in if a member of staff collects the CDs personally from the pharmacy.	**Detail the process for collecting CDs from pharmacy. Include security/ID requirements.**
Transfer of CDs between theatres/departments Theatres should hold sufficient stocks to avoid the need to obtain supplies from other theatres/recovery when they cannot be obtained from the pharmacy service. In exceptional circumstances it may be necessary to transfer CDs between theatres.	**Detail process for transferring CDs between theatres/recovery.**

Transfer of Patients to Other Clinical Areas With CDs Attached Patients will frequently be transferred from the theatre recovery to the ward with either a PCA or epidural infusion in situ.	**Detail the responsibilities of the recovery nurse/midwife/ODP in regards to the transfer of the patient, e.g. Chart recording and hand over**

Returning CDs to Pharmacy Where a pharmacy is present on site, CDs which are no longer required or which have expired should be returned to the relevant pharmacy department during normal working hours.	**Detail process for returning CDs to pharmacy.**

Storage, Key security And Missing CD Keys (SOP) 2.

Storage of CDs CDs must be stored in a locked CD Cabinet. The cabinet must conform to BS2881 or be approved by pharmacy.	**Detail whether or not the CD cabinets either conform to BS2881 or have been approved by pharmacy.**
CDs stored within the CD cabinet.	**Detail the storage points regarding CDs that must be followed e.g. CDs locked away when not in use, only CDs are be stored in the cabinet ,etc.**

Security of CD Keys	
The registered nurse/midwife or ODP in charge is responsible for the CD key, and any duplicate keys.	**Give details of the Senior Nurses/Managers who hold overall responsibility for your department.**
Key-holding may be delegated to other suitably-trained, registered nurses/midwives, or ODPs but the legal responsibility remains with the registered nurse, midwife, or ODP in charge.	**Give details of who can and cannot hold the CD keys within the department.**
The keys for the CD cabinet must be kept separate from other keys and stored securely at all times.	**Detail how the CD keys are kept during the day, who keeps them? Detail where the keys are stored out of hours and how to obtain them.**

Missing CD Keys	
If the CD keys cannot be found, every effort must be made to retrieve these as speedily as possible.	**Detail step by step the process that you would follow if keys were discovered to be missing, i.e. check that no other theatre staff have possession of the keys, check any areas visited by key carrier in case they have been dropped, contact senior nurse etc.**
Keys that cannot be found must be reported in accordance with NHSG Policy.	**Detail who to contact if the keys cannot be found. Detail the appropriate action to be taken once entry to the cabinet has been regained i.e. full stock check of contents, risk assessment etc.**

Prescribing, Administration And Disposal of CDs (SOP) 3.

Prescribing of CDs Who is authorised to prescribe CDs?	**Detail staff groups, i.e. all Consultant Anaesthetists, Specialist Registrars, etc.**
Prescription stationery	**i.e. anaesthetic charts. Prescription and Administration Record (PAR)**
Administration of CDs Who can administer a CD?	**Detail staff groups, include for nursing and ODP staff acting under the direct supervision of anaesthetists in exceptional circumstances, etc.**
Assembly	**Removal from cabinet, reconstitution, etc.**
Special precautions	**i.e. IV, Calculations.**
Disposal of CDs Management of CD spillages and part used doses should comply with the trust waste management policy. When the dose to be administered to a patient is less than the contents of the smallest available ampoule, the required dose should be administered and the remaining drug denatured.	**Detail what steps to take should there be a spillage of a CD or accidental breakage of an ampoule/vial.** **Detail the requirement to document any spillages/breakages.** **Detail how to discard part used CD ampoules and syringe contents. Describe what should be recorded in the Theatre Controlled Drug Record Book following a discard.** **Detail where to obtain new medicinal waste bins and Pre-Gel/Vernagel.**

CD Checks, Discrepancies and Security/Suspected Loss of CDs (SOP) 4.

CD Checks The stock balance of all CDs entered in the Theatre Controlled Drug Record Book should be checked and reconciled with the amounts in the cabinet with sufficient frequency to ensure that discrepancies can be identified in a timely way.	**Detail the frequency of checks in your area and how they are documented.**
CD Discrepancies Any discrepancy must be investigated without delay.	**Detail what process you would follow to deal with a CD discrepancy including who you would report the discrepancy too and in what time frame.**
If an error is traced appropriate amendments should be made to the Theatre Controlled Drug Record Book.	**Detail how to amend/update the Theatre Controlled Drug Record Book following a resolved discrepancy, include information regarding the recording of the discrepancy within the stock check sheets and any follow up investigation/action.**
Security/Suspected Loss of CDs A breach of security includes any deviation from the procedures that cause actual or potential loss or theft of medicines.	**Detail what steps you would follow and who you would contact should you discover any of the following;** • **CDs found to be missing** • **CD stationery found to be missing** • **A CD cabinet Key found to be missing** • **Any suspicious/inappropriate behaviour in relation to the management of CDs.**

Controlled Drugs SOPs Accountability/Training Record

The undersigned have read and received training on the SOPs relevant to their responsibilities and will work to them and any future SOP.

Date	Name	Registered nurse, midwife, ODP or other (specify)	Signature

Appendix 3 - NHS Grampian Controlled Drugs Team

NHSG Controlled Drug Accountable Officer (CDAO)	e-mail: gram.directorofpharmacy@nhs.scot
Controlled Drugs Team	e-mail: gram.cdteam@nhs.scot