Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This Protocol must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the Protocol should be used. Health professionals should always access the Protocol via the PTHB internet to ensure that they are always working to the most up to date version

Protocol

for the administration of

lidocaine 10mg/ metered dose spray (Xylocaine® Spray)

by registered Nurses working in endoscopy departments

to patients to provide **surface anaesthesia** to perform

oesophago-gastro duodenoscopy

or

trans nasal endoscopy

in Powys Teaching Health Board endoscopy departments

Version number: MMP 423

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

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys
Powys Teaching Health Board is the operational name of Powys Teaching Health Board

Change history

Version number	Change details	Date
MMP 423	New protocol to replace PGD 0147A and add the indication for trans nasal endoscopy	17/11/2023

For advice on protocol use in practice/advised supporting governance please refer to When Patient Group Directions are not required.

This Powys Teaching Health Board (PTHB) protocol is based on a template developed on behalf of the Specialist Pharmacy Service (SPS) in January 2023.

Protocol authorisation

Name	Job title and organisation	Signature	Date
Senior doctor **Dr Kate Wright**	Lead doctor for PTHB	DocuSigned by: Kate Wright 1F267952823F473...	11/15/2023
Chief Pharmacist **Jacqui Seaton**	Chief Pharmacist for PTHB	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	11/15/2023
Senior representative of professional group using the Protocol **Claire Roche**	Executive Director of Nursing and Midwifery for PTHB	DocuSigned by: Claire Roche FC9C4C63FC374A7...	11/21/2023
Clinical Governance Lead **Amanda Edwards**	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	11/29/2023

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

The final authorised copy of this Protocol should be kept by PTHB for 8 years after the Protocol expires.

Competencies of registered health professionals working under the Protocol	
Qualifications and professional registration	Practitioners must only work under this Protocol where they are competent to do so. Practitioners must also be a registered professional with the following body: • nurses currently registered with the Nursing and Midwifery Council (NMC) All registered health professionals should have a current contract of employment with Powys Teaching Health Board, and be working in PTHB Endoscopy units. The practitioners must also fulfil the training and additional requirements detailed below. Check Appendix A: Staff permitted to use the Protocol.
Initial training	• The administration of lidocaine 10mg/metered dose spray during oesophago-gastro-duodenoscopy or trans nasal endoscopy and knowledge of its uses, contraindications and adverse effects. • Be alert to changes in the BNF/ Summary of Product Characteristics • Must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Basic Life Support skills. Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this Protocol before working to it • must have undertaken appropriate training for working under Protocols for administration of medicines • must have access to the Protocol and associated online resources • must have undertaken and completed Safeguarding of Children, Young people and

	Vulnerable adults – Training and Competency passport, as applicable to the role **THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PROTOCOL BEFORE WORKING ACCORDING TO IT.** **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 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 on PADR.
Ongoing training and competency	Updating at least every 2 years on the use of Protocols and lidocaine 10mg/metered dose spray. Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, Basic Life Support Skills, safeguarding, with evidence of appropriate Continued Professional Development (CPD). Compliance with all mandatory NHS training. Practitioners should be constantly alert to any sources of medicines information. **It is the responsibility of the healthcare professional to maintain their own competency to practice within this 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.

Clinical condition or situation to which this Protocol applies	
Clinical condition or situation	To provide surface anaesthesia for the oropharyngeal and tracheal areas to reduce reflex activity and facilitate insertion of an endoscope to perform oesophago-gastro-duodenoscopy (OGD) on selected patients **Or** To be applied to mucous membranes to provide surface anaesthesia in nasal and pharyngeal areas prior to trans nasal endoscopy **It is the responsibility of the administering healthcare professional to ensure that the individual 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. These tasks cannot be delegated and so the registered nurse making the decision to administer a medicine under this protocol must carry out the administration.**

