SAFE AND SECURE HANDLING OF MEDICINES

Section 8.7 Controlled drug (CD) incident reporting and discrepancy investigation

8.7.1. CD Incident reporting [Return to Section 8.7.]

Effective adverse event and risk management processes are in place throughout the organisation to enable learning from adverse events. It focuses on reporting and reviewing adverse events and near misses in an open, honest and safe environment; continually highlighting good practice and identifying improvements. Reporting an adverse event is not about blame, but recognising when something hasn't gone to plan whilst considering what has occurred and any actions or learning which can be implemented following the event which may reduce the likelihood of a similar incident again. Reporting an adverse event may also highlight good practice which has occurred following this event.

There is a legal requirement for the Controlled Drugs Accountable Officer (CDAO) to be notified of all incidents and concerns regarding CDs and they must be recorded and investigated by local management and reported on Datix in line with existing procedures for clinical or medication incidents. These reports must be recorded fully and include details of:

- the action taken, including the immediate steps to prevent or reduce harm to patients,
- any investigations undertaken and
- the actions taken to prevent recurrence.

This will provide assurance to the CDAO that the incident has been thoroughly investigated. All incident reports involving a CD must be tagged accordingly on Datix to ensure the report is automatically sent to the CD team.

Any concerns regarding the management or use of CDs must be raised with the CDAO. All concerns will be treated with the strictest confidence. All investigations will be carried out discreetly. Appropriate support will also be provided during an investigation.

In the event of a serious incident, harm or concern, the CDAO or lead pharmacist for the CD team must be notified directly immediately by emailing tay.cdteam@nhs.scot.

Where there is evidence or a strong suspicion of criminal activity or risk to patient/staff safety, Police Scotland may also need to be informed (suspected or actual theft of medicines).

The CDAO should receive information on issues related to:

<u>Clinical governance and professional practice:</u>

- All events or near misses involving prescribing, administration, supply or dispensing of CDs
- Any concern(s) about professional practice or behaviour of staff in relation to CDs for example unusual prescribing pattern
- Complaints from patients/carers/service users relating to CDs

<u>Record keeping and stock discrepancies:</u>

- Unexplained losses/discrepancies of any CD, regardless of schedule.
- Explained loss of any CD including where a CD is dropped, damaged or spilled.

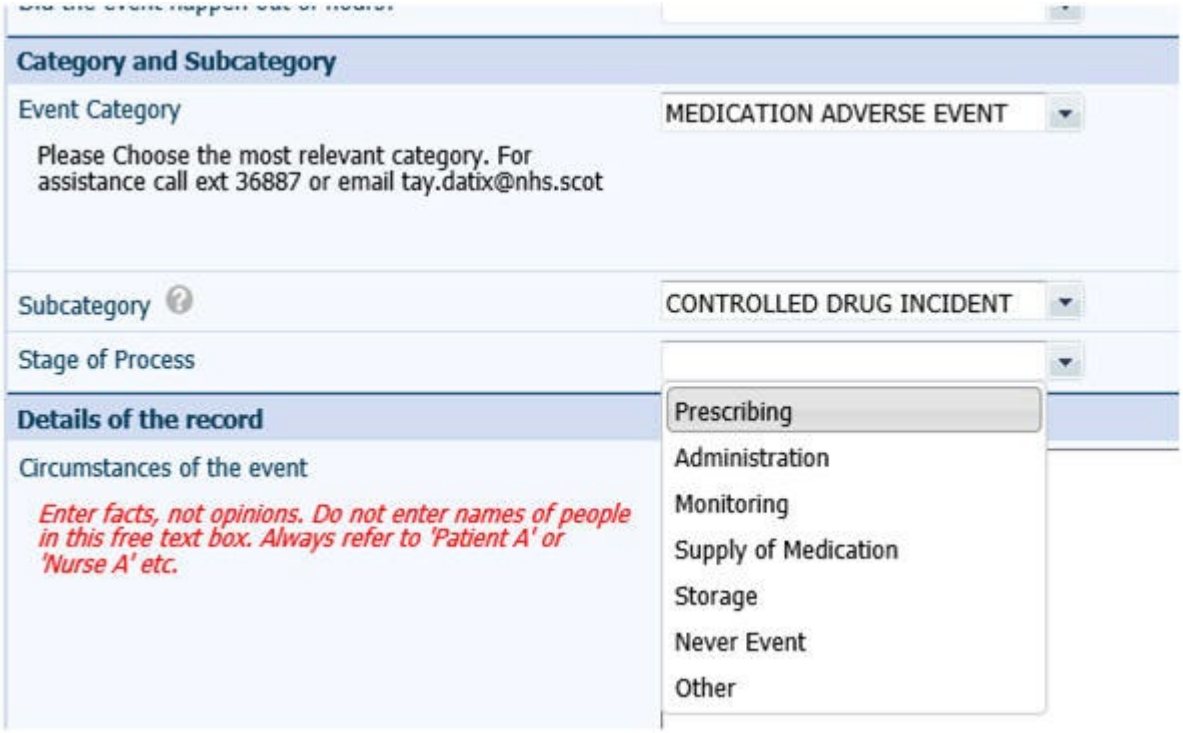
- Any discrepancy in CD stock which, although resolved, raises concerns.
- Events or near misses involving CD destruction.
- Loss of CD register/order book or other relevant controlled stationery.

