

This Patient Group Direction (PGD) must only be used by registered healthcare 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.

PATIENT GROUP DIRECTION (PGD)

Administration of lidocaine hydrochloride 1% injection to facilitate insertion and/or removal of subdermal etonogestrel (e.g. Nexplanon®) implant in University Hospitals Sussex NHS Foundation Trust Sexual Health & Contraception (SHAC) Service

Version Number 1.0

| Change History | |
|---------------------------|-----------------------|
| Version and Date | Change details |
| Version 1 October 2020 | New template |

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

PGD DEVELOPMENT GROUP

| | |
|--------------------------------------|------------------------------|
| Date PGD template comes into effect: | 1st October 2020 |
| Review date | March 2023 |
| Expiry date: | 31 st August 2023 |

This PGD template has been peer reviewed by the Reproductive Health PGDs 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 September 2020.

This section MUST REMAIN when a PGD is adopted by an organisation.

| Name | Designation |
|-------------------|---|
| Dr Cindy Farmer | Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH) |
| Michelle Jenkins | Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH) |
| Michael Nevill | Director of Nursing British Pregnancy Advisory Service (BPAS) |
| Katie Girling | British Pregnancy Advisory Service (BPAS) |
| Julia Hogan | CASH Nurse Consultant Marie Stopes UK |
| Kate Devonport | National Unplanned Pregnancy Association (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) |
| Leanne Bobb | English HIV and Sexual Health Commissioners Group (EHSHCG) |
| Deborah Redknapp | English HIV and Sexual Health Commissioners Group (EHSHCG) |
| Dipti Patel | Local authority pharmacist |
| Emma Anderson | Centre for Postgraduate Pharmacy Education (CPPE) |
| Dr Kathy French | Pan London PGD working group |
| Dr Sarah Pillai | Pan London PGD working group |
| Alison Crompton | Community pharmacist |
| Andrea Smith | Community pharmacist |
| Lisa Knight | Community Health Services pharmacist |
| Bola Sotubo | Clinical Commissioning Group pharmacist |
| Tracy Rogers | Associate Director Specialist Pharmacy Service |
| Sandra Wolper | Associate Director Specialist Pharmacy Service |
| Amanda Cooper | Specialist Pharmacy Service |

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| Jo Jenkins (Woking Group Co-ordinator) | Specialist Pharmacist PGDs Specialist Pharmacy Service |
| Silvia Ceci | Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service |

PGD approval - meets local need and guidelines

| Name | Job title and organisation | Signature | Date |
|---|--|----------------------------------|----------------------|
| Lead author: Reproductive Health PGDs Short Life Working Group | As listed on Page 2/3 | | |
| Lead Doctor: Dr Juliet Bowie | Associate Specialist, SHAC Service, UHSussex | Email approval | 03/12/20 |
| Lead pharmacist: Claire Richardson | Lead Pharmacist, HIV & Sexual Health Service, UHSussex | Email approval | 10/12/20 |
| Lead Clinician for area: Dr Debbie Williams | Consultant (HIV & GUM), SHAC, UHSussex | Email approval | 26/11/20 |
| Reviewed by: Dr Daniel Richardson Ruth Bailey | Consultant HIV & SHAC Service, UHSussex Nurse Team Leader, SHAC Service, UHSussex | Email approval Email approval | 25/11/20 03/12/20 |
| Representative of other professional group using PGD Wendy Gardiner | Advanced Nurse Practitioner, SHAC Service, UHSussex | Email approval | 25/11/20 |

Organisational authorisations

University Hospitals Sussex NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Sexual Health & Contraception (SHAC) Service.

Limitations to authorisation

Only Registered Nurses who work within the SHAC Service, hold a relevant contraception qualification, and are signed to the PGD.

| Name | Signature & Name | Date |
|---|------------------------------------|------------|
| Chair of PGD Group | Joanne Pendlebury – email approval | April 2021 |
| Chief Pharmacist | Mike Cross – email approval | April 2021 |
| Medicines Governance Group chair | Mike Okorie – email approval | April 2021 |

Local enquiries regarding the use of this PGD may be directed to uhsussex.pgdgroup@nhs.net or PGD group chair.

Appendix 1 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD.

