NHS Grampian

Patient Group Direction For The Administration Of Medicines As Included In The Advanced Practitioner Radiographers Formulary By Advanced Practitioner Radiographers Working in the Breast Screening, Symptomatic Mammography Departments And Clinic E Within NHS Grampian

Lead Author: Advanced Practitioner Radiographer	**Consultation Group**: See relevant page in the PGD	**Approver:** Medicines Guidelines and Policies Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NHSG Identifier: NHSG/PGD/APR_Form/ MGPG1183	**Review Date:** August 2023 **Expiry Date:** August 2024	**Date Approved:** August 2021

NHS Grampian have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Board. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 2

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD supersedes NHSG/PGD/APR_Form/MGPG1009	
Date of change	**Summary of Changes**	**Section heading**
January 2020	2 Year review.	

NHGS Identifier:	NHSG/PGD/APR_Form/MGPG1183
Keyword(s):	PGD Patient Group Direction advanced practitioner radiographer local anaesthetic lidocaine xylocaine

Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	January 2021
	Completed:	June 2021
	Approved:	August 2021 (published – October 2021)
	Amended and reauthorised:	

Organisational Authorisations

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

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Gerald Lip **Title:** Consultant Radiologist **Contact email:** Gerald.lip@nhs.scot **Signature** ..... **Date:** 29/09/2021
Senior representative of the professional group who will provide care under the direction	**Name:** Alice Dewar **Title:** Advanced Practitioner Radiographer **Contact email:** alice.dewar@nhs.scot **Signature** ..... **Date:** 14/09/2021
Lead author	**Name:** Michelle Cumming **Title :** Advanced Practitioner Radiographer **Contact email:** michelle.cumming@nhs.scot **Signature** ..... **Date:** 31/08/2021
Pharmacist	**Name:** Keira Watson **Title :** Clinical Pharmacist **Contact email:** keira.watson@nhs.scot **Signature** ..... **Date:** 29/09/2021

Approved and authorised for use within NHSG by;

Medicines Guidelines and Policies Group Chair	Signature	Date Signed
Lesley Coyle		13/10/2021

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Michelle Cumming	**Lead Author:** Advanced Practitioner Radiographer
Keira Watson	**Pharmacist:** Haematology Rotational Pharmacist
Dr Gerald Lip	**Medical Practitioner:** Consultant Radiologist
Susan Cook	Staff Nurse , Breast Screening
Alice Dewar	**Senior Representative:** Advanced Practitioner Radiographer
Dr Daina Basko	Consultant Radiologist
Lynsey McLennan	Advanced Practitioner Radiographer

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Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise Advanced Practitioner Radiographers (APR) to administer medicines included in the APR PGD Formulary (Appendix 3) to individuals aged 16 years and over. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Individuals aged 16 years and over requiring; • Biopsy under x-ray or ultrasound guidance of indeterminate lesions of the breast • Breast abnormalities to be localised prior to surgical excision. Prior to the administration of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current NHSG consent policy.
Exclusion criteria	Individuals who: • Are under 16 years of age • Have any known hypersensitivity to local anaesthetics of the amide type • Have any hypersensitivity to any of the excipients contained in the local anaesthetics • Have complete heart block • Have Myasthenia Gravis • Have hypovolaemia • With infection/inflammation or damaged skin at the site of injection. • Where there is no valid consent.
Precautions and special warnings	If there is any concern about the appropriate use of the medicine in the specific indications given within the PGD then medical advice should be sought. If there is any doubt about the appropriateness of using this PGD, medical advice should be sought. Precautions listed in the individual medicine monographs should be taken into account.

	Note: Lidocaine/Xylocaine should be used with caution in individuals who have conditions as listed in the special warnings and precautions for use section of the SmPC for both lidocaine and adrenaline; however it should be noted that these conditions do not exclude individuals from receiving therapy. APRs must be familiar with the relevant SmPCs and should exercise their professional judgement with regard to administering lidocaine. If there is any doubt as to the individual's suitability they should be discussed with a radiologist or appropriate medical professional.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Inform/refer to the relevant medical practitioner if individual declines treatment. Document that the administration was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the PGD

Name form and strength of medicine	See individual medicine monographs.
Legal status	Medicines referred to in this PGD are all POM (Prescription-only Medicines).
Dosage/Maximum total dose	See individual medicine monographs.
Frequency of dose/Duration of treatment	See individual medicine monographs.
Maximum or minimum treatment period	See individual medicine monographs.
Route/Method of administration	See individual medicine monographs.
Quantity to be administered	See individual medicine monographs.

