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 ceftriaxone injection (reconstituted with lidocaine 1% w/v injection) by intramuscular (IM) injection for the treatment of uncomplicated *Neisseria gonorrhoeae* infection in York and North Yorkshire Sexual health services including specialist clinical outreach services

Version Number 1.2

Change History	
Version and Date	**Change details**
Version 1 July 2020	New template
Version 1.1 October 2020	Removed from criteria for inclusion: *Individuals who present with mucopurulent penile or cervical discharge where there is no access to microscopy facilities to diagnose GND.* Advisory wording added to inclusion criteria section: ***NOTE** – all criteria for inclusion within the BASHH approved national PGD templates for sexual health are based on diagnostic management in line with BASHH guidance. Where services do not have access to diagnostics and treatment is syndromic then the PGD template will need to be locally adapted to reflect local practice being mindful of the BASHH guidance.* Injection site specific administration information removed.
Version 1.2 January 2022	For clarity '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.' Removed from Dosing and frequency of administration section and replaced in updated Route of Administration section with 'Note ceftriaxone PGDs SPC states that up to 1g can be administered as a single IM injection. In adults and children aged over 13 years weighing <50kg consider splitting the dose and injecting at different sites to reduce

	discomfort.' Supporting reference added.

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 July 2020
Review date	February 2023
Expiry date:	30th June 2023

This PGD template has been peer reviewed by the Sexual Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the British Association for Sexual Health and HIV (BASHH)/BASHH Bacterial Special Interest Group (BSIG) in October 2020.

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

Name	Designation
Ali Grant	Highly Specialist Clinical Pharmacist: HIV, Sexual and Reproductive Health
Alison Crompton	Community pharmacy
Amanda Cooper	Associate Director Specialist Pharmacy Service
Andrea Smith	Community pharmacy
Carmel Lloyd	Royal College of Midwives
Chetna Parmar	Pharmacist adviser, Umbrella
Clare Livingstone	Royal College of Midwives
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSHCG)
Dipti Patel	Local authority pharmacist
Dr Achyuta Nori	Consultant in Sexual Health and HIV
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Dr John Saunders	Consultant in Sexual Health and HIV
Dr Kathy French	Pan London PGD working group
Dr Rita Browne	Consultant in Sexual Health and HIV
Dr Sarah Pillai	Pan London PGD working group
Emma Anderson	Centre for Pharmacy Postgraduate Education (CPPE)
Helen Donovan	Royal College of Nursing
Jo Jenkins (Working Group Co-ordinator)	Specialist Pharmacist (PGDs) Specialist Pharmacy Service
Jodie Crossman	Specialist Nurse. BASHH SHAN SIG Chair
Jodie Walker-Haywood	Specialist Nurse, BASHH Board Nurse Representative, BASHH SHAN SIG Secretary
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSHCG)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee

	Faculty of Sexual and Reproductive Healthcare (FSRH)
Portia Jackson	Pharmacist, Cambridgeshire Community Services
Sally Hogan	British Pregnancy Advisory Service (BPAS)
Sandra Wolper	Associate Director Specialist Pharmacy Service
Silvia Ceci	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service
Tracy Rogers	Associate Director Specialist Pharmacy Service

Name	Job title and organisation	Signature	Date
Senior doctor	Dr Ian Fairley, Lead Consultant		16/08/22
Senior pharmacist	Paul Jackson		17/8/22
Senior representative of professional group using the PGD	Steven Evans, ANS ALISON CHORLTON		16.08.22
Person signing on behalf of authorising body	Jennie Booth, Lead Nurse Medicines Management Stuart Parkes, Chief Pharmacist		19.08.2022 19/08/22

1. Characteristics of staff

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 patient leading to diagnosis of the conditions listed. Recommended requirement for training would be successful completion of a relevant sexual health module/course accredited or endorsed by the BASHH, CPPE, RCN or a university or advised in the RCN Sexual Health Education directory. The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for *Neisseria gonorrhoeae* infection testing and/or treatment. • 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 discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required. • Completion of PGD awareness session via Trust Learning HUB
The decision to administer 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	Treatment of individual with uncomplicated *Neisseria gonorrhoeae* infection and sexual contacts of individuals with a confirmed case of gonococcal infection
Criteria for inclusion	• 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 sexual contact of confirmed case of gonococcal infection presenting within 14 days of exposure who is unwilling/unable to defer treatment until repeat testing 2 weeks after exposure. Cultures should be obtained. • 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. • Individuals who present with mucopurulent penile or cervical discharge where there is no access to microscopy facilities to diagnose GND.
Criteria for exclusion	**Personal characteristics** • Individuals under 13 years of age • Individuals aged under 16 years of age and assessed as not competent using Fraser guidelines • 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 beta-lactam 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 • 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 • Acute porphyria • Known epilepsy
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 presenting individual is under 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy (note under 13 years of age excluded from treatment under this PGD). • Discuss with appropriate medical/independent non-medical prescriber any medical condition or medication of which the healthcare professional is unsure or uncertain.
Action to be taken if the individual is excluded or declines treatment	• If declined ensure individual is aware of other treatment options, the need for treatment and potential consequences of not receiving treatment. • Record reason for decline in the consultation record. • Explain the reasons for exclusion to the individual and document 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.

