Patient Group Direction For The Administration Of Ceftriaxone Intramuscular Injection (Reconstituted With Lidocaine 1%) For The Treatment Of Confirmed Or Suspected Uncomplicated Gonorrhoea By Nurses Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author:
Adapted from the
SPS/FSRH National PGD
Template by the
Medicines Management
Specialist Nurse NHSG

Consultation Group: See relevant page in the PGD Approver: NoS PGD Group

Western Isles

Authorisation: NHS Grampian

Signature:

& Adamon.

Signature:

NoS Identifier: NoS/PGD/Ceftriax/ MGPG1156 Review Date: March 2023 Date Approved: March 2021

Expiry Date: March 2024

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded		New PGD adapted from FRSH/SPS national PGD and supersedes NHSG/PGD/Ceftriax/MGPG939	
Date of change	Summary of Changes Sect		Section heading
January 2020	New NoS PGD adapted from FRSH/SPS national PGD and previous PGD from NHSG.		

NoS Identifier: NoS/PGD/Ceftriax/MGPG1156

Keyword(s): PGD Patient Group Direction Ceftriaxone, Lidocaine, Sexual

Health, Gonorrhoea, STD

Policy Statement: It is the responsibility of the individual healthcare professionals 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 individual, 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 and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document: Drafted: January 2021

February 2021 Completed:

Approved: March 2021 (published - March 2021

Amended:

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

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Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle	368	March 2021

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox	1 Histor	March 2021

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 professional group who will provide care under the direction.

Name:	Title:
Frances Adamson Claire O'Brien	Lead Author: Medicines Management Specialist Nurse NHSG Pharmacist: Lead Clinical Pharmacist Women, Children & Families NHST
Dr Ambreen Butt Kimberley MacInnes Kirsteen Hill Julia Penn Sara Beveridge Russell Mackay Liam Callaghan	Medical Practitioner: Consultant Sexual Health NHSG Senior Representative: Senior Charge Nurse Sexual Health NHSH HIV and Antimicrobial Pharmacist NHST Senior Charge Nurse Sexual Health NHSG Clinical Nurse Specialist Sexual and Reproductive Health NHST Lead Pharmacist NHSO Chief Pharmacist NHSWI

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Clinical indication to which this PGD applies

Definition	of
situation/	
Condition	

This Patient Group Direction (PGD) will authorise nurses to administer ceftriaxone 1g intramuscular (IM) injection (reconstituted with lidocaine 1%) to individuals aged 13 years and over for the treatment of confirmed or suspected uncomplicated gonorrhoeal infection, and sexual contacts of individuals with a confirmed case of gonococcal infection.

This PGD should be used in conjunction with the individual Board protocols and the recommendations in the current British Association for Sexual Health and HIV (BASHH) relevant guidelines, British National Formulary (BNF), British National Formulary for Children (BNFC), and the individual Summary of Product Characteristics (SmPC).

Inclusion criteria

- Individuals aged 13 years and over.
- Individuals who have a positive identification of intracellular Gram-negative diplococci (GND) on microscopy.
- Individuals who have a positive culture for *Neisseria* gonorrhoeae indicating sensitivity to cephalosporins.
- Individuals who have a confirmed positive Nucleic Acid Amplification Testing (NAAT) for Neisseria gonorrhoeae.
- Symptomatic sexual contact of confirmed case of gonococcal infection presenting within 14 days of exposure. Cultures should be obtained.
- Asymptomatic individuals (regular or casual partners) presenting within 2 weeks of sexual contact with an individual with a confirmed gonococcal infection. These individuals can be treated at the time of presentation in line with local clinic guidelines. Cultures should be obtained. Asymptomatic individuals presenting after 2 weeks can be treated at clinician's discretion in line with local clinic guidelines.
- Individuals with treated gonorrhoea who have had sexual intercourse within 7 days of receiving treatment or who have had sexual contact with an untreated partner. Cultures should be obtained.
- Prior to the supply/administration of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.