Fraud and Possible Criminal Issues:

- Any suspected illegal activity relating to CDs e.g. theft, patients attempting to obtain CDs by deception.
- Lost or stolen prescription forms.
- Attempts to fraudulently produce prescriptions.

These examples are not mutually exclusive, for example, record keeping issues may escalate to concerns about clinical practice or suspected theft.

When recording an Adverse Event in Datix for a Controlled Drug incident, ensure to complete the following:



By completing the Datix form as above, including all relevant information pertaining to the incident, this will notify the Controlled Drugs Governance Team and the members of staff involved do not need to contact the team directly.

8.7.2. Dealing with Discrepancies [Return to Section 8.7.]

8.7.2.1 Initial investigation [Return to Section 8.7.]

The running balance in the CD register must be checked against the contents of the CD cabinet. If a discrepancy is identified it must be reported immediately to the nurse/midwife/operating department practitioner (ODP) in charge for investigation. A Datix must then be submitted following this verbal communication.

The CD register should be updated by the nurse/midwife/ODP in charge with the correct balance, the Datix reference number and the statement 'discrepancy identified – under investigation'. The entry must be witnessed by another nurse/midwife/ODP and both must sign the CD register.

NAME, FORM OF PREPARATION AND STRENGTH....OXYCODONE 5mg MR TABLETS 8

AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED						
Amount	Date Received	Serial No Of Requisition	Date	Time	Patient's Name	Amount given	Given by (signature)	Witnessed by (signature)	STOCK BALANCE
Carried forward from Page Number.....7.....									Balance on transfer
			24/04/2020	2310	BALANCE B/F FROM PREVIOUS PAGE		A NURSE	B NURSE	10
			24/04/2020	2310	PATIENT A	10mg	A NURSE	B NURSE	8
			25/04/2020	0910	PATIENT B	5mg	C NURSE	D NURSE	6
			25/04/2020	1100	PATIENT A	10mg	C NURSE	D NURSE	4
			25/04/2020	2020	DISCREPANCY IDENTIFIED – UNDER INVESTIGATION DATIX NUMBER 123456		A NURSE	B NURSE	5

Carried over to page number.....

The nurse/midwife/ODP in charge should complete the investigation checklist

The nurse/midwife/ODP in charge should:

- Check arithmetic since last correct balance
- Remove and check **all** of the physical stock held within the CD cabinet with the running balance in the CD register to ensure there are no further discrepancies
- Check all CD stock including out of date CDs and patient own CDs
- Check no medicines have become loose and lodged between shelves in the CD cabinet
- Check the missing CDs have not been stored in the wrong place e.g. main drug cupboard
- Check other CD register sections of the same CD for erroneous entries
- Sense check the CD register (for example correct pack size, potential missing entry)
- Check all CD orders been entered correctly
- Review all patient administration charts to ensure all CDs have been administered
- Speak to all staff on duty during relevant time period to determine any untoward occurrences which may have contributed to this discrepancy
- Check all balance transfers from page to page tally
- Check all patient own CDs have been recorded in the correct CD register
- Check if all patient's own CDs are segregated appropriately within the CD cabinet

8.7.2.2. Reason for discrepancy found [Return to Section 8.7.]

If on completing the investigation checklist the reason for the discrepancy has been found e.g. calculation error, the nurse/midwife/ODP in charge should annotate the CD register appropriately to rectify the error and the correct balance should be recorded. Any entry must be signed, witnessed and dated. No entries should be scored out or obliterated. Square brackets must be placed around any erroneous entries and annotated with an *. A corresponding * should be placed at the bottom of the page (if the next line is unavailable in the CD register) and an annotation made giving a clear explanation for the error. This entry must be signed, witnessed and dated at the bottom of the page.

The Datix record should be updated and the investigation checklist uploaded to the record

For more detailed guidance on oral liquid discrepancies see section 8.5.6.

