OXFORDSHIRE COUNTY 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.

Emergency Hormonal Contraception (EHC) Call-off Contact sits within the Dynamic Approved Provider List (DAPL) Agreement for the Provision of Community Healthcare Service with a Commencement Date of 1st April 2022. The most recent and in-date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION

for the supply and/or administration of

Levonorgestrel 1500micrograms tablet(s)

by registered Community Pharmacists for

Emergency Hormonal Contraception

in authorised Community Pharmacies in Oxfordshire

Version Number 2.0

Change History	
Version and Date	**Change details**
Version 1 March 2020	• New template
Version 1.1 November 2020	• Addition of acute porphyria to exclusion criteria
Version 1.2 December 2021	• Updated in line with the Pharmaceutical Services Negotiating Committee there is no material changes in it. • The training sections have been updated. • The age cap of under 21 years provision only has been removed.
Version 2.0 March 2023	• Updated template (no clinical changes to expired V1)

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

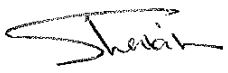
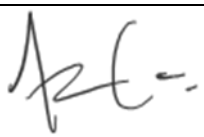
Date PGD template comes into effect:	1st April 2024
Review date	30th September 2025
Expiry date:	31st March 2026

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 October 2022.

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)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant MSI Reproductive Choices
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)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Associate Specialist
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	NHS North East London ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

OXFORDSHIRE COUNTY COUNCIL AUTHORISATIONS

Role / Name	Job title and organisation	Signature	Date
Lead Author, Shakiba Habibula	Consultant in Public Health, Public Health, Oxfordshire County Council		28.2.2024
Lead Clinician for Contraception, Dr. Julia Shefras	Consultant in Community Gynaecology and Sexual Health, Oxford University Hospital NHS Foundation Trust		28.2.2024
Lead Pharmacist, Ian Dunphy	Superintendent Pharmacist Hanborough Pharmacy Long Hanborough Witney		11.3.2024
Representative of professional group using PGD David Dean	Chief Executive Officer, Local Pharmacy Committee, Pharmacy in Thames Valley		28.2.2024
PGD Development Lead, Liz Benhamou	Health Improvement Practitioner, Public Health, Oxfordshire County Council		28.2.2024
Person signing on behalf of authorising body, Ansaf Azhar	Corporate Director of Public Health & Community Safety Oxfordshire County Council		27.03.24

1. Training and Competency of Registered Community Pharmacist

Qualifications and professional registration	Currently working within a Community Pharmacy in Oxfordshire that holds EHC Call-off Contact within the DAPL Agreement for the Provision of Community Healthcare Service with a Commencement Date of 1st April 2022 Community Pharmacists registered with the General Pharmaceutical Council (GPhC). 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 patients ensuring safe provision of the medicines listed in accordance with Oxfordshire local policy. Within three months of enrolment pharmacists must complete the standards required in the Declaration of Competence for Community Pharmacy Services – Emergency Contraception, hosted by CPPE. This must be completed at least every two years. The healthcare professional has completed training (including updates) in safeguarding children and vulnerable adults hosted by the CPPE. Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme Prior to signing Appendix A (and as part of enrolling for the service on PharmOutcomes) pharmacists providing the service must meet the local training requirements which are as follows: • Level 1 – Safeguarding in Oxfordshire - OSCB online safeguarding[i] EHC provision in Oxfordshire (available on the OSCB learning website)[ii]
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 • Hold a satisfactory Enhanced Disclosure and Barring Service (DBS) check because of one-to-one work with people aged under 16 years, renewed every three years.

