

STANDARD OPERATING PROCEDURE:	CONTROLLED DRUGS INCIDENTS
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**AT ALL TIMES, STAFF MUST TREAT EVERY INDIVIDUAL WITH RESPECT
AND UPHOLD THEIR RIGHT TO PRIVACY AND DIGNITY**

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1 CONTROLLED DRUG LOSSES OR DISCREPANCIES

- 1.1 In the event of a discrepancy between stock balance and register for controlled drugs, the nurse/midwife/ODP or departmental lead in charge of the area (hereafter referred to as 'the person in charge of the area') must immediately investigate the loss.
- 1.2 If the discrepancy is unresolved at this stage then the ward/department pharmacist must be contacted and asked to attend the ward/department to try and resolve the discrepancy.
- 1.3 When the pharmacy is closed, the On-Call Pharmacist must be notified.
 - 1.3.1 If the discrepancy involves more than one unit of an oral solid-dose medicine, loss of one or more original packs or suspected loss of any amount of injectable controlled drugs then the On-Call Pharmacist must attend the ward/department as soon as possible.
 - 1.3.2 Other discrepancies can at the discretion of the On-Call Pharmacist be investigated when the pharmacy is open the next morning.
- 1.4 If the discrepancy remains unexplained after further investigation then a Controlled Drugs Incident Reporting Proforma (CDIRP) (Appendix 1) must be completed.
- 1.5 A DatixWeb incident report must also be completed and the WEB reference quoted on the CDIRP.
- 1.6 The CDIRP must be submitted to the Trust Controlled Drugs Accountable Officer (CDAO) within 24 hours of the incident being discovered. At WWL NHSFT the CDAO is the Director of Pharmacy. In the absence of the CDAO the CDIRP must be submitted to one of the Associate Directors of Pharmacy within the same timescale.
- 1.7 For oral liquid medicines where the discrepancy is 5% or less of the original volume in the container no incident reporting is required. The balance can be adjusted in the register by a pharmacist and registered nurse provided there is no suspicion of divergence.
- 1.8 For oral liquid medicine where the discrepancy is more than 5% of the original volume (but less than an original pack) incident reporting is required. The incident will usually be investigated internally unless other circumstances are present that warrant consideration of police involvement (suspicion of criminal activity or multiple occurrences in a given location for example.)
- 1.9 For single missing doses of oral solid-dose medicines incident reporting is required. The incident will usually be investigated internally unless other circumstances are present that warrant consideration of police involvement (suspicion of criminal activity or multiple occurrences in a given location for example.)
- 1.10 For discrepancies of more than one unit of an oral solid dosage form, loss of one or more original packs of CDs or suspected loss of any amount of injectable controlled drug losses then the incident reporting process will be followed as above but the CDAO must be notified as soon as possible. The CDAO will contact the Controlled Drug Liaison Officers of Greater Manchester Police for information and further advice.
- 1.11 Statements must be taken from all relevant staff on duty between the time of the last correct balance check and the time if a CD Incident Reporting Proforma has been completed due to an unresolved discrepancy. This is the case regardless of whether police involvement is being considered.

2 CONTROLLED DRUG PRESCRIBING, DISPENSING OR ADMINISTRATION ERRORS

- 2.1 If a CD prescribing, dispensing or administration error is discovered then the person discovering the error must report it to the person in charge of the area where the error is discovered.
- 2.2 If the CD error involves incorrect administration to a patient then the first action is to have the patient reviewed by an appropriately trained medical practitioner and any immediate action taken to correct any health issues. Any monitoring required must be put in place. The patient must be fully informed in all cases as part of the 'open and transparent' culture employed at WWLNHSFT. For moderate or severe harm incidents Duty of Candour requirements must be followed as per TW10-054 Being Open and Duty of Candour Policy and associated SOP.
- 2.3 The person in charge of the area must then ensure that a CDIRP (Appendix 1) is completed.
- 2.4 A DatixWeb incident report must also be submitted and the WEB reference quoted on the CD Incident Reporting Proforma
- 2.5 The CDIRP must be submitted to the CDAO within 24 hours of the incident being discovered. In the absence of the CDAO the incident must be reported to one of the Associate Directors of Pharmacy within the same timescale.

