Patient Group Direction for the administration of : lidocaine hydrochloride 1% prior to the insertion or removal of the etonogestrel subdermal contraceptive implant	
Title of patient group direction	Patient Group Direction for the administration of lidocaine hydrochloride 1% prior to the insertion or removal of the etonogestrel subdermal contraceptive implant
Approved at	NMP/PGD Group
PGD approved / valid from	July 2018
Review date	February 2021
Expiry date	July 2021
Clinical area(s) where PGD applies	Sexual heath and HIV outreach services within contractive and sexual health clinics, and in sexual health outreach services/locations
Identified Lead for monitoring / review and contact details	Wendy Billsborough

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

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 . Dr Frances Baker Alison Chorlton – Lead Nurse Sexual Health Dr Ian Fairley, Clinical Director Lead

CLINICAL CONDITION	
Condition	Subdermal infiltration prior to insertion or removal of the etonogestrel sub-dermal contraceptive implant
Inclusion criteria	• Women 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.
Exclusion criteria	• Child aged 12 years or under • Children under 16 years not considered competent under Fraser guidelines • Known hypersensitivity to lidocaine hydrochloride or any of the excipients in the product • Interacting medicines • 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 • Renal impairment • Hepatic impairment
Action if 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

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		**NO**
Form	Subdermal		
Strength	1% (10 mg in 1 mL) in 2mL, 5 mL 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	Injection		
Total Treatment Quantity	A maximum of 2mL in total may be used as appropriate to ensure insertion or removal can proceed without discomfort or up to 3mL when replacing an implant.		
Interactions with other medicines (This must include all potentially serious interactions listed in the BNF)	Interactions are rare when used as a local anaesthetic • Check any medicines in appendix 1 of the British National Formulary (BNF) or 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: • Respiratory depression • Convulsions • Hypotension • Bradycardia • Hypersensitivity See Summary of Product Characteristics (SPC) for full details	**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/latoxicity 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

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 25°C
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 • Any reason for exclusion and action taken • Any known allergies • 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 and any follow up • 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 <u>Education, training, qualifications and competencies</u>: • Sexual health Nurse • Clinical competence in sexual history taking. • Completion of the Trust PGD awareness session or Trust HUB e-learning. • Knowledge of the current FSRH Progestogen Only implant guidance and completion of the e-SRH module 17 theory training for etonorgestrel subdermal implant – (assessed via e-lfh) • 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) • Knowledge base of the interaction of lidocaine with other drugs, and other exclusions and

	contraindications to lidocaine • Training to establish competence in working within the PGD for the administration of lidocaine • Maintain professional accountability with the NMC and ensure continual professional development • 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 educational clinical governance sessions and nurse updates • Ensure keeps up to date with any changes to FSRH/manufacturers guidance relevant to this PGD

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

PGD Development / Review Team – responsible for PGD content

Title	Name	Signature	Date
Lead Author	WENDY BILLSBOROUGH	Wendy Billsborough	2/7/2018.
Clinical Director Lead Approval	Dr IAN FAIRLEI		28/06/18.
Directorate Pharmacy Lead Approval	JILL McENANEY	Jill McEnaney	10.8.18

PGD Approved by the NMP/PGD Group

Title	Name	Signature	Date
NMP Lead / Lead Nurse Medicines Management	Jennie Booth		16.8.18
Chief Pharmacist / Deputy Chief Pharmacist	Stuart Parkes		15/8/18

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

Staff authorised to work under this PGD	
Ward / Department	Sexual Health and Sexual Health Outreach Clinics
Professionals to whom this Patient Group Direction applies	Qualified nurses who work within sexual health and have completed the agreed training programme

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:

Name (Capitals)	Sign	Job Title	Authorising Manager	Date
This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved	This is to be completed when the PGD has been approved

When the review date is exceeded, this PGD ceases to be a legal document	
TEMPLATE DOCUMENTATION CONTROL	
The template documentation control refers to the PGD template not the completed PGD. **Do not alter this section.**	
Author:	Jennie Booth, Lead Nurse Medicines Management Carol Belt, Principal Pharmacy Technician Stuart Parkes, Deputy Chief Pharmacist
Owner:	NMP/PGD Group
Date of issue:	February 2018
Version:	3
Approved by	NMP/PGD Group
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