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| **Patient Group Direction for the administration of:**  lidocaine hydrochloride 1% prior to the insertion or removal of the etonogestrel subdermal contraceptive implant | |
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| **Title of patient group direction** | Patient Group Direction for the administration of lidocaine 1% injection for the insertion and removal of etonogestrel subdermal contraceptive implant |
| **Approved at** | NMP/PGD Group |
| **PGD approved / valid from** |  |
| **Review date** |  |
| **Expiry date** |  |
| **Clinical area(s) where PGD applies** | Sexual heath and HIV outreach services within contraceptive and sexual health clinics, and in sexual health outreach services/locations |
| **Identified Lead for monitoring / review and contact details** | Wendy Billsborough |
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| **CONSULTATION PROCESS ADOPTED IN DEVELOPING THE PATIENT GROUP DIRECTION (PGD)** | |
| **New Document** | No |
| **Reviewed Document** | Yes |
| **If the PGD is revised what revisions were required and for what reasons e.g. change in medical procedures or change in legislation** | Due for renewal –wording amended in line with the National PGD  Total treatment quantity amended to 4mls |
| **List of persons involved in the consultation process.**  (The group must include a sponsoring clinician, a pharmacist and a senior representative of the professional group. The job title and level of consultation should also be listed). | Wendy Billsborough – Advanced Nurse Specialist .  Alison Chorlton – Lead Nurse Sexual Health  Dr Ian Fairley, Clinical Director Lead  Jill McEnaney – Directorate Pharmacist |

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| **CLINICAL CONDITION** | |
| **Condition** | Local anaesthetic for insertion and/or removal of the etonogestrel sub-dermal contraceptive implant |
| **Inclusion criteria** | * Individuals requiring local anaesthetic prior to the insertion or removal of the etonogestrel subdermal contraceptive implant * The etonogestrel contraceptive implant PGD inclusion criteria should also be met. * Consent given |
| **Exclusion criteria** | * Child aged 12 years or under * Children under 16 years not considered competent under Fraser guidelines * Individuals 16 years of age and over and assessed as lacking capacity to consent * Consent not given * Known hypersensitivity to lidocaine hydrochloride, amide type anaesthetics or any of the excipients in the product * Individual who had received a previous maximum infiltration of local anaesthetic within 4 hours * Interacting medicines - see current British National Formulary (BNF) [www.bnf.org](http://www.bnf.org) or individual product SPC <http://www.medicines.org.uk>Existing implant cannot be palpated (for removals only) * Heart block * Hypovolaemia * Porphyria * Inflammation, infection or skin damage in the tissue to be injected * Bradycardia * Impaired cardiac conduction |
| **Actions for patients excluded** | * Discuss/offer an alternative contraceptive method * If implant preferred choice refer to clinic doctor/independent nurse prescriber or GP if in an outreach setting for further assessment * Document all action taken in the patient records   If implant unable to be palpated for removal refer into a scanning appointment and consider contraceptive cover |
| **Action for patients not wishing to receive care under the PGD** | * Record the refusal in the clinical record * Refer to clinic doctor/independent nurse prescriber if agreed with the client |

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| **DESCRIPTION OF TREATMENT** | | | | | | | |
| **Name of Medicine** | Lidocaine hydrochloride | | | | | | |
| **Legal Classification** | POM | | | | | | |
| **Licensing information** |  | | | | | | |
| **Is the medicine licensed for the intended use?** | | | | **YES** |  | |
| **Does it have a black triangle status?** | | | |  | **NO** | |
|  | **Does it have a Risk Minimisation Measures (RMM) recommendation** | | | | **YES** | **NO** | |
| **Form** | Subcutaneous | | | | | | |
| **Strength** | 1% (10 mg in 1 mL)  in 2mL, 5mL or 10 mL ampoules | | | | | | |
| **Dose** | Single episode of treatment at time of implant insertion, removal or replacement   * Recommended dose for insertion 1 to 2mL * Recommended dose for removal 0.5 to 1mL | | | | | | |
| **Frequency** | Single episode of treatment | | | | | | |
| **Route** | Subcutaneous or intradermal surface infiltration only | | | | | | |
| **Total Treatment Quantity** | A maximum of 2mL in total may be used as appropriate to ensure insertion or removal can proceed without discomfort  **Total maximum dose for concurrent removal and insertion is 40mg (4ml).** | | | | | | |
