This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

The Trust accepts responsibility for the actions of the approved practitioner, properly acting in the course of his/her duties and in accordance with the current PGD in force in his/her area of practice. However the Trust accepts no responsibility for an approved practitioner who attempts to act outwith the scope of the approved PGD.

**Patient Group Direction**

for the administration of

**Lidocaine 1% Injection**

by Registered Midwifes for

**Insertion of Subdermal Contraceptive Implant (Nexplanon)**

in Maternity Department

Version number: 1

Change history

|  |  |  |
| --- | --- | --- |
| **Version number** | **Change details** | **Date** |
| 1 | Amendment to Sexual Health PGD to be used by midwives | Sept 21 |
|  |  |  |
|  |  |  |

# YOU MUST BE AUTHORISED BY NAME IN THE CURRENT VERSION OF THIS PGD BEFORE USING IT

# 1. Clinical condition/situation for use of the PGD

|  |  |  |
| --- | --- | --- |
| **1.1** | **Indication** | Subdermal infiltration prior to insertion of contraceptive implant (Nexplanon®) |
| **1.2** | **Criteria for confirmation of above** | Clients requiring insertion of contraceptive implant (Nexplanon®). |
| **1.3** | **Inclusion criteria** | Clients requiring local anaesthetic prior to insertion or removal of hormonal contraceptive implants (Nexplanon®).  For women <16years, they must meet Fraser guidelines.  **Fraser Guidelines**:  A midwife can give contraceptive advice or treatment to young people under 16 provided that the nurse is satisfied that all of the requirements are met:   * The young person understands the midwifes’ advice. * The midwife cannot persuade the young person to inform his or her parents or allow the nurse to inform parents that he/she is seeking contraceptive advice. * The young person is likely to begin or continue having sexual intercourse with or without contraception. * The young person’s physical or mental health or both is likely to suffer without contraceptive advice or treatment. * The young person’s best interests require the midwife to give contraceptive advice and/or treatment without parental consent. |
| **1.4** | **Exclusion criteria** (if any of those listed apply, the PGD cannot be used and the patient must be referred to a prescriber) | * Known hypersensitivity to lidocaine or previous sensitivity to local anaesthetics * Cardiac impairment e.g. cardiac arrhythmias, complete heart block, impaired cardiac conduction, bradycardia * Hypovolaemia * Porphyria * Myasthenia gravis * Previous nerve damage to site or neuropathy * Client requests to see a Doctor * Severe hepatic, respiratory or renal impairment * Pregnancy * Epilepsy * Clients taking the following medications. * Antibacterials - quinupristin/dalfopristin, * Antivirals - amprevenair, darunavir * 5HT3 antagonist - dolasetron,   (Consult the BNF for details): |
| **1.5** | **Caution – seek further advice from doctor before proceeding and document advice** | See 1.4 |
| **1.6** | **Arrangements for referral for medical advice** | Refer to supervising doctor or refer to the Department of Sexual Health, Salisbury Foundation Trust. |
| **1.7** | **Action to be taken if patient excluded or declines treatment under PGD** | * Refer patient to doctor. * Document refusal/action taken in patient’s healthcare record |

# 2 . Staff characteristics

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| --- | --- | --- |
| **2.1** | **Qualifications and professional registration** (eg Level 1 Registered Nurse | Registered Midwife |
| **2.2** | **Relevant training, experience and competence required in the clinical context of the PGD** (eg Health & Physical Examination module, RCN accredited course, ALS) | Midwives   * Completion of FSRH Contraception after childbirth course (formerly contraception for midwives course) * FSRH Letter of Competence for the insertion of Subdermal Implants (SDI) * Up to date basic life support and anaphylaxis training * Up to date Level 3 Child Safeguarding * Working under Expanded Practice protocol EPP 206 * Completeion of MLE training package and assessment on PGDs |
| **2.3** | **As above relevant to the medicine to be used** | * All suspected reactions should be reported via a yellow card, or on line at www.yellowcard.gov.uk |
| **2.4** | **Details of assessment undertaken to demonstrate competency to work under PGD** | Midwives   * Attendance a designated PGD training session at implant training and updating training. * Completion of e-Learning for PGDs on MLE. * Peer review and case based discussions are recommended and should be evidenced/discussed at appraisal. * . |
| **2.5** | **Ongoing competency** | * The practitioner should be aware of any changes to the recommendations for the medicine listed. * It is the responsibility of the practitioner to keep up-to-date with clinical developments as part of their continued professional development. * The midwife should be familiar with the current FSRH guidelines on Subdermal Implants. |

# Details of the medicine

|  |  |  |
| --- | --- | --- |
| **3.1** | **Name, form and strength of medicine**  *Include ▼for* [*black triangle medicines*](http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/BlackTriangleproducts/index.htm) | Lidocaine (Lignocaine) Hydrochloride 1% injection  (10mg/ml) |
| **3.2** | **Legal category** | POM |
| **3.3** | **Indicate if PGD involves medicine being used off label** | No |
| **3.4** | **Route/method of administration** | * Give by subdermal infiltration * Care must be taken to avoid intravascular injection -syringe to be drawn back to ensure not in a vessel before injection of lidocaine. * Insertion of Nexplanon®: 1-2ml injected just subdermally along the ‘insertion canal’ in the chosen arm. |
| **3.5** | **Dose and frequency** (where a range is applicable the criteria for deciding on a dose must be stated) | 1-2ml of 1% lidocaine injection, repeated after 5 minutes if anaesthesia not achieved.  **MAXIMUM dose 4ml of 1% lidocaine injection** |
| **3.6** | **Quantity to be administered and/or supplied** | See 3.5 |
| **3.7** | **Total dose & number of times treatment can be administered over what time frame** | Maximum 2 doses of 2ml lidocaine 1% injection |
| **3.8** | **Side effects** | * Clients may experience the following during the procedure; if so seek medical advice: * Light-headedness, * Drowsiness, * Dizziness, * Fear, * Confusion, * Tremor, * Tinnitus, * Blurred or double vision, * Nystagmus, * Vomiting, * Feeling hot or cold or numb. |
| **3.9** | **Specify advice and information to be given to patient or carer.** | * Standard information leaflet regarding care after implant insertion given to all patients. * Clients should be advised that complications arising from the local anaesthetic are unlikely. If however they need to seek advice they should contact their GP or Department of Sexual Health. If necessary seek appropriate advice and assistance. |
| **3.10** | **Specify advice to be given to patient or carer regarding follow-up** (if required) | No formal follow up but advised to return if any concerns. |
| **3.11** | **Facilities & supplies which should be available at sites where care is provided** | * Equipment and medication for use in the event of cardiac arrest or anaphylaxis |

