University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of Entonox
By State Registered non-medical staff in Imaging Facilities at all sites where UHDB Imaging deliver services

Documentation details

Reference no:	UHDB251
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Change history

Version number	Change details	Date
5.0	Reformatting, now applies to all UHDB sites	31/03/2023

Glossary

Abbreviation	Definition
RDH	Royal Derby Hospital
QHB	Queen's Hospital, Burton on Trent
FNCH	Florence Nightingale Community Hospital, Derby
SJCH	Samuel Johnson Community Hospital, Lichfield
SRPCH	Sir Robert Peel Community Hospital, Tamworth
ICH	Ilkeston Community Hospital
RCH	Ripley Community Hospital
LEHC	Long Eaton Health Centre
St. O	St. Oswald's Hospital, Ashbourne
Mob CT	UHDB owned and operated Mobile CT scanner
Mob MRI	UHDB owned and operated Mobile MRI scanner
Mob BS	UHDB owned and operated Mobile Mammography
UHDB	University Hospitals of Derby and Burton NHS Foundation Trust
POM	Prescription only medication

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
Mike Barnard	Clinical Manager: Compliance, Imaging Business Unit (HCPC Registered Diagnostic Radiographer)
Dr Rathy Kirke	Consultant Radiologist & Imaging Clinical Director
Dr Rajeev Singh	Consultant Radiologist & Imaging Clinical Director
James Hooley	Medication Safety Officer, Clinical governance pharmacist

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	n/a	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
University Hospitals of Derby and Burton NHS Foundation Trust staff at the following sites: RDH, QHB, SRPCH, SJCH, FNCH, ICH, RCH, LEHC, St. O and Mob CT / Mob MRI / Mob BS units at locations in Staffordshire and Derbyshire
Limitations to authorisation
This organisation does not authorise the use of this PGD by staff not employed by UHDB, either directly or via an agency.

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer (Pharmacist)	James Hooley	Signed copy held by Pharmacy	28/04/2023

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer (Pharmacist)	James Hooley	Signed copy held by Pharmacy	28/04/2023
Consultant Radiologist & Imaging Clinical Director	Dr Rathy Kirke	Signed copy held by Pharmacy	02/03/2023
Consultant Radiologist & Imaging Clinical Director	Dr Rajeev Singh	Signed copy held by Pharmacy	02/03/2023
Professional Lead for Radiography	David Tipper	Signed copy held by Pharmacy	02/03/2023

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	HCPC registered Radiographers and NMC registered Nurses
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Completion of training to ensure competent in all aspects of IV injection (Trust IV training, SCoR accredited training for IV contrast agent administration, or equivalent) - Individual has read and understood full content of this PGD and signed authorisation (section 7) The completion of NICE's self-competency check lists available at: https://www.nice.org.uk/guidance/mpg2/resources/competency-framework-for-health-professionals-using-patient-group-directions-msword-13672765
Competency assessment	Competency evidence through core qualifications, recognised IV training or masters level training which will have included assessment for the following: - Surface anatomy and palpation skills - Injection and aseptic techniques - Knowledge of medically screening patients - Knowledge of relevant pharmacology - Contraindications and precautions - Emergency procedures - Safety - A period of supervised clinical practice by a medical practitioner, or an authorised non-medical injector Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions. https://www.nice.org.uk/guidance/mpg2/resources/competency-framework-for-health-professionals-using-patient-group-directions-msword-13672765 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 clinical manager for their Imaging modality so that further training can be provided as required. Training for use of Entonox at UHDB requires staff to have read the UHDB guideline and completed the on-line eLearning assessment on My Learning Passport (or equivalent training offered within Radiology BU).
Ongoing training and competency	Staff working under this PGD must take part in continuing professional development. Staff are encouraged to complete the self-assessment competency tool NICE Competency Framework for health professionals using patient group directions.

