South Central Ambulance Service
NHS Foundation Trust

MEDICINES MANAGEMENT POLICY

South Central Ambulance Service NHS Foundation Trust
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DOCUMENT INFORMATION

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CONTENTS

1. Introduction

1.1 South Central Ambulance Service NHS Foundation Trust (“the Trust”) is committed to the safe and secure management of medicines.

1.2 The principles which govern the management of medicines must be applied to all the activities in which medicines are involved. The key principles are:

- compliance with current legislation;
- adherence to guidance issued by the Department of Health and other national guidance;
- management of the risks to patients and staff arising from the use of medicines.

1.3 The policy should be read in conjunction with the Standard Operational Procedures (SOPs) approved by the Medicines Manager for each of the activities concerned with the safe use and security of medicines. The SOPs should define responsibilities, competencies, training and performance standards of staff involved in the activity.

2. Scope

2.1 This policy applies to all individuals employed by the Trust, including those that work under a contract for services, and those supplied to do work by a third party, including volunteers, agency staff and students engaged by SCAS.

3. Aim

3.1 To ensure that the Trust complies with relevant legislation governing the storage, supply and administration of medicines;

3.2 To ensure that all Trust staff are aware of the procedures for the safe and effective management of medicines.

4. Roles and Responsibilities

4.1 The Trust Board has responsibility and accountability for ensuring the provision of the appropriate resources required to implement this policy. The Board, Committee and Meeting structure is at Appendix 1.

4.2 The Chief Executive has overall responsibility for ensuring that systems for the safe and secure management of medicines are followed and that the security of medicines handled by the Trust is maintained.

4.3 The Executive Director of Patient Care is the board member responsible for medicines management

4.4 The Medicines Manager is responsible for managing the process for the safe and secure management of medicines in the Trust and reports through the Executive Director of Patient Care to the Trust Board for this purpose.

4.5 The Executive Director of Finance has responsibility for the procurement of medicines and ensuring that they are of a suitable quality.

4.6 The Chief Operating Officer has responsibility and accountability for the safe and secure handling of medicines within the Trust.

4.7 The Operations Directors and Area Managers are responsible and accountable for the day to day safe and secure handling of medicines within the operational environment, and must ensure that:

- Copies of the Medicines Management Policy and SOPs are available to their staff;

- Staff understand and are competent to carry out the duties described by these policies and procedures.

4.8 Clinical staff have a responsibility to maintain their competency in the management of medicines and to ensure their familiarity with changes to therapeutic guidelines as they are adopted by the Trust.

4.9 The Local Security Management Specialist has responsibility for reviewing Trust security management measures including the security of controlled drugs, s/he is also responsible for conducting investigations, as requested, for the Trust.

5. Definitions

Adverse Drug Reaction
An adverse drug reaction is an unwanted or harmful reaction experienced following the administration of a drug or combination of drugs under normal conditions of use that is suspected to be related to the drug.

Controlled Drugs
The management of Controlled Dugs is governed by the Misuse of Drugs Act (1971) and its associated Regulations. Additional statutory measures are laid down in the Health Act (2006) and its associated Regulations.

Medical Product/Medicine
For the purpose of this policy a `medicinal product' (or a `Medicine') is defined as a substance or article, or an ingredient of either of these, (not being an instrument, apparatus or appliance) supplied for administration to human beings for a medicinal purpose. Medicinal purpose means any one or more of the following:

a) treating or preventing disease;
b) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

Exclusions:

a) Disinfectants (being applied to inanimate objects);
b) Sterile Non-Injectable Water;
c) Unmedicated dressings, ligatures and sutures;
d) Medical gases except that 3 of the main (i.e. prescribing and administration) applies for Oxygen;
e) Antiseptics used as cleansing agents for the skin and wounds.

Patient Group Direction

A Patient Group Direction (PGD) is a specific written instruction for the supply and administration of a named medicine to a group of patients in an identified clinical situation. A PGD is drawn up by doctors (or dentists), pharmacists and other health professionals and must meet certain legal criteria. Further guidance is contained in NICE Medicines Management Guidance 2 Patient Group Directions (August 2013). The qualified practitioners who may supply or administer medicines under a Patient Group
Direction are Nurses, Midwives, Health Visitors, Optometrists, Pharmacists, Chiropodists, Radiographers, Orthoptists, Physiotherapists and Ambulance Paramedics.

6. Abbreviations

- AACE – Association of Ambulance Chief Executives • COSHH – Control of Substances
- Hazardous to Health PGD – Patient Group Direction
- SOP – Standard Operating Procedure

7. Medicines Policy

7.1 Supply of Medicines

The Executive Director of Finance (with delegation as appropriate and with the advice of the Lead Pharmacist) is responsible for obtaining all medicinal products, which are required and approved by the Trust, through a licensed Wholesale Dealer ensuring that they are of a suitable quality in accordance with the Purchasing for Safety Policy (at Appendix 2).

Only those medicines approved by the Clinical Review Group or on a Trust approved formulary will be purchased by the Trust.

A “New Medicines” form should be completed for all applications to add a medicine to a Trust formulary (Appendix 3). The application will be considered by the Medicines Governance Group and will formally be approved or rejected by the Clinical Review Group.

All Medicines (with the exception of patients' own) administered or supplied to patients will be supplied and/or purchased by the Trust.

Medicines will be issued in their original manufacturers packaging and medicines labelled for supply under a Patient Group Direction or by a medical practitioner must be supplied in packs produced by a pharmacist.

The list of medicines carried on each ambulance and the Trust formularies are at Appendix 4. This list is reviewed and approved by the Medicines Group and signed off by the Clinical Review Group.

SOPs will document the method of supply from the pharmaceutical supplier to the authorised staff.

7.2 Ordering and Records

Medicines are requisitioned on agreed Trust stationary, for each authorised location, by individuals authorised by the Trust.

Where electronic ordering systems are used, they should be designed in such a way that a permanent record of orders is kept.

The pharmaceutical supplier has the responsibility to ensure that medicines are only supplied on the instruction of an authorised person.

Upon arrival at an authorised location, the quantities of medicines received will be recorded by the appropriate persons.

Unwanted or Outdated Medicines

- All unwanted medicines should be labelled for return to the pharmaceutical supplier as soon as practicable.
- Out of date, recalled and medicines unsuitable for use should be stored in a locked cupboard, separate from medicines available for use.
- Pharmaceutical waste must be disposed of in accordance with the Waste Management Policy.

Medicines Modules

- Modules should be secured with tamper-evident seals and once opened a record of medicines used must be documented.
- Where there is a local arrangement for modules to be supplied, a record of issue must be held.