3. Description of treatment

Name, strength & formulation of drug	Ceftriaxone injection (dry powder vial) reconstituted with lidocaine 1% w/v injection The 1g dose will be given from either 4x250mg vials or 1g vial as follows: **Using 4x250 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. Discard any unused injection.
Legal category	POM
Route of administration	• Deep intramuscular injection • Note ceftriaxone PGDs SPC states that up to 1g can be administered as a single IM injection. In adults and children aged over 13 years weighing <50kg consider splitting the

	dose and injecting at different sites to reduce discomfort.
Dose and frequency of administration	1g administered as a single dose
Off label use	The indication for use and dose of ceftriaxone stated in this PGD are taken from the British Association for Sexual Health and HIV (BASHH) guideline. Not all available licensed ceftriaxone products include this indication/dose within their licence and as such use may be 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 SPCs 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 guidelines • 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. 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 drugs for use lies with pharmacy/Medicines Management. Where a medicine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	All concurrent medications should be reviewed for interactions. A detailed list of all drug interactions is available in the BNF www.bnf.org or the product SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
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 The following side effects are common with ceftriaxone/lidocaine (but may not reflect all reported side effects):

	Ceftriaxone • Gastrointestinal – loose stools, nausea, vomiting • Haematological reactions (e.g. anaemia) • Localised injection site reaction **Lidocaine** • Gastrointestinal – nausea, vomiting • Urticaria • Localised injection site reaction • CNS effects include: o Confusion o Respiratory depression o Convulsions o Hypotension o Bradycardia o Dizziness
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers 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 patient's medical record. • Report via organisation incident policy.
Written information and further advice to be given to individual	**Medication:** • Offer patient information leaflet (PIL) provided with the original pack. Explain mode of action, side effects, and benefits of the medicine • Advise the individual to stay within the department/clinic for 10-15 minutes following administration of ceftriaxone injection. 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 **Condition:** • 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 sexually transmitted infections (STIs) • Where treatment not supplied via a sexual health clinic ensure the individual has contact details of local sexual health services.

Follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • Individuals who have not had a full 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: o test of cure o retaking the sexual history to explore the possibility of re-infection o pursuing partner notification and health promotion
Records	**Record:** • The consent of the individual and o If individual is under 13 years of age record action taken o If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. o If individual over 16 years of age and not competent, record action taken • If individual not treated under PGD record action taken • Name of individual, address, date of birth • GP contact details where appropriate • Relevant past and present medical and sexual history, including medication history. • Examination including individual's weight (<50kg split dosing) • Microbiology finding/s where relevant. • Any known allergies and nature of reaction • Name of registered health professional • Name of medications administered • Any administration outside the terms of the product marketing authorisation • Date of administration • Dose administered • Site of injection • Batch number and expiry date of administered injections in line with local procedures. • Details of any adverse drug reactions and actions taken • Advice given, including advice given if excluded or declines treatment • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Any referral arrangements made • Recorded that supplied via Patient Group Direction (PGD) 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.

4. Key references

Key references (accessed April 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 • 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/ • NICE Clinical Knowledge Summaries - https://cks.nice.org.uk • Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines • Queensland Hospital and Health Services; Medication Administration – Intramuscular Injection Developed by the State-wide Emergency Care of Children Working Group, March 2020 https://www.childrens.health.qld.gov.au/wp-content/uploads/PDF/qpec/nursing-skill-sheets/medication-administration-intramuscular-injection.pdf • Medusa Guideline, ceftriaxone IM https://medusa.wales.nhs.uk/

Appendix A - Registered health professional authorisation sheet

PGD: Administration of ceftriaxone injection (reconstituted with lidocaine 1% w/v injection) by intramuscular (IM) injection for the treatment of uncomplicated *Neisseria gonorrhoeae* infection
Valid from: May 2022 **Expiry: 30th June 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 PGD you are indicating that you agree to its contents and that you will work within it.

PGDs 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 and Scarborough Teaching Hospitals 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.

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