Approved date: April 2021 Expiry date: 31st August 2023

1. Characteristics of staff

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| <p>Qualifications and professional registration</p> | <p>Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation.</p> <p>Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.</p> |
| <p>Initial training</p> | <p>The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of individuals ensuring safe provision of the medicines listed in accordance with local policy.</p> <p>Recommended requirement for training would be successful completion of a relevant module/course accredited or endorsed by the FSRH, CPPE or a university or advised in the RCN training directory. In addition, completion of the FSRH Letter of competence (LOC) in Subdermal implants (LOC SDI/LOC SDI-IO) or locally agreed additional training and been assessed as competent at the insertion and/or removal of the subdermal implant which should also include training and been assessed as competent in the administration of lidocaine</p> <p>The healthcare professional must keep up to date with current FSRH guidance relevant to the insertion/removal of the contraceptive implant including any relevant MHRA Drug Safety Updates.</p> <p>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.</p> <p>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</p> <p>Register and complete PGD training module (certificate can be printed out as evidence) https://portal.e-lfh.org.uk/ (3 yearly)</p> <p>Has undertaken training appropriate to recognise and manage allergic/anaphylactic reactions.</p> <p>Has undertaken appropriate Trust approved resuscitation training.</p> |
| <p>Competency assessment</p> | <ul style="list-style-type: none"> • Individuals operating under this PGD must be assessed as competent (see section 7) or complete a self-declaration of competence for contraception supply. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions |
| <p>Ongoing training and competency</p> | <ul style="list-style-type: none"> • Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. |

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| | <ul style="list-style-type: none">• Organisational PGD and/or medication training as required by employing Trust/organisation, including:<ul style="list-style-type: none">➤ PGD e-learning 3 yearly➤ Up to date with mandatory training |
| <p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p> | |

2. Clinical condition or situation to which this PGD applies

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| Clinical condition or situation to which this PGD applies | Local anaesthetic for insertion and/or removal of subdermal etonogestrel subdermal contraceptive implant. |
| Criteria for inclusion | <ul style="list-style-type: none"> Any individual requiring the insertion and/or removal of etonogestrel subdermal contraceptive implant under the etonogestrel subdermal contraceptive implant PGD. Individuals requiring lidocaine for the insertion of a subdermal contraceptive implant should also meet the inclusion criteria of the etonogestrel subdermal contraceptive implant PGD. Consent given. |
| Criteria for exclusion | <ul style="list-style-type: none"> Consent not given. Individuals under 16 years of age and assessed as not competent using Fraser Guidelines. Individuals 16 years of age and over and assessed as lacking capacity to consent. Known hypersensitivity to the active ingredient or to any constituent of the product - see Summary of Product Characteristics or other amide type anaesthetics Individual who had received a previous maximum infiltration of local anaesthetic within 4 hours <p>Cardiovascular Disease</p> <ul style="list-style-type: none"> Complete heart block Hypovolaemia <p>Other conditions</p> <ul style="list-style-type: none"> Porphyria <p>Interacting medications</p> <ul style="list-style-type: none"> Interacting medicines – see current British National Formulary (BNF) www.bnf.org or individual product SPC http://www.medicines.org.uk |
| Cautions including any relevant action to be taken | <ul style="list-style-type: none"> If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. |
| Action to be taken if the individual is excluded or declines treatment | <ul style="list-style-type: none"> 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. |

2. Description of treatment

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| Name, strength & formulation of drug | Lidocaine 1% w/v (10 mg in 1 mL) in 2mL, 5 mL or 10 mL ampoules |
| Legal category | POM |
| Route of administration | Subcutaneous or intradermal surface infiltration only |
| Off label use | <p>Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with pharmacy/Medicines Management.</p> <p>Where a medicine is recommended off-label consider, as part of the consent process, informing the individual that the medicine is being offered in accordance with national guidance but that this is outside the product licence.</p> |
| Dose and frequency of administration | <p>A dose of 5-20mg (0.5-2ml) should be used for insertion and 5-20mg (0.5-2ml) for removal if required.</p> <p>Maximum total dose on any occasion should not exceed 40mg (4ml).</p> |
| Duration of treatment | A maximum of two doses are permitted under this PGD in a single episode of care – one for insertion and one for removal (if required) to a maximum of 40mg (4ml) total. |
| Storage | Medicines must be stored securely according to national guidelines. |
| Drug interactions | <p>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 and FSRH CEU Guidance: Drug Interactions with Hormonal Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/</p> |
| Identification & management of adverse reactions | <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org</p> <p>Note when used for surface anaesthesia rapid and extensive absorption may result in systemic side effects.</p> <p>CNS effects include:</p> <ul style="list-style-type: none"> • Confusion • Respiratory depression • Convulsions • Hypotension • Bradycardia • Hypersensitivity |

