NHS
York and Scarborough Teaching Hospitals
NHS Foundation Trust

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 York and North Yorkshire Sexual health services including specialist clinical outreach services

Version Number 1.1

Change History	
Version and Date	**Change details**
Version 1 October 2020	New template
Version 1.1 June 2021	**Dose and frequency of administration section amended to:** **Insertion:** Initially 5-20mg (0.5-2ml). A further dose of up to 10mg (1ml) may be used if required to a total maximum dose of 30mg (3ml). **Removal:** 5-10mg (0.5-1ml). **Total maximum dose for concurrent removal and insertion is 40mg (4ml).**

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.

Reference Number: v1
Valid from: March 2022
Review date: March 2023
Expiry date: 31st August 2023

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1st October 2020
Review date	March 2023
Expiry date:	31st 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
Jo Jenkins (Woking	Specialist Pharmacist PGDs Specialist Pharmacy Service

Group Co-ordinator)	
Silvia Ceci	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

The PGD is not legally valid until it has had the relevant organisational authorisations.

Name	Job title and organisation	Signature	Date
Senior doctor	Ian Fairley, Lead Consultant		07/06/22
Senior pharmacist	~~Jill McEnaney~~ KATE NIXON		11/8/22
Senior representative of professional group using the PGD	Simone Layton, Advanced Nurse Specialist		9/6/22
Person signing on behalf of <u>authorising body</u>	Jennie Booth, Lead Nurse Medicines Management		04.08.2022
	Stuart Parkes, Chief Pharmacist		15/8/22

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. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

- Trust PGD policy is available via on Staff Room
- An audit must be completed at renewal- see Trust PGD Policy for audit requirements

1. Characteristics of staff

The practitioner should be aware of any change to the recommendations for **lidocaine hydrochloride 1% injection** and current guidance from national authorities e.g. the BNF and NICE.

It is the responsibility of the individual to keep up to date with continued professional development and to work within the limitations of their individual scope of practice

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	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. 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 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. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent. 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
Competency assessment	• 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
Ongoing training and competency	• 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. • Completion of Trust PGD hub e-learning
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

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	• 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	• 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 **Cardiovascular Disease** • Complete heart block • Hypovolaemia **Other conditions** • Porphyria **Interacting medications** • 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	• 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	• 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.

1. Description of treatment

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	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. 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.
Dose and frequency of administration	**Insertion:** Initially 5-20mg (0.5-2ml). A further dose of up to 10mg (1ml) may be used if required to a total maximum dose of 30mg (3ml). **Removal:** 5-10mg (0.5-1ml). **Total maximum dose for concurrent removal and insertion is 40mg (4ml).**
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) as detailed above to a maximum dose of 40mg (4ml) total.
Storage	Medicines must be stored securely according to national guidelines.
Drug interactions	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/
Identification & management of adverse reactions	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 Note when used for surface anaesthesia rapid and extensive absorption may result in systemic side effects. CNS effects include: • Confusion • Respiratory depression • Convulsions • Hypotension • Bradycardia • Hypersensitivity

Additional facilities and supplies	• 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	• 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	• Offer Manufacturer's Patient Information Leaflet (PIL). • Explain mode of action, side effects, and benefits of the medicine.
Advice/follow up treatment	Advise individual: • 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	**Record:**
	• The consent of the individual and
	  ○ 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
	• 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 Records should be signed and dated (or a password-controlled e-records) and securely kept for a defined period in line with local policy. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

2. Key references

Key references (accessed May 2020)	• 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 • Resuscitation Council (UK) Emergency Treatment of anaphylactic reactions: Guidelines for health care providers Resuscitation Council, 2013 www.resus.org.uk • FSRH Clinical Guideline: FSRH Clinical Guideline: Progestogen-only Implant (February 2021) https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-implants-feb-2014/

Appendix A - Registered health professional authorisation sheet

PGD - Administration of lidocaine hydrochloride 1% injection to facilitate insertion and/or removal of subdermal etonogestrel (e.g. Nexplanon®) implant V 1
Valid from: March 2022 Expiry: 31st August 2023

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.			
Name	**Designation**	**Signature**	**Date**

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 York & Scarborough Teaching Hospital NHS Foundation Trust 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.

When the expiry date is exceeded, this PGD ceases to be a legal document. Staff authorisation records must be maintained for 8 years if the PGD relates to adults only, 10 years for implants and 25 years after the expiry date if the PGD relates to children