7.3 Storage of Medicines

Medicines will be stored under the control of the Chief Operating Office.

- The Area Manager must safeguard all medicines issued to any ambulance station or vehicle.
- An SOP will define the person responsible in other locations.

Standards for medicines storage within the trust will be determined by the Safe & Secure Handling of Medicines Policy. This includes security standards for appropriate storage locations as well as how the trust manages temperature control.

Medicines must be stored in a locked cupboard in a safe environment in an area that is not accessible by the public.

- An SOP should be in place to ensure that medicines are stored within the specified conditions from receipt to the point of use or disposal.
- The following need not be stored in a locked cupboard but a risk assessment must be undertaken to ensure that storage location is appropriate:

    - medicines in emergency kits
    - antiseptics and irrigation solutions.
    - Medicines for internal and external use must be stored separately.
    - Intravenous fluids should be stored separately off the floor in a locked cupboard
    - Items requiring refrigeration must be stored in a locked refrigerator, solely for this purpose. Temperatures of refrigerators must be recorded each working day by a nominated person. If the refrigerator is being shared, one named clinician must take responsibility.
    - Stock must be regularly rotated and checked to ensure medicines have not expired.

Health professionals are personally responsible for the security of all medicines while they are in their possession.

Medicines may only be issued by non-clinical staff for whom training and SOPs are agreed and in place.

Reporting of Losses/Misuse

- The loss or suspected loss or misuse of any medicinal product must be reported according to the Adverse Incident Reporting and Investigation Policy no later than the next working day.
- The Local Security Management Specialist may be asked to carry out an investigation (See 4.9).

Monitoring of Storage

- The Head of Operations Area Manager will make checks to ensure compliance with the medicines policy at least every six months.
- A record book must be kept on each station of all checks made, including the identities of the staff members carrying out those checks, and retained for a period of two years from the date of last entry.
- The Pharmacy team will audit the storage of medicines on an annual basis (see section 7.12)

7.4 Prescribing Medicines

Only those employed by the Trust (directly or indirectly) and authorised to prescribe, e.g. Doctor, Dentist or Non-Medical Prescriber may prescribe medicines.

Registered prescribing practitioners are permitted to prescribe all items in the British National Formulary (BNF); prescribers should be familiar with what can be prescribed on an NHS prescription.

All prescribers:

- may prescribe working within their clinical competence from the relevant formulary depending on their level of registration;
- an annual review of the prescribers prescribing portfolio (including competence, updates undertaken and support needed) will be reviewed annually at the appraisal and returned to the Prescribing lead.

Prescribing will be reviewed at the Medicines Governance Group at least once a year.

Responsibilities for medicines prescribed by practitioners employed indirectly by the Trust will be defined in the Service Level Agreement.

Prescriptions should be written legibly in ink or otherwise so as to be indelible and SOPs will be in place for the safe management of prescription pads, in accordance with the Trust Prescription Security Policy and Counter Fraud guidance.

Staff that prescribe must ensure they remain clinically competent.

- A policy will be in place for the exceptional circumstances in which a faxed or verbal prescription is used (Appendix 5)
- Except in exceptional circumstances employees of the Trust (directly or indirectly) must not prescribe medicines for personal use or for those with whom they have a close personal relationship.
- Staff may not prescribe for other staff or colleagues unless:

    - the patient is receiving formal and recorded NHS care in the usual way
    - the prescribing is for exceptional, emergency or urgent care.

7.5 Patient Group Directions (PGD)

PGDs will be developed and consulted on through the Medicines Governance Group and appropriate specialists, and approved by the Clinical Review Group.

The PGD policy defines how PGDs are developed and used within the trust.

7.6 Administration of Medicines to Patients

The following groups are authorised to administer medicines:

- Competent health professionals (within a framework approved by the Trust)
- Competent registered health professionals (within the legislative framework)
- The patient (to him/herself) either under supervision or by self-administration

    - The list of medicines authorised for administration by Paramedics, Associate Ambulance Practitioners and Technicians is at Appendix 4. These should be administered in accordance with the AACE Clinical Practice Guidelines, a Trust PGD or the Trust “Protocols for the administration of non-parenteral medicines”.

- Student Associate Ambulance Practitioners

Student Associate Ambulance Practitioners will attend education and training for underpinning knowledge on medicines, and will be signed off by the education team before working as a student under supervision

The list of medicines Student Associate Ambulance Practitioners are authorised to administer when working under supervision is at Appendix 7.

- Student Paramedics

The list of medicines student Paramedics signed off as competent are authorised to administer under supervision is at Appendix 7 and the framework for the competency assessment is at Appendix 8.

Student paramedics can **NOT** administer paramedic only medicines. A registered paramedic, ambulance nurse or doctor must administer the medicines, but the student should be involved in the decision and the reasoning behind the administration, considering all appropriate indications, cautions, contra-indications and side-effects accordingly

The list of medicines student Paramedics signed off as competent are authorised to administer under supervision is at Appendix 7 and the framework for the competency assessment is at Appendix 8.

- Nurses

Registered Nurses may administer medicines in accordance with a Patient Group Direction, a Patient Specific Direction or the Trust “Protocols for the administration of non-parenteral medicines”.

- Specialist Paramedics

The guidance for Paramedics or Nurses applies (according to specific professional registration group).

- Emergency Care Assistants

Emergency Care Assistants can administer aspirin, dextrose oral gel, Nitrous Oxide 50% - Oxygen 50% (Eentonox) and oxygen when training has been provided.

- Community Responders and Patient Transport Services

These healthcare workers can administer aspirin, dextrose oral gel, Nitrous Oxide 50% - Oxygen 50% (entonox) and oxygen when training has been provided.

- Patient Transport Services Ambulance Care Assistants

These healthcare workers can administer oxygen and aspirin when training has been provided.

- A patient's own medicines may be administered by the specified Trust employees, where a Trust Patient Specific Treatment Plan has been completed and signed off by the Executive Director for Patient Care.

- All registered health professionals are accountable for their practice and must be able to demonstrate competence.

- Sufficient information should be available to the staff and/or patient to enable identification and correct use of the medicine. As a minimum this would comprise the patient information leaflet, the PGD, Trust protocol or the Clinical Practice Guidelines.

- Any authorised person administering a medicine to a patient must be satisfied that s/he knows the therapeutic uses of the medicine, its normal dosage, side effects, precautions and contra-indications.

Consent to Treatment

- In general, patients have a right to receive information about a medicine prior to use and to refuse administration. o Consent should be obtained in accordance with the Trust Consent Policy and Procedure.