Storage requirements	See individual medicine monographs.
Follow-up (if applicable)	Individuals should not leave if they are feeling unwell without speaking to the APR first. If necessary a radiologist should be contacted for advice.
Advice (Verbal)	Advice should be given on what to expect and what to do for major and minor reactions. The individual should be made aware that there may be initial stinging, transient local swelling and erythema associated with the injection followed by a loss of sensation which may last for 30 – 60 minutes. There may be a continued sensitivity and awareness of touch/pressure at the injection site. Limit movement of site for 24/48 hours. Paracetamol can be taken for pain post procedure according to manufacturer's instruction. Contact GP if signs of Infection arise, i.e. redness/heat/swelling. Avoid showering for 24 hours to ensure the dressing remains intact and dry.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.
Identifying and managing possible adverse reactions	See individual medicine monographs. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: https://about.medicinescomplete.com/ **SmPC/PIL/Risk Minimisation Material:** https://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm https://www.medicines.org.uk/emc/rmm-directory If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. https://yellowcard.mhra.gov.uk/

Facilities and supplies required	The following are to be available at sites where the medicine is to be administered: • Appropriate storage facilities • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to administer medicine(s) under PGD

Professional qualifications	Radiographers as registered with the Health and Care Professional Council (HCPC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's capacity to understand the nature and purpose of the medicine administration in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD. • Competent to undertake administration of the medicine • Competent to work under this PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken PGD training as required/set out by NHSG • Have undertaken basic life support training either face to face or online and updated in-line with Board requirements • Have undertaken NHS e-anaphylaxis training or equivalent (including annual updates) which covers all aspects of the identification and management of anaphylaxis

	• Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct • Have knowledge and familiarity of the following; ○ SmPC for the medicine(s) to be administered in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to administer the medicine(s) specified in this direction.

Documentation

Authorisation of administration	Advanced practitioner radiographers working in the North East Breast Screening Program clinics, symptomatic mammography departments and clinic E within NHS Grampian can be authorised to administer the medicine specified in this PGD by their Clinical Manager/Radiologist. All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed locally.
Record of administration	An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of administration • Individuals name and CHI • Exclusion criteria, record why the medicine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route (batch number, expiry date and site where appropriate for injectable medicines) of the medicine administered

	• Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the medicine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • Secondary Care Medical Notes • Individual service specific systems.
Audit	All records of the medicine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Lidocaine Hydrochloride 1% (Hameln) – Date of revision of text 01/04/20, accessed 17/06/21. Xylocaine 1% with Adrenaline (Aspen) - Date of revision of text 02/04/20, accessed 17/06/21. British National Formulary and the British National Formulary for Children https://www.bnf.org accessed 17/06/21.

Appendix 1

Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

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I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

Appendix 2

Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
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Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Appendix 3

NHS Grampian APR PGD Formulary

The information in these monographs is not exhaustive. They must be read in conjunction with the current issue of the British National Formulary, and the Summary of Product Characteristics for each product.

Lidocaine Hydrochloride 1% W/V Solution For Injection (2mL, 5mL, 10mL And 20mL Ampoules) (Administer)	
Drug Legal Status	POM
Indication	Lidocaine 1% is used in stereotactic and ultrasound core biopsies of indeterminate lesions and in the localisation of a breast abnormality prior to a theatre excision.
Inclusion Criteria	As per criteria listed in main PGD.
Exclusion Criteria	As per criteria listed in main PGD.
Dose/Maximum total dose	The dose to be administered is dependent on site(s) and proposed size of the biopsy/biopsies; however single doses of lidocaine (for anaesthesia other than spinal) should not exceed 4.5 mg/kg (or 200mg lidocaine 1%). **The lowest possible volume should always be used.** **Maximum of 20mL (200mg lidocaine 1%) only under this PGD for both single site and multi-focal biopsies.**
Frequency of dose/Duration of treatment	Commonly one treatment, but consideration is required when multifocal or bilateral breast biopsies are required.
Maximum or minimum treatment period	N/A
Route/Method of Administration	Lidocaine hydrochloride 1% injection is injected subcutaneously and to deeper tissue (maximum of 20mL (200mg lidocaine 1%)) directed toward the indeterminate lesion that is to be biopsied. The needle should be inserted subcutaneously and lidocaine hydrochloride 1% injection injected slowly, allowing 1-2 minutes for the injection to take effect. Each injection of lidocaine hydrochloride 1% injection **must be preceded by aspiration** to ensure needle is not intravascular. A cold compress can be applied to site for a minimum of 10 minutes to reduce the risk of haematoma.
Quantity to be administered	The dose to be administered will vary according to site(s) and size of biopsy/biopsies, but must never exceed 20mL (200mg lidocaine 1%) under this PGD.