Inclusion criteria	• Adult patients over 18 years of age, who either:
	  ○ Have requested topical anaesthesia prior to OGD either alone or with intravenous sedation.
	  ○ Require trans nasal endoscopy
	• Informed consent obtained. NB Refer to PTHB Consent to Treatment and Examination Policy
	• Individual will have been triaged by an endoscopist and assessed as suitable for the procedure
	• Medical and drug history taken, no reason for exclusion
	• In case of any doubt, contact medical team

Exclusion criteria (Exclusion under this Protocol does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)	• Individuals under 18 years of age • Conditions outside of the clinical situations criteria • Consent not given. 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 the individual is excluded" and "action to be taken if the individual declines treatment". • Hypersensitivity or allergy to lidocaine, to any of the ingredients of the preparation (see SPC www.medicines.org.uk), or to any local anaesthetics of the amide-type • Individual concurrently receiving/using any other local anaesthetic or agents structurally related to amide-type local anaesthetic e.g. antiarrhythmic drugs such as mexiletine, since the toxic effects are additive. • Pregnant individuals • Any open wounds or traumatized mucosa affecting the application area or the immediate vicinity
Cautions /reasons for seeking further advice from a	• If the dose or site of administration is likely to result in high blood levels, lidocaine should be used with caution in the following individuals who will require discussion with a prescriber and special attention to prevent potentially dangerous side effects in individuals:

prescriber- NB monitor individual closely for adverse effects	○ With known epilepsy ○ With known cardiovascular disease and/or heart failure ○ With known impaired cardiac conduction or bradycardia ○ With known severe renal impairment ○ With known hepatic impairment ○ Known porphyria ○ In severe shock ○ Who are elderly and individuals in poor general health or debilitated If there is an indication of risk, then the prescriber should prescribe the medicine. • Individuals currently taking antiarrhythmic drugs class III (e.g. amiodarone) should be under close surveillance and ECG monitoring considered, since cardiac effects may be additive. • Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk • If being applied to the oropharyngeal and tracheal areas, caution in individuals with swallowing difficulties or at risk of aspiration. The oropharyngeal use of topical anaesthetic agents may interfere with swallowing and thus enhance the danger of aspiration. Numbness of the tongue or buccal mucosa may increase the danger of biting trauma. • Individuals with complex multiple pathologies, polypharmacy or multiple allergies. • Avoid contact with the eyes. • Xylocaine Spray should not be used on cuffs of endotracheal tubes (ETT) made of plastic. Lidocaine base in contact with both PVC and non-PVC cuffs of endotracheal tubes may cause damage of the cuff. This damage is described as pinholes, which may cause leakage that could lead to pressure loss in the cuff. • Risk of cross contamination: **nozzle is for a single use in an individual patient.**

	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 PTHB safeguarding policies followed. 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: 0345 0544847 Advice can also be sought from local Safeguarding leads
Arrangements for referral for medical advice	Record reason, seek medical advice and document advice given.
Action to be taken if individual excluded	Individuals will immediately be brought to the attention of an appropriate medical prescriber. Record reason for exclusion and any action taken. Explain reason to individual / carer.
Action to be taken if individual declines treatment	Explain consequences of refusing treatment. Record reason for decline, any advice given and any action taken in the consultation record. Individuals having oesophago-gastro-duodenoscopy will be offered intravenous conscious sedation using Midazolam (see separate PGD0146) or referral to another endoscopist. Follow local procedures as appropriate.

Details of the medicine	
Name, form and strength of medicine	Lidocaine 10 mg/metered dose spray Non-sterile solution for topical application supplied in a pump spray The contents of each 50ml spray bottle is sufficient to provide approximately 500 sprays with a metering spray pump.
Legal category	Pharmacy Only (P) medicine
Route/method of administration	For surface oropharyngeal administration immediately prior to OGD (oesophago-gastro-duodenoscopy) **or** To be applied to mucous membranes to provide surface anaesthesia in nasal and pharyngeal areas prior to trans nasal endoscopy The product is non-sterile, so is not recommended for use prior to procedures that require aseptic technique. Xylocaine spray (lidocaine 10mg/dose) should not be used on cuffs of endotracheal tubes (ETT) made of plastic. As with any local anaesthetic, reactions and complications are best averted by employing the minimal effective dosage (see Overdose section below). It is unnecessary to dry the site prior to application. Lidocaine spray is administered using the supplied nozzle. Nozzles are supplied in the finished product packaging and also available separately in boxes of 50.