Checking of Medicines Before Administration

- Wherever possible a second suitable person e.g. ambulance staff, the patient or member of the public must check all medicines for accuracy before administration.
- Staff are encouraged to seek additional information about possible medicine interactions prior to administering a medicine (when appropriate). The Clinical Support Desk, hospital pharmacy departments and the Trust Pharmacists are useful resources for such information. o Staff must check appropriateness of any medicine, including its contra- indications, in the Clinical Practice Guidelines, Trust protocols or appropriate PGD.
- Any medicine that is found or thought to be defective should not be used and the Adverse Incident Reporting and Investigation Policy should be followed.

Administration

- Administration to the patient should be in accordance with a prescription written by an authorised health professional or in accordance with the AACE Clinical Practice Guidelines, Trust protocol or PGD or in the case of patients own medicines, the signed Trust Treatment Plan (Appendix 9).
- All calculations must be conducted in accordance with the AACE Clinical Practice Guidelines, Trust protocol or PGD.
- A record of administration should be made, including the administering person and the quantity, timing, and route of each medicine given in accordance with the Trust Patient Clinical Record Policy. o Adverse effects should be recorded.
- Medicines refused, wasted or disposed of should be recorded.
- Medicines must not be prepared in advance of administration.

Unused Medicines

- Medicines removed from their container/packaging and not immediately administered must be discarded.
- Unused or discarded medicines must be disposed of in an appropriate waste disposal bin.

Medicine Administration Errors

A medicine administration error occurs when a patient has received:

- the wrong medicine
- the wrong dosage of the intended edicine a dose at the wrong time
- a medicine administered by the wrong route a medicine that is wrongly prescribed or given without an authorised prescription or a current authorised Patient Group Direction.
- the medicine is omitted without a documented clinical reason.

Whenever an error in the administration or supply of a medicine is found the Adverse Incident Reporting and Investigation Policy should be followed.

Near Misses

- A near miss is any situation in which either a patient or staff member was close to suffering injury in relation to a medicine.
- Staff should report near misses in accordance with the Adverse Incident Reporting and Investigation Policy.
- A near miss provides an opportunity for learning in the same way as an actual incident.

Self-Administration of Medicines by Patients

- Any medicine taken by a patient in the presence of ambulance personnel must be documented according to the Patient Clinical Record Policy and Procedure.
- The only medicines offered by the Trust for self-administration by the patient is Nitrous Oxide 50% - Oxygen 50% (Entonox) and methoxyflurane for the relief of pain.

Medicines for Staff

- Staff must not take medicines from stock for personal use. Normally the member of staff should consult their General Practitioner or the Occupational Health Service.

Hazards

- Handling of hazardous substances should be in accordance with COSHH Regulations.
- An SOP should cover actions to be taken, including reporting and record keeping, in the event of unplanned incidents such as spillages.

7.7 Disposal of Medicines

- The disposal of medicines from medicine stores must be in accordance with the Trust Waste Management policy.
- Patients' medication remains the property of the patient and may only be removed from a patient's home in accordance with a local policy.

7.8 Retention of Records of Administration

See Clinical Records Policy and Procedure

7.9 Reporting Defects in Medicinal Products

In the event of a defect or suspected defect in a medicine:

- The medicine must be labelled and stored separate from other medicines to prevent inadvertent use.
- The Line Manager must be notified and will decide (in consultation with the Medicines Manager or a Medical Director) if it is appropriate to withdrawn from use all medicine of the same batch in accordance with the Adverse Incident Reporting and Investigation Policy
- The defect or suspected defect must be reported in accordance with the Trust Adverse Incident Reporting and Investigation Policy
- The incident will be reviewed in accordance with the Trust Adverse Incident Reporting and Investigation Policy

7.10 Adverse Drug Reactions

Adverse Drug Reactions (ADRs) should be recorded in accordance with the Clinical Records Policy.

The following ADRs should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) by completing a yellow card (https://yellowcard.mhra.gov.uk/. This can be done either via the yellow card app, online or via paper copy):

- all serious adverse reactions in adults;
- all serious and minor reactions in children (under 18);

- Serious reactions include those that are:
    - fatal
    - life threatening
    - disabling
    - incapacitating
    - result in or prolonged hospitalisation and / or are medically significant congenital abnormalities

If in doubt about the seriousness of a reaction, report it.

7.11 Central Alerting System and Patient Safety Alerts

Central Alerting System cascade will be actioned in accordance with the Adverse Incident Reporting and Investigation Policy.

7.12 Risk Management

A risk assessment will be carried out for new medicines to determine the potential risks to patients and staff. This will start with the completion of the application for a new medicine (Appendix 3) and a formal risk assessment undertaken by a Trust pharmacist. Both documents will be presented to the Medicines Governance Group and subsequently to the Clinical Review Group for sign off.

If a medicine without a marketing authorisation is used or if a medicine is to be used knowingly outside its marketing authorisation, then the organisation policy at Appendix 11 will be followed.

The Trust will have a formal program of annual Medicines Management audits.

The Lead Pharmacist will prepare an annual medicines management report for presentation to the Trust Board and monitored by the Patient Safety Group. The report will include a summary of progress towards the Trusts medicines management objectives, a review of the audits and risk assessments conducted and actions relating to Patient Safety Alerts.

7.13 Liability

The Trust generally accepts responsibility for the negligence of its qualified staff who, in emergency situations within the United Kingdom, administers medicines in the treatment of patients. This applies both during and outside working hours whilst a member of staff acts in accordance with his or her training and not for any private or voluntary organisation.

The Trust is not liable for the activities of staff undertaking work for private or voluntary organisations. In these circumstances, to avoid the imposition of personal liability, staff are advised to check beforehand that appropriate insurance cover is in place.

7.14 Review and Monitoring

This Policy and the associated procedures will be reviewed within 2 years or sooner if necessary.

The Lead Pharmacist will undertake an annual medicines management audit to monitor the effectiveness of policies and procedures for the safe and secure management of medicines. An action plan will be developed from the audit and will be included in the annual medicines management report. The audit will cover:

- Supply of medicines
- Storage of medicinal products
- Patient Group Directions
- Administration of medicines
- Disposal of medicines
- Controlled Drugs
- Reporting defects in medicinal products
- Adverse drug reactions
- Safety Alert Broadcasts and Patient safety alerts

8. Training

The Trust recognises the importance of Training and Education in increasing awareness of the safe and effective use of medicines. On Induction, all clinical staff will receive information and education on medicines and Trust medicines policies and procedures. The trust has a training plan in place for all staff involved in handling medicines. This plan is reviewed and developed by training & education under the guidance of the Lead Pharmacist.

