Patient Group Direction For The Administration Of Lidocaine 1% Injection For The Insertion/Removal Of The 68mg Etonogesterel Contraceptive Implant By Nurses And Midwives Working Within NHS Grampian

<table>
<thead>
<tr>
<th>Lead Author:</th>
<th>Consultation Group:</th>
<th>Approver:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicines Management Specialist Nurse</td>
<td>See relevant page in the PGD</td>
<td>Medicine Guidelines and Policies Group</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Signature:</th>
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<table>
<thead>
<tr>
<th>Identifier:</th>
<th>Review Date:</th>
<th>Date Approved:</th>
</tr>
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<tbody>
<tr>
<td>NHSG/PGD/lido_eton/MGPG789</td>
<td>April 2018</td>
<td>April 2016</td>
</tr>
</tbody>
</table>

A Patient Group Direction is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by Doctors, Pharmacists and other appropriate professionals, approved by the Employer and advised by the relevant professional advisory committees. In most cases, appropriate clinical care is provided on an individual basis by a specific prescriber to a specific individual patient. Patient Group Directions should only be considered where they offer a benefit to patient care without compromising patient safety in any way.

Uncontrolled when printed

Version 5
Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Approval date of PGD that is being superseded</th>
<th>Summary of Changes</th>
<th>Section heading</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 2016</td>
<td>March 2013</td>
<td>Updated to new PGD template</td>
<td></td>
</tr>
<tr>
<td>April 2016</td>
<td>March 2013</td>
<td>Changed strength of Lidocaine from 2% to 1% in line with SPC and FRSH</td>
<td>Throughout</td>
</tr>
<tr>
<td>April 2016</td>
<td>March 2013</td>
<td>Added antipsychotics, beta blockers and anti-arrhythmics under precautions.</td>
<td>Precautions and special warnings</td>
</tr>
<tr>
<td>April 2016</td>
<td>March 2013</td>
<td>Breast feeding added as a precaution.</td>
<td>Precautions and special warnings</td>
</tr>
<tr>
<td>April 2016</td>
<td>March 2013</td>
<td>Added further medications to concurrent medication list.</td>
<td>Concurrent medications</td>
</tr>
<tr>
<td>April 2016</td>
<td>March 2013</td>
<td>Added common side effects</td>
<td>Adverse effects</td>
</tr>
</tbody>
</table>

Subject: Patient Group Direction
Identifier: NHSG/PGD/lido_eton/MGP6789
Replaces: NHSG/PGD/lido_eton/MGP652
Keyword(s): PGD Patient Group Direction, Implant, Contraceptive, Lidocaine, Etonogesterol

Policy Statement:

It is the responsibility of individual nurses, midwives and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect patient, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD as well as its dissemination. Pharmacy and Medicines Directorate is responsible for ensuring registration of this document.
**Review date:** At least every 2 years or sooner if current treatment recommendations change.

Document: Drafted: August 2006  
Completed: August 2006  
(published – June 2016)
Patient Group Direction for the Administration of Lidocaine 1% Injection For The Insertion/Removal Of The 68mg Etonogestrel Contraceptive Implant By Nurses and Midwives Working Within NHS Grampian

Clinical indication to which this PGD applies

| Definition of situation/condition | This patient group direction (PGD) will allow nurses and midwives to be authorised to subcutaneously administer lidocaine 1% injection to individuals prior to the removal or insertion of the 68mg etonogestrel contraceptive implant Nexplanon®.

This PGD should be used in conjunction with the PGD for the Insertion of Etonogestrel Contraceptive Implant.

This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF) and individual Summary of Product Characteristics (SPC). |
| Inclusion criteria | Individuals aged between 14 years and up to and including 49 years who require the insertion or removal of the 68mg etonogestrel contraceptive implant Nexplanon®. |
| Exclusion criteria | • Known anaphylactic hypersensitivity to Lidocaine or any of the excipients.
• Aged less than 14 years.
• Inflammation or infection in the tissues to be injected.
• Porphyria.
• Known impaired cardiac conduction. |
| Precautions and special warnings | Lidocaine should be used with caution in patients with:
Myasthenia Gravis, epilepsy, congestive cardiac failure, bradycardia, impaired respiratory function, or impaired hepatic function. |
|  | Lidocaine should be used with caution in patients taking the following medications; Antipsychotics, beta blockers and anti-arrhythmics. |
Breast feeding: Small amounts of lidocaine are secreted into breast milk and the possibility of an allergic reaction in the infant, albeit remote, should be borne in mind when using lidocaine in nursing mothers.