Exclusion criteria

Personal characteristics

- Individuals under 13 years of age*
- Under 16 years of age and judged to be incapable of understanding the nature and possible consequences of procedures or treatment as per Age of Legal Capacity (Scotland) Act 1991 (commonly referred to as Fraser competency)
- Individuals aged 16 years and over and assessed as not competent to consent
- Sexual contacts of gonorrhoea positive individuals presenting after 14 days of exposure and are asymptomatic.

Medical history

- Known allergy or hypersensitivity to ceftriaxone and/or other cephalosporin antibiotics and/or known immediate or delayed hypersensitivity reaction to penicillin or other betalactam antibiotics.
- Contraindications to lidocaine, e.g. known cardiac arrhythmias, complete heart block, bradycardia, hypovolaemia.
- Known hypersensitivity to lidocaine and/or other anaesthetics of the amide type.
- Individual is taking interacting medicines. Check Appendix 1 of current edition of the British National Formulary (BNF) for full list of interacting medicines for ceftriaxone and lidocaine which includes:
 - Anticoagulants
 - Beta blockers 0
 - Antiarrhythmics
 - **Diuretics**
 - Antipsychotics that prolong QT interval, e.g. pimozide, olanzapine, quetiapine, zotepine
- Individuals with epididymitis or testicular pain where the clinician is not competent in assessing and managing epididymitis/epididymorchitis
- Individuals with or suspected to have pelvic inflammatory disease where clinician is not competent in assessing and managing individuals with pelvic pain
- Severe hepatic impairment or severe renal impairment
- Intramuscular injection is contraindicated, e.g. where individual has known thrombocytopenia (low platelet count) or coagulopathy (bleeding tendency) or is receiving treatment with anticoagulants
- Impaired cardiac conduction, congestive heart failure, bradycardia, myasthenia gravis, and recent cardiac surgery
- Acute porphyria
- Known epilepsy

	Where there is no valid consent.
	*Children under the age of 13 years should not be treated under this PGD. (The Child Protection Team must be contacted for children of 12 years and under who present having had sexual intercourse).
Precautions and special warnings	If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.
	When lidocaine 1% solution is used as a vehicle for administration, ceftriaxone solutions must only be used for intramuscular injection. Contraindications to lidocaine, warnings and other relevant information as detailed in the SmPC for lidocaine must be considered before use. The lidocaine solution should never be administered intravenously.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner.
	Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Ensure the individual is aware of other treatment options, the need for treatment and potential consequences of not receiving treatment.
	Inform/refer to the relevant medical practitioner if individual declines treatment, and/or provide them with information about further options.
	If the presenting individual is under 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy.
	Document that the administration was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the PGD

Name form and strength of medicine	Ceftriaxone 250mg and 1g injection (dry powder vial) reconstituted with lidocaine 1% w/v injection.
Legal status	Ceftriaxone 250mg and 1g injection is a Prescription-only Medicine (POM).
Off-label use	The indication for use and dose of ceftriaxone stated in this PGD are taken from the BASHH guideline. Not all available

licensed ceftriaxone products include this indication/dose within their licence and as such use may be off label. The individual should be informed prior to the administration that the use is off-label.

Individuals who are pregnant or breastfeeding. The use of these medicines in pregnancy/breastfeeding is outside the product licences. The individual must formally give verbal consent to treatment outside the SmPC, and this must be documented in the clinical record. The individual should be informed of the following risks and benefits of this treatment:

- That although the use of ceftriaxone in pregnancy is thought to be safe there is limited research available. However, its use is recommended by current BASHH quidelines
- Lidocaine can cross the placenta but the benefit of treatment is thought to outweigh the risk to pregnancy of leaving the gonorrhoea untreated
- Small amounts of ceftriaxone and lidocaine may be excreted into the breast milk
- The availability of alternative treatment options and can be referred to a prescriber if requested.