9. Equality and Diversity

The Trust is committed to promoting positive measures that eliminate all forms of unlawful or unfair discrimination on the grounds of age, marriage and civil partnership, disability, race, gender, religion/belief, sexual orientation, gender reassignment and pregnancy/maternity or any other basis not justified by law or relevant to the requirements of the post.

By committing to a policy encouraging equality of opportunity and diversity, the Trust values differences between members of the community and within its existing workforce, and actively seeks to benefit from their differing skills, knowledge, and experiences in order to provide an exemplary healthcare service. The Trust is committed to promoting equality and diversity best practice both within the workforce and in any other area where it has influence.

The Trust will therefore take every possible step to ensure that this procedure is applied fairly to all employees regardless of age, marriage and civil partnership, disability, race, gender, religion/belief, sexual orientation, gender reassignment and pregnancy/maternity or any other basis not justified by law, length of service, whether full or part-time or employed under a permanent or a fixed-term contract or any other irrelevant factor.

Where there are barriers to understanding e.g. an employee has difficulty in reading or writing or where English is not their first language, additional support will be put in place wherever necessary to ensure that the process to be followed, is understood and that the employee is not disadvantaged at any stage in the procedure. Further information on the support available can be sought from the Human Resource Department.

A full 'Equality Impact Assessment' is available on request.

10. Monitoring

In order to ensure safe and secure management of medicine this policy is reviewed annually by carrying out an audit of standards at ambulance sites. The monitoring of storage is reviewed every six months in compliance with standards and the monitor of prescribing is reviewed annually by the correct committee's and individuals via reviewing prescribing reports.

11. Consultation and review

This policy is open to consultation and is regularly reviewed with input from the Patient Safety Group and Medicines Governance Group.

12. Implementation (including raising awareness)

This should include any specific e.g. staff briefings, newsletters, team brief, divisional meetings that are going to be used to raise awareness of the changes within the policy. This section should also include any requirements to ensure full implementation of the policy for example training – it is acceptable to state that there are training requirements and refer to the training section. It may be that there needs to be equipment purchased to allow full implementation and this should be included within this section.

13. References

- Department of Health (2009) Reference Guide to Consent for Examination or Treatment
- General Medical Council (2013) Good practice in prescribing and managing medicines and devices
- Medicines and Healthcare Products Regulatory Agency https://www.gov.uk/government/organisations/medicines-and-healthcare-products- regulatory-agency
- National Institute for Health and Care Excellence (2017) Medicines Practice Guidelines: Patient Group Directions
- Royal Pharmaceutical Society (2016) A competency framework for all prescribers
- NHS Counter Fraud Authority (2018) Management and control of prescription forms: A guide for prescribers and health organisation

- NHS Protect (2013) Security standards and guidance for the management and control of controlled drugs in the ambulance sector
- Nursing and Midwifery Council (2006) Standards of Proficiency for Nurse and Midwife Prescribers
- Royal Pharmaceutical Society (2018) Professional guidance on the safe and secure handling of medicines Royal Pharmaceutical Society (2019) Professional Guidance on Administration of Medicines in Healthcare Settings

14. Associated documentation

Controlled Drug Policy
Prescription Security Policy
Patient Group Direction Policy
Safe and Secure Handling of Medicines Policy
Medicines and Controlled Drug Standard Operating Procedures

15. Appendix 1 Review

This policy is regularly reviewed and updated with information in line with relevant national guidance and legislation.
A full 'Review Table of Contents' is available on request.

16. Appendix 2 Responsibility

The responsibility for this policy is shared between various Policy Groups, Lead Director/Officers, Working Groups and Committee members.

A full list of all responsible parties can be made available upon request.

17. Appendix 3 Equality impact assessment - screening

Employees exercising their rights and entitlements under the regulations will suffer no detriment as a result.

The Screening element of the 'Equality Impact Assessment' is available on request.

18. Appendix 4 Equality impact assessment – full assessment

Employees exercising their rights and entitlements under the regulations will suffer no detriment as a result.

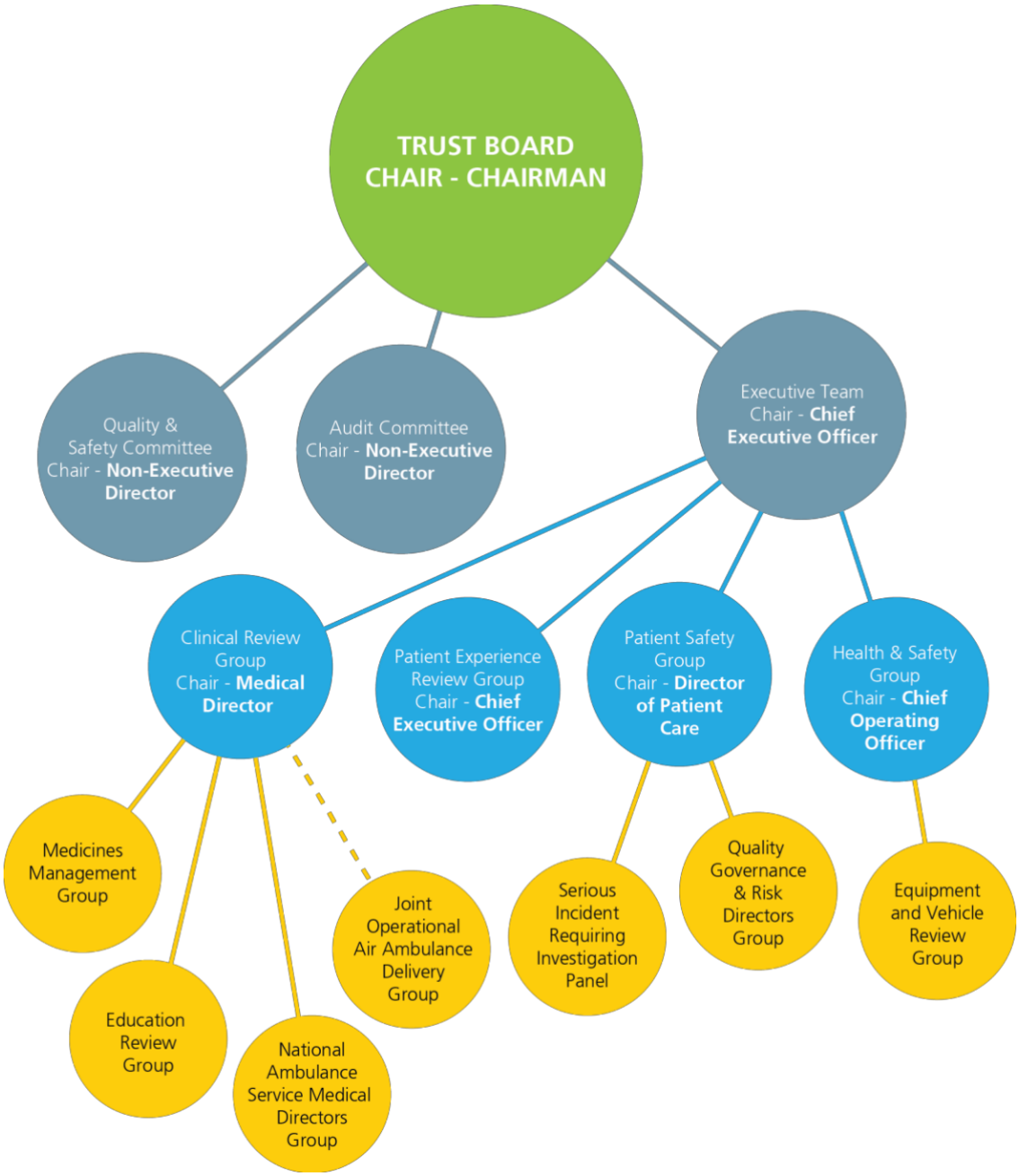
A full 'Equality Impact Assessment' is available on request.

