Protocol

for the administration

of Pharmacy (P) classified

Entonox® (Nitrous Oxide and Oxygen)

as short-term pain relief

by registered nurses and midwives

to

adults and children aged 5 years of age or over

in Powys Teaching Health Board and Powys community settings.

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Do not print this document. The latest version will be accessible via the intranet. If the review date has passed, please contact the Author for advice.

Disclaimer

Powys teaching Health Board is the operational name of Powys teaching Local Health Board

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

Protocol authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	7/15/2022
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	7/20/2022
Senior representative of professional group using the PGD **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: claire roche FC9C4C63FC374A7...	7/19/2022

Appendix A provides a Staff Permitted to use Protocol Signature Sheet. Individual practitioners must be authorised by name to work to this protocol.

Version Control

Version No.	Summary of Changes/Amendments	Issue Date
1	Initial issue to replace PGD 0003-C to enable administration of Entonox® without supply and to guide administration of Entonox® to manage pain in labour and during perineal repair and for short term pain relief.	July 2022

ENGAGEMENT & CONSULTATION

Key Individuals/Groups Involved in Developing this Document

Role / Designation
Advanced Clinical Pharmacist – Medicines Management & Medicines Optimisation
Senior Pharmacist Governance and Training

Circulated to the following for Consultation

Date	Role / Designation
12/7/22	Jo Wolfenden – MIU Lead Nurse – no further comments
5/7/22	Shelly Higgins – Consultant Midwife – comments via tracked changes

Evidence Base
Please list any National Guidelines, Legislation or Health and Care Standards relating to this subject area • Royal Pharmaceutical Society: Professional Guidance on the Administration of Medicines in Healthcare Settings (2019) • British National Formulary, current online edition. Accessed June 2022 • NICE Clinical guideline CG190 – Intrapartum care for healthy women and babies; last updated 21 February 2017.

IMPACT ASSESSMENTS

Equality Impact Assessment Summary					
	No impact	**Adverse**	**Differential**	**Positive**	**Statement** Please remember policy documents are published to both the **intranet** and **internet.** The version on the internet must be translated to Welsh.
Age	x				
Disability	x				
Gender	x				
Race	x				
Religion/ Belief	x				
Sexual Orientation	x				
Welsh Language	x				
Human Rights	x				
Risk Assessment Summary					

Have you identified any risks arising from the implementation of this policy / procedure / written control document? No risks identified as long as protocol directive is followed. If yes, note the risk/s and action taken to mitigate. Protocol awareness training and signature of line manager who must confirm that the registered practitioner is competent to administer Entonox® under this protocol.
Have you identified any Information Governance issues arising from the implementation of this policy / procedure / written control document? No governance issues identified
Have you identified any training and / or resource implications as a result of implementing this? Awareness training will be provided by the Medicines Management Team. Target audience will be registered general nurses and midwives working in Powys Teaching Health Board and Powys community settings. Compliance with this Protocol will be monitored by annual retrospective audit of 10 instances where this Protocol has been used. This audit may be conducted by the department lead or Medicines Management team.

1. Protocol Statement & Introduction

This protocol provides a clear framework to support registered nurses and midwives to administer Pharmacy (P) Entonox® gas.

The gaseous mixture consists of 50% oxygen/50% nitrous oxide and has been found to be an effective analgesic when inhaled.

Entonox® is administered through a mouthpiece, which is connected to an Entonox® supply through a demand valve system. The valve is operated by the act of inhalation by the patient and it closes down when the patient ceases to inhale.

In all cases Entonox® is self-administered under the direct supervision of a registered practitioner and with the demand apparatus it safeguards the user from overdose from nitrous oxide. When the patient becomes drowsy, the mouthpiece drops away from the face and the flow of gas ceases.

This protocol applies to administration of Entonox® by registered nurses and midwives (who have the appropriate authorisation – see Appendix A) ONLY.

The most recent and in date final signed version of the protocol should be used.

Patients/ carers should be informed that they are being treated within a protocol, and where possible, consent should be obtained before administering.

2. Objective.

The objective of this protocol is to provide a standardised clinical pathway for safe provision of patient care during the administration of Entonox® gas to patients aged 5 years or older in Powys Teaching Health Board and Powys community settings.

