Best practice guidelines for training professional carers in the administration of Buccal (Oromucosal) Midazolam for the treatment of prolonged and / or clusters of epileptic seizures in the community

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1. Foreword

One of the most important components of epilepsy care is the pre-hospital community management of prolonged or repeated seizures, which, if untreated, can increase the risk of status epilepticus. Convulsive status epilepticus is a medical emergency requiring admission to hospital and has a mortality rate of up to 20 per cent. Effective management of seizures in the community in people at high risk of status epilepticus could significantly reduce mortality, morbidity and emergency health care utilisation.

The Joint Epilepsy Council issued guidance until it was disbanded in 2015, leaving a vacuum in the review and update of clinical guidelines. Unfortunately, the clinical processes ensuring the safety and consistency of buccal midazolam usage demonstrates considerable heterogeneity. There are no current guidelines, standards or pathways to ensure the safety of all involved in the process i.e. patient, carer or professional.

ESNA is an organisation principally formed by nurses with an interest in epilepsy. Most ESNA members support or complete training for buccal midazolam to ensure core competencies are up to date and patient safety is protected. ESNA is joined by the International League Against Epilepsy (British Chapter) and the Royal College of Psychiatrists (ID Faculty) as the other principal specialist clinical stakeholders with an interest to ensure governance in this complex care area is addressed robustly. ESNA has collaborated with the ILAE and the Royal College of Psychiatrists to produce updated buccal midazolam guidance.

Dr Rohit Shankar MBE, FRCPsych

Project co-ordinator

2. Executive summary

For consistency of wording through this guideline, oromucosal midazolam will be referred to as buccal midazolam.

Central to the mitigation of the risk posed by prolonged or repeated seizures is the use of emergency epilepsy medication in the community, often termed 'rescue' medication. When intravenous access is not available, non-intravenous routes of administration of benzodiazepines should be considered for the control of prolonged or repeated acute seizures. Buccal midazolam has similar or better efficacy than rectal diazepam(Jain et al., 2016; Brigo et al., 2015). The buccal route of administration for midazolam is also more socially dignified than rectal administration of diazepam. The use of rescue medication by trained carers at the right time for the right purpose can significantly improve outcomes, reducing the risk of hospital admission and the mortality associated with convulsive status epilepticus.

Buccal midazolam is widely used to manage prolonged seizures. Administration should only be undertaken by people who have received both epilepsy awareness and buccal midazolam training. It is recommended that there are two-yearly updates on this training. The administration of buccal midazolam must be delivered in accordance with the individual's protocol/guidelines. All carers of people with epilepsy should receive epilepsy awareness training. In addition if the person with epilepsy is prescribed buccal midazolam, additional training in its administration must be undertaken.

These guidelines have evolved to ensure the safety of people with epilepsy, and to ensure that those who require buccal midazolam receive a consistent level of knowledge and intervention from their carers. These guidelines will be evaluated prior to the next revision in two years' time.

This document is intended to serve as a guideline for those purchasing as well as delivering training. It is hoped the guideline will provide assistance to the local regulatory authority and to help establish a national standard of minimal training.

3. List of contributors

See Appendix 2 for a full list of contributors.

4. Scope of the Guideline

The scope of these guidelines is to address the individual training needs for the safe administration of buccal midazolam.

It is not within the scope of these guidelines to cover other medications used as emergency rescue treatment (e.g. rectal diazepam, rectal paraldehyde).

Where resources do not meet what is outlined in the guidance, employing organisations can use it to benchmark their services and ensure quality. There should be an aspiration to align new services with the standards outlined.

5. Background

In the UK and Ireland, there has been an emphasis on personalised epilepsy care in the community. Buccal midazolam is now recognised as the first line rescue treatment. It is a far more acceptable treatment to both administer and receive compared to rectal benzodiazepines or paraldehyde, which prior to the advent of buccal midazolam, were the recommended treatments. It is recognised that prompt administration of midazolam prevents or reduces the risk of seizures evolving into status epilepticus, resulting in improved outcomes for the patient (SIGN 2015, NICE 2012).

6. Methodology

The ESNA Executive Committee organised two task and finish groups whose main activities were to:

a. Discuss and form consensus on minimum standards of training.

b. Devising/ revising learning resources.

c. Update guidance from the last JEC document.

