**Template protocol for the administration of lidocaine 10mg/ml spray to facilitate intrauterine contraception (IUC) insertion or removal in location/service/organisation**

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](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 Training  Faculty 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 accessed as competent;* * *any going training/CPD requirements.* |
| **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 xxx 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](http://www.medicines.org.uk)) * Severe cervical ectropion * Individual concurrently receiving/using any other local anaesthetic or agents structurally related to amide-type local anaesthetic 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** | Complete with local pathway |
| **Action if individual declines treatment** | Complete with local pathway |
| **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 (note: adapt to reflect local policy – schedule given as an example only):** | 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](https://www.medicines.org.uk/emc/product/882/rmms) 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 (note adapt to reflect local policy – maximum dosages given as an example only):** | 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 paraesthesia, 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.  Insert details of how overdose should be managed locally |
| **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. |
| **References** | [FSRH Clinical Guideline: Intrauterine contraception (March 2023) - Faculty of Sexual and Reproductive Healthcare](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.fsrh.org%2Fdocuments%2Fceuguidanceintrauterinecontraception%2F&data=05%7C01%7Cjo.jenkins2%40nhs.net%7C2da21c96719840811bf308db5abd3adf%7C37c354b285b047f5b22207b48d774ee3%7C0%7C0%7C638203540993103637%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=dwKlT50fQBa5RpRO62q6Y5atKOwuoxttUHCk%2FdgIagI%3D&reserved=0)  Summary of Product Characteristics: [www.medicines.org.uk](http://www.medicines.org.uk) |