| **Interactions with other medicines**  (This must include all potentially serious interactions listed in the BNF) | Interactions are rare when used as a local anaesthetic.   * 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](http://www.bnf.org) and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception <https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/> * Also Check any medicines on UpToDate – Drug interactions via staff room under lidocaine   **If in doubt contact Medicines Information for advice ext 5960** | | | | | | |
| **Adverse Reactions**  (This should include all the common and potentially serious adverse reactions. It is acceptable to state that the BNF should be referred to for further information) | Allergic reactions are rare  Toxic effects are rare from small subdermal doses but may include:   * Feeling of inebriation, nausea and vomiting, drowsiness light-headedness, nervousness, tremor, blurred vision, paraesthesia, restlessness, dizziness, feeling hot or cold, numbness of the tongue   Serious symptoms may result:  confusion   * Respiratory depression * Convulsions * Hypotension * Bradycardia * Hypersensitivity   See Summary of Product Characteristics (SPC) for full details | | **Treatment of adverse reactions**  **Treatment of adverse reactions**   * An anaphylaxis treatment kit and facilities for resuscitation should be available * If necessary seek appropriate emergency advice and assistance * Refer to ‘Guidelines for the management of severe local anaesthetic toxicity. Association of Anaesthetics   <https://www.aagbi.org/sites/default/files/la_toxicity_2010_0.pdf>   * Document any adverse reactions in the client’s records. Inform GP with client consent * Any serious adverse drug reactions should be reported to the MHRA by the yellow card scheme. Guidance on its use is available in the BNF or can be accessed via [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) | | | | |
| **Advice to Patients: Written and Oral advice**  (This should include the provision of a patient information leaflet) | * Explain the mode of action, side effects, benefits and duration of effect (full sensation should return within 2 to 4 hours) * Explain that anaphylaxis is rare but can occur up to 72hrs after the injection and advise to seek urgent medical advice if symptoms develop * Offer the lidocaine patient information leaflet (PIL) | | | | | | |
| **Follow up action** | * Provide contact details for the service and advise to return if any problems | | | | | | |
| **Storage** | * Locked drugs cupboard or locked case for outreach use   Do not store above 25ºC | | | | | | |
| **Records to be Kept** | The following details specific to the administration of lidocaine should be documented in the client’s clinical record:   * Assessment of client request in relation to the implant procedure * Consent of the individual * Any reason for exclusion and action taken * Any known allergies * Inclusion or exclusion form the PGD * Relevant past and present medical and family history, including drug history * Consent of the individual * Date * On the prescription, record drug name and quantity administered * Batch number and expiry date * That the lidocaine was administered under a PGD * Route and site of administration * Advice given about the medication including side effects and what to do if any concerns * Any referral arrangements * Any off label use * Details of any adverse drug reactions and what action taken * Any communication with other health care professionals * Name of health professional supplying the medicine ( may be electronic) | | | | | | |
| **Audit Arrangements** | As per current Trust PGD Policy | | | | | | |
| **References** | * Faculty of Sexual and Reproductive Healthcare UK Medical Eligibility Criteria for Contraceptive Use (2016) * Faculty of Sexual and Reproductive Healthcare Clinical guidance Progestogen-only implants (2014) * Faculty for Sexual and Reproductive Healthcare (2016) Standards for Resuscitation in Sexual Health Services * British National Formulary (BNF) www.bnf.org.uk * NICE Guideline on Long Acting Reversible Contraception October 2005 * Manufacturer’s Summary of Product Characteristics (SPC) Lidocaine 1%: Electronic Medicines Compendium * Faculty of Sexual and Reproductive Healthcare e-lfh/SHR Module 17 | | | | | | |