See Appendix 3 for full methodology.

7. Evidence

There is some evidence that buccal midazolam is equally effective as rectal diazepam in the treatment of prolonged seizures (Scott et al., 1999, de Haan et al., 2010, Nakken and Lossius, 2011). The report of the ILAE task force on the management of status epilepticus (Trinka et al., 2015) is the most up to date, evidence-based material available to date, hence its incorporation into this document.

Status epilepticus (SE) is a condition resulting either from the failure of the mechanisms responsible for seizure termination or from the initiation of mechanisms which lead to abnormally prolonged seizures (Trinka et al., 2015).

At time point (t1) which is considered to be five minutes for tonic–clonic SE; 10 minutes for focal SE with impaired consciousness, and 10-15 minutes for absence status epilepticus, the ongoing seizure can be regarded as abnormally prolonged. This time threshold determines the time at which treatment should be considered or started (Trinka et al,. 2015).

At time point (t2) which is considered to be 30 minutes for tonic–clonic SE and > 60 minutes for focal SE with impaired consciousness, there is a risk of long-term consequences including neuronal death, neuronal injury, and alteration of neuronal networks from ongoing seizure activity. The time point t2 determines how aggressively treatment should be implemented to prevent long-term consequences (Trinka et al., 2015).

8. Training Standards

Guideline for Training Organisations' Responsibilities

The following is intended as a guideline for stakeholders involved in the provision of training.

It identifies trainer's qualifications, knowledge and experience required to deliver safe epilepsy awareness and buccal midazolam administration training.

Deviations from these recommendations must have clear lines of accountability.

It is recommended that individuals providing training to trainers:

a. Have a nursing or medical qualification and a minimum of two years' experience working with people with epilepsy, for example, multi-disciplinary team working, formulating the administration of buccal midazolam in individual care plans.

b. Have a minimum of one year's experience in delivering training/facilitation courses and can provide evidence of a relevant teaching and assessment qualification.

c. Can provide evidence of Continuous Practice Development (CPD) and that their knowledge and experience of epilepsy is kept up to date by attending and contributing to local and national epilepsy peer groups.

d. Have vicarious liability insurance in place or ensure if working via a NHS organisation, third sector provider or other organisation there is indemnity insurance as part of the organisation cover.

Individual trainers

a. Trainers with a nursing or medical qualification must have minimum of two years' epilepsy experience or currently work with people with epilepsy.

b. Trainers without a nursing or medical qualification or nurses/medics who have no epilepsy experience in the last two years must have attended a train the trainer course that meets the above recommendations.

c. Have a minimum of one year's experience in delivering training / facilitation courses and can provide evidence of a relevant teaching and assessment qualification.

d. Can provide evidence of Continuous Practice Development (CPD) and that their knowledge and experience of epilepsy is kept up to date, for example by attending and contributing to local and national epilepsy peer groups.

e. Have vicarious liability insurance in place or ensure if working via a NHS organisation, third sector provider or other organisation there is indemnity insurance as part of the organisation cover.

Core components of epilepsy awareness and buccal midazolam training course

It is recommended that the initial training should be four to six hours, and subsequent refresher training should last two to three hours. Bespoke training for an individual with epilepsy will be tailored to their needs in timing and content.

Epilepsy awareness

Course content	Essential components	Desirable components
What is epilepsy	✓	
What causes epilepsy	✓	
How do we make a diagnosis including differential diagnosis	✓	
Types of seizures	✓	
Treatment options	✓	
First aid	✓	
Status epilepticus	✓	
Care planning and recording mechanisms	✓	
Risk assessment	✓	
SUDEP	✓	
Interactive case discussions	✓	
Sources of support and information	✓	
Stigma		✓
Psychological/psychiatric co-morbidities		✓
Psychosocial issues		✓
Cultural awareness		✓

Administration of buccal midazolam – all these components are essential

- What is midazolam, including different preparations / concentrations.
- Indications for the use of midazolam.
- Appropriate doses when given via the buccal route.
- Benefits of using buccal midazolam.
- Recognise signs of respiratory depression.
- Possible difficulties in administration (e.g. excessive salivation, injury to mouth etc).
- Potential side effects.
- Actions if buccal midazolam is ineffective.
- Identifying and using individual's buccal midazolam care plan.
- Secure storage and safe disposal.
- Duty of care/ responsibility and accountability.
- Practical demonstration using DVD or visual aids and use of water to demonstrate on a volunteer.
- When to seek medical help.
- Aware of potential for misuse.
- Awareness of relevant local policies.
- Interactive case discussions.

