Walsall Safeguarding Partnership

Medication Error Guidance:

When to Raise a Safeguarding Concern

Guidance to support agencies & providers where medication errors have occurred

November 2020

Adapted from guidance produced by Norfolk Safeguarding Adult Board/Norfolk County Council

1. Purpose

The Care Act 2014 defines safeguarding as 'protecting an adults right to live in safety, free from abuse and neglect'. Safeguarding is about preventing and responding to concerns of abuse and/or neglect.

To promote the health and wellbeing of adults, it is important that medication errors are immediately reported as per your organisations guidelines. This enables there to be a prompt response to any adult where an error may have occurred and ensure that medical attention is undertaken where required.

It is on this basis that this guidance has been produced by Walsall Council, Walsall CCG & Walsall Acute Healthcare Trust on behalf of the Walsall Safeguarding Partnership, to enable organisations, agencies and providers to ensure that best practice is maintained for the administration of medication and where errors occur the appropriate actions are taken, assurance is provided and learning is shared.

The purpose of this guidance is to provide:

- Guidance to determine when a medication error needs to be reported to Walsall Council as a safeguarding adults concern
- Clarification and consistency for reporting between statutory notifications for CQC (for providers registered under the Health & Social Care Act, 2008) and the legal requirement for safeguarding adult concerns
- Alignment with Walsall Council provider contractual reporting requirements
- Clarity on reporting processes and pathways

This guidance is relevant to a wide variety of agencies, including Walsall Local Authority Employees, Providers registered under the Health & Social Care Act (2008), Walsall Acute HealthCare Trust, CCG and Informal Carers.

It is, however important to note, that this guidance is not a substitute for individual organisations/agencies to ensure they provide safe and effective care and medication administration and to have their own medication management policies and procedures in place for their staff that include management of medication errors, near misses and adverse drug reactions.

Only staff who have undertaken the necessary medicines administration training and are assessed as competent should administer medicines.

Each organisation/agency is also responsible for ensuring this guidance is appropriately used and any decisions to raise or not raise a medication error as a safeguarding concern are reviewed within each organisations/agencies governance processes.

2. What is a Medication Error?

The National Patient Safety Agency's (NPSA) definition of medication errors is: "Patient safety incidents involving medicines in which there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring, or providing medicine advice, regardless of whether any harm occurred". Errors can be as a result of staff competency, lack of knowledge, failure to adhere to systems and protocols, poor communication, poor handwriting and staff interruptions.

Examples of medication errors are given below: (this is not an exhaustive list)

- Omissions – any prescribed dose not given
- Wrong dose administered, too much or too little
- Medication given to wrong patient
- Extra dose given
- Wrong dose interval
- Wrong administration route
- Wrong time for administration
- Not following 'warning' advice when administering e.g. take with or after food
- Administration of a drug to which the patient has a known allergy
- Administration of a drug past its expiry date or which has been stored incorrectly

Medication errors fall into 2 groups:

- Errors of Commission
  For example, giving the wrong dose or medication
- Errors of Omission
  For example, omitting to give the prescribed dose

In either group, the medication error could be ***accidental*** or ***purposeful***.

As previously stated, it is essential that you follow your organisations policy and procedure for medication errors and remember that any incidents relating to controlled drugs, including the loss or theft of such drugs, must be reported to the NHS Controlled Drugs Accountable Officer. Notification to the controlled drugs officer must take place through the official website and each home needs to register on the site (Please see Appendix 2 for additional information). Where criminality is suspected, they must also be reported to West Midlands Police.

It is also important that **all** medication errors are reported to the adults GP or responsible health professional for advice.

It is recognised that not all medication errors require a safeguarding referral, however any error **does** still require a management response.

3. Medication without Consent

Where an adult is unable to consent to receiving medication, then this must be clearly evidenced. This would need to evidence that an MCA has been completed to determine that the person lacks the mental capacity to consent to receipt of medication, as outlined in Mental Capacity Act (2005).