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| | <ul style="list-style-type: none"> • If side effects are severe, intralipids may be required (treatment for toxicity e.g. following inadvertent IV injection. • Intralipids are located in A&E department. • Medical personnel must be called. • Intralipids to be administered by medical personnel. |
| Additional facilities and supplies | <ul style="list-style-type: none"> • Access to working telephone • Suitable waste disposal facilities • Immediate access to in-date anaphylaxis kit (IM adrenaline 1:1000) |
| Management of and reporting procedure for adverse reactions | <ul style="list-style-type: none"> • Healthcare professionals and individuals 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 individual's medical record. • Report via organisation incident policy. |
| Written information and further advice to be given to individual | <ul style="list-style-type: none"> • Offer Manufacturer's Patient Information Leaflet (PIL) - available from the electronic Medicines Compendium website: www.medicines.org.uk • Explain mode of action, side effects, and benefits of the medicine. |
| Advice/follow up treatment | <p>Advise individual:</p> <ul style="list-style-type: none"> • How to care for the injection site and advise to return if concerns about the injection site. • Give information on who to contact in the event of an adverse reaction or concerns. |
| Records | <p>Record:</p> <ul style="list-style-type: none"> • The consent of the individual and <ul style="list-style-type: none"> ○ If individual is under 13 years of age record action taken ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. ○ If individual over 16 years of age and not competent, record action taken • Individual's name, address and date of birth • GP contact details where appropriate • Attendance date • Reason for attendance • Relevant past and present medical and family history, including drug history • Any known allergy • Relevant examination findings • Inclusion or exclusion from PGD • A statement that administration is for insertion of subdermal implant and is by using a 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 marketing authorisation |

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| | <ul style="list-style-type: none"> • The consent of the individual • If individual is under 13 years of age record action taken • If individual is under 16 years of age document competency using Fraser guidelines • If individual over 16 years of age and not competent, record action taken • Any referral arrangements • Record the name/brand, dose of the medication, site of injection • Record batch number and expiry date according to local policy or national guidelines • Record follow up and/or signposting arrangements • Any other relevant information that was provided to the individual • Name and signature (which may be an electronic signature) of the nurse supplying and administering the medicine <p>Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p> |
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Audit

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| Plan for audit , It is essential for PGD renewal that audits have occurred. | Service audit to be completed using the recommended Sussex PGD audit template. N. B. Individual PGD users should keep records to audit their own use of PGDs / procedures. |
| Frequency | Minimum of once in lifetime of PGD 2 years after start date of PGD to inform PGD review. |
| Nominated lead to manage audit | Advanced Nurse Practitioner/Clinical Nurse Specialist, SHAC Service will manage Service PGD audit process and support / guide those completing the audit. SHAC Nurse(s) who use the PGD will complete the service audit. |

3. Key references

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| Key references (accessed May 2020) | <ul style="list-style-type: none"> • Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 |
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| | <ul style="list-style-type: none">• Resuscitation Council (UK) Emergency Treatment of anaphylactic reactions: Guidelines for health care providers Resuscitation Council, 2013 www.resus.org.uk• FSRH Clinical Guideline: Progestogen-only Implant (February 2014) https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-implants-feb-2014/• Learning for Health https://portal.e-lfh.org.uk/• UHSussex policies and procedures:<ul style="list-style-type: none">➤ C085 – Policy for Patient Group Directions: accessed on UH Sussex intranet https://www.bsuh.nhs.uk/search/?q=c085+policy+for+patient+group+directions➤ SHAC Service Standard Operating Procedure for supply of medicines following telephone / video consultations. |
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Appendix A - Registered health professional authorisation sheet

PGD Name/Version: **Administration of lidocaine hydrochloride 1% injection to facilitate insertion and/or removal of subdermal etonogestrel (e.g. Nexplanon®) implant (Version 1)**

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

| I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct. | | | |
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| Name | Designation | Signature | Date |
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Authorising manager

| I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of <u>University Hospitals Sussex NHS Foundation Trust</u> for the above named health care professionals who have signed the PGD to work under it. | | | |
|---|--------------------|------------------|-------------|
| Name | Designation | Signature | Date |
| | | | |

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

SHAC SERVICE RETENTION OF PGD AUTHORISATION RECORDS

Records of the authorisation of nurses for the use of this PGD are stored as follows:

- **HARD COPY:** A paper copy of the signature sheet will be kept with the PGD in the PGD Master Copy File in the SHAC Nurse Management Office (if hard copy retained).

- **ELECTRONIC RECORD:**
 - A scanned copy of each authorisation sheet is saved on to the service specific file.

 - An electronic record of SHAC Nurse authorisation for this PGD is recorded on the SHAC Service PGD Assessment Record database which is stored on to the service specific file.

- **INDIVIDUALS:**
 - Individual nurses are provided with the PGD assessment sheet which details the assessment process for PGD approval for their own records.

A copy of this document is stored in the individual nurses' Personal File