

## PATIENT GROUP DIRECTION (PGD)

**Administration of Lidocaine 10% (10mg/Spray)  
By Nurse Endoscopists in Endoscopy at Royal Derby, Queens Burton  
& Sir Robert Peel Hospitals**

### Documentation details

Reference no:	UHDB 123
Version no:	1
Valid from:	03/11/2021
Review date:	03/05/2024
Expiry date:	02/11/2024

### Change history

Version number	Change details	Date
1	New template used to cover multiple sites (replaces legacy QHB and RDH PGDs)	01/07/21

### Glossary

Abbreviation	Definition
HEE	Health Education England
JAG	Joint advisory Group on GI Endoscopy

**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
Dr Stephen Hearing	Endoscopy Lead/ Consultant Gastroenterologist
James Kerr	Divisional Pharmacist
Scott Mackenzie	Lead Nurse Endoscopist

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

## 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
Endoscopy Unit at the Royal Derby Hospital, Endoscopy Unit at the Queens Hospital Burton, Endoscopy Unit at Sir Robert Peel Community Hospital
Limitations to authorisation
This organisation only authorises the use of this PGD by Nurse Endoscopists signed off as being fully competent endoscopy practitioners.

Organisational Authorisation (legal requirement).			
Role	Name	Sign	Date
Medicines Safety Officer	James Hooley	Signed copy held in Pharmacy	03/11/2021

<b>Additional signatories (required as per legislation and locally agreed policy)</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
Divisional Pharmacist	James Kerr	Signed copy held in Pharmacy	<b>03/11/2021</b>
Endoscopy Lead/ Consultant Gastroenterologist	Dr Stephen Hearing	<b>Signed copy held in Pharmacy</b>	<b>23/10/2021</b>
Lead Nurse Endoscopist	Scott Mackenzie	<b>Signed copy held in Pharmacy</b>	<b>26/10/2021</b>

Local enquiries regarding the use of this PGD may be directed to [UHDB.PGDgovernance@nhs.net](mailto: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

<b>Qualifications and professional registration</b>	<ul style="list-style-type: none"> <li>• NMC registered Nurse</li> <li>• JAG or HEE accredited Nurse Endoscopist</li> </ul>
<b>Initial training</b>	<ul style="list-style-type: none"> <li>• Completion of all Essential-to-role training as outlined in the UHDB PGD policy.</li> <li>• Individual has read and understood full content of this PGD and signed authorisation (section 7)</li> <li>• Completion of Medicines Management Drug Assessment</li> <li>• Completion of JAG Upper or Lower GI Endoscopy training</li> </ul>
<b>Competency assessment</b>	<p>Staff operating under this PGD are encouraged to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a></p> <p>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.</p>
<b>On-going training and competency</b>	<ul style="list-style-type: none"> <li>• Ongoing endoscopist training with annual CPD and appraisals.</li> <li>• ILS/ALS life support training competences.</li> <li>• Regular training to maintain and update all induction modules.</li> </ul>
<p><b>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</b></p>	

#### 4. Clinical condition or situation to which this PGD applies

<b>Clinical condition or situation to which this PGD applies</b>	All patients age 16 years and over requesting topical local anaesthesia for their Gastroscopy examination.
<b>Criteria for inclusion</b>	All patients age 16 years and over requesting topical local anaesthesia for their Gastroscopy examination and not identified within the exclusion criteria below
<b>Criteria for exclusion</b>	Patients with the following: <ul style="list-style-type: none"> <li>• Known Lidocaine sensitivity/ allergy</li> <li>• Known sensitivity to local anaesthetics of the amide type</li> <li>• Known sensitivity to the following excipients: Ethanol, Macrogol 400, Essence of Banana (contains propylene glycol), Levomenthol, Saccharin and Water purified</li> </ul>
<b>Cautions including any relevant action to be taken</b>	Lidocaine should be used with caution in the following patients who will require special attention to prevent potentially dangerous side effects: <ul style="list-style-type: none"> <li>• Patients with epilepsy</li> <li>• Patients with cardiovascular disease and heart failure</li> <li>• Patients with impaired cardiac conduction or bradycardia</li> <li>• Patients with severe renal dysfunction</li> <li>• Patients with impaired hepatic function</li> <li>• Patients in severe shock</li> <li>• The elderly and patients in poor general health</li> <li>• Patients on any of the medication mentioned in the drug interaction section below</li> </ul>
<b>Action to be taken if the patient is excluded</b>	<ul style="list-style-type: none"> <li>• Record reasons for exclusion in patient notes</li> <li>• Advise patient on alternative treatment</li> </ul>
<b>Action to be taken if the patient or carer declines treatment</b>	<ul style="list-style-type: none"> <li>• Document details and advice given</li> <li>• Advise patient on alternative treatment</li> </ul>
<b>Arrangements for referral for medical advice</b>	<ul style="list-style-type: none"> <li>• A member of the medical team will always be in the endoscopy department and if on some rare occasion they are not, the medical registrar/consultant on call will be available.</li> <li>• Document details and advice given.</li> </ul>

#### 5. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	<ul style="list-style-type: none"> <li>• Lidocaine 10%, 10mg/Spray (50ml spray bottle, giving approx. 500 spray doses)</li> </ul>
<b>Legal category</b>	<ul style="list-style-type: none"> <li>• Pharmacy (P)</li> </ul>
<b>Route / method of administration</b>	<ul style="list-style-type: none"> <li>• Topical</li> </ul>
<b>Indicate any off-label use (if relevant)</b>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>