19. Appendix 5 Ratification Checklist

This an internal Checklist of items that need to be completed by the Author of this policy prior to submission for ratification.

20. Appendix 6: Accountable Group

There is an Accountable Group that works together to agree the content of this policy. Any changes need to be **completed by the** Accountable Group **of this policy prior to submission for ratification**



21. Appendix 3: Purchasing for Safety Policy

Introduction

The use of all medicines infers risk of a patient safety incident (such as inappropriate reconstitution or administration). Part of this process is to ensure that the procurement of a medicine which is of a suitable quality, and is safe in use i.e. prescribing, dispensing, preparation, administration and disposal. It is essential that the procurement process assesses the capabilities of the upstream supply chain to ensure products are genuine, stored correctly and available when required.

Risk assessment

Risk assessment is at the core of any safety policy. A risk assessment should be undertaken by the Lead Pharmacist in consultation with other clinicians who have an understanding of the purpose and end use of the product being procured. If normal sources are not available (e.g. in a shortage situation) then alternatives will be assessed in the light of the increased risk they may present to patients.

If a product is assessed by the Lead Pharmacist as a high risk of causing a patient safety incident, these will be reported to regional QA and procurement specialists, who use the lists as the basis of discussion with the manufacturers about possible changes in presentation.

Components of Safety

Risk assessment should take account of the following factors.

1. Quality of Products
2. Design and Use of Products (e.g. ready-to-use and ready-to-administer products)
3. Labelling and Packaging of Products
4. Source of Products and Materials
5. Treatment of Product within Supply Chain.

Quality Design and Labelling of Product

1. Licensed Products

Wherever possible ready-to-use or ready-to-administer medicine with a product licence (or a devices licence) issued by the MHRA are used in preference to an unlicensed product.

Licensed ‘concentrate’ products that have to be diluted or reconstituted into an unlicensed product before they can be administered to patients may not be safer in use than unlicensed ready-to-use or ready-to-administer formulations of the same medicine. Injectable products and practices will be risk assessed using the NPSA risk assessment tool (ref National Patient Safety Agency. Alert 20. Safer Practice with injectable medicines. 2007. www.npsa.nhs.uk) and the “Consensus List High Risk Injectable Medicines” (ref Medusa/UKMI Consensus List High Risk Injectable Medicines, 2013. http://www.medicinesresources.nhs.uk/upload/documents/Evidence/Medication_safety/NPSA20%20high%20risk%20consensus%20list%20Final%20Nov%202013.pdf).

The results of the risk assessment will help to identify high risk injectable products that require to have their risks managed in practice
If an unlicensed formulation has to be used it will be procured from a manufacturer with the appropriate MHRA licence (See Unlicensed medicine's policy).

2. Assessed Products

a. South Central Ambulance Service will wherever possible only purchase medicines from NHS hospital pharmacies. These suppliers purchase wherever possible, products included on a NHS CMU contract. Medicines on an NHS CMU contract are assessed by NHS Pharmacy QA staff according to an assessment tool developed by the National NHS QA Committee and given a MEPA score which reflects its suitability for use. Assessed products present a known risk and should be used in preference to those not assessed (and consequently presenting an unknown risk). Where NHS hospitals purchase off contract, they have processes in place for risk assessment.

b. Where South Central Ambulance Service is unable to purchase medicines through an NHS contract, then the Lead Pharmacist will ensure that the medicines are purchased through a supplier with an appropriate MHRA licence, and that quality assurance processes are in place. Advice will be obtained from NHS Pharmacy QA staff.

3. Systems for reporting patient safety incidents, and defects in medicine and medical devices exist both within the trust and external to it. Internal reporting systems form part of the Medicines Management Policy and Adverse Incident and Risk Policy.

Source of Products

It is only by using trusted and appropriate sources of supply that the suitability of products purchased can be assured and the possibility of counterfeit or damaged medicines being purchased can be minimised. Suppliers and wholesalers are required to hold an appropriate licence from the MHRA and this should be checked for authenticity. NHS CMU holds a list of inspected suppliers who hold or have successfully held a NHS CMU contract. Pharmacy QA and procurement staff inspect potential pharmaceutical suppliers and these reports can be used to assess new suppliers. Procurement specialists can give advice about potential new suppliers.

The entire upstream supply chain should be included in these assessment processes as several links may be involved in obtaining the medicine.

The Commercial Medicines Unit (and others) undertake supplier performance measurement and award where possible to those suppliers who have a better supply record. This reduced supply risk is obviously a component for patient safety.

The Pharmacy Team will ensure safe and secure methods of procurement are utilised to minimise the potential for error during the process.

"Ready-to-Use"/ "Over labelled medicines"

Although many medicines are licensed and come from a suitable supplier there may be differences in the presentation. Any risk assessment should involve the complete use of the medicine. That is the identification, reconstitution, administration and disposal in the clinical settings in which it is used. This is important for all medicines but particularly those that have been identified as representing a high risk under the NPSA assessment guidance. Medicines which represent the minimum risk throughout the whole of this process should be preferred. Where possible higher risk products should be prepared by commissioning a (licensed and suitable) manufacturer to prepare the medicine in a suitable format to minimise the risk.

If gaps in this risk process are identified the products involved should be reported to the procurement specialist who can compile lists of these products and engage industrial solutions where possible.