Facilities and equipment for resuscitation should be readily available at all times.

**Referral criteria**

Patients who fall into the categories detailed in the exclusion criteria.

**Action if excluded from treatment**

If a patient is excluded from treatment under this PGD, medical advice should be sought – refer to a doctor.

The reason why the patient was excluded under the PGD will be documented in the patient’s medical notes.

**Action if patient declines treatment**

The patient should be advised of the risks of not receiving the administration of lidocaine 1%. The 68mg etonogestrel contraceptive implant Nexplanon® insertion or removal should **not** proceed under this PGD.

Record outcome in Patient Medication Record if appropriate and refer the patient to their general practitioner.

**Consent**

Prior to the administration of the drug, valid consent must be obtained. Consent must be in line with current NHSG “Staff Policy for Obtaining Consent for Clinical Procedures and Healthcare Interventions”. See link below.

http://intranet.grampian.scot.nhs.uk/ccc_nhsg/15692.html?pMenuID=460&

**Description of treatment available under the PGD**

<table>
<thead>
<tr>
<th><strong>Name of medicine</strong></th>
<th>Lidocaine Hydrochloride Injection BP 1% w/v.</th>
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<tbody>
<tr>
<td><strong>Legal status</strong></td>
<td>Lidocaine 1% is a Prescription-only Medicine (PoM).</td>
</tr>
<tr>
<td><strong>Form/Strength</strong></td>
<td>Solution for injection. Each 1mL of solution contains 20mg of Lidocaine Hydrochloride.</td>
</tr>
</tbody>
</table>
Subcutaneous injection to be given under aseptic technique by appropriately trained staff only.

Great care must be taken to avoid intravascular injection. Syringe to be drawn back to ensure it is not in a vessel before injection of Lidocaine.

**For implant insertion:**
Clean insertion site with antiseptic solution prior to administration, (8-10 cm above the medial epicondyle of the humerus).

Lidocaine 1% is injected subcutaneously along the planned line of implant insertion on the medial aspect of the upper arm. The needle should be inserted subcutaneously and 0.5mL injected directly below the insertion point.

The needle should then be advanced subcutaneously in the line of implant insertion to its full length (3.5cm). Approximately 2.0mL of lidocaine 1% should be injected evenly along the subcutaneous needle track as the needle is withdrawn. A sterile swab should be placed over the injection site in case of bleeding.

**Maximum dose for insertion under this PGD is 5mL**

**For implant removal:**
Clean site with antiseptic solution, refer to insertion notes, implant should be palpated then mark the distal end with sterile marker as a guide prior to insertion of lidocaine.

Between 0.5mL - 2mL lidocaine 1% is injected subcutaneously directly beneath the distal tip of the implant to be removed. The position for injection is identified by first pushing the proximal end of the implant distally and towards the skin surface. The lidocaine 1% should be injected beneath the position of the distal tip when this pressure is exerted.

**Maximum dose for removal under this PGD is 3mL.**

The anaesthetic effect should be tested by light pressure on the overlying skin with the needle tip. The patient may be aware of pressure, but should not feel any sharp sensation. When the area is numb, proceed with implant removal.

