University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of Entonox
By Registered UHDB Staff in Adult UHDB services

Documentation details

Reference no:	UHDB025
Version no:	1.0
Valid from:	16/09/2021
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Expiry date:	15/09/2024

Change history

Version number	Change details	Date

Glossary

Abbreviation	Definition

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD (or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
James Hooley	Medicines Safety Officer (Pharmacist)
Core Adult PGD list maintained by Medicines Safety Group.	Note: No PGD working group convened as this PGD is created by merging detail from multiple authorised PGDs in active use across UHDB which have been developed previously with nursing and medical input.

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
N/a	-	-

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
All UHDB staff providing UHDB services (includes UHDB staff/services undertaken on non-UHDB premises) This is a core PGD and can be implemented in all adult services where training and resources have been allocated by senior staff to do so (see policy and limitations below if in doubt).
Limitations to authorisation
It is the responsibility of the practitioner working under this PGD to ensure that this PGD is in place in the area they are practising at the time of use. In most cases, this is implicit when a senior manager requests the staff to undertake training and then authorises them in section 7 of this document. However, when working in alternative areas (e.g. internal bank or redeployment) it is important that the practitioner confirms with a departmental manager in the new department that the core PGDs are in-use in their area.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Chief Pharmacist	Clive Newman	Signed copy held in Pharmacy	**23/08/2021**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer (Pharmacist) *Clinical Pharmacist from PGD working group*	**James Hooley**	Signed copy held in Pharmacy	**18/08/2021**
Medical Director or deputy *Doctor*	**Magnus Harrison**	Signed copy held in Pharmacy	**18/08/2021**
Chief Nurse or Deputy *Registered Professional representing users of the PGD*	**Catherine Winfield**	Signed copy held in Pharmacy	**11/08/2021**

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	All Divisions, Adult Areas, registered professional with current professional registration operating within their usual scope of practice. Must be a profession permitted by current legislation to practice under a patient group direction.
Initial training	Members of staff using Entonox require drug specific training: - Read the guidelines for the administration of entonox to adults - received appropriate training on use of enotnox, and completed the on line e-learning assessment for Entonox accessed via The Trust My Learning Passport. Additionally, the standard PGD training is to be completed: - Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of Medicines Management Drug Assessment
Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.
Ongoing training and competency	Annual Medicines Safety Training (essential to role) Review/repeat initial training (or check if refresher required via My Learning Passport e.g. Entonox package) when this PGD is revised
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Short term painful procedures (see guidelines for examples in practice) or Short term use in patients awaiting prescription of suitable analgesia No longer than 30 minutes as per trust guidelines.
Criteria for inclusion	• Patients over 16 years presenting with the above symptoms *Notes:* *Separate guidelines and a paediatric PGD is available for areas managing pain in children*
Criteria for exclusion	• Previous sensitivity or intolerance to Entonox, • Pneumothorax • Head injuries with impaired consciousness (may increase possibility of drowsiness or loss of consciousness) • Gross abdominal distension • Bullous emphysema • Air embolus • Middle ear surgery • Following air encephalography
Cautions including any relevant action to be taken	• Intoxication of alcohol or drugs - may increase sedative effects or confusion • Mental illness, learning difficulties and other cognitive impairment which may mean the patient may not understand or follow the instructions for use • Maxillofacial injuries – patients may have difficulty holding mask tightly to face or using mouthpiece • Laryngectomy patients – will be unable to use apparatus • The first 16 weeks of pregnancy • Patients taking methotrexate – isolated acute use of enotnox is justified but there is a risk of toxicity if entonox is used recurrently (e.g. for regular planned procedures) whilst taking methotrexate. • Sedatives and opioids should not be administered prior to the use of Entonox. This may result in a loss of consciousness as the sedative effects would be additive. This can increase the risk of over-sedation. If Entonox is required and opioids have been administered, close monitoring, including oxygen saturations, is recommended.
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Advise patient on alternative treatment • Refer to medical staff for review and prescribing of alternative pain relief.
Action to be taken if the patient or carer declines	• Document advice given • Advise patient on alternative treatment