Delivery and Storage Arrangements

All the above points concentrate on the “external” supply chain. It is equally important though to ensure that the “internal” supply chain is robust and fit for purpose; that is the arrangements ensure products are available, fit for purpose when they are required for patients. The Safe and Secure Handling of Medicines (http://www.rpharms.com/support-pdfs/safsechandmeds.pdf) covers the requirements of the internal supply chain and storage and distribution and forms the basis of the Trusts Medicines Management Policy and the annual audit of medicines management undertaken by the Trusts Pharmacy Advisor.

Louise Maunick Lead Pharmacist, updated March 2020

22. Appendix 4: Medicines Group New Medicines Request

There is an internal form called ‘medicines group new medicines request’ that includes subjects such as background information, evidence of clinical efficacy, safety data, proposals for use and cost implications.

For security and accessibility reasons this form is only available on our Staff Intranet.

23. Appendix 5: South Central Ambulance Service Medicines Formulary

Medicine	Technicians Associate Ambulance Practitioners	Paramedics Nurses
Adrenaline 1mg in 10ml injection		Yes
Adrenaline 1mg in 1ml injection	Anaphylaxis Only (Intramuscular or subcutaneous)	Yes
Amiodarone injection		Yes
Aspirin 300mg tablets	Yes	Yes
Atropine injection		Yes
Benzylpenicillin 600mg injection		Yes
Charcoal (activate)		Yes
Chlorphenamine 10mg in 1ml injection		Yes
Clopidogrel 300mg tablets		Yes
Codeine 30mg tablets		Yes
Dexamethasone 2mg tablets		Yes
Diazepam injection emulsion		Yes
Diazepam Rectal Tubes		Yes
Furosemide Injection		Yes
Glucagon 1mg Injection	Yes	Yes
Glucose 10% intravenous solution		Yes
Glucose 40% Gel	Yes	Yes
Glyceryl Trinitrate spray	Yes	Yes
Hydrocortisone sodium succinate 100mg in 1ml injection	Yes (Intramuscular when trained)	Yes
Ibuprofen 200mg tablets		Yes
Ibuprofen oral solution 100mg in 5ml sachets		Yes
Ipratropium bromide 500mcg in 2ml nebuliser solution	Yes	Yes
Ketamine		Yes

Medicine	Technicians Associate Ambulance Practitioners	Paramedics Nurses
Loratadine 10mg tablets		Yes
Methoxyflurane	Yes	Yes
Midazolam		Yes
Morphine Sulphate 10mg in 5ml oral solution		Yes
Morphine Sulphate 10mg in 1ml injection		Yes
Naloxone 400mcg in 1ml injection	Intramuscular Injection Only	Yes
Ondansetron 4mg in 2ml injection		Yes
Paracetamol Injection		Yes
Paracetamol oral solution 120mg in 5ml sachets		Yes
Paracetamol 500mg tablets		Yes
Salbutamol 2.5mg in 5ml nebuliser solution	Yes	Yes
Sodium Chloride 0.9% injection 10ml		Yes
Sodium Chloride 0.9% intravenous solution		Yes
Syntometrine injection		Yes
Tranexamic Acid		Yes
Water for injection 10ml		Yes

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24. Appendix 6: Specialist Paramedic Formulary

All medicines are to be given according to Patient Group Direction (or the JRCALC by HPC Registered Paramedics where guidance is published).

2.7.3 Cardiopulmonary resusciatation Adrenaline 1mg in 10ml
Atropine

2.9 Antiplatelet drugs
Aspirin
Clopidogrel

3.0 Respiratory system

3.1.1.1
Salbutamol

3.1.2
Ipratropium

3.4.1
Chlorphenamine

3.4.3
Adrenaline 1mg in 1ml

CENTRAL NERVOUS SYSTEM

4.1.2
Diazepam

4.6 Nausea and vertigo
Ondansetron

6.3.2 Non-opioid analgesics
Paracetamol

6.3.3 Opioid analgesics
Codeine
Morphine

INFECTIONS

5.1.1 Penicillins
Amoxicillin
Co-amoxiclav
Flucloxacillin

Penicillin V

5.1.3 Tetracyclines
Doxycycline

5.1.5 Macrolides
Clarithromycin

5.1.8 Sulphonamides and trimethoprim
Trimethoprim

5.1.11 Metronidazole
Metronidazole

5.1.13 Urinary-tract infections
Nitrofurantoin

ENDOCRINE SYSTEM

6.1.4
Glucogel 23 g tube
Glucagon injection 1mg kit
Glucose 10% infusion

6.3.2 Glucocorticoid therapy
Prednisolone

Nutrition and blood

9.2.2.1
Sodium chloride 0.9% injection
Sodium chloride 0.9% infusion
Water for injection

MUSCULOSKETAL AND JOINT DISEASES

10.1.1 Non-Steroidal anti- inflammatory drugs
Ibuprofen
Diclofenac (rectal)
Naproxen

EYE

4.7 Anti-infective eye preparations
Chloramphenicol

ANAESTHESIA

15.1.7 Naloxone

15.2 Local anaesthetic
Lidocaine 1%

Lidocaine 2%, chlorhexidine
gluconate 0.25% lubricant 11ml syringe

MISCELLANEOUS

Sodium Chloride 0.9% sachets

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25. Appendix 7: Admission Avoidance Formulary

All medicines are oral unless otherwise stated

BNF Chapter

GASTRO-INTESTINAL SYSTEM

1.3.5 Proton Pump Inhibitors
Lansoprazole

CENTRAL NERVOUS SYSTEM

4.7 Nausea and vertigo
Prochlorperazine buccal

4.7.1 Non-opioid analgesics
Paracetamol

4.7.2 Opioid analgesics
Codeine

INFECTIONS

5.1.1 Penicillins
Amoxicillin
Co-amoxiclav
Flucloxacillin
Penicillin V

5.1.3 Tetracyclines
Doxycycline

5.1.5 Macrolides
Clarithromycin

5.1.8 Sulphonamides and trimethoprim
Trimethoprim

5.1.11 Metronidazole
Metronidazole

5.1.14 Urinary-tract infections
Nitrofurantoin

ENDOCRINE SYSTEM

6.3.3 **Glucocorticoid therapy**
Dexamethasone (for croup)
Prednisolone

MUSCULOSKETAL AND JOINT DISEASES

10.1.1 Non-Steroidal anti-inflammatory drugs
Ibuprofen
Diclofenac (rectal)
Naproxen

10.2.2 Skeletal muscle relaxants
Diazepam

EYE

11.3 Anti-infective eye preparations
Chloramphenicol

ANAESTHESIA

15.2 Local anaesthetic
Lidocaine 1%

MISCELLANEOUS

Sodium Chloride 0.9% sachets

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26. Appendix 8: Basics Doctors Formulary

All medicines are **parenteral** unless otherwise stated.