Organisations need to ensure they have policies and procedures in place. For individual cases, a best interest decision, following the principles of the mental Capacity Act 2005, must be made and in place, be clearly recorded and evident within the adults care plan. The plan must be clearly followed and regularly reviewed. Where medication is administered without this framework in place, it needs to reported as a safeguarding concern to the Local Authority.

4. When should a Safeguarding Adults Concern be raised?

An adult safeguarding concern describes the process where someone becomes aware that a concern or incident indicates there is reasonable cause to suspect that:

- An adult with care and support needs is
- At risk, or experiencing abuse or neglect, and
- Can't protect themselves as a result of those need
  (S42(1) Care Act, 2014)

There are a number of key areas where a safeguarding concern should be raised. These are:

- Where a medication error triggers the requirement for a CQC notification. This would be where the cause or effect of a medication error results in:
  - Death
  - Injury
  - Abuse or an allegation of abuse
  - An incident reported to or investigated by the Police

(Further information and guidance about how to report to CQC and timescales can be found at https://cqc.org.uk/)

- Where the medication error has resulted in harm to the adult.
- Where medication has been used as a form of unlawful-restraint (e.g. a non-prescribed sedative is given, or a higher dose of prescribed medication is given)
- Medication is deliberately administered/neglected to be administered contrary to the prescribed directive
- Administering medication covertly where no covert medication protocol is in place
- Consecutive or multiple medication errors with the same person, e.g. medication not given overall several drug rounds due to not being ordered)
- Single medication error involving multiple adults (e.g. where a whole medication round was not completed)

- Multiple/repeat incidents by the same service or same perpetrator evidencing a pattern of medication errors
- PRN medication where it is evident that it has been given outside of the guidance the medication should be given for

Systemic Failings

Where medicine management within an organisation evidences systemic failings (e.g. repeated medication errors affecting multiple adults, insufficient preventative measures in place such as auditing and training or previous concerns regarding medication administration and corrective action has not been maintained), then a safeguarding concern should be raised to Walsall Council and concerns also raised with CCG Medication Management Team. Referral details can be found in Section 10 and Appendix 1.

5. Examples of Poor Practice that would not trigger a safeguarding concern

Often errors occur which are a result of poor practice but do not require a safeguarding response. Examples are:

- Gaps in recording e.g. signature missing on MARS sheet (providing it did not cause confusion resulting in the medication being administered twice or not being administered and causing harm)
- Medication not being given on one or more occasions to one individual and no harm occurs
- Medication being given late, was not time specific and no harm occurs

However, it is important to note that in all of these examples, it is essential that each error is investigated/reviewed by the agency/organisation where the error occurred and appropriate actions taken to minimise future risk of reoccurrence

6. What Should I do where a Medication Error does not Trigger a Safeguarding Concern?

It is very evident, that although a medication error may not trigger a safeguarding concern, it is still poor practice and should be immediately addressed by the organisation/agency. This is to ensure that any future risks are mitigated. Organisations/agencies could consider a number of actions including:

- **Medication Audits**
  Robust, regular medication audits enables a service to identify any errors and trends
- **Investigations**
  Investigating medication errors, no matter how minor they may be, enables further actions to be identified to enable future risks to be reduced/mitigated. This might identify actions such as staff training, reviewing procedures or staff disciplinary

- **Recording**
  It is important to keep a record of all medication errors and actions taken as this can also help to identify any trends, provide an audit tool and also evidence actions that have been taken
- **Sharing Learning**
  No matter how minor the medication error is, it is good practice to share the learning with staff as this can help to support a transparent culture where practices improves
- **Reporting**
  Residential and Nursing homes must notify Walsall Quality in Care Team of medication errors where the safeguarding trigger has not been met
- Walsall NHS Trusts must record all medication incidents on Datix and review in keeping with internal Trust assurance purposes.

For support with medication training, Care Homes can make local arrangements with the pharmacist who dispenses their medication or through an accredited training company. Guidance on any medication issues can also be obtained from the medicines management team at Walsall CCG who can be contacted on medicines.walsallccg@nhs.net

Additional guidance for managing medication in care homes can be found at https://www.nice.org.uk/guidance/sc1/chapter/What-is-this-guideline-about-and-who-is-it-for and https://www.nice.org.uk/guidance/ng67 for managing medications safely at home.