**4. Records and audit**

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| --- | --- | --- |
| **4.1** | **Records / audit trail** | Records must include:   * Patient’s name, address, date of birth * Contact details of GP (if registered) * Completion of departmental proformas for the CASH history, Nexplanon and vulnerability assessment for all < 18’s - to include Fraser competence, if appropriate. * Use of these proformas ensures all relevant medical information has been recorded. These have been created in line with the Faculty Service Standards 2013. * A statement that supply is by a PGD * Any inclusions or exclusions from the PGD * Advice given about the medication including side effects, benefits and when and what to do if any concerns * Details of any adverse drug reactions and what action taken * Any referral arrangements * Any administration outside the terms of the product marketing authorisation * The consent of the individual * If the individual is < 13 action taken * If the individual is < 16 document competency using Fraser   Guidelines   * If individual is aged 16 and over and not competent, record action taken * Record the name, dose, brand and quantity supplied * Record batch number and expiry date * Record follow up and sign posting arrangements * Signature & name of practitioner who administered the medication which may be electronic. |
| **4.2** | **Audit** | * Midwives are accountable for their personal clinical practice. * Midwives using this PGD must keep a record, and audits should be performed in line with requests from the Service Manager. * Any incidents related to use of this PGD must be reported to the Service Manager. |
| **4.3** | **References used in development of PGD** | * Manufacturer’s Summary of Product Characteristics: Lidocaine: https://www.medicines.org.uk/emc/medicine/20887 * Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press   <http://www.medicinescomplete.com>   * National Institute for Health and Care Excellence (2013). Patient Group Directions. Medicines Practice Guidelines 2. <http://www.nice.org.uk/guidance/MPG2> * Faculty of Sexual & Reproductive Healthcare Guidance on Progestogen Only Implants (Feb 2021). [FSRH Clinical Guideline: Progestogen-only Implant (February 2021) - Faculty of Sexual and Reproductive Healthcare](https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-implants-feb-2014/) |

# Management of the PGD

# PGD developed by: Dr Jo Halsey (Specialty Doctor), Chris Loader (Clinical Lead Sexual Health Nurse), and Peter Davies (Senior Clinical Pharmacist)

1. **Name and job title of individual(s) responsible for:**
   1. ensuring relevant staff are trained in the use of the PGD
   2. ensuring staff competency to operate under the PGD is assessed & confirmed
   3. ensuring an up to date list of staff assessed as competent and authorised to operate under this PGD is maintained
   4. ensuring the PGD is reviewed regularly
   5. ensuring regular audit of compliance with the PGD.
      * Charlotte Ashman Scott (midwife), Dr Joanna Halsey (Speciality Doctor) & Chris Loader (Clinical Lead Sexual Health Nurse)
2. **PGD supported by:** *(to be signed where indicated)*
   1. Head of service/clinical lead:…………………………….. Date:……
   2. DSN or relevant professional lead:…............................. Date:……
3. **PGD authorised for use in SFT by:**

i) Chief Pharmacist:……………………………………… Date:……

ii) Director of Nursing:……………………………………. Date:……

iii) Medical Director:……………………………………….. Date:……

**6. Individual authorisation**

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTICE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE AND IN ACCORDANCE WITH THEIR OWN CODE OF PROFESSIONAL CONDUCT.

**DECLARATION by healthcare professional:**

* I have read and understand this PGD;
* I have been appropriately trained to understand the inclusion and exclusion criteria listed, the particular cautions in use and the record-keeping required to administer medication in accordance with this PGD
* The training has included a one to one training session with a senior clinician within the Department of Sexual Health, and on-going clinical supervision/support regarding the use of the PGD, as is required.
* I confirm that I have been assessed for my knowledge and clinical competency in relation to this PGD
* I confirm that I am competent to undertake administration of this medication in accordance with this PGD
* I confirm that I will ensure that I remain up to date in all aspects of the administration of this medicine.

Healthcare Professional’s Name………………………………………..

Registration number………………………… Expiry date…………………

Signature:…………………………….. …. Date:……………………………

**Declaration by Authorising Manager[[1]](#footnote-1):**

Managers should only authorise staff who have received the required training and are competent to work to this PGD. Each authorised practitioner should be provided with an individual copy of the PGD, which they should also sign to declare themselves competent. A copy of the signed document should be kept by the individual staff member. The authorising manager should retain a copy of the signed individual; authorisation page.

I have read and understood the PGD and authorise the staff member named above to operate in accordance with this PGD.

Authorising manager’s name:…………………………………

Job title:…………………………………….

Signature:…………………………….. Date:…………………………..

1. The term manager refers to the person taking responsibility for authorising healthcare professionals to operate under the terms of this PGD and includes lead clinicians, nurse manager etc. [↑](#footnote-ref-1)