	The spray nozzle is bent to ensure correct spray function. Do not try to alter the shape as this could affect its performance. The nozzle must not be shortened, as it will affect the spray function. Nozzles are non-sterile single patient single use and local infection control procedures should be adhered to in order to prevent cross contamination – refer to the product's Risk Minimisation Materials to help reduce the risks associated with using this medicine. The nozzles should be handled using gloves and the box of 50 should be kept closed between procedures. **Nozzles should not be reused and should be discarded immediately after use.**
Dose and frequency	Up to 20 doses per procedure. Each spray = 1 dose supplying 10mg Lidocaine • the number of sprays depend on the extent of the area to be anaesthetised • employ the minimum effective dose to achieve the desired anaesthetic effect (determined by asking the patient) • Debilitated or elderly individuals should be given doses commensurate with their age and physical condition.
Maximum dose to be administered under this protocol	A maximum of 20 sprays (total 200mg) administered according to this protocol within a 6 week period.
Off-label use	No
Storage	Do not store above 25°C. During storage at temperatures below +8°C, precipitation may occur, which will dissolve on warning up to room temperature.

Identification, management and reporting of adverse reactions	**Extremely rare:**
	Amide-type local anaesthetic preparations have been associated with allergic reactions (in the most severe instances anaphylactic shock). 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 working telephone to summon assistance if required.
	
	In case of anaphylaxis:-
	• Refer to adrenaline (epinephrine) PGD0017 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 individual's notes
	  • Ensure all patient records are marked **ALLERGIC TO Lidocaine 10 mg/metered dose per spray**
	  • The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers
	
	Report via Once for Wales Reporting System.
	
	Rare:
	Serious adverse effects may result from high plasma levels due to excessive dosage or rapid absorption or from hypersensitivity, idiosyncrasy or reduced tolerance on the part of the individual (see cautions section above).
	
	Absorption from mucous membranes is variable but is especially high from the bronchial tree. Such applications may therefore result in rapidly rising or excessive plasma concentrations, with an increased risk of toxic symptoms, such as convulsions.
	
	CNS reactions are excitatory and/or depressant and may be characterised by nervousness, dizziness, convulsions, unconsciousness and possibly

	respiratory arrest. The excitatory reactions may be very brief or may not occur at all, in which case the first manifestations of toxicity may be drowsiness, merging into unconsciousness and respiratory arrest. Cardiovascular reactions are depressant and may be characterised by hypotension, myocardial depression, bradycardia and possibly cardiac arrest. **Procedure for dealing with severe adverse reactions to treatment provided.** If serious reaction occurs: • assess nature of the event; stop the procedure if applicable. • if necessary/ applicable remove endoscope • monitor vital signs and seek medical attention promptly • commence basic life support and seek prompt medical attention **Unknown frequency:** Local irritation at the application site. Sore throat, hoarse voice or loss of voice. This list is not exhaustive. Refer to BNF or SPC via medicines.org.uk for complete list. Report any suspected adverse reactions to a doctor or prescriber and record in the individual's medical record. Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme at: http://yellowcard.mhra.gov.uk 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. Guidance on the yellow card system is available at the back of the BNF or using the above link. All significant adverse drug reactions and any administration errors must be recorded via the Once for Wales Reporting System.

