

Date as per postmark / e-mail

D Wilson

Ref: FOI 4580

Legal Services Department

Ambulance Headquarters
Springhill
Brindley Way
Wakefield 41 Business Park
Wakefield
WF2 0XQ

E-mail: yas.foi@nhs.net

Dear D Wilson,

Re. FOI 4580 - Response

Thank you for your Freedom of Information Act ("FOIA") request made to Yorkshire Ambulance Service NHS Trust, which the Trust received on 25 February 2021 and the timescale for disclosure began on 26 February 2021.

Your request

- 1. Please could you supply any information you have regarding the trust's policy on non-registered staff (eg. ambulance technicians) using non-parenteral Prescription only medications such as salbutamol?
- 2. Does the trust have a legal framework or policy that describes the legal mechanism for this under the Human medicines regulations 2012?
- 3. Has there ever been any feedback given or action taken by the MHRA or CQC in relation to use of salbutamol or ipratropium bromide by ambulance technicians?
- 4. If the trust has a medicines policy or medicines governance policy, please could you share this?

Trust response

Yorkshire Ambulance Service NHS Trust can confirm it holds this information.

- 1.The Trust policy around non-registered staff using parenteral POMS is that its Advanced Emergency Medical Technicians (AEMTs) can administer certain non parenteral POMS including salbutamol. They are specified in their scope of practice and are suitably trained in the administration and they use JRCALC as guidance.
- 2. The Trust's medicines policy states that technicians can administer non parenteral POMS; the policy refers to the human medicines regulations for its content.



- 3. The MHRA has provided written confirmation via e-mail that the administration of non parenteral POMs by non-registered staff is within the legislation.
- 4. Please find enclosed.

The Trust hopes this response meets your requirements and if you have any queries about the information which has been provided then please contact the Legal Services Department via email at yas.foi@nhs.net. Please remember to quote reference FOI 4580 in any future communications.

If you are unhappy with the way your request for information has been handled, you can request an internal review by contacting the Legal Services Department as outlined above. The Trust will only consider requests for internal reviews, which are received within two months of the date of response. This is in line with the Information Commissioner's Office ("ICO") guidance which can be located here: https://ico.org.uk/your-data-matters/official-information/.

If you remain dissatisfied with the handling of your request or internal review, you have a right to appeal to the ICO; further information about how to appeal is available on its website at https://ico.org.uk/make-a-complaint/. Please note there is no charge for making an appeal.

Once again, thank you for contacting Yorkshire Ambulance Service NHS Trust

Yours sincerely,

Legal Services Department Yorkshire Ambulance Service NHS Trust







Medicines Optimisation Policy

Document Author: Pharmacist

Date Approved: May 2020

Document Reference	PO-Medicines Management-February 2018
Version	V7.0
Document Lead	Pharmacist
Directorate Owner	Medical Director
Responsible Committee	Medicines Optimisation Group
Approved by	Trust Management Group
Date Approved & Ratified	May 2020
Review Date	May 2022
Target Audience	 Accountability – Directors Responsibility and Implementation – Directors, Associate Directors and all Managers responsible for attendance management Awareness – All Trust staff irrespective of contractual status e.g. secondments etc.
Review Responsibility	Rebecca McLaren, Pharmacist
Equality impact assessed	Yes
Protectively Marked	Not protectively marked

DOCUMENT CONTROL INFORMATION

Version	Date	Author	Status (A/D)	Description of Change
3	7.09.12	Rebecca McLaren	S	Update following changes to procedures
				Approved CGG 26/09/12
4.0	17/12/14	Rebecca McLaren	Α	Approved by TMG 17/12/14
4.1	22/12/15	Rebecca McLaren	D	Update and addition of CD and drug management protocols as an appendix
5.0	Feb 2016	Rebecca McLaren	Α	Approved by TMG
5.1	Feb 2018	Rebecca McLaren	D	Review of policy – new visual identity.
6.0	April 2018	Risk Team	A	Policy approved at April TMG.
6.1	January 2019	Rebecca Mclaren	A	Changed meeting name and revised SOP for diazepam and codeine to reflect current process
7.0	April 2020	Rebecca McLaren	D	Review of policy
7.0	May 2020	Rebecca McLaren	Α	Approved at TMG

A = Approved D = Draft

Document Author = Rebecca McLaren

This document is controlled.

If you would like to suggest amendments to this document please contact the document author.

Contents

Section	Contents	Page
1	Introduction	5
2	Purpose	5
3	Scope	5
4	Duties	6
5	Definitions	7
6	Procurement	8
7	Storage	8
8	Prescription	9
9	Dispensing	9
10	Preparation	9
11	Administration	10
12	Recall	11
13	Disposal	11
14	Patients Own Medicines	12
15	Consultation, Approval process	12
16	Review and Revision arrangements	13
17	Dissemination and Implementation	13
18	Monitoring Compliance and Effectiveness	14
19	Equality Impact Assessment	15
Appendix A	Specific requirements relating to Controlled Drugs	16

Section	Contents	Page
Appendix B	POM drugs that Paramedics may administer parenterally under an exemption	19
Appendix C	Exemption for parenteral administration in an emergency to human beings of certain prescription only medicines	20
Appendix D	Equality Impact Assessment	21
Appendix E	Drugs Recall Procedure	23
Appendix F	YAS Prescription Only Medicines Standard Operating Procedure	24
Appendix G	YAS Controlled Drugs Standard Operating Procedure Procedure	46

1 Introduction

1.1 It is a requirement of the organisation to ensure that medicines are safely and securely procured, stored, prescribed, dispensed, prepared, administered, disposed of and monitored in accordance with the statutory requirements of the Medicines Act 1968 (as amended, and subsequent regulations, including the Medicines for Human Use (Prescribing) Order 2005), the Health and Safety at Work etc. Act 1974, as amended, and subsequent regulations including the Control of Substances Hazardous to Health Regulations 2002. The organisation is monitored by the Care Quality Commission (CQC) and NHS Resolution NHSR) to ensure these requirements are satisfactorily met.

2 Purpose

- 2.1 This policy sets out the standards and guidance for the organisation, which aims to ensure that Yorkshire Ambulance Service (YAS) staff are able to comply with the law and Department of Health guidance with regards to the principles of medicines management. It also demonstrates the processes for the collection of evidence to satisfy the requirements of the CQC and the NHSR. This policy is supported by the following documents:
 - 1. YAS Controlled Drug Standard Operating Procedure
 - 2. YAS Prescription Only Medicines Standard Operating Procedure
 - 3. YAS Infection Prevention and Control Policy and guidance documentation
 - 4. YAS Waste Management Policy and Associated Procedures
 - 5. YAS Aseptic Technique and Invasive Devices Guidance
 - 6. YAS Non-medical prescribing policy
 - 7. Incident and Serious Management Policy
 - 8. Assessment and conveyance Policy

3 Scope

3.1 This policy is applicable to all personnel who hold contracts of employment with YAS, including honorary contracts, and are responsible, at any level, for the procurement, storage, prescription, dispensing, preparation, transport, administering or disposal of medicines whilst in the course of their duties for the organisation.

3.2 Research

Where YAS are taking part in Trust-approved research involving drugs (i.e. Clinical Trials of Investigational Medicinal Products – CTIMPs) then the trial protocol must be followed, even if it falls outside of this policy. A patient group direction may be required if stated in the trial protocol. Trial drugs/medicines that are not used should be disposed of as described in the trial protocol, or as described in guidance issued by YAS specific for that trial. Where YAS-specific guidance is required this will generally be to dispose of used trial medicine/drugs in the sharps bin and completion of appropriate documentation to record the event.

4 Duties

- 4.1 The Trust Board has overall responsibility for the implementation and management of this policy, and also review the monthly IPR medication incidents.
- 4.2 The Medicines Optimisation Group is responsible for providing the Trust Board, via the Clinical Governance Group and Quality Committee, with assurance that the policy has been implemented and appropriate monitoring arrangements are in place providing regular reports on outcomes whether adverse or not.
- 4.3 The Trust Pharmacist and Local Security Management Specialist (LSMS) work in collaboration to ensure safe and secure storage of medicines comply with external requirements including national regulation and legislation.
- 4.4 The Medical Director is the lead director for the Trust as regards the management of the policy and is the Accountable Officer for the management of Controlled Drugs.
- 4.5 The Incident Review Group (IRG) and Medicines Optimisation Group receive reports from the Standard and Compliance Directorate identifying any incidents actual or potential in relation to the implementation and management of this policy.
- 4.6 The Head of Procurement is responsible for the purchase of medicines, maintaining adequate stock levels and the safe disposal of out of date stock.
- 4.7 It is the ambulance clinician's own responsibility to ensure that:
 - They maintain their competence utilising all means made available to them.

Medicines Management Policy v 7.0

- The patient receives the correct in date medicine in the appropriate dose via the correct route.
- The medicine stocks in their charge are correct and in date.
- All entries made by them on trust documentation are legible and accurate.
- They work within their own competencies and not to perform tasks which exceed their competence.
- They only administer/supply medicines that have been procured and supplied by the Yorkshire Ambulance Service, with the exception of patients own medicines. When using patients own medicines, the medicines must be in date, be in the original box, and where prescribed for that patient have the correct label and name on the box.

5 **Definitions**

5.1 **Controlled drugs**

- 5.1.1 Controlled Drugs (CDs) are substances that are designated as controlled substances under the *Misuse of Drugs Act 1971*. They are arranged into three Classes (A, B or C) with Class A drugs being the most likely to cause harm. Controlled drugs are also classified into Schedules (1 to 5) under the *Misuse of Drugs Regulations 2001*. It is illegal for anyone other than a doctor, pharmacist or licensed/authorised courier to possess CDs. However, under the *Misuse of Drugs Act* 1971, ambulance paramedics are specifically allowed to possess morphine sulphate (Schedule 2, Class A), ketamine (Schedule 2, Class A) diazepam tablets (Schedule 5, Class C). Midazolam (schedule 3 CD no register), and Codeine tablets.
- 5.1.2 Morphine sulphate is the only Class A CD ordered, carried and administered by YAS paramedics. Any medicines that are listed in Schedules 1 or 2 have restrictions placed on them by the Controlled Drugs (Supervision of Management and Use) Regulations 2006 with regard to their storage, possession and disposal. The YAS procedure relevant to the security, ordering and control of CDs is described in Appendix A Controlled Drugs Standard Operating Procedure

5.2 **Prescription Only Medicines**

5.2.1 Prescription Only Medicines (POMs) may usually only be dispensed and administered to a patient on the direct instructions of a doctor, Allied Health Professional, Independent Prescriber or by adherence to an approved Patient Group Direction (PGD). Non injectable POMs such as salbutamol and ipratropium can be administered by non registered clinicians who have been trained to do so and are employed by the Trust.

5.2.1 However, under Part III, Schedule 5, Prescription Only Medicines (Human Use) Order 1997 and the Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000, which relate to the Medicines Act 1968, ambulance paramedics may administer a number of POMs parenterally, i.e. through the skin, under their own initiative without the need for a written prescription or PGD.

These are listed at **Appendix B**. The indications, contraindications, doses, preparation and routes of administration of these drugs are all covered by the latest version of the Joint Royal Colleges Ambulance Liaison Committee (JRCALC) guidelines.

5.2.2 The *Prescription Only Medicines (Human Use) Order 1997* also allows the administration of a number of POMs parenterally by anybody for the purposes of saving life in an emergency, listed at **Appendix C**.

6 **Procurement**

- 6.1 Medicines are purchased from registered wholesalers. The Head of Procurement is responsible for purchasing and stock control.
- 6.2 Once procured to the central store, medicines are distributed using internal logistics to YAS medicines cabinets in Emergency Departments in all the Yorkshire hospitals, and a small number of station cabinets.