BNF Chapter

CARDIOVASCULAR SYSTEM
2.2.2 Loop diuretics
Furosemide

2.3.2. Drugs for arrhythmias
Adenosine
Amiodarone

2.4 Beta-adrenoreceptor blocking drugs
Labetalol

2.6.1 Nitrates
Glyceryl Trinitrate Buccal Tablets

2.7.2 Vasoconstrictor sympathomimetics
Ephedrine Hydrochloride Phenylephrine

2.7.3 Cardiopulmonary resuscitation
Adrenaline 1mg in 10ml
Atropine

2.9 **Antiplatelet drugs**
Aspirin
Clopidogrel

2.11 **Antifibrinolytic drugs and haemostatics**
Tranexamic acid

RESPIRATORY SYSTEM

3.1.1.1
Salbutamol nebuliser solution

3.1.2
Ipratropium nebuliser solution

3.4.1 Chlorphenamine

3.4.3 Adrenaline 1mg in 1ml

CENTRAL NERVOUS SYSTEM

4.2.1 Antipsychotic drugs
Haloperidol

4.6 Drugs used in nausea and vertigo
Ondansetron

4.7.1 Non-opioid analgesics
Paracetamol (injection and suspension)

4.7.2 Opioid analgesics
Fentanyl
Morphine

4.8.2 Drugs used in status epilepticus
Diazepam
Phenytoin

4.9.2 Antimuscarinic drugs used in parkinsonism
Procyclidine

INFECTIONS

5.1.1 Penicillins
Benzylpeniciilin

5.1.2.1 Cephalosporins
Ceftriaxone

ENDOCRINE SYSTEM

6.1.4
Glucogel 23 g tube
Glucagon injection 1mg kit
Glucose 10% infusion

6.3.2 **Glucocorticoid therapy**
Hydrocortisone
Prednisolone tablets

OBSTETRICS, GYNAECOLOGY, AND URINARY-TRACT DISORDERS
7.1.1 Prostaglandins and oxytocics
Syntometrine

NUTRITION AND BLOOD

9.2.2.

Sodium Bicarbonate 8.4%
Sodium chloride 0.9% injection
Sodium chloride 0.9% infusion
Water for injection

9.5.1.1
Calcium Chloride 10%

9.5.1.3
Magnesium Sulphate 20%

ANAESTHESIA

15.1.1 Intravenous anaesthetics
Etomidate
Ketamine
Propofol
Thiopental

15.1.4 Anxiolytics and neuroleptics
Midazolam

15.1.5 Neuromuscular blocking drugs
Pancuronium Bromide
Rocuronium Bromide
Suxamethonium Chloride

15.1.7
Flumazenil
Naloxone

15.2 **Local anaesthetic**
Bupivacaine
Lidocaine 1%

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27. Appendix 13: Directions for Care (Telephone Prescribing and Advice)

Background

There will always be patients who an ambulance clinician is unable to manage (because the indication for the medicine is one for which the clinician is not competent) and whose best interest would be served by the administration of a medicine in accordance with a "Direction for Care".

A "Direction for Care" for the administration of medicines arises in a variety of settings:

Hospital doctors remotely managing a patient prior to arrival at the Emergency Department;
General Practitioners managing their own patients so that the patient can be left at home;

Ambulance service doctors providing telephone support to ambulance staff;
Discussion and review with GPs and Out of Hours doctors working with ambulance clinicians to prevent unnecessary admissions.

Action

a. "Directions for Care" are only allowed from medical and non-medical prescribers employed by organisations providing NHS services. The prescriber remains responsible and accountable for the "Direction for Care".
b. Registered ambulance clinicians are authorised to implement a "Direction for Care" and share responsibility with the prescriber and are accountable for the clinical decision.
c. Ambulance technicians are authorised to implement a "Direction for Care" for medicines they have been trained to use.
d. All "Directions for Care" for medicines must be recorded. This can be done by using the recorded line facility available to operational crews via the vehicle mobile telephone. This will form the legal record of administration*. The ambulance clinician should note the time and details of the call in the patient's clinical record.
e. The "Direction for Care" should be documented in the Patients Clinical Record and then repeated back to the prescriber, in order to check understanding. Where possible a a text message or email should be requested and ideally a second crew member should confirm the "Direction for Care".
f. *If it is not possible to record a "Direction for Care" using an EOC recorded line, then it is the responsibility of the attending ambulance clinician to obtain the signature of the prescriber as soon as possible after the incident and to also get the "Direction for Care" countersigned by a second person. A text message or email does not constitute a signed order.

Additional Information

If you require further information or have any queries regarding this Directive, please contact the Clinical Team at clinicalteam@scas.nhs.uk

28. Appendix 14: Medicines Protocol

The medicines, protocol and the authorised employed staff to which they relate are:

Medicine	Protocol	Authorised Staff: Emergency Care Assistants	Authorised Staff: HCD Ambulance Technicians	Authorised Staff: Associate Ambulance Practitioners	Authorised Staff: Student Associate Ambulance Practitioners under supervision	Authorised Staff: Registered Nurses	Authorised Staff: Registered Paramedics	Authorised Staff: Student Paramedics signed off as competent
Aspirin tablets for chest pain	Trust Protocol	✓	✓		✓	✓	✓	✓
Aspirin tablets for TIA	Trust Protocol		✓		✓	✓	✓	✓
Charcoal (activated)	Trust Protocol					✓	✓	✓
Citric acid catheter washout	Trust Protocol					✓ 3	✓ 3	
Clopidogrel tablets	AACE guidelines					✓	✓	
Dexamethasone tablets	Trust Protocol					✓	✓	✓
Fluorosein 1% impregnated paper strips	Trust Protocol					✓ 3	✓ 3	
Glucose (dextrose) 40% gel	AACE guidelines	✓	✓		✓	✓	✓	✓
Glyceryl trinitrate	AACE guidelines		✓		✓	✓	✓	✓
Ibuprofen	AACE guidelines					✓	✓	✓
Ipratropium nebuliser solution	AACE guidelines		✓		✓	✓	✓	✓
Loratadine	Trust Protocol					✓	✓	✓
Nitrous oxide 50% - Oxygen 50%	AACE guidelines	✓	✓		✓	✓	✓	✓
Oxygen	AACE guidelines	✓	✓		✓	✓	✓	✓
Oxybuprocaine 0.4% eye drops	Trust Protocol					✓ 3	✓ 3	
Paracetamol oral solution/Suspension/tablets	AACE guidelines					✓	✓	✓
Salbutamol nebuliser solution	AACE guidelines		✓		✓	✓	✓	✓

Notes:

1. Sufficient information should be available to the staff and/or patient to enable identification and correct use of the medicine. As a minimum this would comprise the patient information leaflet, the protocol or the Clinical Practice Guidelines.
2. The decision to administer the medicines should be made by the senior person attending the patient. The senior person must ensure that there are no contra-indications before giving the medicine to the patient.
3. These medicines may be administered by these professionals when working in their role as a Specialist Paramedic

29. Appendix 15: Administration of Medicines by Student Paramedics

Students paramedics, when signed off as competent by their university, can administer under supervision non-parenteral medicines and parenteral “medicines which may be administered for the purpose of saving life in an emergency”.