After the maximum dose of lidocaine 1% for either insertion or removal has been injected and a painful sharp sensation is still felt with needle pressure, refer to doctor. An increased local anaesthetic dose may be needed.
| **Dosage/Total Dose** | Single administration. Total maximum doses under this PGD are:  
Insertion of implant - 5mL.  
Removal of implant - 3mL. |
<table>
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<tbody>
<tr>
<td><strong>Duration of treatment</strong></td>
<td>Single administration.</td>
</tr>
<tr>
<td><strong>Storage requirements</strong></td>
<td>Store below 25°C and keep in outer box.</td>
</tr>
<tr>
<td><strong>Follow-up (if applicable)</strong></td>
<td>Patient advised to remain on premises for at least 15 minutes after injection to monitor for any adverse reaction. If the patient feels at all unwell they should speak to a nurse or midwife. If necessary a doctor or the patient’s GP should be contacted for advice.</td>
</tr>
</tbody>
</table>
| **Advice to patient (Verbal)** | The adverse effects of lidocaine administration must be clearly explained to the patient before administration, including pain produced from the injection of lidocaine and subsequent short stinging sensation.  
Advise the patient the local anaesthetic will have its peak effect within 2-3 minutes and the effects will last approximately 40 minutes. Full sensation should return within 2 hours. |
| **Advice to patient (Written)** | The patient information leaflet contained in the medicine(s) should be made accessible to the patient, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.  
Copies of Patient Information Leaflets and SPCs for all medicines can be found at [http://www.medicines.org.uk](http://www.medicines.org.uk) |
| **Concurrent Medications/Drug Interactions** | Lidocaine 1% can interact with the following medications; Anti-arrhythmics, antipsychotics, beta blockers, loop diuretics, thiazides diuretics and cimetidine.  
This list is not exhaustive. Refer to BNF and SPC for complete list. |
Adverse effects and managing possible adverse reactions

<table>
<thead>
<tr>
<th>Common side effects:</th>
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<tr>
<td>• flushing, redness of the skin</td>
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<tr>
<td>• small red or purple spots on the skin</td>
</tr>
<tr>
<td>• swelling at the site of application</td>
</tr>
<tr>
<td>• unusually warm skin.</td>
</tr>
</tbody>
</table>

Less common side effects:

- bruising, burning, pain, or bleeding at the site of application
- nausea.
- vomiting.

Inadvertent intravascular injection of lidocaine 1% may cause bradycardia, light-headedness, dizziness, blurred vision, restlessness, tremors and occasionally convulsions. If this occurs, stop injecting, and calmly but quickly call for assistance. Lidocaine 1% is rapidly metabolised and any symptoms should resolve within 15 - 20 minutes.

Allergy to lidocaine 1% causing anaphylaxis is very rare. Symptoms include; excessive pain, itching or swelling at injection site. Breathlessness and collapse with tachycardia and hypotension.

This list is not exhaustive. Please also refer to current BNF and manufacturers SPC for details of all potential adverse reactions.

BNF - [https://www.medicinescomplete.com/mc/bnf/current/](https://www.medicinescomplete.com/mc/bnf/current/)


If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

Report the reaction to the MHRA using the Yellow Card System. [https://yellowcard.mhra.gov.uk/](https://yellowcard.mhra.gov.uk/)
**Medical advice in cases of anaphylaxis**

Injections of IM adrenaline/epinephrine 1:1000 must be available to treat an anaphylactic reaction should this occur. Medical advice must be sought as soon as possible from a doctor if any patient develops any signs of hypersensitivity. If there is a delay in medical support arriving and the condition of the patient is deteriorating then an emergency ambulance must be called on 999 or direct via ambulance control or dial 2222 (hospital internal) according to local procedure, or seek urgent medical advice. (Refer to Patient Group Direction for the administration of adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals).

**Facilities and supplies required**

The following should be available at sites where the medication is to be supplied/administered:

- Appropriate storage.
- An acceptable level of privacy to respect patient’s right to confidentiality and safety.
- Resuscitation equipment.
- Access to medical support (this may be via the telephone).
- Approved equipment for the disposal of used materials
- Clean and tidy work areas.
- Copies of the current PGD for the medicine specified in the PGD.
- PGD for the Insertion of Etonogestrel Contraceptive Implant.
- PGD for the administration of Adrenaline (epinephrine) in cases of suspected anaphylactic reactions by qualified health professionals.

**Characteristics of staff authorised to supply/administer medicine under PGD**

<table>
<thead>
<tr>
<th>Professional qualifications</th>
<th>Registered Nurses and Midwives as recognised by the NMC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialist competencies</td>
<td>Be competent to assess the patient’s capacity to understand the nature and purpose of the administration in order for the patient to give or refuse consent.</td>
</tr>
</tbody>
</table>
Has undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD.