treatment	• Refer to medical staff if appropriate.
Arrangements for referral for medical advice	Contact your ward or clinic medical team if available in the first instance. In the event of anaphylaxis/cardiac arrest, follow your local medical emergency procedures (e.g. 2222 / 3333 / 999 procedures) **Pain Team input available as per trust guideline:** **RDH/LRCH site**: Acute Pain Team Mobile: 07788388426 or Bleep 1283 / 3365 / 3078 Out of hours: contact the emergency anaesthetist on call (emergencies only). **QHB/SRP/SJH site:** Acute pain team bleep 581, ext 3173 Out of hours: contact the emergency anaesthetist on call bleep 511 (emergencies only).

5. Description of treatment

Name, strength & formulation of drug	Entonox (50% Nitrous oxide & 50% Oxygen)
Legal category	POM
Route / method of administration	Self-administered inhalation via a demand valve through a dedicated mask or mouthpiece.
Indicate any off-label use (if relevant)	Not applicable
Dose and frequency of administration	To be self-administered after counseling, as required for up to 30 minutes at a time.
Duration of treatment	As required for short-term analgesia or during procedure (refer to guidelines for use). This may be repeated if required but consider referral to a prescriber at an early stage if repeated use is anticipated or required. No further monitoring is required in patients receiving less than 6 hours within a 4 day period.
Quantity to be supplied (leave blank if PGD is administration ONLY)	n/a - Administration PGD only
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: To ensure that the gas is suitable for immediate use, ENTONOX

	cylinders should be maintained at a temperature above 10°C for at least 24 hours before use. Not stored near stocks of combustible materials.
Drug interactions	*The following interactions have been identified and should be considered where it is known a patient is on the following medicines:* - Methotrexate – See cautions above – there is a risk of methotrexate toxicity with recurrent or prolonged use of entonox. - Sedatives and opioids may have additive effects with entonox (see cautions above). A detailed list of drug interactions is available in the BNF online
Identification & management of adverse reactions	**Side-effects:** Nausea, abdominal distension; addiction; agranulocytosis; disorientation; dizziness; euphoric mood; megaloblastic anaemia; middle ear damage; myeloneuropathy; paraesthesia; sedation; subacute combined cord degeneration; tympanic membrane perforation; vomiting **Exposure of patients to nitrous oxide for prolonged periods,** either by continuous or by intermittent administration, may result in megaloblastic anaemia owing to interference with the action of vitamin B12; neurological toxic effects can occur without preceding overt haematological changes. Depression of white cell formation may also occur. A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use. In the event of anaphylaxis/cardiac arrest, follow your local medical emergency procedures (e.g. 2222 / 3333 / 999 procedures)
Written information to be given to patient or carer	
Patient advice / follow up treatment	There is no need to limit the patient's mobility once a 5-10 minute rest period has passed following removal of the mask/mouthpiece. The vast majority of the gas will have been excreted by this time. The patient should be ready to resume normal activities, including driving, within 30 minutes.

	Counsel the patient that they are unable to receive Entonox therapy at home; Verbal advice on why drug administered, action of the drug and subsequent management of condition; monitor for sensitivity reactions.
Records	For inpatients, the record of administration must be documented in the ePMA system or medicines chart used in your area. For other areas, an ePMA system should be used if in-use in your area as this will ensure all legal criteria are fulfilled and auditable. Otherwise, records can be made in the medical notes or within the patient pathway (e.g. in daycase or triage where a pathway booklet is in use) but must include the legal requirements below. Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	• SPC is available via manufacturer. BOC SPC accessed 23/03/2021 https://www.boconline.co.uk/en/images/entonox_tcm410-43539.pdf • *Electronic BNF https://bnf.nice.org.uk/ https://bnf.nice.org.uk/drug/nitrous-oxide.html#indicationsAndDoses accessed 23/03/2021*

7. Registered health professional authorisation sheet

PGD Name [version]: Entonox [v1] PGD ref: UHDB025

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Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional
By signing this patient group direction you are indicating that

a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

Patient group directions 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 Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.