Dosage/Maximum total dose

1g administered as a single dose for all individuals weighing more than 50kg.

For adults and children aged over 13 years weighing less than 50kg a dose of 1g must be split (i.e. two 500mg doses) and injected at different sites.

The 1g dose will be given from either 4 x 250mg vials or 1g vial as follows:

Using 4 x 250 mg vials to administer 1g: Each 250mg vial of ceftriaxone should be reconstituted with 1mL lidocaine 1% w/v injection. The entire contents of the four vials should be drawn up to give the total dose of 1g to be administered.

Using 1g vial: The 1g vial should be reconstituted with 3.5mL lidocaine 1% w/v injection.

Displacement values: it is the responsibility of the practitioner to check the manufacturer's literature for displacement values. to ensure that the correct dose is administered.

Frequency of dose/Duration of treatment

Once only.

	For adults and children aged over 13 years weighing less than 50kg a dose of 1g must be split (i.e. two 500mg doses) and injected at different sites.
Maximum or minimum treatment period	Once only treatment.
Route/Method of administration	Deep intramuscular injection. Volumes of up to 4mL can be administered as a single injection, however individuals less than 50kg should receive a split 1g dose, (i.e. two 500mg doses) and injected at different sites.
Quantity to be administered	1g
Storage requirements	Unopened: Do not store above 25°C. Keep the vials in the outer carton. After reconstitution: After reconstitution use immediately, discard any unused medication in accordance with local guidance.
Follow-up (if applicable)	 Advise the individual to stay within the department/clinic for 10 - 15 minutes following administration of ceftriaxone injection. Individuals who have not had a full Sexually Transmitted Infection (STI) screen (or who did not have diagnosis made in a sexual health clinic) should be advised to attend an appropriate service for a full STI screen. Individuals should be advised to re-attend (face to face or remotely) a sexual health clinic 2 weeks following treatment for: test of cure retaking the sexual history to explore the possibility of re-infection pursuing partner notification and health promotion. NOTE: Test Of Cure (TOC) is recommended for all individuals testing positive for neisseria gonorrhoeae in line with local clinic protocols.
Advice (Verbal)	Advise individual what to expect and what to do for minor and major reactions. Advise that they will experience a numbing sensation at the
	Advise that they will experience a numbing sensation at the injection site due to concurrent administration of lidocaine as a diluent and the effects will gradually wear off after 1-2 hours.

Individuals diagnosed with gonorrhoea should be offered information (verbal, written and/or digital) about their diagnosis and management. Discuss implications of incompletely treated/untreated infection of self or partner(s). Advise to abstain completely from all sexual intercourse. including oral sex for 1 week after treatment and until partner(s) treatment is completed. Where not achievable, advise on use of condoms. Discuss risk of re-infection, and further transmission of infection, if after treatment sexual intercourse takes place with an untreated partner(s). Discuss partner notification and issue contact slips if appropriate. Offer condoms and advice on safer sex practices and the need for screening for STIs. Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services If serious adverse or persistent effects occur, the individual should be advised to contact their GP/Accident and Emergency department/NHS24. Advice (Written) The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Identifying and The following side effects are common with managing ceftriaxone/lidocaine (but may not reflect all reported side possible adverse effects): reactions Ceftriaxone Gastrointestinal – loose stools, nausea, vomiting Haematological reactions (e.g. anaemia) Localised injection site reaction. Lidocaine Gastrointestinal – nausea, vomiting Urticaria Localised injection site reaction Central nervous system effects include:

0	Cont	fusion

- Respiratory depression
- Convulsions
- Hypotension
- o Bradycardia
- Dizziness.