7. Role of Organisations/Commissioners

Where medication failings/errors (safeguarding or poor practice) may be due to factors such as hospital discharge arrangements, GP prescribing or are within a clinical/nursing setting, then it would be expected that these partners/commissioners take a key role in addressing the failings and ensuring assurance actions are taken in line with their own procedures. Actions taken should be reported to the Local Authority where a safeguarding concern has been raised.

Reporting Requirements for Service Providers Commissioned by Walsall Council

In relation to required reporting arrangements for service providers commissioned by Walsall Council, the contract requirements state that the Service Provider:

- Must ensure there is a process in place at the Home for recording and acting upon errors and near misses. Errors which may cause harm to Service Users or other Residents should also be reported by the Service Provider to the CQC and the WCCG's Medicines Management team.
- Make sure there is a process in place at the Home for the recording and management of adverse drug events.
- Ensure that the relevant Service User's GP is informed of any clinically significant adverse events and Yellow Card reports

- Ensure that there is a written protocol in place at the Home which details who is responsible for and how to deal with drug alerts/recalls and other information about medicines which needs to be actioned rapidly.
- Make sure that appropriate and timely actions are taken and documented for issues about medicines which affect the care of any Service User, including alerts from the National Patient Safety Association & Safety alert broadcasts.

8. Where the Care Act (2014) S42 (ii) duty is met – Causing others to undertake enquiries

Where a safeguarding concern regarding a medication error is submitted to Walsall Council and the S42 (ii) duty under the Care Act (2014) to make enquires is met, the safeguarding enquiry will commence in order to decide what action is necessary and by whom to address the concerns (see Appendix 2 Safeguarding Duty). The Care Act (2014) provides the Local Authority with the option to 'cause others to undertake enquires'. Therefore, in relation to medication errors, health professionals within an organisation who have responsibility for the person's treatment may be the most appropriate agency to undertake the enquiry. The principles of Making Safeguarding Personal must be adhered to and therefore there should be discussion with the adult (or their representative/advocate) to identify what they want to happen and what their outcomes are.

For all caused enquires the local Authority will contact you to discuss the enquiry, provide you with a terms of reference and guidance to support the completion of the caused enquiry.

9. Duty Of Candour

It is also important to remember possible links with medication errors and the Duty of Candour. This is the regulation 20 requirement of the Regulated Activities Regulations (2014). It states that where:

- Death;
- Severe harm;
- Moderate harm; or
- Prolonged psychological harm

has occurred then the regulation requires the provider/organisation to be transparent and open with the person or relevant person when something has gone wrong. Further stating that they should:

- Inform the person who uses the service or relevant person of the incident
- Provide them with reasonable support and truthful information
- Apologise when things go wrong

