Rotherham Doncaster and South Humber NHS Foundation Trust

Template protocol for the administration of topical lidocaine 2.5% plus prilocaine 2.5% cream (e.g., EMLA Cream 5%, Nulbia 5% cream) to facilitate intrauterine contraception (IUC) insertion or removal in Rotherham, Doncaster, and South Humber (RDaSH) NHS Foundation Trust.

Version Number 1.0

Change History	
Version and Date	**Change details**
Version 1 January 2023	New template

Publication date:	January 2023
Review date	September 2025
Expiry date:	March 2026

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This template protocol, for local adaptation, has been peer reviewed by the Reproductive Health PGD/protocols 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 November 2022.

For advice on protocol use in practice/advised supporting governance please refer to When Patient Group Directions are not required and About the SPS Medicines Governance Do Once Programme

Protocol development group

Name	Designation
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Kate Devonport	National Unplanned Pregnancy Advisory Service (NUPAS)
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Helen Donovan	Royal College of Nursing (RCN)
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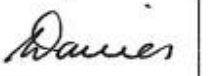
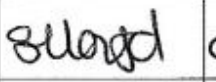
ORGANISATIONAL AUTHORISATIONS.

Name	Job title and organisation	Signature	Date
Dr Graeme Tosh	Medical Director		010623
Stephen Davies	Chief Pharmacist		05/06/23
Sheila Lloyd	Director of Nursing and Quality		01.06.23
Anil Rajpal	Senior pharmacist		05/06/23
Tina Proctor	Nurse Consultant *Senior representative of professional group using the PGD*		7/6/23

Committee Approval:

NAME	DATE
Medicines Management Committee	19/05/2023

Date of Implementation	01/06/2023

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1. Staff competencies	
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 protocol must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy. Recommended requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or as advised in the RCN training directory. Individuals working under this protocol should hold an in date FSRH Letter of Competence Intrauterine Techniques (LoC IUT) which has been achieved or recertified within the last 5 years. Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD eLearning programme Individuals working under this PGD will be required to administer local anesthesia in line with local protocols/PGDs. 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 must complete a self-declaration of competence for LNG-IUD contraception insertion.
Additional requirements	Individuals operating under this protocol are personally responsible for ensuring they remain up to date with the

	use of all medicines and guidance included in the protocol. FSRH LoC IUT must be recertified every 5 years. Organisational PGD and/or medication training as required by employing Trust/organisation.
2. Clinical condition or situation	
Clinical situation	Administration of topical lidocaine 2.5% plus prilocaine 2.5% cream (e.g., EMLA Cream 5%, Nulbia 5% cream) to facilitate intrauterine contraception (IUC) insertion or removal.
Individuals included	• Individuals aged 13 years and above. • Individual consents to treatment. • Planned/emergency insertion or removal of an intrauterine contraception (IUC) device.
Individuals excluded	• Consent not given. • Hypersensitivity to any of the ingredients of the preparation (see SPC www.medicines.org.uk) • Severe cervical ectropion • Individuals currently taking methaemoglobin-inducing medicines (e.g., sulphonamides, nitrofurantoin, phenytoin, and phenobarbital) • Individual with defective glucose-6-phosphate dehydrogenase, hereditary or idiopathic methaemoglobinaemia • Any open wounds affecting the application area or the immediate vicinity
Cautions – monitor individual closely for adverse effects	• Individuals currently taking antiarrhythmic drugs class III (e.g., amiodarone)
Action for individuals excluded	• 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.
Action if individual declines treatment	
3. Description of treatment	
Medicine to be administered	Lidocaine 2.5% plus prilocaine 2.5% cream (e.g., EMLA Cream 5%, Nulbia 5% cream)

Legal status	Pharmacy Only (P) medicine
Dose schedule/administration	Apply 10g of cream in a thick layer to the tenaculum site and into the cervical canal and leave for 7-10 minutes prior to the procedure using an appropriate application device. 1g of EMLA/Nulbia cream pressed out of a tube of 30 g is approximately 3.5 cm. Do not exceed the application time stated. Remove any remaining cream prior to undertaking the IUC insertion/removal. The procedure should be commenced immediately after removal of the cream.
Maximum dosage to be administered under this protocol	One application of 10g of lidocaine 2.5% plus prilocaine 2.5% cream.
Adverse effects	**Common adverse effects/reactions:** Application site: • pruritus • burning sensation • erythema • oedema • warmth • pallor
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: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy.
Record keeping	Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy. • Date and time of administration. • Individual's details such as name, date of birth, hospital, or NHS number (where applicable), allergies, previous

	adverse events, and the criteria under which the individual fits the protocol. • Details of medicines including name, strength dose, route. • A statement that administration is under a protocol. • Name and signature (which may be electronic) of healthcare professional acting under the protocol to supply the medication. • Relevant information that was given to the individual/carer. • Record that consent gained (or refused) – if consent refused record actions taken.
References	FSRH Guideline Intrauterine Contraception https://www.fsrh.org/documents/fsrh-guideline-intrauterine-contraception/ Summary of Product Characteristics: www.medicines.org.uk