To comply with the rules and regulations regarding storage and transportation, particularly regarding use of portable Entonox® cylinders used by the Community Midwives.

3. Definitions and abbreviations.

Administer	A term used throughout this protocol to describe the practitioner's role in providing and supervising a patient's self-administration of this drug.

DGH	District General Hospital
OOH	Out of hours
OTC	Over the Counter – where a medicine is available for supply or purchase through a retail outlet such as a supermarket, local shop or petrol station for [GSL] medicines or Community Pharmacy only for a [P] medicine.
P	Pharmacy medicine – can be sold from a registered pharmacy by a pharmacist or someone working under the supervision of a pharmacist
POVA	Protection of Vulnerable Adults
Datasheet	This provides comprehensive information around a medicine's licensed indications, dose, frequencies, information about adverse drug reactions and interactions and advice around administration

4. Role and responsibilities.

4.1. The registered nurse/midwife has a responsibility to:

- Assess the patient and plan their care.
- Complete the awareness training in order to ensure they are competent and feel confident when administering Entonox®, working under a protocol and also be authorised by name as permitted to use this protocol (Appendix A).
- Access the most recent version of the protocol online.
- Be familiar with the use of Entonox® covered by this protocol, including knowledge of its action and uses, contra-indications and adverse effects.
- Discuss the treatment to be administered with the patient, if possible and/or with the carer and obtain consent.
- Have current competence in assessing capacity and follow the Mental Capacity Act guidance regarding consent to treatment.
- Administer and supervise the administration of the Entonox® for the duration of time specified in the protocol and recognise that the authorisation is invalid after this time.
- Be competent in the recognition and management of recognised adverse reactions, including anaphylaxis.

	• Be competent in the administration of adrenaline and have up to date Basic or Intermediate Life Support skills, relevant to the role. • Record the assessment, any intervention, and arrangements for review in the nursing records, care plan or care pathway. • Record any medication administered in the patient records. • Review the patient's response to treatment and monitor clinical observations as appropriate. • Seek medical advice if the symptoms persist or worsen or if there is an actual or potential reaction to the treatment. • Recognise their limitations and seek medical advice if they are concerned about the patient's overall condition or if the medication has been ineffective. • Report any serious adverse drug reactions via the MHRA Yellow Card Scheme and via Once for Wales Reporting System. • Refer the patient/carer to self-care options for ongoing pain relief • Every registered nurse or midwife must adhere to their appropriate professional code of conduct and the Royal Pharmaceutical Society Professional Guidance on the Administration of Medicines (2019). • Each registered nurse or midwife is professionally accountable for their individual practice. In a local context, they are required to adhere to Powys Teaching Health Board (PTHB) departmental policies available on the PTHB intranet site. **These tasks cannot be delegated and so the registered nurse/midwife making the decision to administer a medicine under this protocol must carry out the administration to the patient.**
	4.2. The Medicines Management Team has a responsibility to: • Update and review this protocol and advise on any major changes. • Ensure safe systems of medicines provision named in the protocol. • Ensure the use of this protocol is audited through annual audit of records and documentation.
	4.3. Line Managers have a responsibility to: • Ensure the competency of registered nurses or midwives administering medicines under this protocol. • Ensure awareness training is included as part of the induction process for new appointees. • Ensure registered nurses or midwives have completed the awareness training before they commence administration of P medicine included in this protocol.

- Sign off the schedule of staff authorised to use this protocol (Appendix A)
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4.4. Head of the department must:

- Ensure all registered staff read and understand this protocol.
- Arrange regular review to monitor compliance with this protocol.

4.5. Senior Nurse has responsibility for:

- Arranging yearly update training
- Arranging rotas

5. Administration of Entonox® process.

NB. It is the responsibility of the administering practitioner to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.

This protocol details all processes required, including record keeping, in order to safely administer Entonox®.

If there are any concerns, medical advice should be sought.
Where further treatment is likely to be required, the patient should be signposted appropriately, in accordance with PTHB policies and procedures.

5.1. Clinical situation and indications.

Nitrous Oxide and oxygen in combination is known as Entonox® and can be used:

- to manage the pain of intermittent procedures or in patients who are in pain awaiting the attention of a member of medical staff.

or

- As a short-term relief of moderate to severe acute pain associated with injury and/or nursing procedures

or

- management of pain in women in labour or requiring perineal repair.