Refresher course

The refresher courses should cover all the essential components of both the awareness and buccal midazolam training outlined above. This should also include all relevant updates in epilepsy.

Assessment of learning

There are recognised difficulties associated with the assessment of knowledge and skills of participants undertaking the training of buccal midazolam. Ongoing assessment using questioning during training is essential to ensure safety and carers' understanding.

ESNA, in conjunction with Virtual College, has developed an external national online test in order to provide an independent assessment of training. We recommend that this resource is used alongside the trainer's assessment.

Learning pathway

- Complete initial face-to-face training.
- Undertake a refresher every two years as a minimum requirement.
- Upon completion of any of the training courses delegates must successfully complete the online test or alternative assessment.

Responsibilities

- Professional carers with the responsibility to administer buccal midazolam should receive biennial training updates for epilepsy awareness and administration of buccal midazolam.
- Employers of staff who administer buccal midazolam should ensure that they receive training updates as above.
- Patients, families and carers of people with epilepsy should have the opportunity to be involved, as far as is practical, in the development of their buccal midazolam care plan.
- The care plans must be reviewed annually, or when circumstances for administering the drug change.
- The care plan must be signed or countersigned by the prescriber/epilepsy specialist.
- It is recommended that patient families/carers source training from trainers who fulfil the recommendations in these guidelines.
- Trainee feedback received needs to be reviewed and evaluated by the trainer as per local guidelines.

Plans for review

Further review suggested for the future includes:

- Is there evidence for whether the update training should be every one or two years?
- How to audit the affect of these guidelines on the standards of care for those who receive buccal midazolam?
- Has the online testing been successful in driving up standards of care delivery?

9. Sources of Further Information

David Lewis Centre
Mill Lane
Warford
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Cheshire SK9 7UD
Helpline: 01565 640000
Website: www.davidlewis.org.uk

Epilepsy Action
New Anstey House
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Epilepsy Nurses Association (ESNA)
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Epilepsy Scotland
48 Govan Road
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Website: www.epilepsyscotland.org.uk
Email: enquiries@epilepsyscotland.org.uk
Enquires: 0141 427 4911

Epilepsy Society
Chesham Lane
Chalfont St Peter SL9 0RJ
Helpline: 01494 601400
Website: www.epilepsysociety.org.uk
Email: helpline@epilepsysociety.org.uk

Great Ormond Street Hospital for Children NHS Foundation Trust
Great Ormond Street
London WC1N 3JH
Tel: 020 7405 9200
Website: http://www.gosh.nhs.uk

International League Against Epilepsy (ILAE)
ILAE British Chapter
PO Box 70977
London SE25 9EA
Website: http://ilaebritish.org.uk
Email: members@ilaebritish.org.uk

Quarriers
The William Quarrier Scottish Epilepsy Centre
20 St Kenneth Drive
Glasgow G51 4QD
Tel: 0141 445 7750
Website: www.scottishepilepsycentre.org.uk

SUDEP Action
18 Newbury Street
Wantage
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Email: info@sudep.org
Website: www.sudep.org

Young Epilepsy
St Piers Lane
Lingfield
Surrey RH7 6PW
Helpline: 01342 831342
Website: https://www.youngepilepsy.org.uk
Email: info@youngepilepsy.org.uk

10. Conclusion

This document supersedes the guidance that was last published by the JEC. It serves as a best practice guidance. However, it is recognised that there remains a variation in resources across the regions of the UK.

11. References

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Veriton Pharma Limited (2018). Summary of Product Characteristics – Epistatus. https://www.medicines.org.uk/emc/product/2679 Accessed 10/02/2018.

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Appendix 1

Example of Buccal Midazolam Care Plan

Name	
Date of birth	Known allergies

Description of seizures which may require buccal midazolam

1.....

.....

.....

Usual duration of seizure

2.....

.....

.....

Usual duration of seizure

3.....

.....

.....

Usual duration of seizure

4.....

.....