7 Storage

- 7.1 Prior to being booked out onto vehicles all medicines are stored in locked pharmacy cupboards on ambulance stations or in hospital emergency departments. Registers of stock levels and batch numbers for each medicine are maintained in accordance with the YAS Prescription only medicines Standard operating procedure appendix F. This excludes CDs.
- 7.2 Once booked out to vehicles, medicines are stored in equipment bags or approved containers. Whilst in service the equipment bags are stored on the vehicles. If a vehicle goes out of service it is parked in a locked garage. If secure garage parking is not available then the equipment bags containing medicines are removed from the vehicle and locked in a building in accordance with the YAS Prescription only Medicines standard operating procedure appendix F. This excludes CDs.
- 7.3 In extremes of temperature where vehicles are kept outside or are parked outside for long periods of time the drugs bags and all other medicines kept on the vehicles must be removed and placed in the boxes provided and kept in a

locked room. The call sign of the vehicle the medicines were removed from must be documented on the label provided. A notice must be placed on the steering wheel of the vehicle to inform the oncoming staff that the vehicle does not contain any medicines and must be replenished before the vehicle can be used for service.

8 Prescription

- YAS does employ a number of Doctors and Independent Prescribers including pharmacists, nurses and paramedics with prescribing rights. Currently electronic prescribing only takes place within the integrated and urgent care setting, and adheres to the Non-medical Prescribing Policy.
- 8.2 Antimicrobial administration

YAS supply, administer and prescribe antibiotics in accordance with JRCALC patient group directions (PGDs) and the Non- medical Prescribing Policy. Antibiotic use is audited and monitored as part of YAS Antibiotic Stewardship.

9 Dispensing

9.1 Urgent Care Practitioners including Emergency Care Practitioners and Specialist Paramedics are the only group of clinicians employed by YAS who issue medicines to patients for later administration. These medicines are issued in accordance with Patient Group Directions (PGDs) signed off by the Chief Executive, Medical Director and Pharmacist. Only clinicians who have received training on each PGD are allowed to issue medicines to patients.

10 **Preparation**

- 10.1 Most medicines do not require preparation prior to administration to a patient other than drawing up into a suitable dispenser. Adherence to the requirements of the YAS Aseptic Technique and Invasive Devices Guidelines as an appendix to the YAS Infection Prevention and Control Policy should be maintained at all times.
- 10.2 Where medicines require preparation prior to administration, and are one of the medicines described in the JRCALC guidelines 2017 the method of preparation is described in the JRCALC guidelines. All YAS clinicians work to these guidelines.
- 10.3 Where medicines require preparation prior to administration and they, or the clinical indication, are not described in the JRCALC guidelines 2017 the method

of preparation is included in the PGD relating to the medicine and the clinical indication for its administration.

11 Administration

- 11.1 Whilst administering medicines to patients adherence to the YAS Infection Prevention and Control Policy and guidance documentation should be maintained at all times.
- 11.2 Where possible the allergy status of a patient must be determined before administration of any medication to a patient.
- 11.3 YAS clinicians may only administer medicines that fall within their skill set according to the YAS Educational Governance Utilisation of Ambulance Staff in the Workforce.
- 11.4 Where medicines are described in the JRCALC guidelines, the method of administration is described in the current JRCALC guidelines available via the JRCALC app or online (paper copies of the guidelines will no longer be issued to clinicians). All YAS clinicians work to these guidelines, either directly as Paramedics or indirectly through PGDs which exactly mirror the JRCALC guidelines.
- 11.5 Clinicians who are not registered professionals, e.g. Emergency Medical Technicians (EMT, are authorised by YAS to administer a limited number of Pharmacy (P) and General Sales List (GSL) and Prescription Only Medicines (POMS) medicines under the protocols covered by the JRCALC guidelines.
- 11.6 Where medicines, or their clinical indication, are not described in the latest version of the JRCALC guidelines, the method of administration is included in the PGD relating to the medicine and the clinical indication for its administration. Only YAS clinicians who have received training on each PGD are allowed to administer these medicines to patients.
- Any medicine administered to a patient is recorded on electronic Patient Report Form (ePRF) or paper copy where ePRF is unavailable, and the vehicle's drug register completed in accordance with the YAS Prescription only Medicines Standard Operating Procedure appendix F.
- 11.8 If the patient is observed to have an adverse reaction during, or shortly after the administration of a medicine, this should be recorded on the Patient Report Form and reported on DATIX for review by the Medicines Optimisation Group. The clinician also has a responsibility to report adverse reactions through the

YellowCard scheme, all reactions associated with a black triangle drug should be reported and adverse reactions from any drug that result in harm to the patient, hospital admission, withdrawal of the medication or administration of an alternative should be reported through the YellowCard scheme. It can be reported online at www.yellowcard.gov.uk

11.9 Incidents and near misses

All incidents including near misses with regards to medicines and patients including storage, administration, safe and secure handling, and destruction should be recorded on the Patient Report Form and reported on DATIX for review and action by the Medicines Optimisation Group. Please refer to the incident and Serious Incident Management policy for further information. Any incident relating to medicines that are not patient related must be reported via DATIX.

12 **Recall**

12.1 A drug recall process exists and a flowchart has been provided in Appendix E. Hospital pharmacists and Clinical Directorate should be alerted following identification and the decision made to withdraw the drug. It should be identified by the batch number.

13 **Disposal**

- 13.1 All unused medicines with exception of controlled drugs are disposed of in accordance with the YAS Waste Management Policy. For the procedure for disposing of controlled drugs please refer to the YAS Controlled Drug Standard operating procedure
- 13.2 Records of out of date stock, including source and batch number, are made and returned to Procurement prior to disposal of the out of date medicine in order to inform stock control.

14 Patients Own Medication

The Yorkshire Ambulance Service transports patients to and from a variety of environments. To ensure that the patient receives the best and most efficient and effective care and to aid medicines reconciliation and optimisation it is essential that their medications travel with the patient and are transferred to the appropriate health care professional/setting using the green bags provided.

Patient Transport Service

The patient transport service transfers patients to and from hospital, and also between different health care environments. To enable the patient to receive the best possible care the transference of their own medications is essential. It is recommended that all PTS staff remind the patient to bring their medications with them when being transferred to any health care setting.

Once the medications have been labelled with a patient's name they legally belong to the patient and the regulations and legal requirements for safe and secure storage do not apply. The Patient is responsible for their medications and if physically able must keep them on their person. Where the patient is not physically able (medical transfer to hospice etc.) the medications must be kept with the patient's belongings or with a carer/family member if available in the ambulance and transferred with the patient at handover.

999

The same recommendations apply to the emergency ambulance as to the patient transport service, if the patient is able they should carry their own medications, in the event that the patient is unable too, then the medications must be stored with the patients other belongings or with the carer/family member if one is traveling with them, the medication must be transferred to the Emergency Department/Health care provider during handover. If a member of staff is unable to transfer the medications a full list of regular medication must be handed over to the provider. This can be hand written or the repeat list (the left hand side of a prescription).

15 Consultation, Approval Process

- 15.1 This policy will be distributed to the members of the Medicines Optimisation Group for consultation, the membership of which represent all interested parties from within YAS.
- 15.2 The Clinical Governance Group will agree the policy following consultation.

15.3 Following agreement, the policy will be presented to the Trust Management Group for approval.

16 Review and Revision Arrangements

16.1 **Process**

16.1.1 This policy will be reviewed on an annual basis or earlier if indicated by:

Changes in legislation

Adverse incident reports

Request of the Trust Board/Clinical Governance Group

Result of internal audit

Any other identified relevant event

16.1.2 The Medicines Optimisation Group will review and revise the policy following the consultation process identified in Section 13. All reviews and amendments will be identified and recorded by version control.

16.2 **Version Control**

16.2.1 Published versions of this policy are held on the YAS electronic library system

17 Dissemination and Implementation

- 17.1 The policy will be available via the YAS documents library, on approval the highlights and changes will be documented and disseminated through Staff Update/Clinical Update. It is recommended that all staff read the updated policy.
- 17.2 Publications in Operational Update will provide information to staff outlining the policy and protocols.

18 **Monitoring Compliance and Effectiveness**

Standard	Monitoring
Compliance with administration of medicines	 PGDs are reviewed on an annual basis to ensure that they provide direction on current best clinical practice. Progress against action plans to correct any deficiencies is monitored at subsequent meetings. Training and Education provide assurance on an annual basis that all clinical staff has signed all PGDs relevant to their role. Regular clinical updates are provided by the education team. Medicines Audit
How medicines are disposed of	 Prescription only Medicines are disposed of centrally. Weekly collections of expired prescription only medications. Findings are collated monthly by the Head of Procurement The data is submitted to the Medicines Optimisation Group on a quarterly basis Issues are dealt with and the minutes and actions reviewed at the next meeting Expired controlled drugs are disposed of using an Authorised Witness at the relevant stations
How any adverse reactions to medications are recorded	Adverse reactions to medications are recorded on the PRF and reported through DATIX where they are reviewed and investigated by the clinical manager and further reviewed on a monthly basis by the Medicines Optimisation Group
Storage of medicines	 Weekly checks of all centrally managed medications are undertaken. Discrepancies are highlighted to the clinical manager for investigation and reported through DATIX where it will be seen at the monthly Medicines Optimisation Meeting for action. Annual audits of all areas are undertaken and discrepancies dealt with in the same way as the weekly checks.

	 24 hour CD stock checks Monthly CD audits Quarterly POM audits Monthly usage review of CDs for each station in relation to stock levels. Linked to the EPR data for individual CD usage. The reports are presented at Medicines Optimisation group.
How incidents and near misses involving medicines are managed	 Incidents and near misses are reported through DATIX and are a standard agenda item at the Medicines Optimisation Meeting for review and action. This includes when controlled drug losses and significant prescription only medicines concerns are identified and disseminated to the Counter Fraud Specialist by the LSMS. The LSMS also reviews any thefts of medicines and ensures if necessary are transferred into SIRS. Trends and anomalies are identified and training/disciplinary plans are drawn up. Progress against action plans is monitored at subsequent meetings. Any Serious Incidents (SIs) that arise, National Patient Safety Agency (NPSA) reports or information received from the Central Alerting System relating to medicines issued in the period between meetings are acted upon immediately by either the Clinical Directorate or the Risk and Assurance Directorate and action plans reported to the next Medicines Optimisation Group meeting. Progress against the action plans is monitored at subsequent meetings

19 **Equality Impact Assessment**

19.1 All public bodies have a statutory duty under a range of equality and human rights legislation to undertake an Equality Impact Assessment on all procedural documents. **Appendix D**.

Appendix A

Specific requirements relating to controlled drugs

Home Office – Ambulance Service Group Authority

THE MISUSE OF DRUGS REGULATIONS 2001: GROUP AUTHORITY FOR NATIONAL HEALTH SERVICE (NHS) AMBULANCE PARAMEDICS AND EMPLOYING NHS AMBULANCE TRUSTS

In pursuance of Regulations 8(3), 9(3) and 10(3) of The Misuse of Drugs Regulations 2001, the Secretary of State hereby authorises:

- 1. The person in charge, or acting person in charge, of any NHS ambulance trust to supply or offer to supply:
- **Diazepam** and/or **morphine sulphate injection** (to a maximum strength of 20mg) and/or **morphine sulphate oral** to any registered paramedic serving with or employed by that trust.

