Bath & North East Somerset Council

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)

Supply and/or administration of levonorgestrel 1500micrograms tablet(s) for emergency contraception

For Community Pharmacists providing an emergency contraception service under the sexual health enhanced service contract commissioned by Bath and North East Somerset Council

Version Number 1.6

Change History	
Version and Date	**Change details**
Version 1 May 2021	FSRH template modified to include B&NES-specific information
Version 1.1 May 2021	Amended references to 96 hours post UPSI to 72 hours
Version 1.2 May 2021	Guidance wording removed
Version 1.3 June 2021	Confirmed reference changes from 96 hour post UPSI to 72 hours as per licencing agreement
Version 1.4 9th June 2021	Amended changes back to 96 hours
Version 1.5 21st June 2021	Added Nick's details to local group and sign off section
Version 1.6 22nd June 2021	Added BR, AF, PM, ND signatories

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 comes into effect:	1st July 2021
Expiry date:	30th June 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 November 2020 and modified to include information and details specific to Bath and North East Somerset in May 2021.

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

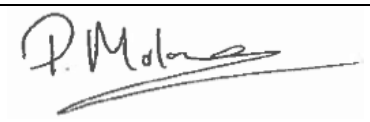
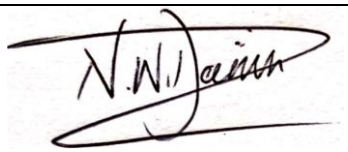
Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michael Nevill	Director of Nursing British Pregnancy Advisory 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 Group Co-ordinator)	Specialist Pharmacist PGDs Specialist Pharmacy Service
Samrina Bhatti	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service

Bath and North East Somerset local PGD development group:

Name	Designation
Paul Moloney	Lead Pharmacist, Virgin Care B&NES
Dr Arnold Fernandes	Consultant in Genitourinary Medicine and Contraception, The Riverside Clinic, Royal United Hospital NHS Foundation Trust
Jayne Elton	Lead Nurse Practitioner, The Riverside Clinic, Royal United Hospital NHS Foundation Trust
Richard Brown	Chief Officer, Avon Local Pharmaceutical Committee
Nick Daines	Superintendent Pharmacist, Lifestyle Pharmacy Bath
Paul Sheehan	Public Health Commissioning and Development Manager, Bath and North East Somerset Council

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Senior doctor	Dr Arnold Fernandes Consultant in Genitourinary Medicine and Contraception, The Riverside Clinic, Royal United Hospital NHS Foundation Trust		29th June 2021
Senior pharmacist	Paul Moloney Lead Pharmacist, Virgin Care B&NES		29th June 2021
Senior representative of professional group using the PGD	Nick Daines Superintendent Pharmacist, Lifestyle Pharmacy Bath		29th June 2021
Person signing on behalf of authorising body	Becky Reynolds Director of Public Health and Preventative Services, Bath and North East Somerset Council		29th June 2021

1. Characteristics of staff

Qualifications and professional registration	Registered Pharmacists who have received training to undertake administration and supply of medicines under Patient Group Directions and are competent in the management of contraception care, working in a community pharmacy under the Sexual Health enhanced contract
Initial training	The 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 patients ensuring safe provision of the medicines listed in accordance with local policy: • have undertaken appropriate training for working under patient group directions for the supply and administration of medicines • have been assessed as competent to work with this PGD • have undertaken training in the role, care and administration of the medicine specified in this PGD • have access to the current BNF (https://www.medicinescomplete.com/mc/bnf/current) The healthcare professional has completed locally required training: • CPPE distance learning: Emergency Hormonal Contraception • CPPE distance learning: Safeguarding Children and Vulnerable Adults Level 2 • An enhanced DBS certificate is in place
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for emergency contraception. • 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 that 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. • Organisational PGD and/or medication training as required by employing Trust/organisation.
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	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular contraception has been compromised or used incorrectly.
Criteria for inclusion	• Patients aged 13 years to 25 years at risk of unwanted pregnancy presenting to pharmacists who are agreed participants in the sexual health enhanced service contract, between 0 and 96 hours following UPSI or when regular contraception has been compromised or used incorrectly. • No contraindications to the medication. • Informed consent given.
Criteria for exclusion	• Patients aged 25 and over. • Informed consent not given. • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • This episode of UPSI occurred more than 96 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 96 hours. • Known or suspected pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period since UPSI). • Less than 21 days after childbirth. • Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD). • Known hypersensitivity to the active ingredient or to any component of the product - see Summary of Product Characteristics • Use of ulipristal acetate emergency contraception in the previous 5 days. • Acute porphyria.
Cautions including any relevant action to be taken	• All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider – the patient's GP or Riverside Clinic. • Ulipristal acetate can delay ovulation until closer to the time of ovulation than levonorgestrel. Consider ulipristal if the individual presents in the five days leading up to estimated day of ovulation. • Levonorgestrel is ineffective if taken after ovulation. • If individual vomits within three hours from ingestion, a