.....

Usual duration of seizure

5.....

.....

.....

Other useful information

6.....

.....

.....

Midazolam treatment plan

When should buccal midazolam be administered?

(Note here should include whether it is after a certain length of time or number of seizures)

2. Initial dosage: how much buccal midazolam is given initially?

   Prescribing weight (if relevant):

3. What is the usual reaction(s) to buccal midazolam?

4. If there are difficulties in the administration of buccal midazolam, e.g. Excessive salivation, what action should be taken?

5. Can a second dose of buccal midazolam be given? Yes / no this would be in exceptional circumstances following a multi-disciplnary discussion, the outcome of which should be recorded in medical records. It is recommended that an ambulance is called if a second dose is administered.

6. When should 999 be dialled for emergency help? (Please tick appropriate box)

   If the full prescribed dose of midazolam fails to control the seizure after…….Minutes? ☐
   Other (please give details, e.G. If concerned about breathing, serious/head injury, unable to administer midazolam etc). ☐

7. **Precautions – maximum dose of midazolam to be administered in a 24-hour period**

All occasions when buccal midazolam is administered must be recorded

This plan has been agreed by the following:

Prescriber/epilepsy specialist	Signature: Date:
Patient/ patient's representative (note below):	Signature: Date:
Care plan author:	Signature: Date:

NB Patient's representative e.g. responsible family member or care manager.

Appendix 2 - List of Contributors

Project lead-ESNA Phil Tittensor
Consultant Nurse for the epilepsies, Chair of the Epilepsy Nurses Association (ESNA) Royal Wolverhampton NHS Trust.

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Special thanks to ESNA locality and WENF leads for collating member's feedback.

Conflict of Interests

Rohit Shankar RS has received institutional and research support and personal fees from LivaNova, UCB, Eisai, Special Products/ Veriton, Bial and Desitin outside the submitted work.

Matthew Walker has received consultancy fees and/or honorarium from UCB Pharma, Eisai, GSK, Pfizer, Special Products and Sage pharmaceuticals outside the submitted work.

Phil Tittensor has received honoraria and educational support from from Veriton, Bial, Eisai and UCB Pharma. He has worked on advisory boards for Eisai, Bial and Veriton outside the submitted work.

Sarah Tittensor has received honoraria from Veriton Pharma and Accretio outside the submitted work.

Erica Chisanga has received honoraria from Sanofi for an Advisory Board and has received Locality Meeting Sponsorship from UCB Pharma, Eisai and Veriton Pharma (Special Products) outside the submitted work

Carrie Burke has received honoraria and support from UCB Pharma outside the submitted work.

Caryn Jory has received honoraria from UCB Pharma and educational support from Veriton outside the submitted work.

Catherine Doherty has attended events sponsored by UCB Pharma, Eisai and LivaNova outside the submitted work

Marie Hooper has no conflicts of interest to declare.

Richard Hills has no conflicts of interest to declare.

Manny Bagary has no conflicts of interest to declare.

Reena Tharian has no conflicts of interest to declare.

Ashok Roy has no conflicts of interest to declare.

Jean O'Hara has no conflicts of interest to declare.

Dominic Slowie has no conflicts of interest to declare.

Juliet Solomon has no conflicts of interest to declare.

Mike Wilcock has no conflicts of interest to declare.

Appendix 3 - Methodology

ESNA members were contacted. Representation was sought from the various regions of the UK and Ireland and nurses in the three main categories, i.e. adult, paediatric and learning disabilities. The first meeting was held in February 2017, where the terms of reference for the project were laid out, and the overarching guideline and testing principles established by reviewing relevant evidence. The development of the guidelines was shared through on-going consultations and cascading of draft documents back to the locality groups for comments. It was recognised that there were variations in training and that some standards were not practical depending on location and resources, in particular, the availability of appropriately qualified staff to deliver training, available in various regions. Comments and suggestions from the locality groups have been taken into account, to allow scope for addressing or accommodating the variation between regions in the guidance.

Following this extensive internal consultation process, the document was sent to expert practitioners, external from ESNA, for peer review in a two-stage process: firstly, key clinical stakeholders (ILAE & RCPsych), followed by other stakeholders (e.g. epilepsy charities, RCN). All stakeholders were given time to comment on the guidelines.

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