In pursuance of the above Regulations, the Secretary of State further authorises:

- 2. Registered paramedics, serving or employed at any approved ambulance station, to supply or offer to supply:
- Diazepam and/or morphine sulphate injection (to a maximum strength of 20mg) and/or morphine sulphate oral to any person who may lawfully have any of these drugs in their possession; and
- Registered paramedics, serving or employed at any approved ambulance station to possess
 - diazepam and/or morphine sulphate injection (to a maximum strength of 20mg) and/or morphine sulphate oral for the purposes of that service or employment, subject to and in accordance with the following terms:
 - a) Paragraph 2 does not extend to the supply of the drugs, or any offer to supply them, otherwise than as required for the purpose of its administration for the immediate necessary treatment of sick or injured persons
 - b) Paragraph 3 does not extend to the possession of the drugs, otherwise than as required for the purposes of their administration for the immediate necessary treatment of sick or injured persons, and subject to the following conditions:

- any drug in the possession of any person by virtue of this authority shall be produced by that person for inspection when so required by a constable, an officer of the Home Office (Drug Licensing) or any person authorised in writing by the Secretary of State for the purpose of regulation 26(1) of those Regulations; and
- If any drug in the possession of any person by virtue of this authority is stolen or otherwise lost, the loss shall be reported by that person as soon as possible to the YAS Local Security Management Specialist.

In this authority:

- "registered paramedic" has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997
- "approved ambulance station" means any ambulance station approved for this purpose in England and Wales by an authority or trust constituted for the purposes of the National Health Service and in Scotland by the Common Services Agency of the Scottish National Health Service.

YAS received confirmation that its procedures meet all these requirements in a letter from the Home Office on 18 September 2008.

Authorised couriers

Only the following individuals are allowed to act as authorised couriers for Morphine Sulphate in YAS:

- Security Officers
- Assistant Director Risk and Assurance
- Clinical Managers
- Assistant Director Emergency Preparedness
- Emergency Preparedness Managers
- Yorkshire Air Ambulance Locality Manager
- Locality Managers
- Clinical Supervisors
- Named logistics drivers

Current YAS provision in ambulance stations and vehicles

At each of its Ambulance stations YAS has provided

- A secure room for the storage of controlled drugs and other high value items / consumables accessed only by smart card issued by ICT directorate.
- A secure safe in this room which is alarmed and monitored internally and externally by a security monitoring company. Only HPC registered paramedics or YAS authorised couriers have permission to access this safe.
- Each ambulance station has a supply of DOOP (CD destruction) containers in order to ensure the correct disposal of unused controlled drugs
- Controlled drugs register to record withdrawal and return of morphine stock to the safe.
- Urgent Care and specialist Practitioner sites will have a Medicines Cabinet with integral controlled drug safe.

3.1 On each of its front line ambulances and rapid response vehicles YAS has provided

- A secure cupboard within which is located a drug safe
- A drug safe with either separate key locking or with a numeric key pad
- Each vehicle has a DOOP container in order to ensure the correct disposal of unused controlled drugs
- Controlled drug administration record book.

YAS Motorcycle, Lifecycle Paramedics and staff working for YAA

Motorcycle, Lifecycle and YAA vehicles do not have safes fitted to the bikes or aircraft and as such are only authorised to carry two ampoules of morphine sulphate injection on their person at any one time. This coincides with the maximum dose to be administered per patient.

Appendix B

Prescription only medicines that Paramedics may administer parenterally under an exemption

Diazepam 5 mg per ml emulsion for injection

Succinylated Modified Fluid Gelatin 4 per cent intravenous infusion

Adrenaline Acid Tartrate

Anhydrous Glucose

Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution)

Ergometrine Maleate

Glucose

Heparin Sodium

Lignocaine Hydrochloride

Nalbuphine Hydrochloride

Naloxone Hydrochloride

Polygeline

Sodium Bicarbonate

Sodium Chloride

Ergometrine Maleate 500mcg per ml with Oxytocin 5 iu per ml

Benzylpenicillin

Furosémide

Metoclopramide

Morphine Sulphate

Streptokinase

Ondansetron

Statutory Instrument 1997 No. 1830 The Prescription Only Medicines (Human use) Order 1997 Schedule 5

Statutory Instrument 2000 No. 2899 The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 2000

Appendix C

Exemption for parenteral administration in an emergency to human beings of certain prescription only medicines

Adrenaline Injection 1 in 1000 (1 mg in 1 ml)
Atropine Sulphate Injection
Chlorphenamine Injection
Dicobalt Edetate Injection
Glucagon Injection
Glucose Injection 50%
Hydrocortisone Injection
Naloxone Hydrochloride
Promethazine Hydrochloride Injection
Snake Venom Antiserum
Sodium Nitrite Injection
Sodium Thiosulphate Injection
Sterile Pralidoxime

Statutory Instrument 2005 No. 1507. The Prescription Only Medicines (Human use) Order 1997

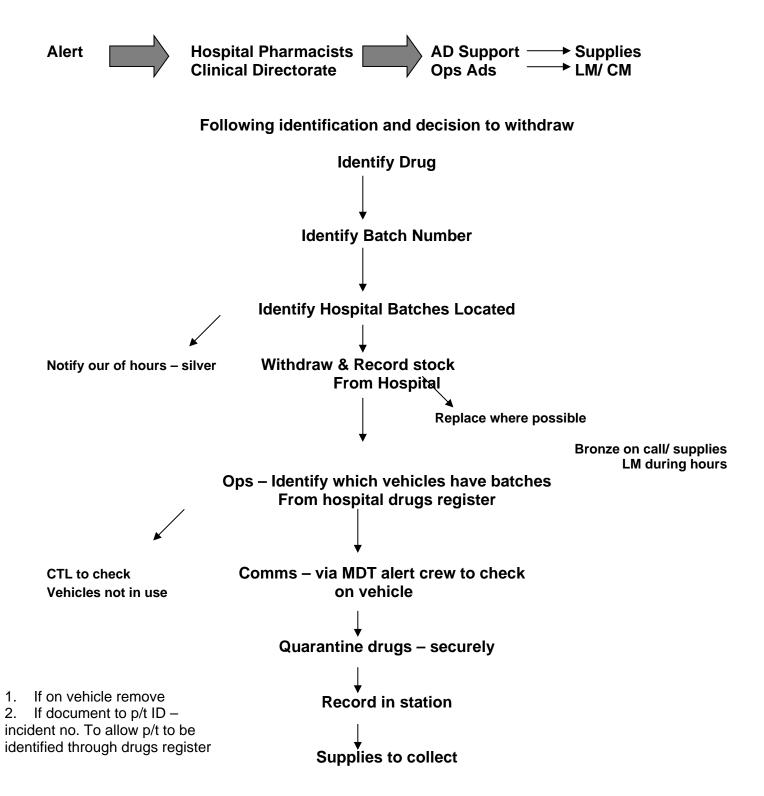
Appendix D

Equality Impact Assessment

1.	Name of Policy	Medicines Management Policy	
2.	Responsible Manager	Dr Julian Mark	
3.	Date Screening / EIA Completed	30 th August 201	1
4.	Description and Aims of Policy (including relevance to equalities)	This policy sets out the standards and guidance for the organisation, which aims to ensure that Yorkshire Ambulance Service (YAS) staff are able to comply with the law and Department of Health guidance with regards to the principles of medicines management. It also demonstrates the processes for the collection of evidence to satisfy the requirements of the CQC and the NHSLA.	
5.	Brief Summary of Research and Relevant Data and Methods and Outcome of Consultation	Stakeholders and Medicines Management Committee	
6.	Does the policy/guidance affect one group less or more favourably than another on the basis of:	Yes/No	Comments (Positive, Neutral, Negative)
	Race	No	
	Ethnic origins (including gypsies and travellers)	No	
	Nationality	No	
	Gender	No	
	Culture	No	
	Religion or belief	No	
	Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
	Disability - learning disabilities, physical disability, sensory impairment and mental health problems	No	
	Is there any evidence that some groups are affected differently?	No	
	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	N/A	
	Is the impact of the policy/guidance likely to be negative?	No	
	If so can the impact be avoided?	N/A	
	What alternatives are there to achieving the policy/guidance without the impact?	Nil	

Can we reduce the impact by taking different action?	No	

DRUGS RECALL PROCEDURE



Appendix F	
	edicines Standard Operating Procedure.
(Excludi	ng Controlled Drugs)
Medicines Management Policy v7.0	Page 24 of 78

Contents

Section	Contents	Page
1	Introduction	27
2	Purpose	27
3	Duties	27
4	Process	28
5	Drug security	31
6	Monitoring Compliance - Quality assurance of vehicle based drugs	32
7	Exceptions	32
10	Appendix F1 – Medicines Pouch Tagging/checking system	33
11	Appendix F2 – Booking out vehicle stocks	34
12	Appendix F3 – Replenishment of vehicle stocks (cupboard)	35
13	Appendix F4- Replenishment of vehicle stocks (vehicle)	36
14	Appendix F5-Investigation Checklist Cupboard	37
15	Appendix F6-Drug investigation flow chart	38
16	Appendix F7-Investigation Checklist Vehicle	39
17	Appendix F8-POM Audit Medicines Code	40
18	Appendix F9- Monthly POM Audit Form	42
19	Appendix F10-UCP Monthly POMS Cabinet Audit	44

1. Introduction

Yorkshire Ambulance Service NHS Trust (YAS, the 'Trust') has a duty to ensure that it has an enforceable protocol in place for the security and maintenance of drugs stocks. This document sets out the protocol which every clinician is required to follow in the management of drugs stocks. It provides guidance and a framework to ensure that drugs usage and flow can be fully audited.

This protocol does not include the management of controlled drugs which is managed under Appendix G of the Medicines Optimisation Policy.

Clinicians are reminded that; 'they are responsible for the management and maintenance of the drugs stocks in their care'. Any instances where there has been a failure to do so could lead to disciplinary action. If clinicians find that their colleagues have not followed procedure, or have failed to comply with this protocol, they have a professional duty to advise their line manager of such issues.

2. Purpose

The aim of this document is to provide the procedure for safe and secure storage and administration of medicines with the Yorkshire Ambulance Service. It also details the audit required to provide assurance to the Trust Board that the Yorkshire Ambulance Service is adhering to regulations described by the Care Quality Commission and Medicines Act.

3. Duties

It is the duty of the Medicines Optimisation Group (MOG) to gain assurance that his protocol are being adhered to, and provide actions and outcomes where non-compliance is an issue. The MOG will provide assurance to the Trust Board.

4. Process

At the start of a shift the medicines pouches tags and nearest expiry must be checked as per **Tagging Guide Appendix F1**



At the scene of an incident if a medicines is administered it should be replenished at the next opportunity (conveyance to ED/return to station along with any identified close to expired medicines)



When a POM is administered to a patient the **administration guide AppendiF2** must be followed



Medicines must be booked out of the ED/station medicines cupboard as detailed in **Appendix F3**



The medicines must then be placed on the vehicle and recorded in the vehicle POM register as detailed in **Appendix F4**



Where there are alternative medications kept in the vehicle i.e. Urgent Care Practitioners medications they must be documented as per protocol above, however where the drugs are kept in alternative containers other than the response bag pouches they must be secured at all times and where possible be tagged for assurance that the drugs are adequately stocked and within the expiry date. Where possible the pouch system should be put in place. Where medicines pouches cannot be kept on the vehicle (Specialist Paramedic medicines) they must be kept in a locked cupboard/morphine safe until required for the next shift. Tag, stock and expiry checks must be made at the beginning and end of each shift and recorded in the same manner as any other prescription only medicines record.



