This Patient Group Direction (PGD) must only be used by registered healthcare 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 PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Administration of lidocaine hydrochloride 1% injection to facilitate insertion and/or removal of subdermal Etonogestrel (e.g., Nexplanon®) Implant in Rotherham, Doncaster, and South Humber (RDaSH) NHS Foundation Trust.

Version Number 2.0

Change History	
Version and Date	**Change details**
Version 1 October 2020	New template
Version 1.1 June 2021	**Dose and frequency of administration section amended to:** **Insertion:** Initially 5-20mg (0.5-2ml). A further dose of up to 10mg (1ml) may be used if required to a total maximum dose of 30mg (3ml). **Removal:** 5-10mg (0.5-1ml). **Total maximum dose for concurrent removal and insertion is 40mg (4ml).**
Version 2.0 May 2023	Updated template (no clinical changes to expired V1). Updated exclusions, adverse effects, and references. Minor changes to some wording and formatting. Aligned content with other PGDs for same or associated medicine / group. Updated PGD development group members.

PGD DEVELOPMENT GROUP

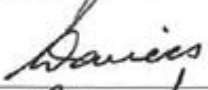
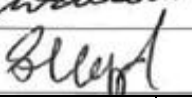
Date PGD template comes into effect:	September 2023
Review date:	March 2026
Expiry date:	August 2026

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in April 2023

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Dr Cindy Farmer	Vice President, General Training FSRH
Michelle Jenkins	Advanced Nurse Practitioner FSRH
Vicky Garner	Consultant Midwife British Pregnancy Advisory Service (BPAS)
Sim Sesane	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Heather Randle	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Associate Specialist
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins	Lead Pharmacist PGDs and Medicine Mechanisms, Medicines Use and Safety, Specialist Pharmacy Service
Rosie Furner (Working Group Co-ordinator)	Governance Pharmacist, Medicines Use and Safety, Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Dr Graeme Tosh	RDaSH Medical Director		31/08/23
Steve Davies	RDaSH Senior Pharmacist		5/9/23
Sheila Lloyd	RDaSH Executive Director of Nursing		31/8/23
Person signing on behalf of [authorising body]	Tina Proctor Nurse Consultant		12/09/23

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of individuals ensuring safe provision of the medicines listed in accordance with local policy. Recommended requirement for training would be successful completion of a relevant module/course accredited or endorsed by the FSRH, CPPE or a university or as advised in the RCN training directory. In addition, completion of the FSRH Letter of competence (LOC) in Subdermal implants (LOC SDI-IR/LOC SDI-IO) or locally agreed additional training and been assessed as competent at the insertion and/or removal of the subdermal implant which should also include training and been assessed as competent in the administration of lidocaine. Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme The healthcare professional must keep up to date with current FSRH guidance relevant to the insertion/removal of the contraceptive implant including any relevant MHRA Drug Safety Updates. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent. The healthcare professional must ensure that they have an up-to-date certificate for Basic Life Support (BLS) and anaphylaxis as required by the employing Trust/organisation
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see section 7) or complete a self-declaration of competence for contraception supply. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to administer any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies.

Clinical condition or situation to which this PGD applies	Local anaesthetic for insertion and/or removal of subdermal etonogestrel subdermal contraceptive implant.
Criteria for inclusion	• Any individual requiring the insertion and/or removal of etonogestrel subdermal contraceptive implant under the etonogestrel subdermal contraceptive implant PGD. Individuals requiring lidocaine for the insertion of a subdermal contraceptive implant should also meet the inclusion criteria of the etonogestrel subdermal contraceptive implant PGD. • Consent given.
Criteria for exclusion	• Consent not given. • Individuals under 16 years of age and assessed as not competent using Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • Known hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics or other amide type anaesthetics. • Individual who had received a previous maximum infiltration of local anaesthetic within 4 hours. **Cardiovascular Disease** • Complete heart block • Hypovolaemia **Other conditions** • Porphyria
Cautions including any relevant action to be taken	• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. • **Individuals who are breastfeeding.** The individual should be informed that small amounts of lidocaine may be excreted into the breast milk. The possibility of an allergic reaction in the infant, albeit remote, should be borne in mind when receiving lidocaine when breastfeeding. • The SmPC recommends use with caution in the following patient groups. Given the dose and route used, they are not excluded under this PGD. No additional monitoring is required. This is in line with FSRH feedback. ○ Bradycardia ○ Congestive heart failure ○ Known acute porphyria. ○ Known epilepsy. ○ Known myasthenia gravis. ○ Impaired respiratory function ○ Severe renal impairment (eGFR <10ml/min/Stage 5)