<b>Dose and frequency of administration</b>	<ul style="list-style-type: none"> <li>Up to 20 sprays from the supplied, unmodified nozzle to produce the desired anaesthetic effect</li> <li>Debilitated or elderly patients should be given doses commensurate with their age and physical condition. Reactions and complications are best averted by employing the minimal effective dosage</li> </ul>
<b>Duration of treatment</b>	<ul style="list-style-type: none"> <li>Once only</li> </ul>
<b>Quantity to be supplied (leave blank if PGD is administration ONLY)</b>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
<b>Storage</b>	<p>Stock must be securely stored according to UHDB medicines policy in a drug cupboard and in conditions in line with SPC as detailed below:</p> <ul style="list-style-type: none"> <li>Do not store above 25°C.</li> <li>During storage at temperatures below +8°C precipitation may occur. The precipitate dissolves on warming up to room temperature.</li> </ul>
<b>Drug interactions</b>	<ul style="list-style-type: none"> <li>Lidocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics e.g. antiarrhythmic drugs such as mexiletine, since the toxic effects are additive</li> <li>Specific interaction studies with Lidocaine and antiarrhythmic drugs class III (e.g. amiodarone) have not been performed, but caution is advised</li> </ul>
<b>Identification &amp; management of adverse reactions</b>	<p>Severe reactions include:</p> <ul style="list-style-type: none"> <li>Swelling of the face, lips, tongue or throat, making it difficult to swallow</li> <li>Sudden swelling of the hands, feet and ankles</li> <li>Breathing difficulties</li> <li>Itching of the skin (with raised lumps)</li> <li>Respiratory arrest</li> <li>Cardiac arrest</li> </ul> <p>Other adverse reactions include:</p> <ul style="list-style-type: none"> <li>Irritation where Lidocaine spray has been used</li> <li>Nervousness</li> <li>Dizziness</li> <li>Drowsiness</li> <li>Loss of consciousness</li> <li>Sore throat</li> <li>Hoarse voice or loss of voice</li> <li>Hypotension</li> <li>Seizures or fits</li> <li>Bradycardia</li> </ul> <p>In the event of anaphylactic shock or cardiac or respiratory arrest emergency help should be summoned immediately.</p>

	<p>Serious or unusual adverse reactions that could be attributed to the drug should be reported to a doctor, and a yellow card and incident form should be completed and submitted as appropriate.</p>
<p><b>Management of and reporting procedure for adverse reactions</b></p>	<ul style="list-style-type: none"> <li>• 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: <a href="https://yellowcard.mhra.gov.uk">https://yellowcard.mhra.gov.uk</a></li> <li>• Record all adverse drug reactions (ADRs) in the patient's medical record</li> <li>• 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.</li> </ul>
<p><b>Written information to be given to patient or carer</b></p>	<p>Individuals may be affected by Lidocaine for up to 3-4 hours and will need care until the sedative effects have worn off.</p> <p>For 3-4 Hours patients should:</p> <ul style="list-style-type: none"> <li>• Take care when eating or drinking as Lidocaine causes a loss of feeling in the patient's throat, making it more likely that food or liquid may go down the wrong way. Also, this may make it difficult to swallow or cause some people to accidentally bite their tongue or cheek.</li> <li>• Monitor for sensitivity reactions</li> </ul>
<p><b>Patient advice / follow up treatment</b></p>	<ul style="list-style-type: none"> <li>• Inform the individual/carer of possible side effects and their management.</li> <li>• The individual/carer should be advised to seek medical advice in the event of an adverse reaction.</li> </ul>
<p><b>Records</b></p>	<p>The following must be recorded in the patients endoscopy Medical record/notes the healthcare practitioner working under this PGD:</p> <ul style="list-style-type: none"> <li>• Name of individual, address, date of birth and GP with whom the individual is registered (if relevant)</li> <li>• Name of registered health professional</li> <li>• Name of medication administered</li> <li>• Date of supply/administration</li> <li>• Dose, form and route of administration</li> <li>• Quantity supplied/administered</li> <li>• Batch number and expiry date (if applicable e.g. injections and implants)</li> <li>• Details of any adverse drug reactions and actions taken</li> <li>• Confirm whether <u>administered</u> via Patient Group Direction (PGD)</li> <li>• Records should be signed and dated</li> <li>• All records should be clear, legible and contemporaneous</li> </ul>



## 6. Key references

<b>Key references</b>	<ul style="list-style-type: none"><li>• Electronic Medicines Compendium: <a href="https://www.medicines.org.uk/emc/product/882/smpc">https://www.medicines.org.uk/emc/product/882/smpc</a></li><li>• NICE Medicines practice guideline: “Patient Group Directions” <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li><li>• BSG: <a href="https://www.bsg.org.uk/wp-content/uploads/2019/12/AOMRC-guideline-on-safe-sedation-practice-for-healthcare-procedures.pdf">https://www.bsg.org.uk/wp-content/uploads/2019/12/AOMRC-guideline-on-safe-sedation-practice-for-healthcare-procedures.pdf</a></li></ul>
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## 7. Registered health professional authorisation sheet

PGD Name [version]: Endoscopy - Lidocaine [v1] PGD ref: UHDB 123

Valid from: 03/11/2021

Expiry date: 02/11/2024

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.