Please follow the guidance around discrepancies found in Appendix F5 and F6



Any medicine that is due to expire/expired must be removed from the stock at the earliest opportunity (1st of the month the medicines will expire) and documented in the POM register and the out of date medicines form. The medicines must be place in the bags provided within the cabinets to await

removal by internal logistics. The medicines will be returned to central supplies for logging and waste disposal in accordance with YAS Waste Policy.

Where in date medicines are required to be removed from a vehicle, please return the medicines to central store rather than returning to the ED cupboards.

PLEASE NOTE

Paramedics, Emergency Medical Technicians and Emergency Care Assistants are all responsible for checking and replenishing the stocks within the vehicle. However staff must ensure that they only administer medicines within their skill set.

4.1 Vehicle drug stock levels

Each vehicle will have drugs packs containing the following:

RED DRUG POUCH	Quantity	Check
Adrenaline 1:1000 - 1mg in 1ml	2	
Atropine 600mcg in 1ml	3	
Benzyl penicillin 600mg	2	
Chlorphenamine 10mg in 1ml	2	
Diazemuls 10mg in 2ml	2	
Diazepam Rectal 5mg in 2.5ml	4	
Furosemide 50mg in 5ml	1	
Hydrocortisone 100mg	2	
MAD	1	
Naloxone 400mcg in 1ml	3	
Ondansetron 4mg in 2ml	2	
Prednisolone 5mg tablets (6-16 tablets)	1	
Water for Injection 5ml	4	

YELLOW DRUG POUCH	Quantity	Check
Aspirin 300mg tablets (box of 32)	1	
Glucagon 1mg in 1ml	1	
GTN spray	1	
Hypostop Gel 10g	2	
Ibuprofen 100mg in 5ml Sachets	2	
Ibuprofen 200mg tablets (box of 24)	1	
Ipratropium Bromide 250mcg in 1ml	4	
Paracetamol 250mg in 5ml sachets	4	
Paracetamol 500mg tablets (box of 32)	1	
Salbutamol 2.5mg in 2.5ml (2 packs of 5)	2	

Resus Bag Quantity Chec

Adrenaline 1:10,000 - 1mg in 10ml	5	
Amiodarone 300mg in 10 ml	1	
Glucose 5%100ml	1	
Glucose 10% 500ml	1	
Saline 0.9% 500ml	1	
Tranexamic Acid 500mcg in 5 ml	2	
Misoprostol 200mcg tablets	10 tabs	

5. Drug Security

- When the vehicle is not required for the next shift, the security of the drugs remains the responsibility of the last crew to use that vehicle.
- Vehicles inside a station garage are deemed as being secure; it is the responsibility of all individuals to ensure that station premises remain secure.
- Any off-duty vehicle that cannot be secured inside a station garaging facility should have its drug stores removed and secured within the station's controlled drugs store.
- A tag providing details to this effect must be displayed on the steering wheel
 of the vehicle and the drugs themselves must be clearly identifiable for that
 particular vehicle.
- On remote stations where on duty vehicles maybe stood for extended periods
 of time vehicles must be kept inside stations in order to reduce the risk of
 adverse temperatures affecting the drugs.

5.1 **Medical gases**

4.2 Medical gases

Oxygen and Entonox are also POM medicines and have an expiry which must be checked at the beginning of each shift this includes cylinders that are found on the Patient Transport Vehicles (PTS).

Staff working on the PTS vehicles must refer to the PTS Oxygen Standard Operating Procedure for details of how to store, administer and record patients own and YAS oxygen when transporting patients.

All medical gases must be administered in accordance to JRCALC guidelines

Medical gases must be stored:

- under cover, preferably enclosed and not subjected to extremes of temperature
- Be kept dry, clean and well ventilated (both top and bottom)
- Have good access for delivery vehicles and reasonably level floor areas
- Be large enough to allow for segregation of full and empty cylinders and permit
- separation of different medical gases within the store
- Be totally separate from any non-medical cylinder storage areas
- Be sited away from storage areas containing highly flammable liquids and other combustible materials and any sources of heat or ignition
- Have warning notices posted prohibiting smoking and naked lights within the vicinity of the store
- Be secure enough to prevent theft and misuse (behind a locked door/within a secured locked cage)

The expiry of medical gases must be checked before they are transferred to the vehicle, if they are due to expire within 7 days they must be stored with the empty cylinders and supplies informed.

6. Monitoring Compliance - Quality assurance of vehicle based drugs

To ensure that the procedure is being adhered to and to ensure that medicines pouches contain the correct amount of medicines and are in date routine audit must be completed. See audit forms and guides in **Appendix 8** and **F9**.

- A quarterly POM audit of 100% of vehicles (see exceptions below).
- Audit forms can be completed by any member of staff and can be completed if a check is done as part of routine checks post administration of medicine.
- Completed audit forms must be given to Clinical Supervisors, on a monthly basis the data will be forwarded to the Clinical Managers who will present an overview at the monthly Medicines Optimisation Meeting, and also at a local level at Locality Meetings.
- When completing a POM audit any medicine that is due to expire before the next audit (within the next 3 months) should be removed and placed in the out of date cupboard.
- The responsibility to complete these audits lies within the Operational Directorate.

7. Exceptions

The areas below must undertake a POM audit on a monthly basis on 100% of its vehicles/bags

- Responding Managers
- Staff responders
- Emergency Operations Centre response bag

Audit sheets must be sent to the appropriate Clinical Manager once completed. For the YAA the appropriate Clinical Manager is David Guest – Clinical Manager for the South CBU.

Appendix F1

Drug Pouch Tagging / Checking system

The following checks MUST be carried out at the START OF EACH SHIFT

The three drugs pouches Medical (Red) Cardiac (Yellow) and Resus pouch are composite elements of the YAS medicines system on front line vehicles. Each pouch is tagged the tag number of which should corresponds to the drug tag sheet. This is also a requirement for all UCP medicines located in vehicles regardless of how they are stored.

At the start of each operational shift

- 1. Check the tag number on each drug pouch matches the tag number last documented in the tagging book, check the tag has not been tampered with. If the tag is incorrectly attached it does not provide assurance and must be replaced and a check performed on all medicines with that pouch making sure each medicine corresponds to the vehicle drug register and is in date.
- 2. Check expiry dates on the index sheet. Drugs MUST be exchanged on or as close to the 1st of the month of expiry.
- 3. Document the time and date, then sign the Tag Log Sheet.
 - Providing Tag numbers correspond to those listed in the book and the Tags are intact, the drugs should all be present and there is no need for further checks
 - Expiry dates are on the index sheet
 - Any drugs not present or below levels required to treat a patient should be reported to the duty clinical supervisor and a DATIX completed. The Clinical Supervisor will then investigate and update DATIX.
- At the end of each shift it is the crew's responsibility to ensure all drug pouches are tagged and the tag number are correctly documented in the tag book
- 5. If a crew is late off duty and it is not possible to restock POM's used, this must be reported to the duty Clinical Supervisor and a Red Tag used stating the deficiency, date and name of the staff member reporting. The pouch should Check that all drug seals e.g. tags are intact

Appendix F2

Administering drugs while on duty; Booking out vehicle drug stocks.

Vehicle Stock Register requirements

Column Number:

- **1. Date** Enter the date the drug(s) are taken from the vehicle stock.
- **2. Time** Record the time the drug(s) are taken from the vehicle stock.
- **3. Incident Number** The incident number must be recorded for any drug administered to any patient to ensure there is a robust audit trail.
- **4. Booked In/Given By** The name and PIN of the individual that has administered the drug must be recorded.
- 5. Witness This should be completed by the witness, ensuring their PIN and initials are included. For lone responders enter "SOLO" where no suitable witness is available.
- **6. Number Booked In** Leave blank when booking drugs for an incident.
- 7. Number Booked Out The total number of drugs administered to an individual patient at the incident should be recorded. (Remember: where a patient has received more than one batch number of the drug, record each batch on a separate line, together with the other details required).
- **8. Balance** The total number of the drug(s) administered under each batch number to each individual patient needs to be deducted from the balance shown in the line above. This final figure must match the numbers of the same drug(s) left in the vehicle stock.

Any discrepancies must be noted in the drugs register. The duty CS must be informed and the issue recorded on DATIX. Should you have any problems or concerns, in the first instance please speak to one of the Clinical Supervisors.

Replenishment of vehicle drugs stocks; taking drugs out of the main supply cupboard

Main Supply Cupboard Stock Register requirements

Column Number:

- **1. Date** The date(s) any drugs are removed from the cupboard must be logged here. The date(s) any drugs are added to stock must also be logged.
- **2. Name** Write your PIN number in this column.
- **3. Signature** Sign or initial this box.
- **4. Vehicle Call-sign** Write the vehicle call-sign to which the drugs are being allocated.
- **5. Signature Of Witness** This should be completed by the witness, ensuring their PIN and initials are included. For lone responders enter "SOLO".
- **6. Supplied By** Leave this box blank for pharmacy use only.
- **7. Remarks** Write the vehicle call-sign to which the drugs are being allocated, if not already completed in column 5 (only applicable to the old version of the drugs registers).
- 8. Amount Received Into Stock Leave this blank for pharmacy use only.
- **9. Amount Supplied** Note the number of drugs taken with that particular batch number. (Remember; if different batch numbers are taken, each different batch must be recorded separately, on a separate line).
- **10. Balance In Stock** Deduct the number of drugs taken from the previous total and enter the figure here.

Any discrepancies must be noted in the drugs register. The duty Clinical Supervisor (CS) must be informed and the issue recorded on DATIX. Should you have any problems or concerns, in the first instance please speak to one of the Clinical Supervisors.

Replenishment of vehicle drugs stocks; placing drugs on the vehicle.

Vehicle Stock Register requirements

Column Number:

- **1. Date** Enter the date the drug(s) are booked onto the vehicle.
- **2. Time** Record the time the drug(s) are being added to the vehicle stock.
- **3. Incident Number** Leave blank when *booking in* drugs.
- **4. Booked In/Given By** Record the name and PIN of the individual booking the drugs onto the vehicle.
- **5. Witness** This should be completed by the witness, ensuring their PIN and initials are included. For lone responders enter "SOLO".
- **Number Booked In -** Enter the total number of drugs being booked onto the vehicle under that specific batch number. Remember; different batch numbers must be recorded separately, on a separate line.
- 7. Number Booked Out Leave blank when booking drug(s) on to the vehicle.
- 8. Balance The total number of drug(s) placed into the vehicle stock should be added to the previous stock level and the total figure entered here. (NB. Any drugs stored in the back-up pouch are considered correct if the tag is intact and everything is in accordance with the record sheet.

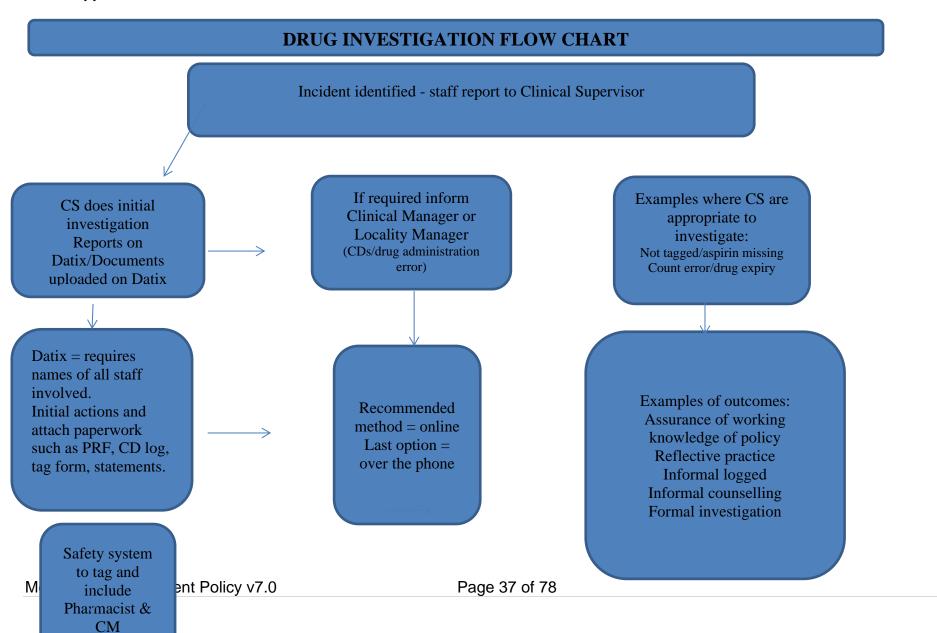
Any discrepancies must be noted in the drugs register. The duty CS must be informed and the issue recorded on DATIX. Should you have any problems or concerns, in the first instance please speak to one of the Clinical Supervisors.

