

Medicines management for the volunteer responder workforce in NHS ambulance service trusts

The purpose of developing guidance for the implementation and management of medicines for volunteer responders is to promote consistency, efficiency and collaboration by providing a common framework for action.

Such guidance helps prevent duplication of effort by ensuring that different ambulance trusts are not independently creating similar resources, processes, or solutions. Instead, they can build upon shared knowledge, align their practices, and focus their efforts on addressing gaps or adding value.

This coordinated approach not only saves time and resources but also fosters a culture of transparency and continuous improvement across the ambulance sector.

This editable template has been produced to facilitate the implementation of this guidance by ambulance trusts. Text **highlighted in blue** should be replaced with the ambulance trust's own text. Fields **highlighted in yellow** are advisory for organisational governance and should be completed in line with the organisation's own governance and approval processes or removed/replaced if the organisation has a preferred template.

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Name of originator/ author:	Ambulance Chief Pharmacist Network and the Association of Ambulance Chief Executives (AACE)

Review / Comments

Person / Committee	Comments	Version	Date
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Policy	
Approved by:	
Date approved:	

Fit for purpose according to:	INSERT RESPONSIBLE MANAGEMENT TEAM HERE
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Review due by responsible management group:

Period	Every three years or sooner if new legislation, codes of practice or national standards are introduced	Date:
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Record information:

Security Access / Sensitivity	[select either Official (Public Domain) or Official – Sensitive for document(s) which should not be made available to the public routinely]
Where held	Corporate records register
Disposal method and date	In line with national guidelines

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1 Statement of aims and objectives

- 1.1. Ambulance trusts (the trust) are committed to providing high quality patient care.
- 1.2. This guidance outlines the considerations involved in the use of medicines by volunteer responders within NHS ambulance trusts.
- 1.3. The purpose is to ensure decisions regarding the use of medicines for the volunteer responder workforce are based on a guiding set of principles to ensure robust governance and oversight.

2 Introducing medicines

- 2.1.1. Any request to introduce a medicine to the volunteer responders must go through the usual medicines governance routes in the trust.
- 2.1.2. A clear case for need should be described to support the use of medicines by volunteer responders. This should include an assessment of risks as well as financial impact and any training or competency requirements.

3 Legal mechanisms

- 3.1. Volunteer responders are not permitted to work under Patient Group Directions (PGDs) as they are not one of the permitted groups as defined in the Human Medicines Regulations 2012.
- 3.2. Therefore, volunteer responders can only administer medicines under a trust-approved protocol. An example of a protocol template is provided in appendix 1.
- 3.3. The protocol must be authorised and approved via the usual medicines governance route in the organisation.

3.4. Parenteral medicines

- 3.4.1. Parenteral medicines are those administered by injection. Only parenteral products that are listed in Schedule 19 of the Human Medicines Regulations 2012 can be included for consideration in the volunteer responder workforce.
- 3.4.2. These are medicines that can be administered by anybody in an emergency and includes medicines such as adrenaline auto-injectors (Epipen®, etc). However, it is up to the trust to define the scope of practice and training requirements for this group of staff and therefore which, if any, of the parenteral products are suitable for inclusion.

3.5. Non-parenteral medicines

- 3.5.1. Non-parenteral prescription only medicines are medicines that are classified as Prescription Only Medicines (POMs) under the Medicines Act 1968 for supply, but the legislation does not currently specify requirements for administration. Controlled Drugs (CDs) should be excluded as they are subject to the stricter controls under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001.
- 3.5.2. This means that non-parenteral POMs (excluding CDs) can be legally administered by anyone and can be included for consideration for administration by the volunteer responder workforce at the discretion of the trust.

3.6. Off-label use of medicines

- 3.6.1. The term 'off-label' describes the use of a medicine in a way that is different from the conditions or parameters stated in the product's marketing authorisation or product licence.
- 3.6.2. It is permitted to use a licensed medicine outside of its marketing authorisation (product licence) where there is evidence this is safe and effective. For example, using paracetamol 250mg/5mL oral suspension for children under the age of 6 years would be 'off-label' as it is not licensed for this age group.
- 3.6.3. A risk assessment should be performed to demonstrate robust governance when considering using medicines off-label for the volunteer responder workforce. The trust retains liability where they permit medicines to be used off-label by the volunteer responder workforce.