3 OTHER CONTROLLED DRUG INCIDENTS

All Controlled Drug Incidents require the person in charge of the area to ensure that a CD Incident Reporting Proforma (CDIRP) is completed and submitted to the Controlled Drug Accountable Officer (CDAO) within 24 hours and that the incident is logged on DatixWeb. This ensures that all incidents are notified to the NHS England Local Intelligence Network and investigated appropriately.

3.1 Spillages or breakages

- 3.1.1 These should be treated as per controlled drug losses or discrepancies except as there is a known cause police involvement would not normally be required.
- 3.1.2 Two trained staff must document the spillage/breakage in the CD register and amend the balance accordingly.
- 3.1.3 The broken/spilt CD requires appropriate denaturing and so the pharmacy team must be contacted to assist with this. Staff, patients and visitors must be kept away from the area until the area has been made safe and the CD appropriately disposed of.

3.2 Theft

- 3.2.1 Any witnessed/suspected theft must be investigated as per controlled drug losses or discrepancies but if initial investigations are unable to prove otherwise then the incident must be escalated to the CDAO and Senior Manager on Call (SMOC)
- 3.2.2 They will then discuss the case and contact the police for further advice on how to proceed if appropriate.
- 3.2.3 The person in charge of the area must take statements of all relevant staff on duty since between the times of the last correct balance check and the time of the witnessed/suspected theft.

3.3 **Loss of keys**

- 3.3.1 The person in charge of the area must conduct a thorough search of the location and check with all staff on duty to try and locate the keys.
- 3.3.2 If the keys cannot be located then the person in charge of the area must contact all staff who may have had possession of the CD keys since they were last used in order to try and locate them.
- 3.3.3 The person in charge of the area must inform the ward pharmacist at this point.
- 3.3.4 If all staff have been contacted and the keys have not been found then the works department must be contacted as soon as practicable to change the locks and provide new keys. The Site Co-Ordinator must be informed if this is the case.
- 3.3.5 Unless a criminal act is suspected then the police would not normally require to be informed.

3.4 **Controlled Drug Fraud, Illegal Sale or Supply of CDs, Alleged Abuse by Staff or Patients**

- 3.4.1 Any person witnessing or with suspicion of any such incidents must notify the person in charge of the area.
- 3.4.2 If the person in charge of the area believes there is evidence of any of the above incidents being the case then they must escalate it to the Site-Co-ordinator, SMOC and CDAO.
- 3.4.3 The police would usually be informed in such cases but all other circumstances would need to be considered.

3.5 **Illicit Substances**

- 3.5.1 A Home Office license would be required to possess Schedule 1 Controlled Drugs (such as LSD, ecstasy-type substances, opium or cannabis.)
- 3.5.2 If such substances are removed from patients on admission to hospital, they should be handed to a pharmacist as they have specific exemptions for two purposes. Pharmacists can be in possession of Class 1 CDs for the purpose of destruction or handing over to a police officer.
- 3.5.3 Trust security staff would be committing an offence if they take possession of such substances and should not be asked to do so.
- 3.5.4 Patient confidentiality should be maintained and the police should be called only on the understanding that the source will not be identified. If the quantity is so large that it could not be for personal use only then the pharmacist may decide to contact the police. This must only take place after discussion with the patient's consultant, named nurse, Director of Pharmacy, Head of Security and SMOC.
- 3.5.5 The patient should give authority for the drug to be removed and destroyed. This should be witnessed and recorded in the patient's notes. If the patient refuses then the pharmacist may have no option other than to call in the police. The team described in 3.5.4 must be involved.
- 3.5.6 Under no circumstances can a suspected illicit drug be handed back to the patient.
- 3.5.7 All transfer of suspected illicit drugs requires completion of the Illicit Drug Transfer Form (Appendix 2). The form must accompany the suspected illicit drug through to final destruction in the presence of the police and then the form is to be retained in the pharmacy for 7 years.
- 3.5.8 Out of hours: Suspected illicit substances can be stored in the Controlled Drugs cupboard until the pharmacy is next open, at which time the ward pharmacist can be contacted for assistance.