Entonox® may be used alone or in combination with other analgesics, however, please refer to cautions section.

5.2. Inclusion criteria.

- Patients requiring immediate relief of acute moderate and severe pain associated for example with:
  - Fractures
  - Back pain
  - Burns

- During procedures such as wound debridement, the application or change of dressings or suturing
- Labour, as part of intrapartum care
- Perineal repair

- Patients who are able to follow the instructions to self-administer **NB**. Self-administration using a demand valve may be used in children who are able to self-regulate their intake (usually over 5 years of age) with consent from the person with parental responsibility.
- Patients with no concerns about potential airway or breathing problems
- Medical and drug history taken, no reason for exclusion
- Informed consent obtained from the individual or a person legally able to act on the person's behalf.

Refer to PTHB Consent to Treatment and Examination Policy.

In case of any doubt, contact medical team.

5.3. Exclusion criteria.

- Conditions outside of the clinical situations criteria
- No valid consent or patient/representative refuses treatment. Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "Action to be taken if patient is excluded" or "Action to be taken if patient declines treatment"
- Children aged under 5 years old
- Patients unwilling or unable to self-administer
- Intoxicated (e.g., alcohol), confused uncooperative patients
- Any condition where gas is trapped within the body and where its expansion may be dangerous, e.g.
  - Artificial, traumatic or spontaneous pneumothorax
  - Air embolism
  - Chest injuries
  - Decompression sickness (bends)
  - Following a recent dive
  - Use during myringoplasty/middle ear surgery
  - Gross abdominal distension
  - Severe bullous emphysema
  - Following air encephalography
  - In patients having received recent intraocular injection involving use of gas (such as SF6 or C_3F_8).
- Patients with:
  - Head injury, impaired consciousness or heavily sedated
  - Suspected or known increased pressure on the brain
  - Maxillofacial injuries
  - Acute psychiatric disturbance

	○ Early pregnancy (less than 16 weeks) ○ Exposure to agents which are toxic to the lungs such as Paraquat (a type of weedkiller) ○ Intestinal obstruction ○ Middle ear occlusion ○ Known hypersensitivity to nitrous oxide ○ Previous use of Entonox® within the last 4 days
	5.4. Action to be taken if patient is excluded. • Explain reason to the individual, if possible • Offer alternative analgesia appropriate to the condition being treated • Record reason and any advice given and seek medical advice from GP/DGH/OOH or prescriber as appropriate
	5.5. Action to be taken if the patient/carer/representative declines treatment. • Explain consequences of refusing treatment. • The patient information leaflet should be available to inform consent. • Make patient or representative aware of alternative sources of treatment. • If patient has capacity to consent and refuses treatment, then follow locally agreed pathway. • In the unlikley situation, if patient's carer/representative refuses treatment for the patient, the decision would be overridden by a *decision to treat* in the individual's best interests in accordance with the Mental Capacity Act 2005. • Document refusal and any advice given. Complete a Discharge Against Advice Form if appropriate/ complete a discharge summary of care on the WPAS system. If urgent, contact GP surgery • Inform or refer to medical team/follow local procedures as appropriate.
	5.6. Cautions. • Entonox® can be used during the early postnatal period but should not be used during breast-feeding itself. Breast-feeding can be resumed as soon as the mother has recovered sufficiently. • Patients with complex multiple pathologies, polypharmacy or multiple allergies. • Patients with a known vitamin B12 deficiency, those with a diet low in animal products, e.g. vegetarians or vegans, or patients with poor nutritional status, or those with a history of anaemia. In patients with undiagnosed vitamin B12 deficiency, neurological toxicity has occurred after single exposures to nitrous oxide during general