3.7. Oxygen cylinders

- 3.7.1. Volunteer responders can be issued with an oxygen cylinder at the trust's discretion.
- 3.7.2. The cylinder should then be managed in line with the trust's Compressed Medical Gas Standard Operating Procedure, or equivalent.
- 3.7.3. When a cylinder reaches the agreed minimum volume, expires or is faulty or damaged, the cylinder must be returned to the local ambulance base and segregated correctly within the designated medical gas storage facility for that site.
- 3.7.4. A supply of oxygen must only be undertaken by the volunteer responder requiring it on a 1:1 exchange basis.

4 Managing medicines

4.1. **Distribution**

- 4.1.1. Trusts should have a robust process to manage the distribution of medicines to volunteer responders.
- 4.1.2. Only medicines procured and supplied by the trust can be used on the trust's patients, as per the authorised loads list for volunteer responders.
- 4.1.3. There should be a system in place to record which medicines are in the possession of the volunteer responder. This may be a paper-based process or digitised.
- 4.1.4. The purpose is to ensure the organisation knows where its medicines are and can therefore trace them if necessary.

4.2. **Record keeping**

- 4.2.1. Documenting medicines administration will vary depending on the I.T. systems and processes in place. However, there must be a mechanism by which volunteer responders can document what they have administered, who they have administered it to and any associated monitoring parameters.

4.3. **Storage and security**

- 4.3.1. It is the responsibility of the volunteer responder to ensure any medicines in their possession are kept secure and out of the reach of children and pets.
- 4.3.2. Volunteer responders should follow the medicines management processes mandated by their trust.
- 4.3.3. In some trusts, volunteer responder equipment, including medicines, are kept in their personal vehicle or in their property. When not 'booked on' the medicines should be kept inside their property to provide a steady storage temperature.

4.4. **Temperature control**

- 4.4.1. Most medicines are stored at room temperature, also known as 'ambient' temperature. The acceptable temperature range is generally between 15°C and 25°C, although this does depend on the medicine. For example, salbutamol nebuliser solution (Cipla brand) does not have any particular temperature storage requirements, whereas aspirin 300mg tablets are recommended to be stored <25°C. Where no temperature storage requirements are stated on the product, the generally accepted storage range is between 8°C and 30°C.
- 4.4.2. Volunteer responders must ensure any medicines in their possession are protected from extremes of temperature and not left in direct sunlight.

4.4.3. In the event of exposure to an extreme of temperature (known as a temperature excursion), the relevant medicines or pharmacy team should be contacted for advice. Ensure to record the maximum or minimum temperature reached and the likely duration of the exposure (hours, days, etc).

5 Reporting incidents

5.1. Any incidents or 'near-misses' relating to medicines or oxygen cylinders, including incidents of damaged or faulty cylinders, must be reported via the trust's usual reporting mechanism.

5.2. This should be done as soon as possible by the volunteer responder or operational management team

6 Responsibilities

6.1. The **Chief Executive Officer (CEO)** is accountable for medicines use and governance in the trust. If in doubt, discuss this with the responsible management group and check with your director.

6.2. The **Chief Medical Officer or Executive Medical Director** through delegation by the CEO, has overall responsibility for medicines governance system design and overall assurance. The Chief Medical Officer has responsibility for the implementation, review, and thus revision where required, of this procedure.

6.3. It is the responsibility of the **Chief or Trust Pharmacist** to ensure that the processes and Standard Operating Procedures (SOPs) meet the requirements of any relevant pharmaceutical governance, guidance and legislation.

6.4. It is the responsibility of the **trust's designated head of volunteering** to ensure that there are adequate processes and reporting in place to assure compliance with the agreed processes and SOPs.

6.5. It is the responsibility of the local **Community Resuscitation Development Officer or equivalent** to monitor compliance with the agreed processes in their designated areas. They should ensure that any deviations from agreed SOPs are proactively managed and reported through the trust's incident reporting systems as appropriate.