NAME, FORM OF PREPARATION AND STRENGTH....OXYCODONE 5mg MR TABLETS 8

AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED						
Amount	Date Received	Serial No Of Requisition	Date	Time	Patient's Name	Amount given	Given by (signature)	Witnessed by (signature)	STOCK BALANCE
Carried forward from Page Number.....7.....									Balance on transfer
			24/04/2020	2310	BALANCE B/F FROM PREVIOUS PAGE		A NURSE	B NURSE	10
			24/04/2020	2310	PATIENT A	10mg	A NURSE	B NURSE	8
			25/04/2020	0910	PATIENT B	5mg	C NURSE	D NURSE	(6)*7
			25/04/2020	1100	PATIENT A	10mg	C NURSE	D NURSE	(4)*5
			25/04/2020	2020	DISCREPANCY IDENTIFIED – UNDER INVESTIGATION DATIX NUMBER 123456		A NURSE	B NURSE	5*
			25/04/2020	2103	PATIENT B	5mg	B NURSE	A NURSE	4

*CALCULATION ERROR IDENTIFIED DURING COMPLETION OF INVESTIGATION CHECKLIST. DATIX UPDATED. NURSE IN CHARGE A /B NURSE 25/04/2020

Carried over to page number.....

8.7.2.3 Reason for discrepancy not found [Return to Section 8.7.]

If on completing the investigation checklist the reason for the discrepancy has **not** been found the nurse/midwife/ODP in charge should inform the senior charge nurse/midwife/ODP or on-call duty manager for the area/site in the OOH period. The ward pharmacy team should also be informed.

The senior charge nurse/midwife/ODP should review the discrepancy checklist to make sure that all parts have been completed appropriately. They may want to repeat the steps in the checklist with another nurse/midwife/ODP who was not involved in the initial checks.

If the reason for the discrepancy has **not** been found then the senior charge nurse/midwife/ODP should update the CD register detailing that the investigation is complete and the discrepancy has not been found either as a footnote or on the next line of the CD register if it is available. The entry must be signed, witnessed and dated.

The Datix record should also be updated and the investigation checklist uploaded to the record.

For more detailed guidance on oral liquid discrepancies see section see section 8.5.6.

NAME, FORM OF PREPARATION AND STRENGTH....OXYCODONE 5mg MR TABLETS **8**

AMOUNT(S) OBTAINED			AMOUNT(S) ADMINISTERED						
Amount	Date Received	Serial No Of Requisition	Date	Time	Patient's Name	Amount given	Given by (signature)	Witnessed by (signature)	STOCK BALANCE
Carried forward from Page Number.....7.....									Balance on transfer
			24/04/2020	2310	BALANCE B/F FROM PREVIOUS PAGE		A NURSE	B NURSE	10
			24/04/2020	2310	PATIENT A	10mg	A NURSE	B NURSE	8
			25/04/2020	0910	PATIENT B	5mg	C NURSE	D NURSE	7
			25/04/2020	1100	PATIENT A	10mg	C NURSE	D NURSE	5
			25/04/2020	2020	DISCREPANCY IDENTIFIED – UNDER INVESTIGATION DATIX NUMBER 123456*		A NURSE	B NURSE	4
			25/04/2020	2103	PATIENT B	5mg	B NURSE	A NURSE	4
			24/04/2020	2305	PATIENT A	10mg	A NURSE	B NURSE	2

* INVESTIGATION CHECKLIST COMPLETED AND UPLOADED TO DATIX. INVESTIGATION COMPLETE, NO REASON FOR DISCREPANCY FOUND. SENIOR CHARGE NURSE A/NURSE B 27/04/2020

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8.7.3. Security/Suspected Loss of CDs [Return to Section 8.7.]

Theft of CDs is a serious criminal offence under the Medicines Act 1968, the Human Medicine Regulations 2012, the Misuse of Drugs Act 1971 and other legislation which will be dealt with accordingly by NHS Tayside.

A breach of security includes any deviation from the procedures that cause actual or potential loss or theft of medicines:

- CDs found to be missing
- CD stationery found to be missing
- CD cabinet key found to be missing
- Patient's own CDs found to be missing
- An unauthorised person has access to CDs or CD stationery

Any person who discovers a breach of security is responsible for reporting it immediately to the nurse / midwife/ODP in charge and completing a Datix. The nurse/midwife/ODP in charge must take reasonable steps to establish if CDs are in fact missing by carrying out a full stock check of the CD cabinet with another nurse/midwife/ODP. All investigations must be carried out in a discrete manner.

If the nurse/midwife/ODP in charge is unsatisfied that all medicines are accounted for, their suspicions must be reported to the senior charge nurse/midwife/ODP or on-call duty manager for the area/site in

the out of hours (OOH) period. The ward pharmacy team should also be informed. The discrepancy investigation process should be initiated as detailed in section 8.7.2.

If there is evidence or a strong suspicion of criminality or risk to patient/staff safety, the senior charge nurse/midwife/ODP or the on-call duty manager for the area/site in the OOH period should give consideration to contacting Police Scotland. Further advice can be obtained from the CD team if required by emailing tay.cdteam@nhs.scot.

[Return to Section 8.7.]