	anaesthesia. Consider assessment of plasma vitamin B12 concentration. • If there are concerns about a potential airway or breathing problem, e.g. COPD, due to the relatively high concentration of oxygen contained in Entonox® which may cause respiratory depression and increases in $PaCO_2$. • Where Entonox® is used for more than a total of 6 hours but less than a total of 24 hours, within a 4 day period, it should be used with caution. • Use with caution in patients with a known history of substance abuse • Patients who are pregnant- NB early pregnancy is an exclusion under this protocol. See exclusion criteria • Check for any other medications that the patient is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. Especially: o Methotrexate (Nitrous oxide inactivates vitamin B12 and potentiates the effects of methotrexate on folate metabolism). o Sedating drugs e.g., benzodiazepines, opioid analgesics, antipsychotics or antidepressants – increased risk of sedation, consequently, may have effects on respiration, circulation and protective reflexes o Antihypertensives and diuretics- there may be an increased hypotensive effect o Administer with caution at levels as low as possible in patients who have been administered bleomycin, amiodarone or nitrofurantoin or similar antibiotics- as the risk of pulmonary toxicity may be increased. (Refer to BNF/datasheet for full list) • Seek medical advice and document advice given and action taken.
	5.7. Medication information: Entonox® (nitrous oxide 50% and oxygen 50%)
	5.7.1. Legal category: P Pharmacy
	5.7.2. Form and strength. Medicinal gas, compressed
	5.7.3. Route of administration Inhalation

5.7.4. Information for administration

- *Cylinder* – check if there is gas in the cylinder, by turning on, and examining the gauge. Ensure that the cylinder is not frosted.
- *Piped Entonox®* - check the flow of Entonox® by pressing the purge button.
- Do not leave the patient unattended when using Entonox®.
- Entonox® should only be administered under the direct supervision of personnel experienced in its use, with approved training in the use of Entonox® and airway management, and when resuscitation equipment is available.
- Always check expiry date prior to use.

<u>Self-administration using a mouthpiece or facemask connected through a demand valve.</u>

- Patient to be positioned comfortably.
- Give clear instruction on the self-administration of the Entonox® gas via the mouthpiece.
- Fit mouthpiece to anti -bacterial filter. Attach this to the demand valve and inhalation tubing and connect tubing to the cylinder.
- Ensure a good seal is maintained around mouthpiece.
- Instruct the patient to inhale and exhale until the desired effect has been achieved. Do not start the procedure until the patient is receiving the full effects of Entonox and is able to co-operate. They should continue to breathe Entonox® throughout the duration of the procedure.
- At the end of the procedure observe the patient until the effects of the gas have worn off and allow to mobilise when safe.
- Clean all non-disposable equipment in accordance with infection control policy.

NB. Entonox® cylinders should be maintained at a temperature above 10°C for at least 24 hours before use to ensure the gases are mixed correctly. If this is not possible or practicable, EA, D and ED size cylinders must be inverted 3 or 4 revolutions before use to ensure mixing.

5.7.5. Equipment

- Entonox® cylinder (blue and white) / piped
- Bodock seal
- Inhalation tubing on non-positive pressure tubing where demand valve sits on the cylinder (in some areas this may be disposable)
- Demand flow valve and disposable antibacterial filter
- Disposable mouthpiece
- Resuscitation equipment available

	5.7.6. Dosage • Self-regulated using a demand valve, dose sufficient for pain relief **NB.** Evaluate the effectiveness of Entonox® with the patient throughout, and following procedures, by verbally questioning and encouraging the patient to self-assess the analgesic effect. • It should be used 30 seconds before a procedure or before contraction becomes painful in labour (onset of action within 30 seconds after the start of administration).
	5.7.7. Frequency of administration. As required
	5.7.8. Maximum total dose in 24 hours. As required for pain relief. Maximum of 24 hours inhalation NB Use with caution if used for more than a total of 6 hours
	5.7.9. Maximum duration of treatment. Maximum of 24 hours inhalation Maximum 24 hours inhalation not repeated more frequently than every 4 days.
	5.7.10. Overdose. **NB.** When used appropriately there is no concern about overdose. • excessive inhalation will ultimately result in unconsciousness progressing through stages of increasing light-headedness and intoxication • remove patient to fresh air, provide mouth to mouth resuscitation and if necessary, use an oxygen resuscitator • immediate assessment/treatment is essential - refer to medical team • manage in accordance with established treatment guidelines • for further advice contact National Poisons Centre 0344 892 0111

