**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 location/service/organisation**

Version Number 1.0

|  |
| --- |
| **Change History** |
| **Version and Date** | **Change details** |
| Version 1January 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. Note the working group and approving organisation(s) agreement to the content only applies to the national template and does not extend to any local adaptations made to any of the content which are solely the responsibility of the organisation authorising the PGD. The most up to date version of the template is available here:

<https://www.sps.nhs.uk/home/guidance/patient-group-directions/templates/>

For advice on protocol use in practice/advised supporting governance please refer to [When Patient Group Directions are not required](https://www.sps.nhs.uk/articles/when-patient-group-directions-are-not-required/) and [About the SPS Medicines Governance Do Once Programme](https://www.sps.nhs.uk/articles/about-the-sps-medicines-governance-do-once-programme/)

Organisations should link to local infection control/PPE guidance relevant to the use of this product.

Each organisation using this protocol must ensure that it is appropriately reviewed and approved for use in line with the organisations’ governance system.

**Protocol development group**

|  |  |
| --- | --- |
| **Name** | **Designation** |
| Dr Cindy Farmer | Vice President, General TrainingFaculty of Sexual and Reproductive Healthcare (FSRH) |
| Michelle Jenkins | Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)  |
| Vicky Garner | Deputy Chief Midwife British Pregnancy Advisory Service (BPAS) |
| Gail Rowley | Quality Matron British Pregnancy Advisory Service (BPAS) |
| Katie Girling | British Pregnancy Advisory Service (BPAS) |
| Julia Hogan | CASH Nurse Consultant MSI Reproductive Choices |
| Kate Devonport | National Unplanned Pregnancy Advisory Service (NUPAS) |
| Chetna Parmar | Pharmacist adviser Umbrella  |
| Helen Donovan | 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 Pharmacy Postgraduate 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 | NHS North East London ICB pharmacist |
| Tracy Rogers | Director, Medicines Use and Safety, Specialist Pharmacy Service  |
| Sandra Wolper  | Associate Director Specialist Pharmacy Service |
| Jo Jenkins (Working Group Co-ordinator) | Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service |

|  |
| --- |
| **1. Staff competencies** |
| **Authorised staff** | To complete locally to include those healthcare professionals who will be authorised to work under this protocol to administer the named product |
| **Additional requirements** | *Insert detail as local agreement to include:* * *staff band/role as appropriate;*
* *requirements of training to be undertaken before assessed as competent;*
* *any going training/CPD requirements.*
 |
| **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 xxx 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](http://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** | Complete with local pathway |
| **Action if individual declines treatment**  | Complete with local pathway |
| **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 advice (note: adapt to reflect local policy – schedule given as an example only):** | 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 (adapt to reflect local procedure). 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 (note adapt to reflect local policy – maximum dosages given as an example only):** | 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** | The following must be recorded on the *medicine chart/EPS or clinical notes as per local protocol*:* 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.
* Batch number and expiry date of product in line with local procedure
* 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.
 |
| **4. References**  |
|  | * FSRH Clinical Guideline: Intrauterine contraception (March 2023)

[Intrauterine Contraception | FSRH](https://www.fsrh.org/Public/Standards-and-Guidance/Intrauterine-Contraception.aspx)* Summary of Product Characteristics: [www.medicines.org.uk](http://www.medicines.org.uk)
 |