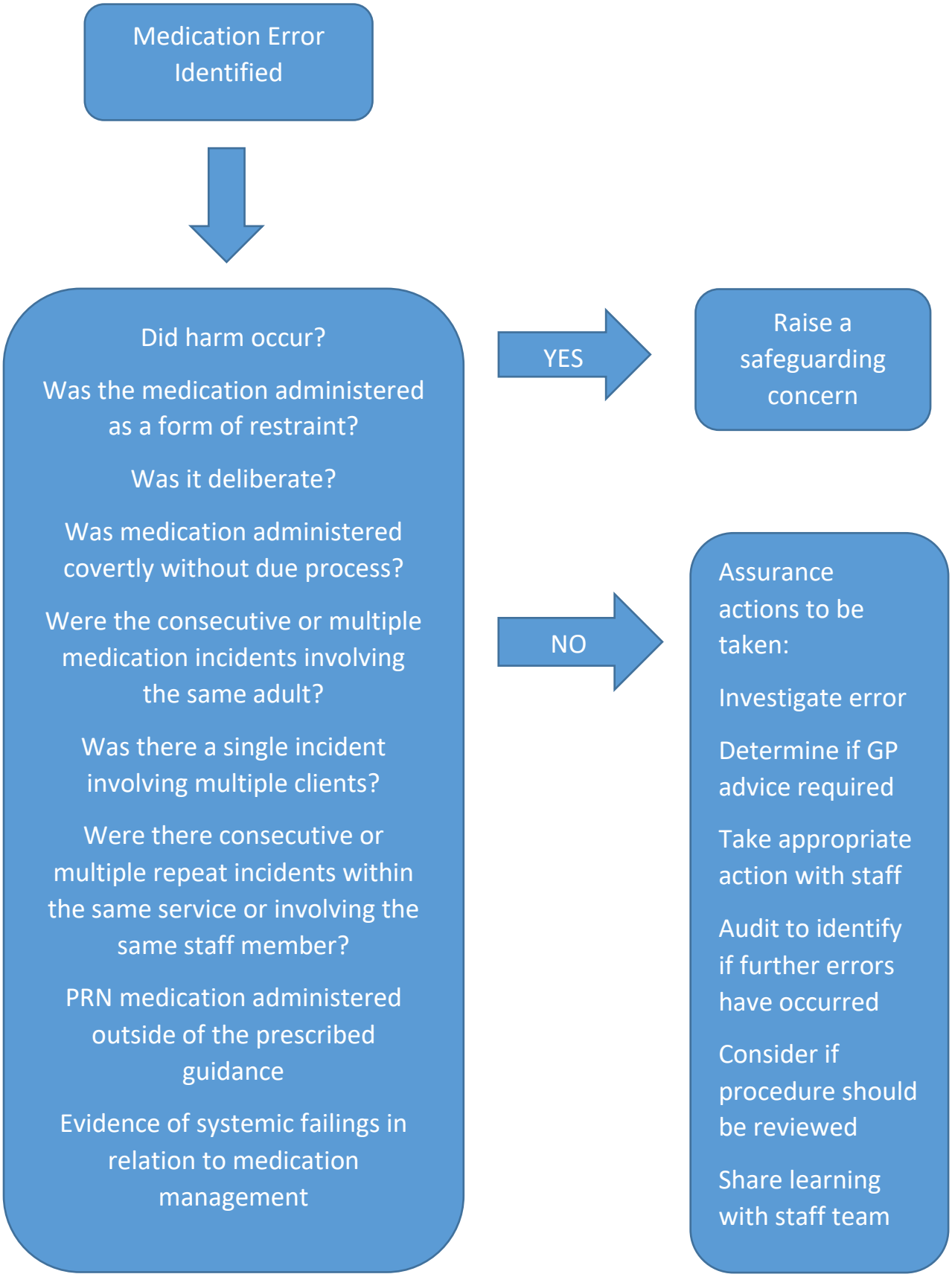
10. Reporting Safeguarding Concerns

If following a review of this guidance and the flow chart in Appendix 1 you feel that a medication error needs to be reported to the Local Authority as a safeguarding concern, please report your concerns to:

Walsall Council Access Team
Telephone - 0300 555 2922 / Out of Hours 0300 555 2922

Secure email (e.g. pnn, nhs.net and .gov accounts) to
initialintake@walsall.gov.uk

Appendix 1 – Medication Error Flowchart



Appendix 2

NHS Walsall Clinical Commissioning Group

Controlled Drug Errors or Discrepancies

Discrepancies

- Routine checks of all CDs held, and the recorded running balances, should be carried out by two nurses or other authorised members of staff on a regular basis, e.g. monthly, and a record kept
- Where a discrepancy is found, it should be reported immediately to the registered manager who should investigate promptly
- If the discrepancy cannot be resolved, the advice of the supplying pharmacist may be sought and the CQC local office should be informed as well as the **Accountable Officer for Controlled Drugs**

Errors

If a resident is given the wrong drug or the wrong dose the Home Manager should be informed immediately. Medical advice should be sought. If the person requires emergency treatment CQC should be informed in compliance with Outcome 20: Notification of other incidents. The **Accountable Officer for Controlled Drugs** should also be informed.