6. Storage.

- Entonox® should be treated as oxygen and although it is not flammable it strongly supports combustion.
- Warning notices (prohibiting smoking and naked lights) must be posted clearly in the storage area and the Emergency Services should be advised of the location of the cylinder store.
- It is essential that cylinders are stored in accordance with manufacturer's instructions- refer to datasheet for further information.
- Entonox® cylinders:
  - should be stored under cover, preferably inside, kept dry and clean.
  - should not be stored near stock of combustible materials
  - should be stored separately from industrial and other non-medical and medical cylinders
  - should be stored to maintain separation between full and empty cylinders
  - should not be subjected to extremes of heat or cold.
- Use in strict rotation so that cylinders with the earliest filling date are used first.
- Ensure that Entonox® cylinders are maintained at a temperature above 10°C for at least 24 hours before use to ensure the gases are mixed correctly. If this is not possible EA, D and ED size cylinders may be used immediately if inverted three times before use to ensure mixing.
- When not in use F size cylinders and larger should be stored vertically. D size cylinders and smaller may be stored horizontally.
- Precautions should be taken to protect cylinders from theft.

NB Please refer to section 11 for Community midwives and the storage of Entonox®

7. Drug interactions.

Check for any other medications that the patient is taking, including topical or inhaled products, food supplements and herbal or homeopathic medications.

NB. This list is not exhaustive. Refer to BNF/datasheet for full list of potential interactions. See **cautions section**.

Refer for medical advice as appropriate and document advice given.

8. Identification, management of, and reporting of adverse effects.

- Euphoria, disorientation, sedation, nausea, vomiting, dizziness and generalised tingling - generally minor and rapidly reversible
- Prolonged or frequent use of Entonox® may result in megaloblastic anaemia
- Agranulocytosis has been reported following prolonged nitrous oxide administration

- Nitrous oxide can cause inactivation of vitamin B12- this interferes with folate metabolism and DNA synthesis is impaired following prolonged administration of Entonox®
- In patients with undiagnosed subclinical deficiency of vitamin B12, neurological toxicity has occurred after a single exposure to Nitrous Oxide for anaesthesia
- Myeloneuropathy, megaloblastic marrow changes and sub-acute combined cord degeneration have also been reported following prolonged or frequent use
- Risk of addiction
- Prolonged exposure may result in bowel distension, middle ear damage and rupture of ear drums, because nitrous oxide passes into all gas containing spaces in the body faster than nitrogen passes out
- If the patient complains of earache, inhalation should be stopped
- Staff in the first trimester of pregnancy or planning to conceive may wish to avoid the area if Entonox® is being administered for long periods. This can be discussed with occupational health and their line manager
- Inappropriate, unwitting or deliberate inhalation of Entonox® can result in unconsciousness, passing through stages of increasing light-headedness and intoxication. Remove Entonox® and follow resuscitation procedures as appropriate
- Adverse psychometric effects will normally ease shortly after administration of Entonox® has stopped. Its influence on the subjective cognitive capabilities may persist for several hours
- May depress neonatal respiration if used during delivery

Note: Staff who administer Entonox® have a duty of care to ensure that those in the immediate vicinity, including the patient and family members where appropriate, are aware of this risk and have the opportunity to remove themselves from the immediate area discreetly if they choose.
This list may not represent all reported side-effects of this medicine. Refer to BNF or datasheet for complete list.

Report any suspected adverse reactions to a prescriber.

All significant adverse drug reactions and any administration errors must be recorded via Once for Wales Reporting System incident reporting system.
If serious adverse effects are noted, healthcare professionals or individuals should complete a Yellow Card (found in the BNF) or submit online through the MHRA website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults that may be attributable to the medication should be reported. All suspected adverse reactions in children that may be attributable to the medication should be reported.

Anaphylactic reactions.

In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a telephone.