| **Competency Requirements**  (attach any competency frameworks / documents) | The Nurse must be authorised by name under the current version of this PGD before working to it  Education, training, qualifications and competencies:   * Sexual health Nurse * Clinical competence in sexual history taking.      * Completion of the Trust PGD awareness session or Trust HUB e-learning. * Knowledge base of the interaction of lidocaine with other drugs, and other exclusions and contraindications to lidocaine * Competence in the above will be demonstrated by the undertaking of a local clinical competency based training and assessment programme, evidenced by completion of theoretical study including e-learning and clinical experience within sexual health * Assessment will be undertaken by the Lead Nurse/ANS or designated PGD assessor, who will be practising as an independent prescriber * Knowledge of the current FSRH Progestogen Only implant guidance. keeps up to date with any changes to FSRH/manufacturers guidance relevant to this PGD * Model arm and local anaesthetic training * Assessment as competent by a faculty registered trainer in the insertion/removal of subdermal contraceptive implants to achieve the required competency level for the FSRH letter of competence (LoC SDI) * Maintain professional accountability with the NMC and ensure continual professional development * Up to date certificate for Basic Life Support (BLS) and anaphylaxis as required by the employing Trust/organisation * Receive clinical supervision and/or audit of case notes on an ongoing basis * Evidence of relevant continuing professional development identified through clinical supervision and appraisal * Regular attendance and participation in the tri annual educational clinical governance | | | | | | |
| **AUTHORISATION OF THE PATIENT GROUP DIRECTION (PGD) FOR ADMINISTRATION OF:** lidocaine hydrochloride 1% prior to the insertion or removal of the etonogestrel subdermal contraceptive implant | | | | | | | |
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| **PGD Development / Review Team – responsible for PGD content** | | | | | | | |
|  | | | | | | | |
| **Title** | | **Name** | | **Signature** | | | **Date** |
| **Lead Author** | |  | |  | | |  |
| **Clinical Director Lead Approval** | |  | |  | | |  |
| **Directorate Pharmacy Lead Approval** | | Jill McEnanney | |  | | |  |
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| **PGD Approved by the NMP/PGD Group** | | | | | | | |
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| **Title** | | **Name** | | **Signature** | | | **Date** |
| **NMP Lead /**  **Lead Nurse Medicines Management** | | Jennie Booth | |  | | |  |
| **Chief Pharmacist / Deputy Chief Pharmacist** | | Stuart Parkes | |  | | |  |
| **Authorisation to work within the PGD**  This patient group direction must be agreed to and signed by all health care professionals involved in its use.  The PGD must be easily accessible in the clinical setting. | | | | | | | |
| **Notes to the NMP/PGD Authorising staff**   * Do not proceed unless this document carries the signatures of the development / review team (Lead Author, Lead Clinical Director and Directorate Lead Pharmacy) * You are responsible for fulfilling the legal requirement that a senior person from the profession ensures that only fully competent, qualified and trained professionals operate under this PGD * Using a PGD is not a form of prescribing | | | | | | | |

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| **Staff authorised to work under this PGD** | | | | | |
| **Ward / Department** | | Sexual heath and HIV outreach services within contraceptive and sexual health clinics, and in sexual health outreach services/locations | | | |
| **Professionals to whom this Patient Group Direction applies** | | Registered nurses Band 5 or above | | | |
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| ***I confirm that I have read and understood the content of this patient group direction and that I am willing and competent to work under it within my professional code of conduct when working for this Trust:*** | | | | | |
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| **Name (Capitals)** | **Sign** | | **Job Title** | **Authorising Manager** | **Date** |
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| **When the review date is exceeded, this PGD ceases to be a legal document** | |
| **TEMPLATE DOCUMENTATION CONTROL** | |
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| The template documentation control refers to the PGD template not the completed PGD.  **\*\*Do not alter the section below for NMP/PGD Group use only\*\*** | |
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| **Author:** | Jennie Booth, Lead Nurse Medicines Management  Carol Belt, Principal Pharmacy Technician  Stuart Parkes, Deputy Chief Pharmacist |
| **Owner:** | NMP/PGD Group |
| **Date of issue:** | June 2021 |
| **Version:** | 4 |
| **Approved by** | NMP/PGD Group |
| **Review date:** | June 2024 |

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