Check list for the investigation of missing POMs in stock cupboards.

Check Sheet

- 1. Double check the contents of the cupboard against the 'Drug Book' to confirm if there is a discrepancy or not add details in the notes.
- 2. Was there a valid drug check carried out? If so, add the date this was completed and by whom in notes.
- **3.** Discrepancy still there? confirm the details in notes.
- **4.** Speak to all relevant crews since the last valid drug check took place (see point 2 above for details).
- **5.** Discrepancy still there? confirm any further details in notes.
- **6.** Double check the stock replenishment with YAS Supplies Department.
- 7. Discrepancy still there? confirm any further details in notes in DATIX.
- 8. Correct / update:
 - **a.** Drug Book
 - **b.** DATIX report.

If a discrepancy cannot be satisfactorily resolved, escalate to the Clinical Manager to be taken to the next Medicines Optimisation Group – ensure the Clinical Manager's name is added in DATIX. In the event that we suspect drugs have been stolen we follow the Local Security Management Procedure.



Check list for the investigation of missing POMs on vehicles.

Check Sheet

- 1. Is the vehicle off the road? If so, locate the vehicle and the relevant bag.
- 2. Refer to the 'Drug Tagging Book' was there a valid drug check carried out? If so, add the date this was completed and by whom in notes.
- 3. Double check the contents of the bag against the 'Drug Book' and the 'Drug Tagging Book' to confirm if there is a discrepancy or not add details in notes.
- **4.** Discrepancy still there? confirm the details in notes.
- **5.** Speak to all relevant crews since the last valid drug check took place (see point 2 above for details).
- **6.** Discrepancy still there? confirm any further details in DATIX.
- **7.** Correct / update:
 - a. Drug Book
 - **b.** Drug Tagging Book
 - **c.** DATIX report.

If a discrepancy cannot be satisfactorily resolved, escalate to the Clinical Manager to be taken to the next Medicines Management Group – ensure the Clinical Manager's name is added in the notes in DATIX In the event that we suspect drugs have been stolen we follow the Local Security Management Procedure.

Appendix F8 POM Audit Medicines Code

Appendix F8		POM Audit Medicines Code
	0	No issue
Yellow	1	Aspirin 300mg
Yellow	2	Glucagon - 1mg in 1ml
Yellow	3	GTN 500mcg
Yellow	4	Hypostop - 10g of glucose
Yellow	5	Ibuprofen 100mg
Yellow	6	Ibuprofen 200mg
Yellow	7	Ipratropium Bromide - 250mcg in 1ml
Yellow	8	Paracetamol 250mg
Yellow	9	Paracetamol 500mg
Yellow	10	Salbutamol 2.5 mg in 2.5 ml
Red	11	Adrenaline 1:1000 - 1mg in 1ml
Red	12	Atropine - 600mcg in 1ml
Red	13	Benzyl Penicillin 600mg
Red	14	Chlorphenamine - 10mg in 1ml
Red	15	Diazemuls - 10mg in 2ml
Red	16	Diazepam - 5mg in 2.5ml
Red	17	Furosemide - 50mg
Red	18	IV Paracetamol 1g
Red	19	Hydrocortisone - 100mg
Red	20	Metoclopramide - 10mg in 2ml
Red	21	Naloxone - 400mcg in 1ml
Red	22	Ondansetron - 4mg in 2ml
Red	23	Prednisolone 5mg
Red	24	Water 5ml
Resus	25	Adrenaline 1:10:000 - 1mg in 10ml
Resus	26	Amiodarone - 300mg in 10ml
Resus	27	Glucose 5% 100ml
Resus	28	Tranexamic Acid - 500mg in 5ml
Resus	29	Saline 500ml
Resus	30	Glucose 500ml
Resus	31	Misoprostol 200mcg
UCP	32	Amoxicillin 250mg/5ml suspension
UCP	33	Amoxicillin 500mg capsules
UCP	34	Chlorphenamine2mg/5ml solution
UCP	35	Chlorphenamine 4mg tablet
UCP	36	Clarithromycin 250mg tablet
UCP	37	Clarithromycin 500mg tablet
UCP	38	Clarithromycin 250mg/5ml suspension
UCP	49	Codeine 15mg tablet
UCP	40	Diazepam 2mg tablet
UCP UCP	41	Diclofenac 100mg suppository
	42 43	Doxycycline 100mg capsule
UCP	45	Flucloxacillin 250mg/5ml suspension

UCP	44	Flucloxacillin 500mg capsules
UCP	45	Ibuprofen 400g tablets
UCP	46	Instillagel
UCP	47	Lidocaine 1% injection
UCP	48	Naproxen 250mg tablets
UCP	49	Omeprazole 20mg capsules
UCP	50	Phenoxymethylpenicillin 250mg/5ml suspension
UCP	51	Phenoxymethylpenicillin 250mg tablets
UCP	52	Prednisolone 5mg EC tablets
UCP	54	Prochlorperazine 3mg Buccal tablets
UCP	55	Salbutamol 100mcg inhaler
UCP	56	Trimethoprim 200mg tablets
UCP	57	Nitrofurantoin 100mg tablets/capsules
GAS	58	Entonox canisters (check all)
GAS	59	Oxygen canisters (check all)

Monthly Vehicle POM Audit Sheet

	Fleet Number:	Date:	
Station:			
Auditor (Print Name):			
	Last staff member to	o use vehicle:	

		1	1	·
		Yellow	YES/NO	If NOT intact record Details & Action taken
		Red	YES/NO	
D • Q • L • L • • • •	Circle	Resus	YES/NO	
Drug Seals Intact	Code	UCP	YES/NO	
		RAT	YES/NO	
		Duodote	YES/NO	
		Yellow	YES/NO	If NOT correct record Details & Action taken
		Red	YES/NO	<u> </u>
Too Numbers Common on A Futured in Ton	Enter relevant	Resus	YES/NO	
Tag Numbers Correspond, Entered in Tag Register & Signed	codes	UCP	YES/NO	
		RAT	YES/NO	
		Duodote	YES/NO	
Check out of date POMs sheet for accuracy		0 = No Iss		If inaccurate give Details & Action taken
including Oxygen & Entonox		Y = Yellov	V	
If No issues enter 0	Enter relevant	R = Red		
	codes from list	Resus		
If any Inaccuracies found record details (refer to drug		UCP		
code list)		RAT		
		Duodote		
Remove tags/ Do Contents Correspond With		0 = No Iss		If issues give Details & Action taken
Register		Y = Yellov	V	
	Enter relevant	R = Red		
If No issues enter 0	codes from list	Resus		
		UCP		
		RAT		
If any Issues found record details (refer to drug code		Duodote		

Medicines Management Policy v7.0

Page 41 of 78

list)					
Integrity of medicines p				0 = No Issues	If issues give Details & Action taken
(Example damage pack	aging, loose tablet	s)		Y = Yellow	
				R = Red	
If No issues enter 0	If No issues enter 0			Resus	
			codes from list	UCP	
				RAT	
If any Issues found record list)	If any Issues found record details (refer to drug code list)			Duodote	
Prior to the POM audit, were all POM pouches compliant (sufficient in date POM's to treat next patient)			Circle Code	YES (Is Safe) NO (Is unsafe)	If non compliant, enter the POM codes and details of why the POM pouch was non compliant and if unable to respond to next patient.
BM meter calibration	Solution 1 result		Solution 2 result		

All vehicles carrying POMs <u>MUST</u> be audited <u>3-Monthly</u>. This includes all UCP, ECP & Specialist Paramedic medicines. <u>Managers MUST</u> send in an audit per month. Audits sheets should be submitted only when ALL POMs & medicines have been audited. Completed Audit forms to be returned to the Clinical Managers, c/o CBU A&E Support Officers

Medicines Management Policy v7.0

YAS UCP MONTHLY POMS CABINET AUDIT

Name of Auditor: (Please print)		St	ation:	Date:		
ALL cabinets MUST be audited in each	ch locality	each MO	<u>NTH</u>			
Drug Name	ug Name Quantity		k Level ter	If NO inform Clinical Manager & complete Datix report		
	I	Yes	No			
AMOXICILLIN 250MG/5ML SUSPENSION 100ML						
AMOXICILLIN 500MG CAPSULES						
CHLORPHENAMINE 2MG/5ML SUSPENSION 150ML						
CHLORPHENAMINE 4MG TABLETS						
CLARITHROMYCIN 250MG TABLETS						
CLARITHROMYCIN 500MG TABLETS						
CLARITHROMYCIN 250MG/5ML SUSPENSION 70ML						
DICLOFENAC 100MG SUPPOSITORIES						
DOXYCYCLINE 100MG CAPSULES						
FLUCLOXACILLIN 250MG/5MLS SUSPENSION 100ML						

Page 43 of 78

FLUCLOXACILLIN 250MG CAPSULES		
IBUPROFEN 400MG TABLETS		
IBUPROFEN 100MG/5ML SACHETS		
INSTILLAGEL 11ML PRE FILLED SYRINGE		
IPRATROPIUM BROMIDE 250MCG 1ML NEBULES		
LIDOCAINE 1% INJECTION		
NAPROXEN 250MG TABLETS		
OMEPRAZOLE 20MG CAPSULES		
PARACETAMOL/CALPOL 250MG/5ML SUSPENSION SACHETS		
PARACETAMOL 500MG SOLUBLE TABLETS		
PARACETAMOL 500MG TABLETS		
PHENOXYMETHYLPENCILLIN 250MG TABLETS		
PREDNISILONE 5MG EC TABLETS 40'S		
PREDNISILONE 5MG EC TABLETS 60'S		
PROCHLORPERAZINE 3MG BUCCAL TABLETS		
SALBUTAMOL 100MCG INHALER		
TRIMETHOPRIM 200MG TABLETS 6'S		
TRIMETHOPRIM 200MG TABLETS 14'S		

Drug Name	Quantity	Contro	ock Level & olled Drug er balance	If NO inform Clinical Manager & complete Datix report
		Yes	No	
CODEINE 15MG TABLETS				
DIAZEPAM 2MG TABLETS				

All audit sheets to be returned to Clinical manager or admin assistant via email or mailed to the CM by 30th of each month

Urgent Care Practitioner Service Drug Expiry Date Monitoring Callsign: First Drug to Expire Date:

Appendix G

YAS Controlled Drug Standard Operating Procedure

Section	Contents								
1	Introduction								
2	Purpose/Scope								
3	Process	51							
4	Training Expectations for Staff	59							
5	Implementation Plan								
6	Monitoring compliance with this Policy								
	Appendix G1 – Safe cabinet failure – G4 Faults	62							
	Appendix G2-24 hour ring round form	68							
	Appendix G3 – Station CD register example	69							
	Appendix G4- Vehicle CD register example	70							
	Appendix G5- Monthly CD cabinet audit form								
	Appendix G6- Monthly CD audit guide								
	Appendix G7- Lost or stolen keys								
	Appendix G8- Daily morphine stock check form	74							
	Appendix G9- Exemptions to SOP	75							

1. Introduction

1.1 The purpose of this guidance is to promote the safe, secure and effective use of all controlled drugs. Controlled Drugs (CDs) are subject to special legislative controls because there is potential for them to be abused or diverted, causing possible harm. The Government has introduced robust measures to ensure controlled drugs are managed safely. These governance arrangements need to be implemented in a way that supports professionals and encourages good practice around the management and use of these important medicines when clinically required by patients.