3.6 Safe storage incidents

3.6.1 CDs must be stored safely and securely at all times as per SOP TW10/037 – SOP 8 ‘Storage of Medicines at Ward and Departmental Level.’

3.6.2 Any incidents where CDs are not stored in accordance with this SOP must be reported to the person in charge of that area so that they can ensure that the incident forms are completed.

4 HUMAN RIGHTS ACT

Implications of the Human Rights Act have been taken into account in the formulation of this document and they have where appropriate been fully reflected in its wording.

5 ACCESSIBILITY STATEMENT

This document can be made available in a range of alternative formats e.g. large print, Braille and audio CD.

For more details please contact the HR Department on 01942 77 3766 or email equalityanddiversity@wvl.nhs.uk.

Appendix 1**Controlled Drugs Incident Reporting Proforma (CDIRP)**

All incidents involving controlled drugs must have this form completed and submitted to the Trust Controlled Drugs Accountable Officer (CDAO) within 24 hours of the incident being discovered.

The CDAO for Wrightington Wigan & Leigh NHS Trust is:

Mike Parks, Director of Pharmacy Michael.parks@wwl.nhs.uk 01942 822489

If he is unavailable then report the incident to one of the Deputy Directors of Pharmacy:

Gary Masterman Gary.Masterman@wwl.nhs.uk 01942 772875

Rachel Ball Rachel.Ball@wwl.nhs.uk 01942 778809

If you require any assistance completing this form contact your ward pharmacist or one of the above pharmacists

NOTE: This is in ADDITION to a DatixWeb Report being submitted

REPORTER DETAILS	
Full Name	
Email	
Contact Phone Number	
Occupation	

PEOPLE INVOLVED	
Name of Person	
Role (State Profession or Patient)	
Registration Number (if known)	
<i>If more than one person was involved please add details in the space at the end of the form</i>	

INCIDENT DETAILS	
Date incident was reported	
Location (E.g. Ward B, Pharmacy)	
Site	
Organisation	
Date CDAO informed	
DATIX WEB REFERENCE	

Incident Type (tick one or more – further detail is added below)	Loss/Theft of Controlled Drug		Loss/Theft of keys	
	Loss/Theft of CD Prescription		Loss/Theft of CD Register/Order Book	
	Fraud – Prescription		Fraud – attempt to obtain	
	Fraud – Recording		Illegal Sale or Supply of CDs	
	Balance Discrepancy		Spillage/unauthorised Destruction	
	Administration Incident		Abuse by patient/staff (alleged)	
	Expired Controlled Drugs		Delivery Incident	
	Dispensing Incident		Individual of Concern	
	Prescribing Incident		Recording Incident	
Safe Storage Incident		Transcribing Incident		

Please add further details over the Page

INCIDENT DESCRIPTION (Please provide as much detail as possible – include facts – how people were involved and if medication was involved full drug details)

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ACTIONS (Please state what actions were taken – what were the outcomes to patients and staff,

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LESSONS LEARNED (What were the lessons learned. How are these lessons to be shared and by whom. What is the action plan to prevent recurrence)

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OTHER PEOPLE INVOLVED	
Name of Person	
Role (State Profession or Patient)	
Registration Number (if known)	
OTHER PEOPLE INVOLVED	
Name of Person	
Role (State Profession or Patient)	
Registration Number (if known)	

DATE AND TIME INCIDENT CLOSED ON DATIXWEB	
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ILLICIT DRUG TRANSFER FORM

To be used for all cases where suspected illicit drugs are transferred from wards /departments to pharmacy for police destruction

Date:	
Time:	
PAS number:	
Ward/Department:	
Details of drug (if known)	
Quantity (if known)	
Comments:	
Received from: (Print and Sign)	
Received by: (Print and Sign)	

To be completed by pharmacy:

Date and time received in Pharmacy	
Date and time police contacted	
Date and time destroyed	
Destroyed in the presence of (Police Officer) (Print and Sign)	
Destroyed in the presence of (Pharmacy) (Print and Sign)	