

**BEST PRACTICE GUIDELINES FOR THE
ADMINISTRATION OF BUCCAL (OROMUCOSAL)
MIDAZOLAM FOR THE TREATMENT OF
PROLONGED AND/OR CLUSTERS OF EPILEPTIC
SEIZURES IN THE COMMUNITY**





1. Foreword

Rarely clinical harm or error is an isolated event. It is usually a manifestation of systematic faults in clinical processes. A clinical process is like a linked chain thus only as strong as its weakest link. Epilepsy care delivery has many clinical processes which need to dovetail into each other to provide optimum support and management to the person with epilepsy. One of the most important procedures is the community management of seizures considered at risk of developing into clinical status epilepticus. Status Epilepticus has a mortality of up to 20% not to mention the need for possible emergency care including hospitalization. It can be confidently said that good community care of seizures in people at high risk of Status Epilepticus could significantly reduce mortality, morbidity and resource costs.

Central to the mitigation of this risk is the use of epilepsy emergency medication such popularly called 'rescue' medication. The most commonly used is buccal midazolam. The administration of the midazolam by trained carers at the right time for the right purpose can heavily influence negative outcomes. It is recognised presently as a beacon of good practice.

Unfortunately the clinical process to ensure safety and consistency of this procedure is diverse across the country with no clear guidance, standards or pathway to ensure the safety of all involved in the process i.e. patient, carer or professional. There is a need for clarity concerning who takes ownership of the process, the role of the prescriber, the trainer and standards to which trainees need to aspire to. This till date has been limited.

Previously the Joint Epilepsy Council till 2015 took responsibility to ensure some guidance on this complex area was available until it was disbanded in 2015 thus leaving a vacuum in the review and update of guidance in this much required area of epilepsy care.

ESNA is an organization principally formed by nurses with an interest in epilepsy, the majority of whom support or complete the required training and thus are a representative body of professionals interested in ensuring patient safety, backed by suitable competencies at all levels of care delivery on this clinical pathway. ESNA is joined by the International League of 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.

I congratulate ESNA for taking ownership of this complex problem and providing a working solution to it in the form of the ESNA buccal midazolam guidance collaborating with the ILAE and the RCPsych. While there is still a lot of work to be done in addressing the multiple complex issues which continue to cause problems on this clinical pathway this is one important concerted step to make the weakest link stronger than what it had been previously.

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.

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 the administration of buccal midazolam must be undertaken.

These guidelines have evolved to ensure the safety of people with epilepsy and those who require administration of buccal midazolam receive a consistent level of knowledge and training 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 in 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.

Manny to email definition of status and evidence percentages insert here. X 2

8. Training Standards

Guideline for Training Organisations Responsibilities.

The following is intended as a guideline for stakeholders involved in provision of training. It identifies trainer's qualifications, knowledge and experience required to deliver safe epilepsy awareness and buccal midazolam administration.

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, 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 that 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 4-6 hours, and subsequent refresher training should last 2-3 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 for 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, on-line test in order to provide an independent assessment of training. We recommend that this resource is used alongside 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 how this set of guidelines has affected standards of care for those who utilise buccal midazolam?
- Has the online testing been successful in driving up standards of care delivery?

SOURCES OF FURTHER INFORMATION

David Lewis Centre

Mill Lane
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Helpline: 01565640129 or 01565640011
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Epilepsy Nurses Association (ESNA)

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Epilepsy Scotland

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National Centre for Young People with Epilepsy

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Website: www.ncype.org.uk
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Quarriers

The William Quarrier Scottish Epilepsy Centre
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Website: www.scottishepilepsycentre.org.uk

9. Conclusion

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

10. References

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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

OTHER USEFUL INFORMATION



MIDAZOLAM TREATMENT PLAN

1. 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 MIZAZOLAM 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-DISCIPLINARY DISCUSSION THE OUTCOME OF WHICH SHOULD BE RECORDED 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/ PATIENTS REPRESENATIVE(Note below):	Signature:

	Date:
CARE PLAN AUTHOR:	Signature:
	Date:

N.B Patient representative e.g. responsible family member or care manager.

Appendix 2 – List of Contributors

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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 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, Esai 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.