We aim to achieve the standards set by NHS Protect, the Ambulance Pharmacists Network and the National Ambulance Service Medical Directors within the following documentation: Security standards and guidance for the management and control of controlled drugs in the ambulance sector. June 2012.

The Government has introduced new monitoring and inspection arrangements for controlled drugs in the Health Act 2006. These will work within, and alongside, existing governance systems and should be seen as an integral part of the overall drive to improve quality in healthcare. Regulations made under the Health Act 2006 require each healthcare organisation to appoint a nominated Controlled Drugs Accountable Officer, responsible for the safe and effective use of controlled drugs in their organisation. The regulations also introduce Standing Operating Procedures (SOPs) for the use and management of controlled drugs.

2. Purpose/Scope

- 2.1 This Standing Operating Procedure (SOP) refers to all personnel employed by the Yorkshire Ambulance Service NHS Trust (YAS) (including Yorkshire Air Ambulance), who are legally authorised to possess and administer controlled drugs. It sets out the procedures that must be adhered to when handling Morphine Sulphate within YAS. The only exception to this is the process of withdrawal and return of morphine requirement for the Hazardous Area Response Team (HART) Paramedics, due to the nature of the incidents and response time. The process can be found in Appendix 10 of the SOP. HART must adhere to all other aspects of this SOP. All other exceptions to the policy can be found in Appendix G11.
- 2.2 It relates to the daily operational management of all controlled drugs used by the Trust.

- 2.3 Within this SOP the term 'Controlled Drugs' applies to:
 - Morphine sulphate injection Schedule 2
 - Midazolam Schedule 3
 - Ketamine Schedule 2
 - Diazepam tablets schedule 4 (UCP only)
 - Oramorph schedule 5 (YAA only)
 - Codeine tablets (UCP/SP only)
 - Diazepam rectal tubes and emulsion (stock only)
- 2.4 The term 'Authorised Person' refers to any of the persons listed below and will be referred to as the Healthcare Professional
 - Paramedics registered with the Health and Care Professions Council (HCPC)
 - Other staff who are trained, competent and legally authorised to supply and administer Controlled Drug Medicines in defined circumstances; this may include qualified Nurses who have an agreed scope of practice and are registered with the Nursing and Midwifery Council (NMC). Other staff may be trained, competent and authorised to conduct checks and/or stock deliveries, as appropriate.
 - It is permissible for Ambulance Technicians, Assistant Practitioners and Emergency Care Assistants to check Schedule 4 and 5 drugs i.e. diazepam, diazemuls and oramorph, excluding ketamine.
- 2.5 This SOP does not cover the use of Morphine Sulphate by Voluntary Ambulance Service (VAS) staff, i.e. St. John, British Red Cross, BASICS or private organisations sub-contracted by YAS (these organisations must have in place their own policies and procedures for the management of medications which are fit for purpose).
- 2.6 To give clear guidance on the record-keeping and security of controlled drugs used with the Yorkshire Ambulance Service NHS Trust.

This SOP will adhere to the guidelines issued in the following:

- Misuse of Drugs Act 1971, 2001 Regulations
- Medicines Act 1968
- The Safe and Secure Handling of Medicines-a team approach (updated Duthie Report) 2005
- Crown Report 1999
- Health & Social Care Act 2001
- Hazardous Waste (England and Wales) Regulations 2005
- Health Act 2006
- Safer Management of Controlled Drugs: Guidance On Standing Operating Procedures For Controlled Drugs DOH 2007

- A Guide to Good Practice in the Management of Controlled Drugs in Primary Care (England) National Prescribing Centre 2007
- Safer Management of Controlled Drugs- Annual Report CQC 2011
- Security standards and guidance for the management and control of controlled drugs in the ambulance sector NHS Protect June 2012
- Controlled Drugs (supervision of management and use) Regulations 2013 Department of Health.
- 2.7 These circulars and legislative documents have clearly defined processes and procedures that must be adhered to in order to maintain 'Best Practice' and operate within the law.

3. Process

3.1 Requirements

- 3.1.1 All stations and vehicles are fitted with a controlled drug safe that comply with the misuse of drugs (safe custody) regulations 1973, in the vehicles it is our aim to ensure the safes are tested and certified to the SOLD SECURE silver rating.
- 3.1.2 The code of the station safes should only be changed in the event of a security breach. Only people with permitted access can operate the digital code after swiping their ID card.
- 3.1.3 The Maximum and Minimum stock level for the drug must be recorded either on the inside of each Controlled Drug Book, or displayed near to CD safe within the morphine room.
- 3.1.4 Air Ambulance Motorcycle and lifecycle Paramedics are required to carry 2 ampoules i.e. 20mg of Morphine Sulphate on their person.
- 3.1.5 The clinicians are responsible for ensuring the morphine stock levels are within the minimum and maximum range.
- 3.1.6 Before a Paramedic can withdraw and administer morphine their Clinical Manager must be assured that they have full understanding of the YAS CD SOP this must be done with a Clinical Supervisor and also have had a full walk through the process. Once fully assured the Clinical Manager gives authorisation for the Paramedics ID card to be updated with the permissions to access morphine rooms and safes and order CDs.

- 3.1.8 In the occasion a paramedic has to take leave of longer than a 4 week period their permissions must be suspended until they return to active duty, i.e. long term sickness, maternity leave, and suspended for disciplinary reason. It is the responsibility of the Locality Managers to ensure that this occurs.
- 3.1.9 All entries in Controlled Drug Books must be made in BLACK ink,

3.2 Shift Commencement – Ambulance Crews/Responders

- 3.2.1 On commencement of duty, it is the responsibility of the Paramedic to ensure that 4 vials of Morphine Sulphate are withdrawn from the station CD safe and 2 vials placed in 2 separate vial holders. Both vial holders must be transferred to the vehicle safe. There may be occasions where it is necessary to withdraw more than 4 vials of morphine i.e. events, on such occasion's authorisation must be given by one of the following: Medical Director, Deputy Medical Director, Associate Medical Director or the Trust Pharmacist. Where there are other controlled drugs to be withdrawn they must be placed in the relevant holders/pouches (e.g. midazolam and ketamine YAA, and codeine and diazepam tablet UCP/SP) and the following checks must be made prior to withdrawal:
 - The drug chosen is the intended medication
 - The correct amounts are present
 - The units are in date
 - The integrity of the ampoules and units are intact
 - All the information is legible
 - A running total of controlled drugs must be kept within the CD book
- 3.2.2 The vehicle safe key must be at all times secured on the Paramedics person using the karabiners provided, whilst morphine is secured in the vehicle safe. For lost or stolen keys please see Appendix G9
- 3.2.3 Any drugs found to be out of date should be placed in the 'Expired drugs' ampoule holder, located in the station drug safe. The stock must remain in the Controlled Drug Cabinet, and entry must be made in the out of date register. The Authorised Witness can then be contacted to witness the destruction.
- 3.2.4 The Controlled Drug register on station must be fully completed in BLACK ink to show date, time, the correct number of units drawn and

the drug balance in the station safe, the vehicle number the morphine is being transferred to, the ID and printed name of the paramedic and witness if possible. See Appendix G4 for example of CD book entry. The number of remaining units must be physically counted to ensure that the recorded balance is correct and the controlled drug book is signed to that effect.

- 3.2.5 Paramedics must, wherever possible, gain a second witness signature in the Controlled Drug Book/ambulance drug book when drawing morphine from the station safe. They must also gain a second signature when returning it, to confirm their actions. If a second person is not available, it is permissible for the Paramedic or doctor to sign unwitnessed, it is in the interests of any clinician to gain a second signature whenever possible.
- 3.2.6 The morphine/controlled drugs must then be transferred to the vehicle safe using the ampoule holders supplied. Where an entry must be made into the Vehicle CD record book including date, time, amount, station the morphine was withdrawn from and paramedic ID number see Appendix G5 for example record.
- 3.2.7 It is permitted for the Paramedics to remove 20mg morphine (2 vials) from the safe and transfer it to the scene on their person. Under no circumstances is it permissible for paramedics to have more than 20mg of morphine on their person at any one time, with the exception of transfers from station stock to vehicle stock.
- 3.2.8 At the commencement of shift where a Paramedic has started the morphine/controlled drug withdrawal process, the process must be fully completed before the Paramedic is available to mobilise to an emergency detail. This has been agreed with Operations as being the only accepted exception to non- immediate mobilisation.

This is only applicable to situations where the morphine safe is physically open in order to withdraw morphine and an emergency detail is passed to the Paramedic.

If the Paramedic has not opened the safe and is passed an emergency detail they must respond immediately without morphine, and inform comms that they need to return to Station as soon as possible to withdraw morphine.

3.2.9 Diazepam rectal tubes and emulsion are kept within the controlled drug station safe as stock, and should only be removed when a vehicle stock level has fallen below the required level and needs replenishing. All documentation, destruction and audit must be completed as per schedule 2 controlled drugs. Expired diazepam must be placed in the out of date box within the safe, and entered into

the out of date register, there may be instances where the safe is full and unable to take any further stock, in this case the red bags provided in each CD room should be used for the out of date diazepam only (it must still be entered in the OOD register and left for destruction by the authorised witness.

3.3 Drug Administration

3.3.1 Where a controlled drug has been administered to a patient during the Course of the shift, it is the responsibility of the paramedic to ensure that the dosage and batch number is clearly documented on the patient report form. This information must also be recorded in the Vehicle CD record book. See Appendix G4 for example.

Recording of Drug Administration in CD record book

- Date and time administered
- Amount administered
- Print name and ID card number
- Witness name and ID card number
- Batch Number and Expiry
- The CAD incident number for cross reference and patient ID

3.4 Destruction of Unused Controlled Drug – including diazepam (diazemuls and rectal tubes)

3.4.1 Where the full dose is not administered, it is the responsibility of the Paramedics to dispose of the remaining dose into the appropriate controlled drug denaturing kit (DOOP container), provided by the Trust for the destruction of controlled drugs. A DOOP container should be kept on the vehicle for this purpose.

Where a Paramedic has arrived at scene in a RRV and administered a part dose of morphine, unless the Paramedic travels with the patient the morphine must be destroyed and recorded in the vehicle drug register. If the RRV Paramedic is able to travel with the patient the morphine can be taken with them for administration enroute, the Paramedic must ensure that he/she records the administration /wastage in the RRV register as soon as possible.

3.4.2 The amount disposed must be recorded in the vehicle Controlled Register with a witness signature to confirm the disposal (this could be a crew member, Doctor, Nurse, Police Officer or another member of the emergency services). The quantity disposed of must match the

difference between the quantity administered and the quantity issued that is recorded in the CD administration record book.

- 3.4.3 DOOP containers are to be used for one shift only.
- 3.4.4 The unused morphine should be immediately put into the DOOP container and kept in the vehicle safe until the end of shift when it must be filled with water as directed on the container. It should then be placed in a clinical waste bag and tagged appropriately as per YAS clinical waste policy. The vial and syringe must be placed in the sharps bin provided.

