GIG CYMRU NHS WALES | Bwrdd Iechyd Addysgu Powys / Powys Teaching Health Board

Standard Operating Procedure for the Management of Concerns or Incidents Relating to Controlled Drugs

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The latest approved version of this document is online.
If the review date has passed please contact the Author for advice.

Version Control

Version	Summary of Changes/Amendments	Issue Date
1	Initial Issue	Oct 2020
2	Review	January 2024

ENGAGEMENT & CONSULTATION

Key Individuals/Groups Involved in Developing this Document

Role / Designation
Kathryn Harries, Senior Medicines Management Technician

Circulated to the following for Consultation

Date	Role / Designation
January 2024	Medicines Management team members
January 2024	Members of PTHB Controlled Drugs Intelligence Network (CD LIN)

Evidence Base

IMPACT ASSESSMENTS

Equality Impact Assessment Summary					
	No impact	**Adverse**	**Differential**	**Positive**	**Statement** ***Please provide supporting narrative for any adverse, differential or positive impacts that may arise from the implementation of this policy***
Age	X				
Disability	X				
Gender reassignment	X				
Pregnancy and Maternity	X				
Race	X				
Religion or Belief	X				
Sex	X				
Sexual Orientation	X				
Marriage and Civil Partnership	X				
Welsh Language	X				

Risk Assessment Summary
Have you identified any risks arising from the implementation of this policy / procedure / written control document? No risks identified
Have you identified any Information Governance issues arising from the implementation of this policy / procedure / written control document? No risks identified
Have you identified any training and / or resource implications as a result of implementing this? None identified

1 Introduction

The Controlled Drugs Accountable Officer is appointed to ensure that systems for the safe and secure management and use of controlled drugs are in place across Powys Teaching Health Board. The appointment and responsibilities of the CDAO are set out in the Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008.

The above regulations contain a requirement for the CDAO to establish and operate systems for recording, assessing and investigating concerns and untoward incidents relating to the safer management of controlled drugs.

Reports relating to the safer management of controlled dugs are routinely received by the health board's Medicines Management Team.

2 Objective

This document sets out how the Medicines Management Team will manage reports of concerns or incidents relating to the prescribing or management of controlled drugs. It is designed to ensure that such reports are managed efficiently and in accordance with current legislation and guidance.

3 Definitions (Mandatory Heading)

- **CD –** Controlled Drug
- **CDAO –** Controlled Drugs Accountable Officer
- **CDLIN** – Controlled Drugs Local Intelligence Network
- **MM** – Medicines Management Team.
- **NWSSP** – NHS Wales Shared Services Partnership
- **PTHB** – Powys Teaching Health Board
- **SOP** – Standard Operating Procedure

4 Responsibilities

4.1 Chief Pharmacist

The Chief Pharmacist must:

- Ensure all staff read, understand and comply with this SOP.
- Arrange regular review to monitor compliance with this procedure

4.2 Controlled Drugs Accountable Officer

The CDAO must:

- Ensure all concerns and incidents are recorded appropriately.
- Assess all concerns and incidents and, where required, initiate an investigation.
- Where considered necessary, establish an incident panel to investigate a concern.
- Ensure that appropriate action is taken to protect staff, patients and members of the public, in relation to concerns about the management of controlled drugs.
- Share relevant information with the CDLIN.

4.3 Senior Pharmacists/ Senior MM Technicians

The Senior Pharmacists must:

- Ensure staff are trained in using this procedure
- Ensure dissemination of this document
- Support MM staff with implementing this procedure
- Manage investigations in support of / as delegated by the CDAO
- Monitor incidents for themes or trends which may indicate wider issues
- Escalate concerns to the CDAO
- Share learning from CD incidents as appropriate to help prevent similar incidents in the future.
- Keeping all documentation updated.

4.4 All MM Staff

All MM staff must:

- Be aware and familiar with this SOP.
- Manage CD incidents/concerns in line with this procedure
- Escalate to a senior colleagues where required.

5 Process

5.1 Receiving a Concern

All concerns or incidents relating to controlled drugs should be reported to the CDAO (Powys.CDAO@wales.nhs.uk) within 48 hours of the concern/incident coming to light, using the CD Incident report form.
Information about concerns or incidents received via an alternative route (e.g. Datix) should be forwarded to the above email address and the reporter should be asked to complete and submit a CD Incident Report Form. If received via DATIX then DATIX email should be used to request a completed CD Incident Report Form.