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

BNF/BNFC:

https://www.bnf.org/products/bnf-online/

SmPC/PIL/Risk Minimisation Material:

https://www.medicines.org.uk/emc/ http://www.mhra.gov.uk/spc-pil/index.htm

https://www.medicines.org.uk/emc/rmm-directory

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

Report any severe reactions using the Yellow Card System. https://vellowcard.mhra.gov.uk/

Facilities and supplies required

The following are to be available at sites where the medicine is to be supplied/administered:

- Appropriate storage facilities
- An acceptable level of privacy to respect individual's right to confidentiality and safety
- Basic airway resuscitation equipment (e.g. pocket mask, bag valve mask, supraglottic airway)
- Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection
- Access to a working telephone
- Another competent adult, who can summon urgent emergency support if required should ideally be present
- Access to medical support (this may be via the telephone)
- Approved equipment for the disposal of used materials
- Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel
- Condoms
- A copy of this current PGD in print or electronically.

Characteristics of staff authorised to administer medicine(s) under PGD

	Registered nurses as recognised by the Nursing and Midwifery Council (NMC).
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Specialist competencies

Approved by the organisation as:

- Competent to assess the individual's capacity to understand the nature and purpose of the medicine administration in order to give or refuse consent
- Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual
- Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD
- Competent to undertake supply/administration of the medicine
- Competent to work under this PGD.

Ongoing training and competency

All professionals working under this PGD must:

- Have undertaken PGD training as required/set out by each individual Health Board
- Have attended basic life support training either face to face or online and updated in-line with individual Board requirements
- Have undertaken NHS e-anaphylaxis training or equivalent (including annual updates) which covers all aspects of the identification and management of anaphylaxis
- Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of **Professional Conduct**
- Have knowledge and familiarity of the following;
 - SmPC for the medicine(s) to be administered in accordance with this PGD.

Responsibilities of professional manager(s)

Professional manager(s) will be responsible for;

Ensuring that the current PGD is available to all 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.

Maintain up to date record of all staff authorised to administer the medicine(s) specified in this direction.

Documentation

Authorisation of administration

Nurses working in sexual health services working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to supply/administer the medicine(s) specified in this PGD by their Professional Line Manager/Consultant/Practice GPs.

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	All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
Record of administration	An electronic or paper record for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: Date and time of administration Individuals name and CHI Exclusion criteria, record why the medicine was not administered (if applicable) Record that valid consent to treatment under this PGD was obtained The name, dose, form, route (batch number, expiry date and site where appropriate for injectable medicines) of the medicine administered Advice given, including advice given if excluded or declined treatment under this PGD Signature and name in capital letters of the healthcare professional who administered the medicine Record of any adverse effects (advise individuals GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: NaSH – Sexual Health Electronic Patient Record Individual's GP records if appropriate
Audit	All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Ceftriaxone 250g Powder for Solution for Injection (Wockhardt Brand) – Date of revision of text 23/10/20, accessed 14/01/21.

Lidocaine Hydrochloride 1% w/v Solution for Injection (ADVANZ Brand) – Date of revision of text 16/04/2019, accessed 14/01/21.

British National Formulary and British National Formulary for Children https://www.bnf.org/products/bnf-online/ accessed 14/01/21.

British Association for Sexual Health and HIV (BASHH) (2019) Guidelines Management of gonorrhoea in adults, 2019 https://www.bashhguidelines.org/current-guidelines/urethritis-and-cervicitis/gonorrhoea-2018/



Appendix 1

Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

l:	(Insert name)
Working within:	e.g. Area, Practice
Agree to administer the medic Direction:	ine(s) contained within the following Patient Group
Intramuscular İnjectio Treatment Of Confirmed Nurses Working Withir	tion For The Administration Of Ceftriaxone n (Reconstituted With Lidocaine 1%) For The d Or Suspected Uncomplicated Gonorrhoea By n NHS Grampian, Highland, Orkney, Shetland, ayside And Western Isles
administer the medicine(s) un	ate training to my professional standards enabling me to der the above direction. I agree not to act beyond my out with the recommendations of the direction.
Signed:	
Print Name:	
Date:	
Profession:	
Professional Registration number/PIN:	



Appendix 2

Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.

The Senior Nurse/Professional who approves a healthcare professional to supply/, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.

The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.

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Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

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Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date