The amount that has been disposed should be entered into the vehicle record along with:

- Amount disposed (if any, in mgs)
- Signature of Paramedics or Doctors
- Witness signature and ID card number
- CAD incident number
- A running balance of the vehicle safe must be documented See Appendix G4 for example
- 3.4.5 Errors in entries must be bracketed and, "written in error" written at the bottom of the page. Errors must never be obliterated in any way. A second signature should always be obtained wherever possible to confirm correctness.
- 3.4.6 When a CD book becomes full, it should be returned to the Station where a supervisor will arrange for transfer to central stores for secure storage for a minimum of 2 years.
- 3.4.7 If a CD book is lost or stolen it must be reported to a Clinical Supervisor immediately and a DATIX incident filled in, the procedure as with lost or stolen morphine should be followed.

3.5 Completion of Shift

3.5.1 At the end of a shift the morphine and all other controlled drugs MUST always be booked out of the vehicle register see AppendixG4 for example, and transferred back into the station safe using the ampoule holders, and an entry made in the station CD register see Appendix G3. The running balance check must be performed and documented in the station CD register. Normal practice for staff working on a double crewed ambulance (DCA) must always be that the Paramedic returns the morphine and records the transfer in the CD register and a second member of staff (normally the crew mate) witnesses the

transfer and countersigns the register. For those Paramedics working in a rapid response vehicle (RRV) attempts should be made to get a witness and countersignature, it is appreciated that operational demand may mean that this cannot be achieved.

Under no circumstances should morphine be transferred between paramedics on the vehicle, with the exception of vehicle breakdown as described below.

3.6 Vehicle Breakdown / Service

3.6.1 Where a vehicle breaks down and is recovered from the roadside, it is the responsibility of the Paramedics to ensure that morphine sulphate is removed from the vehicle by themselves or a Clinical Supervisor.

The removal must be documented in the vehicle CD register as being booked out from that vehicle into the alternative vehicle. This could be any vehicle which has capacity to carry controlled drugs and would normally be another ambulance. An entry should be made in the alternative vehicles/ambulance CD register clearly documenting the transfer of morphine from one vehicle to the other clearly documenting the reason for transfer i.e. vehicle breakdown.

At the earliest opportunity or end of shift, the alternative vehicle/ ambulance must take the transferred morphine to the station of origin which it was originally withdrawn from. A record must be made in the Station register detailing the breakdown, the transfer to the alternative vehicle and the vehicle details that the morphine was originally booked out too.

Vehicle breakdowns are the only time controlled drugs can be transferred between vehicles

3.7 Stock Checks, Monitoring and Auditing

3.7.1 In a 24 hour period the Controlled Drug Register in each station This can either be carried out by the Clinical Supervisor (CS) or if the CS is unable to attend each station a member of staff with morphine access rights can conduct the check and telephone the appropriate CS to give assurance that it has been done. A daily check sheet must be kept on the side of the safe which must be signed once the check has been carried out. The daily stock check must also be recorded within the register including date, time and signature. In the event that there are any expired morphine this must be stock checked at the same time and signed for on the daily check sheet:. See Appendix G10 for details.

Any discrepancies must be reported to the CS, who will then fill out a DATIX report and start an investigation. Where there is an actual loss of a controlled drug the Police must be informed. The Accountable Officer for the Trust must be notified.

It is the responsibility of a Clinical Supervisor to ensure that a station stock check is completed at least once a month to ensure the Station stock balance for morphine is correct and the CD registers are correct. This will include collecting and emailing the daily stock check sheet along with the audit form to the Clinical Managers. The CD order/requisition book must also be checked against the entries in the register to ensure they balance. A signature must be recorded on the requisition page(s) and the corresponding entry(s) in the CD register.

- 3.7.2 A stock check consists of balancing the CD register book against the actual CD cabinet stock and the operational stock booked out by Paramedics.
- 3.7.3 Any Authorised Officer of this Trust may request any Paramedic to produce vehicle and station registers to check compliance with this standard operating procedure (SOP) at any time.
- 3.7.4 When completing the monthly stock check, the auditor must record in the CD book the words 'monthly stock'. It must record the balance, the person's name and ID card number, conducting the stock check.
- 3.7.5 In the event of non-compliance with this SOP, identified through daily and monthly audit, the Clinical Supervisor will provide a proposed action plan to the Locality/Clinical Manager to rectify the non-compliance. The Locality/Clinical Manager will provide a copy of the report to the Accountable Officer (Medical Director). In the event of non-compliance disciplinary action may be taken.

3.8 Damaged and Expired Stock - including diazepam and codeine.

- 3.8.1 In the event of a damaged ampoule of morphine the on duty Paramedic must attempt to retain it in its current condition for examination.
- 3.8.2 A Clinical Supervisor must be informed within the current operational shift, and ensure that the correct procedure is followed regarding damaged stock.

- 3.8.3 Damaged stock must recorded in the Station CD book.
 - Date
 - Record of the damage and signature of the paramedic on duty and witness including ID card numbers
 - An incident should be entered in DATIX and the DATIX ID number recorded in the record book alongside the entry.

When expired stock is identified it must be clearly marked 'EXPIRED NOT FOR USE' and the ampoules placed in the expired stock ampoule holder/ container at the bottom of the station safe. Any damaged stock that is still intact (where there is a problem with the label/unable to open etc.) must be transferred into the out of date register and stored in the out of date holder to await destruction by the Authorised Witness. Expired rectal and injectable diazepam must be placed in the red bag provided.

- 3.8.4 Expired and damaged stock must be recorded and booked out of the Station CD register and entered into the Expired Stock CD register. This will be checked within the Monthly Audit Process.
- 3.8.5 The Clinical Manager must be notified so that an authorised witness can come and destroy the expired/damaged stock.
- 3.8.6 Completed/expired CD registers must be kept for a period of 2 years. When any controlled stationary becomes full it must be returned to central supplies for secure storage. The books must have the station name on the front and dates of opening and closing. Supplies must be contacted to make them aware that controlled stationary will need to be transferred to them via the authorised courier.

 Upon receipt of the controlled stationary supplies will document the return of a book and place in secure storage.

3.9 Discrepancies

- 3.9.1 All discrepancies in stock balances that cannot be resolved or accounted for must be reported as an untoward incident on to the Accountable Officer (Medical Director) and copied to the Clinical Manager/Security Manager. An entry must be made in DATIX as soon as possible. These incidents are reviewed regularly as a standard agenda item on Medicines Optimisation Group.
- 3.9.2 If a controlled drug is stolen or otherwise lost, the Controlled Drugs Accountable Officer will be responsible for informing the Chief Inspector of the Drugs Branch in writing within seven days of the incident being reported. If classed as an SI, the SI procedure will be followed.

- 3.9.3 If a Paramedic discovers Morphine Sulphate on the vehicle when placing the drug in the vehicle safe, it must be returned to the Morphine Sulphate store and the balance checked. The incident must be reported to the relevant Supervisor at the earliest opportunity. This must be recorded in the morphine CD book and a second signature obtained wherever possible.
- 3.9.4 In case of any discrepancy not covered specifically in this document the first contact point would be EOC for recording and further advice.
- 3.9.5 Clinicians are reminded that; 'they are responsible for the management and maintenance of the drugs stocks in their care'. Any instances where there has been a failure to do so could lead to disciplinary action. If clinicians find that their colleagues have not followed procedure, or have failed to comply with this protocol, they have a professional duty to advise their line manager of such issues.

3.10 Re-ordering of Controlled Drugs

Controlled drugs are stored centrally within supplies. The supplies and logistics directorate will top up the CDs on a rotational basis using the set maximums and minimums, if between regular deliveries there is a requirement for further supplies the Clinical Supervisors or clinical managers can email supplies using morphineorders@yas.nhs.uk, they then complete a requisition order form for the same amount and arrange a date and time for delivery. Supplies deliver the controlled drugs as per email request sign the requisition and remove the top copy.

On a quarterly basis the Trust pharmacist audits the central store CD safe, register and requisitions.

3.11 Controlled Drugs Safe Failure

3.11.1 Refer to safe failure. Appendix G1

3.12 Lost or Stolen Vehicle Safe Keys

3.12.1 See Appendix G9 for procedure.

4. Training Expectations

- 4.1 Before a Paramedic can have access to morphine they must have sign off from training and education for assurance from a clinical and legal aspect. Only then can the Clinical Managers walk through the SOP with them and they will only put morphine access on their ID cards once they are fully assured that they understand they processes and procedures.
- 4.2 It is the responsibility of the Clinician to ensure that they have read and have access to a copy of the SOP and fully understand the procedure.

5. Implementation Plan

- 5.1 The latest ratified version of this document will be posted on the Trust Intranet site for all members of staff to view. New members of staff will be signposted to how to find and access this guidance during Trust Induction
- 5.2 Communications will go out via Corporate Communications to explain the changes to all staff including questions and answers.
- On ratification of the SOP, a training plan will be put in place to ensure all Clinical Supervisors are aware and understand the changes. This will then be disseminated down to the road staff.

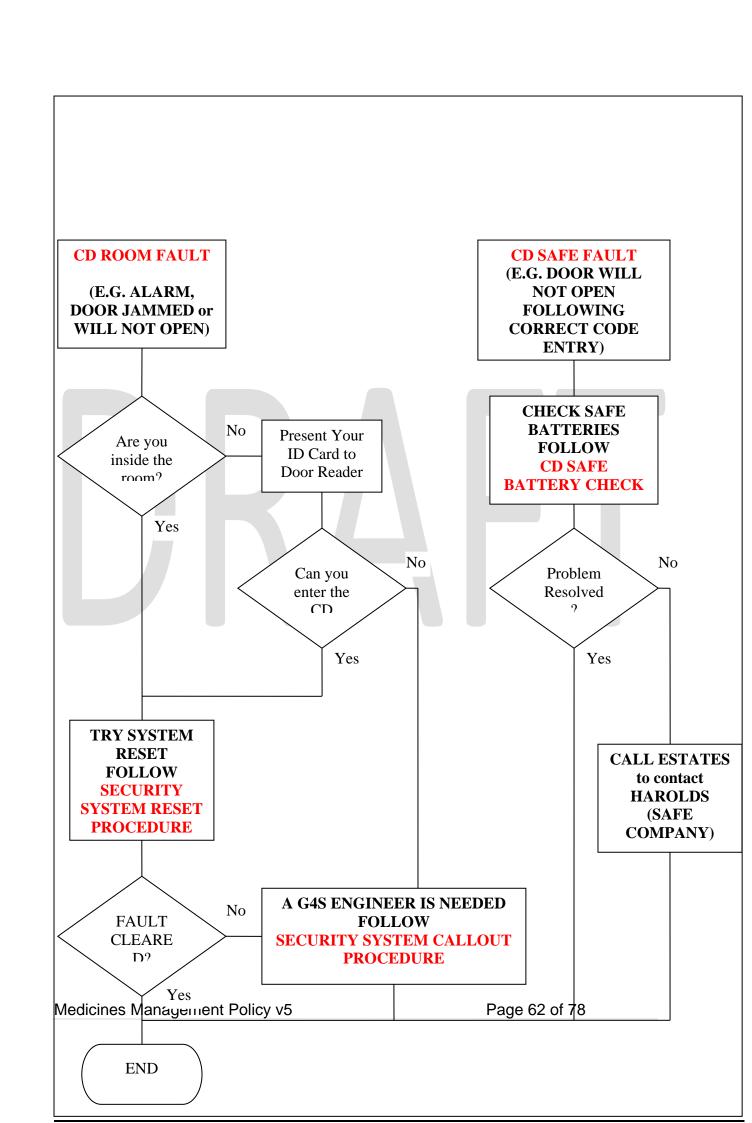
6. Monitoring Compliance with this Policy

- In the event of non-compliance with this SOP, identified through daily and monthly audit, the Clinical Supervisor will provide a proposed action plan to the Locality/Clinical Manager to rectify the non-compliance. The Locality/Clinical Manager will provide a copy of the report to the Accountable Officer (Medical Director). In the event of non-compliance disciplinary action may be taken which may have an impact on your professional registration.
- 6.2 It is at the Managers discretion to remove morphine rights at any stage with regards to controlled drugs. Rights will not be returned until the Clinical Manager is re-assured the Clinician understands the procedure fully.
- All medicines related incidents are reviewed via DATIX by the Trust Pharmacist, as soon as they are entered. They are then highlighted to the relevant Clinical Manager for further investigation if needed. The actions and outcomes are reviewed on a monthly basis at The Medicines Optimisation Group.
- 6.4 Guidance for manager/supervisor

In the event of non-compliance the manager/supervisor should refer to the disciplinary policy for guidance on procedures. However where there is failure to follow the SOP informal counselling should be offered for the following actions:

- 3 breakages in 6 months
- Any loss of keys, controlled stationery
- Any loss of controlled drug
- Failure to follow SOP with regards to returning the morphine back at the end of the shift
- Administrative errors
- 6.5 Investigation and informal counselling must be done at the earliest opportunity AND RECORDED AND DOCUMENTED AGAINST THE DATIX REPORT
 - In the event of members of staff receiving more than one informal counselling it should be escalated to formal counselling. If the Manager/Supervisor feels they need further advice they should contact a Clinical Manager/Locality Manager.