In case of anaphylaxis:

- Refer to adrenaline (epinephrine) PGD0017 Patient Group Directions (PGDs) - Powys Teaching Health Board (nhs.wales) and anaphylaxis policy
- Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E
- Ensure reaction is fully documented in patient notes
- Ensure all patient records are marked **ALLERGIC TO ENTONOX®**
- The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers
- Report via Once for Wales Reporting System
-

9. Safety Information and risk management.

- The area where the Entonox® is used should be well-ventilated to prevent the accumulation of nitrous oxide
- Entonox should not be used near sources of ignition
- Check that hands are clean and free from any oils or grease
- Staff should be aware of the risks of occupational exposure and safe working recommendations as published in "Entonox- The Essential Guide" https://www.bochealthcare.co.uk/en/products-and-services/products-and-services-by-category/medical-gases/entonox/entonox.html
- Under no circumstances should oils or grease be used to lubricate any part of the Entonox® cylinder or associated equipment used to deliver the gas to the patient.
- If moisturising preparations are required for use with a facemask or in nasal passages, oil-based creams should not be used.
- Where alcohol gels are used – ensure that all alcohol has evaporated before handling Entonox® cylinders or equipment.
- Ensure that the Entonox® cylinder cannot fall when stored and when in use.

10. Safety of healthcare practitioners (HCPs) administering Entonox®.

Warning notices prohibiting smoking or naked lights must be clearly posted. There is evidence that the following are potential risks to HCP's:

- Chronic exposure to nitrous oxide can cause impairment of vitamin B12- dependent enzyme, which may in turn result in bone marrow depression, megaloblastic changes, and neurological dysfunction
- Prolonged occupational exposure to nitrous oxide may affect a persons ability to become pregnant
- May have an adverse effect on the developing foetus as determined by the Health and Safety Executive in it's setting of the Occupational Exposure Standard (OES): developmental toxicity

Effective ventilation and/ or scavenging systems should reduce waste gas levels in the ambient air of treatment rooms to acceptable levels. Levels in these environments should be tested to ensure they are below the workplace exposure limits (WEL) as listed in the HSE publication.

11. Community Midwives and the use and storage of Entonox®.

- Green hazardous gas Entonox® sticker should be displayed on rear windscreen of Community Midwife's car when Entonox® cylinders are being transported. Follow local procedure.
- Entonox® portable cylinders should be stored in the cases provided. Secure, and not knocking each other.
- The cylinders should be in a separate compartment from the driver.
- The cylinders should not be subjected to extremes of heat or cold. Community Midwives storing cylinders in the car should take extra care overnight during freezing weather. Cylinders should be stored under cover, preferably inside, kept dry and clean.
- When transporting cylinders, they should be turned off. E size cylinders and smaller should be stored horizontally. Ensure the cylinder valve is properly closed, that the tubing is disconnected and that the equipment is carried securely in the cases provided, in the vehicle.
- Midwives should ensure they attend training days on the transportation of Entonox®, as per the Management of Health and Safety at Work Regulations and the Provision and Use of Workplace Equipment Regulations.
- The vehicle must be adequately ventilated. Ensure the driver is aware of the potential hazards of the load and knows what to do in the event of an accident or an emergency. It is advisable to provide the driver with written instructions that detail the actions to be taken in the event of an accident or emergency. Cylinders should be removed from the vehicle as soon as possible.

- Midwives using their own cars for transporting Entonox® must ensure they inform their car insurance company of this fact.

12. Written/verbal advice for patients/carers.

- Provide patient information leaflet. Draw patient's or representative's attention to the label and patient information leaflet.
- Explain indications, contraindications, cautions, possible adverse reactions and management of these.
- Provide advice on self-administration and how to hold the facemask or mouthpiece and how to breathe to operate the demand valve.
- It is essential that only the patient holds the mask/mouthpiece
- Explain that pain relief is rapid with Entonox®. Analgesia is maximal within 2-3 minutes of inhaling the gas, but its effects are apparent within a matter of breaths.
- When Entonox® is used as a sole analgesic, driving or the use of machinery is not recommended until:
  - The patient has returned to their normal mental status
  - The patient feels that they are competent to drive after the relevant procedure is completed
  - At least 30 minutes has elapsed after the administration of Entonox® has ceased.
- Additional care is needed if patients have received other sedating drugs
- Where Entonox® is to be used in the Outpatient setting, all patients should receive information prior to the day of procedure regarding Entonox® to allow them to make an informed choice as to whether they wish to drive their own motor vehicle. Patients should be reminded of this on the day prior to the start of the procedure.
  Information given to patients prior to the procedure should include:
  - How Entonox® is used for the relevant procedure
  - Contraindications and Side Effects of Entonox®
- The possible effects on driving and the need for the patient to consider whether they should drive themselves to the appointment. Should a patient choose to do this, it is done entirely at their own risk.
- If patients are receiving Entonox® in an outpatient setting it is advisable to avoid operating mechanical equipment (including motor vehicles) until the patient feels safe to do so. This may be anything between 30minutes - 24hrs (BOC 2011). Side effects are individual to every patient. Every patient will have different exposure time and different reactions to it use. It is advisable therefore to suggest to patients coming to any outpatient/Day Case environment for any test/examination or procedure where Entonox® is to be used that they consider whether they wish to drive themselves to and from their appointment.
- British Oxygen Corporation (2011) state that it is safe the drive after 30 minutes providing that the patient feels capable to do so. This is done entirely at the patients' own risk. The Healthcare professional should have