6.6. It is the responsibility of all **volunteer responders** to be familiar with and follow the agreed trust processes.

7 Financial checkpoint

7.1. This document has no unbudgeted financial implications.

8 **Equality analysis**

- 8.1. Ambulance trusts believe in fairness and equality, and value diversity in their role as both a provider of services and as an employer. Ambulance trusts aim to provide accessible services that respect the needs of each individual and exclude nobody. They are committed to comply with the Human Rights Act and to meeting the Equality Act 2010, which identifies the following nine protected characteristics: Age, Disability, Race, Religion and Belief, Gender Reassignment, Sexual Orientation, Sex, Marriage and Civil Partnership and Pregnancy and Maternity.
- 8.2. Compliance with the Public Sector Equality Duty: If a contractor carries out functions of a public nature, then for the duration of the contract, the contractor or supplier would itself be considered a public authority and have the duty to comply with the equalities duties when carrying out those functions.

Appendix 1: Medicine Protocol Template

Medicines Protocol

for the administration of

[Name of medicine].....

by [VOLUNTEER ROLE(S)]

**Indication such as To treat an asthma attack or an exacerbation of Chronic
Obstructive Pulmonary Disease (COPD)**

in [NAME OF TRUST]

Date issued:	
Issued by:	
Protocol reference:	001
Review date:	
Expiry date:	

Protocol Approved for use by:

Medicines Governance Group	Date:
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Change History

Version number	Change details	Date

Protocol Development

Job title and organisation	Name	Date
Lead HCP		
Lead doctor		
Lead pharmacist		
Other specialists involved in development / review		

Training and Competency

Overview	<p>This document describes the requirements and processes for [VOLUNTEER ROLE] to safely administer [MEDICINE NAME] to patients in the community prior to the arrival and handover of care of the patient to a [NAME OF TRUST] clinician.</p> <p>This protocol applies to all volunteers undertaking the role of the [VOLUNTEER ROLE] for [NAME OF TRUST].</p> <p>The purpose of this protocol is to:</p> <ul style="list-style-type: none"> • Support the delivery of safe, effective care to patients. • Minimise the risk to patients associated with receiving a prescription only medication (POM). • Ensure consistency of medicine administration.
Initial training	Has undertaken appropriate training and successfully completed the competencies to undertake clinical assessments of patients leading to a diagnosis of the conditions listed.
Competency assessment	Volunteer responders should declare their own competence to use, assuring themselves that they have the necessary clinical skills and knowledge for the treatment of the conditions included and the use of the medicine involved.

Ongoing training and competency	<p>Individuals must meet the requirements of the current prevailing level of education required at this level of practice. This may include completion of e-learning, attending regular medicines management update training, and regular peer review.</p> <p>All ongoing regular training requirements (e.g. statutory and mandatory training) as required by the trust for this role must be completed.</p> <p>Individuals are responsible for keeping themselves aware of any changes to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date and to work within the limitations of their own individual scope of practice.</p>
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Clinical condition

Clinical condition or situation	•
Inclusion criteria	
Exclusion criteria	•
Cautions	
Pregnancy and breastfeeding	
Arrangements for referral for medical advice	Obtain advice from EOC or ICC Clinician.
Action to be taken if patient excluded	Obtain advice from EOC or ICC Clinician.
Action to be taken if patient declines treatment	<ul style="list-style-type: none"> • Explain the risks of non-administration. • Offer all other reasonable treatment that the patient consents to. • Obtain advice from EOC or ICC clinician. • Record treatment and advice given on patient record. • Handover to the [NAME OF TRUST] clinician.

Details of the medicine

Name, form and strength of medicine	
Legal category	POM / P / GSL (<i>delete as appropriate</i>)
Route / method of administration	
Dose and frequency	
Administration details	
Ongoing treatment and monitoring	•
Actions	
Adverse effects Adverse effects should be reported via the Yellow Card Scheme, and via Datix (DIF1)	

Interactions	
Records to be kept	<p>Complete the Patient Clinical Record (PCR) and:</p> <p>If using a paper PCR, the crew must upload a photo of the form to the electronic PCR and take the paper PCR to file at the station's PCR box.</p> <p>OR</p> <p>Volunteer responder to take form to designated station PCR box.</p> <p>[ADD PREFERRED TRUST/SERVICE PROCESS]</p>
Additional information	<p>Volunteer responders must adhere to the relevant trust's standard operating procedure (SOP).</p> <p>Volunteer responders must ensure that their medicines are kept within manufacturing temperature guidelines and are secure at all times.</p>

Patient information

Written information to accompany the patient	(DELETE IF NOT RELEVANT)
Follow-up advice to be given to patient or carer	(DELETE IF NOT RELEVANT)

Appendix A: Key references

1.