Appendix G1HANDLING G4S TECHNOLOGY SYSTEM FAULTS



PROCEDURE FOR EXTERNAL ACCESS INTO THE CD ROOM



The Key safe is opened via the key pad, key in the access code (contact your local Clinical Supervisor for the code) then slide down the top button to open the safe, when you replace the keys enter the access code back into the key pad hold the top

button down and replace the key pad into the safe release the button to secure in place. The bottom button on the safe when pushed down clears the key pad if wrong numbers are inserted.



Located inside each safe are three keys, 1) Abloy key (the long thin key opens the door), 2) The Yale type key is for the key slot on the door jamb this disarms the door alarms to allow access, 3) The small key, is for the key switch located on the backboard located in the room.



Located in the door jamb is a key slot to disarm the door alarms this is open by the Yale type key which is insert to turn the horizontal once entry has been gained

before the keys are replaced it **IMPORTANT** re insert the key and turn into a vertical

position has shown in the photograph.



Located on the back board inside the CD Room you will see a silver box as shown in the photograph.

In the event of a total power failure to the room, once access is gained into the room via the procedures above the small key located in the key safe is used in the silver box once turn the key overrides the system and re arms the safe key pad which will allow access into the safe to either retrieve or replace Morphine.

IMPORTANT

Once you have completed and entry has been gained into the room you must ensure you immediately replace the keys back into the key safe and secure.

Access to the keys is for managers the code must not been given out to staff.

Appendix G2 MEDICINES MANAGEMENT COMPLIANCE

MORPHINE - 24hr Station Ring Round

FORM TO BE ATTACHED TO EACH CS REPORT

Station	Date	Name of staff member completing 24hr Morphine check	& am	ules I in safe ount d with ecord	Discrepa Datix No		Without Re-en	Do drawals & etries in 24hrs. espond ?	If No – Record Details Below	Name of duty CS completing 24hr station ring round
			Cou	Rec	Disc rep-	Dati × Nu	Yes	No		
Example	01.01.14	A Blogs	10	10			Yes			AN Other
Example	01.01.14	B Blogs	8	10	2	1234		No	J Doe booked Morphine out 31.12.13 no record of return to station safe	AN Other
York										
Haxby										
Selby										
Harrogate										
Ripon										
Wetherby										
Pateley Bridge										

Duty CS to Datix any discrepancy not already Datixed by staff member completing 24hr check & begin investigation

Appendix G3	Drug	Strength	Form
-------------	------	----------	------

Date and time	Vehicle number	Quantity OUT	Quantity IN	Incident Number	Vehicle/hospital	Requisition number	Crew 1 Print name and ID card number	Witness signature and ID card number	Balance	Crew 1 Signature
							30 3			

Medicines Management Policy v5

Page 68 of 78

Appendix G4 Vehicle CD Register example

NAME, FORM OF PREPARATION AND STRENG	GTH
AMPOULE / VIAL SIZE	PROPRIETARY NAME

AMOU	INT TO AN	D FROM	STATION		AMOUNTS ADMINISTERED											
Date IN/OUT	Amount IN/OUT	3	Initials and card number	5 Date	JOB number	7 Time	8 Amount Given B= Batch and expiry A= Administered D= Destroyed	9 Given by (Signature)	Witnessed by (Signature) and card n		Stock Balance					
10/2/13 IN	4 IN	Leeds/ 21	JB 7754				B				4					
							D									
				10/2/ 13	4335	14.30	B 20315 11/15									
							A 8mg D2mg			3445	3					
11/2/13	3 OUT	Leeds/	JB 7754				B									
11, 2, 13		21					A									
							D				0					
							В									
							Α									
							D									
							В									
							Α									
							D									
							В									
							A									
							D									

Appendix G5 CD MONTHLY AUDIT FORM

South CBU Barnsley Area

STATION	Date of check	No. In stock MORPHINE	No. In stock MIDAZOLAM	No in stock FENTANYL	No. In stock KETAMINE	Date batteries changed	Signed	Witness	Discrepancy identified
Barnsley St									
Escape button									
Check number of ampoules in Morphine safe									
Check CD Record book									
Check CD Order book									
Check expired stock									
Check CD expired record book									
Check batteries in safe keypad									
Hoyland St									
Escape button									
Check number of ampoules in Morphine safe									
Check CD Record book									
Check CD Order book									
Check expired stock									
Check CD expired record book									
Check batteries in safe keypad									

Confirmation all Controlled Duves stock has b	and about a few the month of
Confirmation all Controlled Drugs Stock has be	een checked for the month of
Signed	Clinical
Manager	
Date	ONLY DOCUMENT THE CONTROLED DRUGS STORED ON YOUR STATION, OTHERWISE
Once completed this document must be sent t	to Erin Witton & David Guest Thank You!

Appendix G6 Morphine Sulphate Monthly Audit Guide

Escape button:

Check that the escape button is intact (Y/N). If (N) report to healthandsafetydepartment@yas.nhs.uk.

Number in stock:

Open the safe, check the number of vials of morphine in each morphine container. Does the amount in each container match up with the amount recorded in the CD book assigned to the safe (Y/N). If (N) report in DATIX and begin investigation. The requisition book must be checked to ensure that the stock book matches the amount specified in the requisition book. The clinician must initial both the requisition page and the entry in the register

CD Register:

Is the controlled drug book assigned to the safe being completed correctly e.g. vehicle call sign morphine dispensed to, date, time, paramedic booking morphine out, signatures and daily stock level checks (Y/N). If (N) DATIX and begin investigation.

CD order book:

Is it in the safe (Y/N). Do the requisitions within the CD order book correspond to the CD register – sign both requisition(s) and corresponding CD entry to confirm.

Expired stock:

Check expired stock n safe, does the amount match up with the expired stock CD register (Y/N). If (N) DATIX and begin investigation.

- Make sure the date is recorded on the audit form and the person completing the audit has signed the form.
- Make an entry in the CD register recording a monthly morphine audit took place including date, ID card number, and signature with a witness if possible.
- Check the batteries in the safe key pad and replace if necessary.
- Any problems that are found should be recorded within DATIX comments section for action/investigation.
- Completed forms should be returned to the relevant Clinical Managers for reporting.
- Once received by the Clinical Managers the form should be scanned onto the I drive and the hard copy kept for 24 months then put in the confidential waste.

Appendix G7

Lost, Stolen or broken Keys

- In the event of a vehicle safe key being lost, broken or stolen, the Paramedic responsible must inform Emergency Operations Centre (EOC) and the local C/S immediately, who will then inform the onduty Locality Manager.
- The Police must be informed within 24 hours if the key has been lost or stolen.
- Where a key is broken a spare key must be collected by the Supervisor to replace the broken key, where a key has been lost or stolen the spare key can be used to enable the morphine to be removed.
- A Datix report must be fully completed immediately by the Paramedic responsible.
- The crew must transfer onto a pool vehicle until a replacement lock is fitted, the on duty Supervisor must arrange for the new lock to be fitted within 24 hours.
- The areas Local Security Management Specialist/ Clinical Manager must be notified as soon as possible.

Appendix G8 Daily Controlled Drug Stock Check Form

Station	Month

	MORPHINE	DISCREPANCY	Initi al & ID card No	MIDAZOLAM	DISCREPANCY	Initial & ID card No	FENTANYL	DISCREPANCY	Initi & ID care No	ial d	KETAMINE	DISCREPANCY	Initial & ID card No	CI 01	Dis cre pan cy	Initial & ID card No	Dia zep am	dis epa cy	an	Initial & ID card No
1																				
2																				
3																				
4																				
5																				
6																				
7																				
8																				
9																				
1 0									4											
1																				
1																				
1 2																				
1																				
3																				
4																				
1																				
<u>5</u>																				
6																				
1 7																				
1																				
8																				
1 9																				
2																				
2																				
1																				
2 2																				
2																				

3									
2									
4									
2									
5									
2									
6									
2									
7									
2									
8									
2									
9									
3									
0						_			
3									
1									

Appendix G9 – Exemptions to SOP.

1. HART amendment to Controlled drug standard operating procedure: Vehicle Possession

Process for withdrawal of controlled drugs

- At the start of a shift a drugs pouch which includes Morphine, Ketamine, Midazolam and Flumazenil is assigned to each Hart vehicle safe.
- The controlled drugs within the pouch will be individually signed out to the stated vehicle in the station CD register, and signed into respective vehicle register. Where the pouch will be kept until it is necessary to re-stock.
- All vehicle safe keys will be locked in the drugs safe and a signing in/out book for the safe keys kept in the cupboard.
- At the start of their shift, each paramedic will sign out the key for their assigned vehicle and check that the correct drugs are in the pouch, the vehicle register must be signed to give assurance that the drugs are correct.
- The clinician is responsible for the vehicle safe key and must sign it back in at the end of shift.
- In order that a full daily audit occurs, the duty Team Leader would be responsible for a full drug stock check once in every 24 hour period, counting all station safe and vehicle assigned drugs and checking against the record books. An entry into both the vehicle and Station registers must be recorded to state that the stock is checked and correct.
- In the event of a discrepancy the YAS CD SOP must be followed.
- Should a Technician be assigned to a particular vehicle, the vehicle safe key must remain in the station safe if the drugs remain on the vehicle. Where possible the paramedic leaving the vehicle should sign the drugs back to the station safe.
- At the start and end of a shift, should duty teams need to swap vehicles on scene, all drugs can remain safely in the vehicles and just the vehicle safe keys be exchanged and documented. The CD's must be checked and the transfer of responsibility must be signed over and documented in the vehicle CD register.

NOTE: Where a vehicle is not in use the controlled drugs must be removed and returned to the safe as per regular CD process.

2. Ingelton Ambulance Station procedure

- Ingelton Station have been authorised to only remove 2 vials of morphine per vehicle (one rapid response vehicle and one double cabbed ambulance).
- At scene the morphine may be transferred between vehicles if necessary.
- Any transfer between vehicles must be documented fully to ensure the morphine journey can be audited