	All concerns should be brought to the attention of the CDAO without delay. Where the CDAO is not available, the concern should be brought to the attention of the most appropriate senior pharmacist or senior pharmacy technician, depending upon availability and which setting the concern relates to. The CD concern/incident should be allocated a number according to the year in which the incident/concern was received and the number of incidents received to date (e.g. if the incident/concern is the first incident received in 2024, it will be allocated number 2024-01). A folder should be set up, named with the appropriate incident number. Any documents (e.g. emails) relating to the concern/incident should be recorded in the relevant folder of the CD incident folder. Details of the incident/concern should be recorded on the CD Concerns Incident Record log.
	5.2 Allocating a Concern for Assessment or Investigation The CDAO, or the pharmacist or pharmacy technician notified of the concern in the CDAO's absence, will risk assess the concern in line with the Controlled Drug Risk Assessment Tool (Appendix One). Considering the nature of the concern and risk assessment, the concern should be delegated in writing (e.g. by email) to an appropriate member of the Medicines Management Team(*the delegated person*) for further investigation. The CDAO, or deputizing member of the MM team will indicate if immediate contact with one or more external authorities is required, including but not limited to: • Police • Counter Fraud Services • NWSSP • Health Inspectorate Wales • The appropriate professional regulator (e.g. NMC, GPhC, GMC) Any request to an external authority to undertake or support an investigation should be recorded on the *Controlled Drug Concern Incident Record*
	5.3 Recording a Concern The delegated person should ensure that the incident/concern has been recorded on the *Controlled Drug Concern Incident Record* and ensure that the record is kept up to date.

In all cases where they have not already done so, the original reporter of the concern should be requested to complete and return a CD Incident Report Form.

Where indicated by the risk assessment, the concern should also be recorded on Datix at http://nww.powysthb.wales.nhs.uk/incident-reporting-datix. The initial Datix should be recorded by the original reporter where possible, but may be recorded by a member of the MM dept. where necessary (e.g. the original reporter does not have access to DATIX).

If not already submitted, a request should be made by the DATIX investigator (via DATIX internal email system) for a completed CD Incident Report Form *to be submitted.*

All documentation relating to an incident/concern should be saved in the relevant folder (i.e. the folder named according to the CD incident number) in the CD incident folder.

5.4 Investigating a Concern

The delegated person should take all reasonable steps to support the investigation of a concern, fully and within an appropriate timescale considering the nature of the concern and the risk assessment.

In the majority of low risk cases, the investigation should be undertaken by the contractor/professional who raised the concern (e.g. a dispensing "near miss" should be investigated by the dispensing contractor). The delegated person should offer advice and support as appropriate.

The investigation should produce, or support the production of a significant event analysis which indicates that:

- The concern has been fully investigated; and
- The concern has been reflected upon; and
- Relevant learning has been considered and shared; and
- Action has been taken to reduce the risk of recurrence; and
- The concern is not reflective of a theme or trend which may indicate wider issues

For concerns of moderate risk or higher, the delegated person should lead the investigation, with support, where appropriate, from the relevant contractor/professional who raised the concern. The delegated person may engage external authorities in the investigation where necessary and appropriate. These may include, but are not limited to:

- NHS contractors (e.g. GP practices, community pharmacies, dentists, optometrists)
- Professional regulators (e.g. GMC, GPhC, NMC, GDC, GOC)
- Dyfed-Powys Police (link is PC Andrew Smart, andrew.smart@dyfed-powys.pnn.police.uk, Tel 01267 226225)
- Counter Fraud (link is Louisa Steele, louisa.steele@wales.nhs.uk Tel 01874 712419)
- Health Inspectorate Wales (hiw@gov.wales, Tel 0300 062 8163)

Consideration should be given to the risks and benefits associated with sharing personal identifiable information with external authorities. Such sharing should only be undertaken in accordance with Powys CD LIN Information Sharing Code, and at the request of the CDAO. Where there is any doubt, guidance should be sought from the CDAO and PTHB Information Governance dept.

The records outlined in 5.3 should be routinely updated throughout the investigation, in sufficient detail to support a full review of the investigation at a later date should this be considered necessary.