judged the patient is safe to be discharged following their procedure, having returned to a normal mental state.

- Should a patient seek reassurance about their ability/fitness to drive from a medical professional, then whilst a Doctor (DSA 2013) may be able to assess competence to drive after such a procedure this will not necessarily be the case and no Doctor should act beyond their competence. Where such a reassurance is requested by the patients then the outcome of such request must be clearly documented in the medical notes prior to discharge.

13. Follow up and referral.

- Refer to local procedures for medical review
- Arrange appropriate transfer if required.
- Document advice given.
- After commencement of use check with the patient that the full effects have been achieved.
- Maintain contact with the patient throughout the procedure
- Check for excess sedation.
- Monitoring should continue for 30 minutes after the procedure to ensure the effects have completely worn off.
- Prior to discharge, ensure:
    - vital signs have returned to normal
    - the person is awake and there is no risk of further reduced levels of consciousness
    - nausea, vomiting and pain have been adequately managed
- Inform individual of possible side effects and their management.
- Advise them to seek medical advice immediately if they have any unexpected reaction or other cause for concern. Contact 111 for advice or attend A & E.

Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and the Minor Injury Unit/ midwifery guidelines, as appropriate followed, along with PTHB safeguarding policies. Consider discussing with GP.

Any safeguarding concerns need to be directed to Safeguarding Hub:

- to generic email address: PowysTHB.Safeguarding@wales.nhs.uk

and

- Central Safeguarding number: 01686 252806.
- Out of hours: 08457 573818.

Advice can also be sought from local Safeguarding Leads:

- CNS for Safeguarding North Powys Office: 01874 442082; mobile: 07964 132698
- CNS for Safeguarding South Powys Office: 01874 442098; mobile: 07973 686520.

14. Record keeping.

Record consultation details as required by local procedures.
Administration of any medication must be clearly recorded in the patients' notes.
The following must be included:

- Symptoms allowing patient to be treated under this protocol.
- Rationale for administering under this protocol
- Relevant past and present medical history, including medication history.
- That valid informed patient consent to treatment was obtained or a decision to treat was made in the individual's best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent, if appropriate. Record advice given and action taken, if patient excluded or declines treatment.
- Name of individual, address, date of birth.
- GP contact details where appropriate.
- Any reasons for exclusion or referral, including actions taken.
- Examination findings where relevant.
- Any known allergies or previous adverse events and nature of reaction.
- Printed name and signature of registered health professional responsible for administration.
- For administration, record:
  - Date and time of administration
  - Name, form, and duration of Entonox® use in minutes
  - Route of administration
  - Expiry date(s)
- Details of any adverse reactions and actions taken.
- Effectiveness of treatment.
- If there is handover to any external services - that medication has been given in accordance with this protocol and details of what was given.
- Advice given about the medication including side effects, benefits, and when and what to do if any concerns.
- Any advice received from medical cover and advice given to patient/carer.
- Any advice given to the patient, including self-care/OTC recommendations for ongoing symptoms and when and who to refer to if symptoms are ongoing or worsen.
- Record that medication was administered via a protocol, record protocol title and version number.

Records should be signed and securely kept for a defined period in line with local policy.

All records should be clear, legible and contemporaneous.

A record of all individuals receiving treatment under this Protocol should be kept for audit purposes in accordance with local policy.