Overdose	Toxic reactions originate mainly in the central nervous and the cardiovascular systems. Central nervous system toxicity is a graded response with symptoms and signs of escalating severity. The first symptoms are circumoral paraesthesia, numbness of the tongue, light-headedness, hyperacusis and tinnitus. Visual disturbance and muscular tremors are more serious and precede the onset of generalised convulsions. Unconsciousness and grand mal convulsions may follow, which may last from a few seconds to several minutes. Hypoxia and hypercarbia occur rapidly following convulsions due to the increased muscular activity, together with the interference with normal respiration. In severe cases, apnoea may occur. Acidosis increases the toxic effects of local anaesthetics. Cardiovascular effects are only seen in cases with high systemic concentrations. Severe hypotension, bradycardia, arrhythmia and cardiovascular collapse may be the result in such cases. Cardiovascular toxic effects are generally preceded by signs of toxicity in the central nervous system, unless the patient is receiving a general anaesthetic or is heavily sedated with drugs such as a benzodiazepine or barbiturate. Recovery is due to redistribution and metabolism of the local anaesthetic drug from the central nervous system. Recovery may be rapid unless large amounts of the drug have been administered. Request medical assistance urgently. Treatment of acute toxicity should be instituted at the latest when twitches occur. If the GP is not immediately available dial 999 to transfer to A&E.

Records to be kept	Record consultation details as required by local procedures, on the standard PTHB endoscopy nursing documentation, a copy of which will be held in the individual's medical records and a further copy forwarded to the individual's GP. In addition, record: • Name, address and date of birth of individual • Name and address of GP • Medical and drug history taken, including any allergies and previous adverse events. • Any reasons for exclusion or referral, including actions taken. • Criteria under which the individual fits the protocol. • Any advice received from medical cover and advice given to individual/carer. • If the individual has refused treatment, and any advice given in this circumstance. • That valid informed patient consent to treatment was obtained, or a decision to treat made in the individual's best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent if appropriate. • That the drug is being administered in accordance with a Protocol- record title and version. • Date and time of administration. • Name, form, strength and dose of drug administered. • Expiry date • Route of administration • Details of any adverse reactions and actions taken. The record must include the printed name and signature (which may be electronic) of the healthcare professional responsible for administration.

	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.
Patient information	
Written/verbal information to be given to individual or carer	Provide patient information leaflet. Inform individual of possible side effects and their management. Inform individual that they are being treated within a protocol. Lidocaine spray has minor influence on the ability to drive and use machines. Depending on the dose, local anaesthetics may have a very mild effect on mental function and may temporarily impair locomotion and co-ordination. The individual must not drive or use machinery if affected. Individual should be advised of reduced sensation following administration. Individual should be advised not to eat or drink anything for 1 hour post application (due to risk of aspiration).
Follow-up advice to be given to individual or carer	Follow PTHB discharge procedures. All individuals are to be given written discharge instructions including relevant contact numbers (endoscopy unit during working hours, GP outside of those hours). Advise individual to seek medical advice immediately if they have any unexpected reaction or other cause for concern. Contact GP via surgery or emergency on call service.

Key references

1. Summary of Product Characteristics: www.medicines.org.uk. Xylocaine spray, Aspen Pharma, last updated 30/10/2018. Accessed 19/10/23.
2. Patient Information Leaflet, Xylocaine 10mg spray, Manufacturer: Aspen, last revised March 2021
3. Risk materials: Xylocaine 10mg spray; Aspen, last revised: 19/2/2019
4. BNF accessed 18/10/23

Appendix A Staff Permitted to use the Protocol Signature sheet

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 for the named healthcare professionals below who have signed the Protocol to work under it.
The authorising manager may wish to use the competency checklist (below).

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.

Printed name of health professional	**Signature of health professional**	**Printed name of senior representative authorising health professional (Authorising Manager)**	**Signature of 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 (info.medicinesmanagement.powys@wales.nhs.uk) for audit purposes. This list should be kept by PTHB for 8 years after the protocol expires.
The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Protocol. Review of authorisation will take place on each Protocol update and at the individual's annual PADR.

Name: **Role:**		Sign / Initial	Further training identified (Y/N) Specify in " " comments	Comments
1	The Protocol sign off is for the following Protocol:(document the exact title and Protocol number) _____			
2	We have discussed the expiry of the Protocol and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the Protocol			
4	The Protocol has been read in full by the staff member			
5	The identified training has been completed as specified in the Protocol and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager, to the staff member, and to medicines management department (info.medicinesmanagement.powys@wales.nhs.uk), in conjunction with the Protocol Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.