How to report an incident to the Controlled Drugs Accountable Officer;

From 1st April 2018 the Controlled Drugs Accountable Officer will only accept incidents reported via an online CD reporting tool www.cdreporting.co.uk

All reporters of controlled drug concerns / incidents will need to register on the website. Registration is required on an individual basis and there are no limits to the number of people from the same organisation that can register or access the website. The majority of reporters use their email address as their username and then select a password that is easy to remember. Please select the West Midlands region when you register. You will also need to link your CD account to a CQC profile using the tool.

If you have any questions about reporting controlled drug incidents please ring 0121 611 0813.

The Accountable Officer should be informed of any errors or discrepancies to do with Controlled Drugs

The medicines management team at Walsall CCG can be contacted for advice on 01922 619908
Email: wendy.bagnall@walsall.nhs.uk

Improving Health and Wellbeing for Walsall

Controlled Drug Errors or Discrepancies

In accordance with the Government's response to the Shipman enquiry, NHS bodies and the private sector must put arrangements in place for the safe management of Controlled Drugs (CDs). Additionally, there is a statutory requirement for NHS bodies to appoint an Accountable Officer for Controlled Drugs (AOCD) within their organisation, responsible for the safe management of Controlled Drugs

The Registered Nurse or Midwife in Charge of a ward or department (Operating department practitioners- ODP in theatres) is responsible and accountable for the safe keeping and management of Controlled Drugs in that area. The Registered Nurse, Midwife or ODP in charge may delegate related tasks to another Registered Nurse, Midwife or ODP, however legal responsibility remains with the Registered Nurse, Midwife or ODP in charge

Storage and Maintainance

All Controlled Drugs (legal class schedule 2 and 3) must be stored in a locked Controlled Drugs Cupboard except Tramadol. Tramadol is exempted from the safe custody requirements in the latest legislations.
Specifically, Tramadol preparations and Morphine Sulphate 10mg in 5ml Oral Solution are exempt from the requirement of:
1. Storage in controlled drug cupboard,
2. The maintenance of a record in the controlled drug register, and
3. Witnessed administration.

However, a nurse/midwife/ODP in charge of a ward/dept. is required to order tramadol preparations and Morphine Sulphate 10mg in 5ml Oral Solution by means of a Controlled drug order book

Discrepancies

Any entry in the CD Record book found to be wrong or any actual or suspected loss should be regarded as a clinical incident and must be entered onto safeguard and reported immediately to the Senior Nurse Manager on duty and the Accountable

officer. When such incidences occur during the night shift or out of hours, it is the onsite coordinator and emergency duty pharmacist who must be in formed. It is the onsite coordinators responsibility to then inform the relevant head of nursing as soon as practical and the emergency duty pharmacist to inform an Accountable officer as soon as it is practical. An investigation must be commenced as soon as possible. Any loss of controlled drug must be investigated in full and an appropriate action plan must be approved by the Accountable officer. Any suspected theft must be reported to the Controlled Drug Accountable officer as soon as possible who will liaise with the police as soon as possible. Where a report to the police is made, security must be informed prior to the referral to the police being made.

When the CD Record book is not in use it must be stored securely in a locked cupboard. The CD Record book and order books shall be retained by the ward for two years after the last entry or according to the up to date legal requirement, from the date of last entry, in a designated place. They may then be disposed of as 'confidential waste'.

A new Controlled Drug Record Book and Order Book will only be issued to a ward / department / clinic or theatre in the current one is full and must be ordered by using a valid CD Order Book.

Errors / Management of adverse incidences

Management of medication errors will need to be incident reported and investigated and would need to notify the CD Accountable Officer for the Trust, Director of Pharmacy.

For all 'near misses' or actual incidences that occur in any aspect of medicines management in clinical areas , staff must follows the *Trust Incident Reporting policy.*

The Medicines safety group will review and monitor all reported medicines related incidents. Any cause for concern or actions required will be reported to the Divisional Quality teams and Trust Quality Executive via the Medicines management committee

Management and Learning from Medicines errors

For all medicines error that occurs, staff should follow the Trust policy for reporting and investigating adverse incidents and Near Misses.