Each student will have a competency sheet which will be signed off by the university so that Trust clinicians are aware of the medicines a student can administer for each indication and condition.

Student paramedics will be signed off by the universities for individual medicines and indications following the assessment of competence and/or learning for the following:

- safe medicines administration processes (including competencies such as administering intramuscular injections);
- underpinning knowledge of relevant medical conditions, and the medicines used to manage the condition;
- individual medicine indications, contraindications, cautions, side effects and how to manage side effects.

The medicines student Paramedics signed off as competent are authorised to administer under supervision, and the relevant protocol, are listed below:

Medicine	**Protocol**
Adrenaline injection (1 in 1000)	AACE guidelines
Aspirin tablets for chest pain	Trust Protocol
Aspirin tablets for TIA	Trust Protocol
Charcoal (activated)	Trust Protocol
Clopidogrel tablets	AACE guidelines
Dexamethasone tablets	Trust Protocol
Glucagon injection	AACE guidelines
Glucose (dextrose) 40% gel	AACE guidelines
Glyceryl trinitrate	AACE guidelines
Hydrocortisone injection	AACE guidelines (adrenal crisis only)
Ibuprofen	AACE guidelines
Ipratropium nebuliser solution	AACE guidelines
Loratadine	Trust Protocol
Naloxone hydrochloride	AACE guidelines
Nitrous oxide 50% - Oxygen 50%	AACE guidelines
Oxygen	AACE guidelines
Paracetamol oral solution/Suspension/tablets	AACE guidelines
Salbutamol nebuliser solution	AACE guidelines

30 Appendix 16: Patient Specific Treatment Plan

31 Appendix 17: Unlicensed Medicines Policy

Background
The majority of medicines used within the Trust have a UK Marketing Authorisation issued by the Medicines and Healthcare Products Regulatory Agency (MHRA) and are used within the terms of their Marketing Authorisation. Wherever possible, licensed products are used to treat patients. This policy does not refer to repackaged licensed medicines supplied for their authorised use or temporarily-authorised medicinal products supplied in response to the spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm (in accordance with Article 5(2) of Directive 2001/83/EC).

- Medicines which do not have a UK Marketing Authorisation (an unlicensed medicine)

These include medicines manufactured by a licensed manufacturer which are awaiting a UK Marketing Authorisation, are manufactured for export, have been withdrawn from the UK market, or where the manufacturer does not intend to apply for a UK licence.

If a licensed product becomes unavailable, it may be necessary for an unlicensed equivalent to be supplied. In these circumstances the use of the unlicensed equivalent will cease as soon as the licensed product becomes available.

- Unlicensed medicines prepared by a manufacturer with a Special Manufacturing Licence

These are usually referred to as “specials” and are prepared by a manufacturing unit that holds a Manufacturing License (Specials) issued by the MHRA.

- The use of licensed medicines outside their Marketing Authorisation

The indication, dose, age of the patient, route of, or method of administration may be outside the licence. In some circumstances, the product may require unlicensed reformulation before administration. The MHRA does not recommend the use of medicines outside the licensed indications, however if a UK licensed product can meet the clinical need, even “off-label”, it should be used instead of an unlicensed product.

Risk Management
The Trust acknowledges the use of unlicensed medicines as stock does not comply with the MHRA Guidance Note No. 14 which states that “An unlicensed medicinal product may only be supplied in order to meet the special needs of an individual patient Responsibility for deciding whether an individual patient has “special needs” which a licensed product cannot meet should be a matter for the doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber responsible for the patient’s care.” All unlicensed products should be risk assessed. This policy identifies how this risk should be managed.

Policy Statement

Liability for problems adverse effects??? arising from the use of unlicensed medicines, or the use of licensed medicines outside their Marketing Authorisation, will be accepted by the Trust if the agreed policy is followed.
It is accepted that the unlicensed use of medicines are necessary if the clinical need cannot be met by licensed medicines. Acceptance of liability by the Trust for the use of a medicine without a UK Marketing Authorisation will be dependent on the concept of "peer group" support, which will be based on the use of published evidence. Unlicensed medicines included in the BNF, the BNF for Children and the UK Ambulance Services Clinical Practice Guidelines will be accepted as "peer group" approved.

Use of a licensed medicine outside its Marketing Authorisation
The Trust will accept liability for problems associated with the use of these medicines when the medicines are used in accordance with Trust guidelines.
The Trust will accept liability for problems associated with the use of these medicines when prescribed when such use has peer group support (as above). When the Trust becomes aware of prescribers using medicines outside of both their Marketing Authorisation and Trust guidelines, the prescriber will be required to provide written acknowledgement that they are aware of their practice. An individual prescriber who routinely uses an "off label" medicine (not supported by the BNF, BNF for Children or Ambulance Service Guidelines) must inform the Medicines Group, which will review the practice.
Where medicines are prescribed outside of their licence it is good practice for the prescriber to obtain the patient's consent (where possible).

Stock
Medicines used outside of their Marketing Authorisation and "specials" are held as stock within the Trust. The Clinical Review Group will be supplied with an up-to-date list of these products and will be asked to authorise the use of these products by clinicians within the Trust. The Clinical Review Group will be asked to approve any requests for additional unlicensed medicines to be held as stock.

Purchase of "specials" or supply of extemporaneously prepared products.
It is the responsibility of the Lead Pharmacist to take all reasonable steps to establish the quality of the product in line with their procedures. A Certificate of Analysis will be obtained whenever possible. Where the quality of the product is judged to be unsuitable or cannot be established, the Medical Director will be informed.

Guidance
General Medical Council (2013). *Good practice in prescribing and managing medicines and devices* http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp
Medicines and Healthcare Products Regulatory Agency (2014). *The supply of unlicensed medicinal products ("specials") MHRA Guidance Note 14* http://www.mhra.gov.uk/home/groups/is- lic/documents/publication/con413520.pdf