15. Training.

Initial training:

- Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) and working in PTHB.
- The assessment and management of pain
- The administration of Entonox® gas including knowledge of its actions and uses, contraindications and adverse effects. The registered nurse should also be alert to changes in the British National Formulary and Data sheet
- The recognition, management and reporting of adverse drug reactions, including anaphylaxis and the administration of adrenaline.
- Must have adequate knowledge of properties of the gas
- Correct operating procedures for the cylinder
- Precautions and actions to be taken in the event of an emergency
- Up to date BLS or ILS skills, relevant to the role.
- Must have current competence in assessing capacity and follow Mental Capacity Act guidance regarding consent to treatment in an emergency situation.
- Must have undertaken and completed Safeguarding of Children, Young People and Vulnerable Adults - Training and Competency Passport, as applicable to the role.

THE DECISION TO ADMINISTER ANY MEDICATION RESTS WITH THE INDIVIDUAL REGISTERED PRACTITIONER WHO MUST ABIDE BY THE PROTOCOL AND ANY ASSOCIATED ORGANISATION POLICIES.

Competency assessment

- Evidence of ongoing protocol training for the administration of medicines to be submitted to Line Manager annually.
- Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly.
- Practitioners must make a self-declaration of competency in their Personal Appraisal and Development Review (PADR).
- Nurses and midwives must be authorised by name as an approved practitioner under the current terms of this Protocol before working to it.

Individuals operating under this protocol are personally responsible for ensuring they remain up to date with the use of the medicine included in the protocol. If any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the protocol and further training provided as required. It is the responsibility of

the healthcare professional to maintain their own competency to practice within this protocol.

Ongoing training and competency

- Update at least every 2 years, or earlier in response to new local/national guidance on the use of protocols and Enotnox®.
- Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, BLS or ILS (relevant to their role), with evidence of appropriate Continued Professional Development (CPD).
- Compliance with all mandatory NHS training.
- Evidence of appropriate Continued Professional Development (CPD) must be retained and made available on request.

16. Monitoring compliance & audit.

This document will be reviewed in two years.

Compliance with this protocol will be monitored by annual retrospective audit of 10 instances in each department where this protocol has been used.

This will be undertaken by reviewing any records of administration of Entonox®, as stated in the patient records. This audit may be conducted by the departmental manager, unscheduled care lead or medicines management team.

Records will be reviewed for rationale behind administering medication, to check that administration was in accordance with the relevant monograph and that clear documentation is in place and appropriate referral to self-care options have been given.

All incidents involving Entonox® will be reported via Once for Wales Reporting System and monitored via incident reports.

17. Review

This document will be reviewed after two years or earlier should audit results or changes to legislation/ practice within PTHB indicate otherwise.

18. References.

- BNF online edition and British National Formulary for Children (BNFC); accessed
- BOC Healthcare (2011) Entonox Safety Information. Medical Gas Data Sheet HLC/5056051/2011
- BOC (2015) Entonox – The Essential Guide HLC/509940/UK5/0715
- BOC Entonox leaflet. *How to provide full benefit from Entonox pain relieving gas.* G2345/bb/9.92/2m
- BOC website – www.entonox.co.uk

- Driving Standards Agency DSA (2013) Customer Service Guide for drivers with medical conditions. INF94
- Joint Royal Colleges Ambulance Liaison Committee (2004) Clinical Guidelines for practice
- Lister S , Dougherty L (2008). Royal Marsden Manual of Clinical Nursing
- Entonox Essential safety information
- SPC Entonox, last updated October 2019
- Summary of Product Characteristics, Medical Gas Data Sheet BOC 8/5/19
- Competency framework: For health professionals using Patient Group Directions. Implementing the NICE guidance on Patient Group Directions (MPG2). Updated March 2017.

Appendix A. Staff Permitted to use Protocol Signature Sheet

Department name: _____

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this protocol. I give authorisation on behalf of Powys Teaching Health Board or a Powys GP practice for the named healthcare professionals below who have signed the protocol to work under it.
Practitioner: By signing this **protocol** you are indicating that you agree to its contents and that you will work within it. Protocols do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Protocol and that I am willing and competent to work to it within my professional code of conduct.

Name of health professional	Signature	Senior representative authorising health professional (Authorising Manager)	Date

The authorising manager should retain a copy of the list and a copy must be sent to the Medicines Management Team, PTHB, Bronllys Hospital, Powys LD3 0LU for audit purposes.

The healthcare professional should retain a copy of the document after signing.