Rotherham Doncaster and South Humber NHS Foundation Trust

Administration of lidocaine 10mg/ml spray 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

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

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Protocol development group

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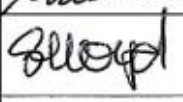
ORGANISATIONAL AUTHORISATIONS.

Name	Job title and organisation	Signature	Date
Dr Graeme Tosh	Medical Director		01 06 23
Stephen Davies	Chief Pharmacist		5/6/23
Sheila Lloyd	Director of Nursing and Quality		07.6.23
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 PGD should hold an in date FSRH Letter of Competence Intrauterine Techniques (LoC IUT) which has been achieved or recertified within the last 5 years. Users should have read thoroughly and be familiar with the FSRH IUC guidance. 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 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 should complete a self-declaration of competence.
Ongoing training and competency	Individuals operating under this protocol are personally responsible for ensuring they remain up to date with the use of all medicines and guidance - if any training needs are identified these should be addressed and further training provided as required. FSRH LoC IUT must be recertified every 5 years.

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2. Clinical condition or situation	
Clinical situation	Administration of lidocaine 10 mg/metered dose spray 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 contraceptive (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 • Individual concurrently receiving/using any other local an aesthetic or agents structurally related to amide-type local an aesthetic e.g., antiarrhythmic drugs such as mexiletine. • Any open wounds affecting the application area or the immediate vicinity
Cautions – monitor individual closely for adverse effects	• Known epilepsy. • Known cardiovascular disease and/or heart failure. • Known impaired cardiac conduction or bradycardia. • Known severe renal impairment. • Known hepatic impairment. • Known porphyria. • 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.

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Action if individual declines treatment	
3. Description of treatment	
Medicine to be administered	Lidocaine 10 mg/metered dose per spray The contents of each 50ml spray bottles are sufficient to provide approximately 500 sprays with a metering spray pump. Each depression of the metered spray pump delivers 10 mg lidocaine base.
Legal status	Pharmacy Only (P) medicine
Dose schedule/administration advice.	Apply 4 metered dose sprays (total dose 40mg) to the surface of the cervix and external os and wait 3 minutes after application. 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 nozzles. 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 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 bottle should be covered in a sterile cover for each use. 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.
Maximum dosage to be administered under this protocol	A maximum of 4 sprays (total 40mg) applications per episode of care may be administered.
Off label use	The use of lidocaine spray for the indications detailed within this protocol are outside the product licence but are supported by national guidance from the FSRH.
Storage	Do not store above 25°C.
Adverse effects	**Extremely rare:** Amide-type local anaesthetic preparations have been associated with allergic reactions (in the most severe instances anaphylactic shock). **Adrenaline 1:1000/anaphylaxis kit should be readily available in areas where lidocaine spray is administered as should access to a phone to summon assistance if required.** **Rare:** Systemic adverse reactions 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). 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. **Unknown frequency:** Local irritation at the application site.

	Vaginal irritation
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.
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 paranesthesia, 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. 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.

	how overdose should be managed locally – As per Intrauterine Device emergency management flowchart.
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. The following must be recorded on the Records. • 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