Action to be taken if the individual is excluded or declines treatment	• Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Where required refer the individual to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, strength & formulation of drug	Lidocaine 1% w/v (10 mg in 1 mL) in 2mL, 5 mL or 10 mL ampoules
Legal category	POM
Route of administration	Subcutaneous or intradermal surface infiltration only
Off label use	Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with pharmacy/Medicines Management. Where a medicine is recommended off-label consider, as part of the consent process, informing the individual that the medicine is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	**Insertion:** Initially 5-20mg (0.5-2ml). A further dose of up to 10mg (1ml) may be used if required to a total maximum dose of 30mg (3ml). **Removal:** 5-10mg (0.5-1ml). **Total maximum dose for concurrent removal and insertion is 40mg (4ml).**
Duration of treatment	Single episode of care permitted under this PGD (i.e., insertion or removal only or concurrent removal and insertion).
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	All concurrent medications, including those purchased should be considered for interactions. A detailed list of drug interactions is available in the individual product SPC, which is available from the electronic Medicines Compendium website www.medicines.org.uk the BNF www.bnf.org and, as this PGD supports the administration of hormonal contraception, FSRH CEU Guidance: Drug Interactions with Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/

	Refer to a prescriber if any concern of a clinically significant drug interaction.
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org Note when used for surface anaesthesia rapid and extensive absorption may result in systemic side effects. Hypersensitivity reactions (allergic or anaphylactoid reactions, anaphylactic shock) Adverse effects are rare and usually a sign of accidental intravascular injection, excessive dosage, or rapid absorption from highly vascular areas, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Systemic toxicity mainly involves the central nervous system and/or the cardiovascular system. Monitor individual for signs of: • Confusion • Respiratory depression • Convulsions • Hypotension • Bradycardia • Dizziness If overdose or severe adverse reaction suspected manage following local policy for vasovagal incident.
Additional facilities and supplies	• Access to working telephone. • Suitable waste disposal facilities • Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000)
Management of and reporting procedure for adverse reactions	• Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the individual's medical record. • Report via organisation incident policy.
Written information and further advice to be given to individual	• Offer Manufacturer's Patient Information Leaflet (PIL). • Explain mode of action, side effects, and benefits of the medicine.
Advice/follow up treatment	Advise individual: • How to care for the injection site and advise to return if concerns about the injection site. • Give information on who to contact in the event of an adverse reaction or concerns.

Records	**Record:**
	• The consent of the individual and
	  ○ If individual is under 13 years of age record action taken
	  ○ If individual is under 16 years of age document capacity

	using Fraser guidelines. If not competent record action taken. ○ If individual over 16 years of age and not competent, record action taken. • Individual's name, address, and date of birth • GP contact details where appropriate • Attendance date • Reason for attendance • Relevant past and present medical and family history, including drug history. • Any known allergy • Relevant examination findings • Inclusion or exclusion from PGD • A statement that administration is for insertion of subdermal implant and is by using a PGD. • Advice given about the medication including side effects, benefits, and when and what to do if any concerns. • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any administration outside the marketing authorisation • Any referral arrangements • Record the name/brand, dose of the medication, site of injection. • Record batch number and expiry date according to local policy or national guidelines • Record follow up and/or signposting arrangements. • Any other relevant information that was provided to the individual. • Name and signature (which may be an electronic signature) of the clinician supplying and administering the medicine. Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy. All records should be clear, legible, and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references (accessed January 2023)	• 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 • Resuscitation Council (UK) Emergency Treatment of anaphylactic reactions: Guidelines for health care providers

	Resuscitation Council, 2021 www.resus.org.uk • FSRH Clinical Guideline: FSRH Clinical Guideline: Progestogen-only Implant (February 2021) https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-implants-feb-2014/

Appendix A – Example registered health professional authorisation sheet.

PGD Name/Version: lidocaine hydrochloride 1% injection
Valid from: 01/09/23 Expiry: 31/08/26

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional
By signing this patient group direction, you are indicating that you agree to its contents and that you will work within it.

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

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 RDaSH 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 should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

This information will be retained by the Chief Pharmacist for RDASH NHS Foundation Trust.