	https://www.nice.org.uk/guidance/mpg2/resources/competency-framework-for-health-professionals-using-patient-group-directions-msword-13672765 and present this as part of their evidence of CPD at their Appraisal at least once every 3 years. Managers and staff must consider the need for any additional local training if staff d not regularly undertake work covered by the PGD, for example career breaks or parental leave, or when gaps in knowledge arise. Annual mandatory training updates for Immediate Life Support/ Resus Automatic External Defibrillation AED training *, managing anaphylaxis and aseptic 'non-touch' technique provided by UHDB. *Unless exempt from doing life support training due to personal risk assessment
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 (e.g., Fine Needle Aspiration. Biopsy, Interventional Radiology, Catheterisation, Removal of drains) Short term use in patients awaiting prescription of analgesia. Use should not exceed 30 minutes.
Criteria for inclusion	• Adult patients undergoing a justified interventional radiology procedure. • Valid consent for the administration of local anaesthesia forms part of the general consent process for interventional radiology. Consent must have been gained from the patient after the benefits and risks and alternative treatments have been discussed. Such consent must be documented in line with Imaging policy, either via a formal written consent process or documented verbal consent.
Criteria for exclusion	• Consent not gained. • Patients aged 16 years and under • Previous sensitivity or intolerance to Entonox • Pneumothorax • Head injuries with impaired consciousness • Gross abdominal distension • Bullous emphysema • Air embolus • Middle ear surgery • Following air encephalography
Cautions including any relevant action to be taken	The following conditions will need to be discussed with Radiologist or other relevant medical practitioner before proceeding. Decision to proceed remains the responsibility of the practitioner working under this PGD: • 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 Entonox 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. If the patient is receiving any concomitant medication or treatment it is the responsibility of the person identified on the 'Professional Authorisation Sheet' to ensure that treatment with the drug detailed in this direction is appropriate. Check all concurrent medication with the patient and in the current/online BNF before treatment. Refer to a doctor if the patient is taking any medication that may interact with the intended treatment. **If in any doubt, advice should be sought and recorded before the drug is administered.**
Action to be taken if the patient is excluded	• Discuss alternative pain relief / anaesthetic options with a Radiologist. • Record reasons for exclusion in patient record (CRIS) • Advise patient on alternative treatment (or arrange for this advice to be provided by the referring clinical team)
Action to be taken if the patient or carer declines treatment	• Discuss with a Radiologist or the referring clinical team • Document advice given / arrangements made Mark the procedure as not done on CRIS and produce a report to inform the referring clinician that the procedure has not been performed, why and the advice given to the patient.
Arrangements for referral for medical advice	Medical advice should be sought from a Radiologist in the first instance. Advice provided, including the need for the patient to discuss their ongoing care with the referrer is documented as a report; available as hardcopy, or on CRIS, PACS, Lorenzo, Meditech and other IT systems.

5. Description of treatment

Name, strength & formulation of drug	Entonox (Nitrous Oxide 50% + Oxygen 50%)
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)	*N/A*
Dose and frequency of administration	To be self-administered after counselling, as required for up to 30 minutes at a time.
Duration of treatment	Dependent on clinical case / need
Quantity to be supplied (leave blank if PGD is administration ONLY)	*N/A*
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	For details of potential interactions and their severity see https://bnf.nice.org.uk/ - 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 SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
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 Summary of Product Characteristics (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. • Patients who are exhibiting signs of anaphylaxis will be referred for medical assistance (call Resuscitation Team if at an acute hospital: QHB or RDH) and call 999 and request urgent medical assistance if in a community setting. Patients who are exhibiting signs of sepsis following interventional radiology will be advised to seek an immediate assessment from a medical practitioner (GP, or local ED)
Written information to be given to patient or carer	Patients and/or carers advised to: • Monitor for adverse reactions • Read the patient information leaflet covering risks / side-effects provided before giving consent (sensitively ensure patient is able to read and understand, if not then cover verbally) Patients are provided with contact details during working hours and are advised what to do outside working hours in case of any adverse reaction. Any specific advice for a particular patient will be written down and given to the individual patient. This will also be documented in the healthcare record.
Patient advice / follow up treatment	The patient/carer will be provided with verbal advice on aftercare requirements following their procedure. 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. The patient will be warned of any after effects including that there can be some discomfort when the effect of the Entonox wears off and advice on analgesia, if required. Follow up appointments will usually be with the referrer. Imaging staff should ensure that the patient has details of their follow up

	appointment or has details of how to contact the referrer to make this appointment.
Records	Patient records may be written in the hospital notes, written and scanned or electronic (Lorenzo, Meditech, CRIS, etc.) 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 • That the medications used were 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 using an 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. State 'administered under PGD' with name and signature of authorised registered Radiographer or Nurse. A second check should be obtained before administration and the name of the checker recorded.

6. Key references

Key references	• *Electronic Medicines Compendium* http://www.medicines.org.uk/ • *Electronic BNF* https://bnf.nice.org.uk/ • *NICE Medicines practice guideline "Patient Group Directions"* https://www.nice.org.uk/guidance/mpg2 https://medusa.wales.nhs.uk • Imaging department workflow for examinations involving medications. • Imaging scheme of work the supply of laxative or contrast agent to patients for preparation and self-administration at home. • Imaging scheme of work the supply of contrast agent to inpatients for self-administration in the Imaging Department.

	• Imaging scheme of work the supply of contrast agent to inpatients for self-administration on the ward. • Imaging IV injections policy. • Trust Clinical Guideline for the Prevention of Contrast Induced Kidney Injury.

7. Registered health professional authorisation sheet

PGD Name [version]: Imaging - Entonox [v5.0] PGD ref: UHDB251

Valid from: 28/04/2023 Expiry date: 27/04/2026

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.