Lidocaine Hydrochloride 1% W/V Solution For Injection (2mL, 5mL, 10mL And 20mL Ampoules) (Administer)	
Potential Adverse Reactions	Adverse effects are rare and usually the result of excessively high blood concentration due to inadvertent intravascular injection, excessive dosage, rapid absorption or occasionally due to hypersensitivity. Side effects include nervousness, dizziness, confusion, respiratory depression, convulsions, hypotension and bradycardia. Systemic toxicity reactions can occur and the first symptoms of toxicity are usually, circumoral paraesthesia, numbness of the tongue, light -headedness, hyperacusis, tinnitus and visual disturbances. See SmPC for further details APRs must be aware of the risks, signs and symptoms as well as the treatment for acute systemic toxicity.
Follow up (If applicable)	Individuals should not leave if they are feeling unwell without speaking to the radiographer first. If necessary a radiologist should be contacted for advice.
Storage	Store in a locked cupboard below 25°C, protected from light.

Xylocaine 1% With Adrenaline (Epinephrine) 1:200,000 W/V Solution For Injection (20mL) (Administer)	
Drug Legal Status	POM
Indication	Xylocaine 1% with adrenaline is used to anaesthetise deeper tissue prior to a large volume vacuum assisted biopsy.
Inclusion Criteria	As per criteria listed in main PGD.
Exclusion Criteria	As per criteria listed in main PGD.
Dose/Maximum total dose	The dose to be administered is dependent on site(s) and proposed size of the biopsy/biopsies, however a maximum of 40mL (400mg xyloacaine 1%) should not be exceeded in a single or multifocal biopsy. Injected to deeper tissue in approximately 3mL increments. **The lowest possible volume should always be used.** **Maximum of 40mL (400mg of xylocaine 1%) only allowed under this PGD for both single site and multi-focal biopsies.**
Frequency of dose/Duration of treatment	Commonly one treatment, but consideration is required when multifocal or bilateral breast biopsies are required.
Maximum or minimum treatment period	N/A
Route/Method of Administration	Xylocaine 1% with adrenaline injection is injected to deeper tissue in approximately 3mL increments (maximum of 40mL (400mg xylocaine 1%)) per individual) directed toward the indeterminate lesion that is to be biopsied. The needle should be inserted and Xylocaine 1% with adrenaline injected slowly, allowing 1-2 minutes for the injection to take effect. Each injection of Xylocaine 1% with adrenaline injection **must be preceded by aspiration** to ensure needle is not intravascular. A cold compress can be applied to site for a minimum of 10 minutes to reduce the risk of haematoma.

Xylocaine 1% With Adrenaline (Epinephrine) 1:200,000 W/V Solution For Injection (20mL) (Administer)	
Quantity to be administered	Injected to breast tissue in approximately 3mL increments to a maximum of 40mL (400mg xylocaine 1%). The quantity to be administered will vary according to site(s) and size of biopsy/biopsies, but must never exceed 40mL (400mg xylocaine 1%) under this PGD.
Potential Adverse Reactions	Adverse effects are rare and usually the result of excessively high blood concentration due to inadvertent intravascular injection, excessive dosage, rapid absorption or occasionally due to hypersensitivity. Side effects include paraesthesia, dizziness, bradycardia, hypotension, hypertension, nausea and vomiting. Systemic toxicity reactions can occur and the first symptoms of toxicity are usually, circumoral paraesthesia, numbness of the tongue, light-headedness, hyperacusis, tinnitus and visual disturbances. See SmPC for further details APRs must be aware of the risks, signs and symptoms as well as the treatment for acute systemic toxicity.
Follow up (If applicable)	Individuals should not leave if they are feeling unwell without speaking to the nurse or radiographer first. If necessary a radiologist should be contacted for advice.
Storage	Store between +2°C and +8°C. Do not freeze. The product must be discarded if frozen.