The practitioner must be familiar with the SPC for all medicines supplied in accordance with this PGD.

Be aware of current treatment recommendations and be competent to discuss issues about the drug with the patient.

Is competent in the administration of the drug.

<table>
<thead>
<tr>
<th>Ongoing training and competency</th>
<th>Have attended basic life support training which is required to be updated annually.</th>
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<tbody>
<tr>
<td></td>
<td>Have undertaken the NHS e-anaphylaxis training session (and annual updates) which covers all aspects of the identification and management of anaphylaxis. This can be accessed via eKSF, or the AT Learning® tool.</td>
</tr>
<tr>
<td></td>
<td>Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct.</td>
</tr>
</tbody>
</table>

**Professional managers/Lead Nurses will be responsible for:**

- Ensuring that the current PGD is available to staff providing care under this direction.
- Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.

**Documentation**

<table>
<thead>
<tr>
<th>Authorisation of administration</th>
<th>Nurses and Midwives working within NHS Grampian can be authorised to administer the drug specified in this PGD by their Nurse Manager/Consultant/Practice GP.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All authorised staff are required to read the PGD and sign the Agreement to administer Medicines under PGD (<a href="#">Appendix 1</a>).</td>
</tr>
<tr>
<td></td>
<td>A certificate of authorisation (<a href="#">Appendix 2</a>) signed by the authorising doctor/manager should be supplied. This should be held in the individual practitioners records, or as agreed locally.</td>
</tr>
</tbody>
</table>
### Record of administration/supply

An electronic or paper record for recording the screening of patients and the subsequent administration of the drug specified in this PGD must be completed in order to allow audit of practice. This should include:

- Name and address of patient
- Patient CHI No and date of birth
- Details of parent/guardian, or person with parental responsibility where applicable
- Consultant/General Practitioner details
- Risk group, if appropriate
- Findings of physical examination, if appropriate
- Exclusion criteria, record why drug not administered
- Reason for giving
- Consent to the administration (if not obtained elsewhere)
- Signature and name in capital letters of practitioner who administered the drug
- Date drug given
- Record of any adverse effects (advise patient’s doctor)
- Site and on which arm should be documented

These records should be retained:

**For children and young people**, retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment.

**For 17 years and over** retain for 6 years after last date of entry, for 3 years after death, or in accordance with local policy, where this is greater than above.

### Audit

All records the drug specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each HSCP/practice/service will be responsible for auditing completion of drug forms and collation of data.

### References


Lidocaine Hydrochloride 1% w/v Solution for Injection – Date of revision of text 18/09/2014, accessed 05/02/2016


The Pharmaceutical Press
Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the of the professional group who will provide care under the direction

Name																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																		
Health Care Professional Agreement to Administer Medicines Under Patient Group Direction

I: ____________________________ (Insert name)

Working within: ____________________________ e.g. HSCP, Practice

Agree to administer medicines under the direction contained within the following Patient Group Direction

**Patient Group Direction For The Administration Of Lidocaine 1% Injection For The Insertion/Removal Of The 68mg Etonogesterel Contraceptive Implant By Nurses And Midwives Working Within NHS Grampian**

I have completed the appropriate training to my professional standards enabling me to administer medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor outwith the recommendations of the Patient Group Direction.

Signed: ____________________________

Print Name: ____________________________

Date: ____________________________

Professional Registration No: ____________________________
Appendix 2

Certificate Of Authorisation To Administer Medicines Under Patient Group Direction

This authorises: ____________________________________________________________

Working within: _________________________________________________________ e.g. HSCP, Practice

To administer medicines under the following Patient Group Direction

**Patient Group Direction For The Administration Of Lidocaine 1% Injection For The Insertion/Removal Of The 68mg Etonogesterel Contraceptive Implant By Nurses And Midwives Working Within NHS Grampian**

The above named person has satisfied the training requirements and is authorised to administer medicines under the above Patient Group Direction. The above named person has agreed not to act beyond their professional competence nor outwith the recommendations of the Patient Group Direction.

Signed: ___________________________ Authorising Manager/Doctor

Print Name: __________________________

Date: ____________________________