A completed copy of the CD Incident Report Form must be attached to any related DATIX report completed as part of the investigation.

5.5 Updating the CDAO

The CDAO should be updated at appropriate intervals during the investigation, depending upon the nature of the concern, the risk assessment and the breadth of the investigation.

If at any stage the delegated person is of the view that the investigation is not progressing or believes that the concern is more serious or widespread than that originally suspected, they should raise this with the CDAO at the earliest opportunity.

5.6 Local / National Alerts

Where considered necessary to reduce the risk of further harm or criminality, and at the explicit request of the CDAO, the delegated person may request NWSSP to issue an alert to one or more groups of NHS primary care contractors and NHS service providers in Powys or nationally. NWSSP link is Paula Bainbridge, paula.bainbridge@wales.nhs.uk.

Where considered appropriate, the alert should be distributed within the health board by the MM team, and to other relevant groups or persons e.g. Kaleidoscope Treatment Agency (link is Barry Eveleigh, barry.eveleigh@kaleidoscopeproject.org.uk or Kath Davies kath.davies@kaleidoscopeproject.org.uk, Tel 01686 610422)

	A copy of any alert issued by NWSSP should be retained as part of the investigation process. Where there is any doubt about the need to disclose personal identifiable information, guidance should be sought from PTHB Information Governance dept. A full record of all information disclosed in relation to controlled drugs concerns should be maintained, along with the rationale behind the decision to disclose the information. This information should be added to the Controlled Drugs Concerns Incident Record.
	5.7 Completing the Investigation Upon completion of the investigation, the DATIX report, CD incident form and CD incident record should be fully completed and a summary of the findings made available for the CDAO to review. This will inform whether further recommendations or actions are required. Where agreed by the CDAO, once all records have been completed, the investigation may be closed. Relevant details and learning points should be shared with the CDLIN via the Health Board's quarterly Occurrence Report or if considered appropriate and necessary, via email to CDLIN members if the cascade cannot wait until the CDLIN meeting.

6 Monitoring Compliance, Audit & Review

All information and investigations associated with CD concerns or incidents will be routinely reviewed by the CDAO/Chief Pharmacist.

This document will be reviewed every three years or earlier should incidents, audit results or changes to legislation / practice within PTHB indicate that an earlier update is required.

7 References

NICE (2016), Controlled Drugs: safe use and management [NG46]; https://www.nice.org.uk/guidance/ng46

Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008; https://www.legislation.gov.uk/wsi/2008/3239/contents/made

NPC (2011), Handbook for Controlled Drugs Accountable Officers in England

NPC (2009), A guide to good practice in the management of controlled drugs in primary care

National Clinical Assessment Service, Clinical Governance Toolkit for Controlled Drug Management in Primary Care in the NHS

National Clinical Assessment Service, Investigating Concerns About the Prescription of Controlled Drugs in General Practice

Appendix One - Controlled Drug Risk Assessment Tool

Risk Rating	Incident Type	Actions
Low	• Storage error (no risk of harm) • Minor balance discrepancy • Minor spillage / breakage • Non-deliberate recording error • Prescribing / transcribing / dispensing / administration error – did not reach patient • Policy deviation not affecting patient	MM Team to review Record on DATIX
Moderate	• Lost / missing CD keys • Storage error (potential risk of harm) • Balance discrepancy (Primary care: more than 10% oral liquid, or 5% other, or recurring; Hospital: all) • Significant spillage / breakage • Destruction error • Dispensing / administration error – reached patient, but not administered • Non-significant prescribing / transcribing / dispensing / administration error – reached patient and administered • Patient / public sale or supply of CDs • Concern re prescribing levels and/or patterns	Record on Datix MM Team to review Escalate to external authority where appropriate
High	• Theft / attempted theft by professional • Significant prescribing / transcribing / dispensing / administration error – reached patient and administered • Fraudulent attempt to obtain CDs • Illicit use by professional • Sale / illicit supply by professional • Abuse by patient – illicit or prescribed medication • Deliberate overdose • Police incident	Record on Datix Escalate to Quality and Safety dept. MM Team to support review.
Severe	• Patient death	Escalate to Executive Director and NHS Wales. Record on Datix MM Dept. to support review