	repeat dose may be given. • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them - see dose frequency section. • Body Mass Index (BMI) >26kg/m^2 or weight >70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. If levonorgestrel is to be given see dosage section. • Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of levonorgestrel is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed. • 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. • If the individual has not yet reached menarche consider onward referral for further assessment or investigation. • If the individual presents to a pharmacy following rape or sexual assault can be prescribed emergency hormonal contraception but should be referred to the Sexual Assault Referral Centre (SARC) and encouraged to inform the Police. SARC contact details: **0117 342 6999** **ubh-tr.thebridgecanhelp@nhs.net** **https://www.thebridgecanhelp.org.uk/**
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. • Offer suitable alternative emergency contraception or refer the individual as soon as possible their GP, Riverside Clinic, or another suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, strength & formulation of drug	Levonorgestrel 1500 micrograms tablet (N.B. this is equivalent to 1.5mg levonorgestrel)
Legal category	P/POM
Route of administration	Oral – dose to be taken as supervised consumption on the premises
Off label use	Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes off-label use in the following conditions ○ Use between 72 and 96 hours post UPSI ○ Increased dose for individuals with BMI over 26kg/m^2 or weight over 70kg and in individuals using liver enzyme inducing agent ○ Severe hepatic impairment ○ Individuals with previous salpingitis or ectopic pregnancy ○ Lapp-lactase deficiency ○ Hereditary problems of galactose intolerance ○ Glucose-galactose malabsorption Drugs should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs 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 drug 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
Dose and frequency of administration	• Levonorgestrel 1500mcg (1 tablet) to be taken as soon as possible up to 96 hours of UPSI. • **Dose for those individuals taking enzyme inducing medicines or herbal products:** An individual who requests levonorgestrel whilst using enzyme-inducing drugs, or within 4 weeks of stopping them, can be advised to take a total of 3mg levonorgestrel (two 1500mcg tablets) as a single dose and within 96 hours of UPSI. • **Dose for those individuals with a body mass index of more than 26kg/m^2 or who weigh more than 70kg:** An individual who requests levonorgestrel with a body mass index of more than 26kg/m^2 or who weighs more than

	70kg can be offered a total of 3mg levonorgestrel (two 1500mcg tablets) as a single dose and within 96 hours of UPSI.

Duration of treatment	• A single dose is permitted under this PGD.
	• If vomiting occurs within 3 hours of levonorgestrel being taken a repeat dose can be supplied under this PGD.
	• Repeated doses can be given within the same cycle. Please note:
	  ○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal)
	  ○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel)

Quantity to be supplied	• Appropriately labelled pack of one tablet. • Two tablets can be supplied for individuals taking enzyme inducing drugs and/or individuals with a BMI of more than 26kg/m^2 or who weigh more than 70kg.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org
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 levonorgestrel (but may not reflect all reported side effects): • Nausea and vomiting are the most common side effects. • Headache, dizziness, fatigue, low abdominal pain and breast tenderness, diarrhoea. • The FSRH advises that bleeding patterns may be temporarily disturbed and spotting may occur, but most individuals will have their next menstrual period within seven days of the expected time
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 any adverse reactions via organisation incident policy. •
Written information and further advice to be provided	• All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective

	method of emergency contraception. • Ensure that a patient information leaflet (PIL) is provided within the original pack. • If vomiting occurs within three hours of taking the dose, the individual should return for another dose. • Explain that menstrual disturbances can occur after the use of emergency hormonal contraception. • Provide advice on ongoing contraceptive methods, including how these can be accessed. • Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur. • Individuals using hormonal contraception should restart their regular hormonal contraception immediately. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. • Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern. • Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs. • There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.
Advice/follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. • Pregnancy test as required (see advice to individual above). • Individuals advised how to access on-going contraception and STI screening as required. • Individuals can be advised that local information on sexual and reproductive health, including services, can be found at www.safebanes.com
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 • Name of individual, address, date of birth • GP contact details where appropriate

	• Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight • Any known drug allergies • Name of registered health professional operating under the PGD • Name of medication supplied • Date of supply • Dose supplied • Quantity supplied • Advice given, including advice given if excluded or declines treatment • Details of any adverse drug reactions and actions taken • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Any referral arrangements made • Any supply outside the terms of the product marketing authorisation • 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 December 2019)	• 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 • Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017 Updated December 2018 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception - November 2017 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/ • 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

Appendix A - Registered health professional authorisation sheet

PGD Name/Version: Levonelle 1500 for emergency contraception: Community Pharmacists providing an emergency contraception service under the sexual health enhanced service contract commissioned by Bath and North East Somerset Council; Version 1

Valid from: 1st July 2021
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 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 insert name of organisation 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.

Appendix B - List of abbreviations

ADR	Adverse Drug Reaction
B&NES	Bath and North East Somerset
BMI	Body Mass Index
BNF	British National Formulary
CPPE	Centre for Pharmacy Postgraduate Education
Cu-IUD	Copper IntraUterine Device
DBS	Disclosure and Barring Service
EC	Emergency Contraception
FRSH	Faculty of Sexual and Reproductive Health
GP	General Practitioner
GTD	Gestational Trophoblastic Disease
IUCD	IntraUterine Contraceptive Device
LNG-EC	Levonorgestrel Emergency Contraception
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
PIL	Patient Information Leaflet
POM	Prescription Only Medicine
SARC	Sexual Assault Referral Centre
SPC	Summary of Product Characteristics
STI	Sexually Transmitted Infection
UPA-EC	Ulipristal Emergency Contraception
UPSI	UnProtected Sexual Intercourse