Walsall Healthcare NHS Trust is committed to providing a supportive framework whereby in the event of a medication error the healthcare professional learns from the error and if necessary's facilitated to return to prescribing / dispensing /preparation, administration and the monitoring of any medication as part of their role in a timely and safe manner

All medication errors once notified will be acted upon either by direct feedback to the healthcare professional, or if necessary notified to the individuals line manager / clinical supervisor. Where necessary the individual may be de-authorised from prescribing, dispensing, or administering medicines until such a time they are deemed safe to resume full practice. Where a system failure is identified the process will be reviewed and changed.

Any error resulting in any physical effect to a patient that is directly a result of a medication error will be immediately reported to the consultant responsible for the patient to ensure that all appropriate clinical responses are undertaken. The error will then be reported as for all other errors and escalated as appropriate.

For all incidents graded 3 and above, the reporting must be in line with the Trust policy and procedures regarding duty of candour

3	**Moderate Harm**	Any patient safety incident that caused significant but not permanent harm to the patient
4	**Severe Harm**	Any medication incident that appears to have resulted in permanent harm to a patient
5	**Death**	A medication error that directly resulted in the death of the patient

Disposal of Controlled Drugs

A controlled drug ceases to be classified as a controlled drug once it has been rendered irretrievable, ie all controlled drugs once disposed of should be unrecognisable as a controlled drug and unusable as a controlled drug.

In the interests of safety and containment of environmental pollution, controlled drugs must not be put down the sink or disposed of in any other way in accordance with this controlled drug standard operating procedure

Only in specific circumstances can controlled drugs be destroyed on wards. This includes the following -(i) the surplus when a dose smaller than the total ampoule or vial is drawn up, (ii) when an injectable dose is drawn up but not used, (iii) broken ampoules of controlled drugs, (iv) left over syringe/opiate infusion containing residues or (v) small residual quantities of epidural/PCAs (<10ml in volume).

All of the above may be disposed of on the ward / theatre by placing into a yellow lidded sharps bin. Where a single dose of an oral or topical preparation is prepared for administration but not given, it must be destroyed on the ward using a denaturing kit available from pharmacy. Larger volume (ie more than 10 mls)s of unused opiate infusions/PCA/PCEA/Epidurals must be destroyed o the ward or department by the use of a denaturing kit available from pharmacy (denaturing kit will render unwanted medicines irretrievable and unfit for use, ready to be disposed of in an Initial Medical blue-lidded pharmaceutical bin). The destruction should be entered in the patient's own controlled Record Book on a page dedicated for the destruction of such residues.

For all other controlled drugs eg expired stocks, patients own controlled drug and excess stock, the pharmacist responsible for the ward or department MUST be notified , these controlled drugs MUST NIOT be destroyed on the ward.

All destruction must be documented in ther appropriate section of the Controlled Drug Record Book, It must be witnessed by a second person who may either be another nurse, midwife, ODP , Doctor , pharmacist.

Once used, any denaturing kits must be returned to pharmacy by the pharmacist for waste collection. This process is strictly regulated and must never be left for the ward / department general waste collection.

In community services, it is the responsibility of the patient or their relatives to return controlled drugs to their pharmacist for destruction

The Accountable Officer should be informed of any errors or discrepancies to do with Controlled Drugs

The responsibilities of the Accountable Officer set out in the Health Act 2006 include:

a) Securing the safe management and use of controlled drugs;

b) Monitoring and auditing the management and use of such drugs;

c) Ensuring that relevant individuals receive appropriate training and that their training needs are regularly reviewed;

d) Monitoring and assessing the performance of such individuals in connection with the management or use of such drugs;

e) Making periodic inspections of premises used in connection with the management or use of such drugs;

f) Recording, assessing and investigating concerns expressed about incidents that may have involved improper management or use of such drugs;

g) Ensuring that appropriate action is taken for the purpose of protecting patients or members of the public in cases where such concerns appear to be well-founded;