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. • Ongoing competency and training needs should be assessed as part of the regular review of all staff working under PGDs. • The employing business to support PGD and/or medication training as required.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

1. 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	All of the following: • Any individual presenting for emergency contraception (EC) 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. • If under 16, assessed as being Fraser competent.
Criteria for exclusion	All of the following: • 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/allergies to the levonorgestrel, progestogens or any component of the product - see Summary of Product Characteristics • Use of ulipristal acetate (UPA-EC) 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. • Inform individuals they can contact their GP or the Oxfordshire Sexual Health Service (OSHS) (www.sexualhealthoxfordshire.nhs.uk /01865 231231) to organise this, or as good practice the Pharmacist could contact the OSHS during the consultation if the client gives consent on 01865 231231. • If an individual chooses to contact the OSHS themselves advise them to include the following, '*requesting emergency contraception, would like to arrange for an emergency IUD (coil)*'. Their request will be prioritised. • Ulipristal acetate can delay ovulation until closer to the time of

	ovulation than levonorgestrel. Consider Ulipristal acetate if the individual presents in the five days leading up to estimated day of ovulation. • Ulipristal acetate is also available via the PGD under the EHC Call-off Contact within the DAPL Agreement for the Provision of Community Healthcare Service with a Commencement Date of 1st April 2022, and from OSHS, their GP or a School or College Health Nurse. • 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.
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 to their GP, the OSHS (http://www.sexualhealthoxfordshire.nhs.uk, (01865 231231) or their school or college health nurse for alternative options and further information.
Arrangements for referral for medical or safeguarding advice	• Repeat attendance for EHC must be monitored and any concerns discussed with OSHS. It is good practice to encourage access to reliable contraception. Signpost to GP or OSHS or School or College Health Nurse. • If any doubt about whether to supply under this PGD, or for advice, or copper IUD referral, contact OSHS - http://www.sexualhealthoxfordshire.nhs.uk and 01865 23123. • If aged under 18, consider need for possible child protection process (see PharmOutcomes for guidance) or refer to the Oxfordshire Children's Safeguarding Board "reporting concerns" - http://www.oscb.org.uk/reporting-concerns/ • If aged over 18 and you have concerns, please refer Oxfordshire Safeguarding Adults Board - http://www.osab.co.uk

2. 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
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 • Consideration of increased dose for individuals with BMI over 26kg/m2or weight over 70kg • Increased dose for individuals using liver enzyme inducing agents • Severe hepatic impairment • Individuals with previous salpingitis or ectopic pregnancy • Lapp-lactase deficiency • Hereditary problems of galactose intolerance • Glucose-galactose malabsorption Note some products may be licenced only for certain age groups (e.g. 16 years and over) – supply of these products outside the licensed age groups is permitted under this PGD. Medicines 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. **Note** the effectiveness of this regimen

	is unknown. • **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 LNG-EC (two 1500mcg tablets) as a single dose and within 96 hours of UPSI. **Note** the effectiveness of this regimen is unknown.

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, as separate episodes of care, 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 Refer also to FSRH guidance on drug interactions with hormonal contraception
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. • Provide advice on the use of Levonelle and EllaOne both delay ovulation rather than preventing it when considering future contraception. • 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. • Advise to consult a pharmacist, nurse or doctor before taking any new medicines including those purchased.
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. • If patient reports assault or rape, discuss need for counselling or legal action. Refer as appropriate. If the client needs immediate support or forensics to be carried out they can self-refer to the Sexual Assault Referral Clinic (SARC) at Oxfordshire (https://www.osarcc.org.uk/) or contact the police.

Records	Record:
	• The consent of the individual and
	  ○ If individual is under 13 years of age record action taken
	  ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.
	  ○ 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 including batch number and expiry date in line with local procedures.
	• 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, using PharmOutcomes.
	
	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.
	
	Safeguarding points
	Gillick competence and Fraser guidelines | NSPCC Learning
	Safeguarding According To Age
	Whilst Frasers guidelines and Gillick competency apply to all children, there are certain differences in how they are applied depending on a child's age.
	Under 13
	There isn't a lower limit for either Gillick competence or Fraser guidelines to be applicable. Most children under the age of 13 have parent involvement when consent to treatment is concerned as it is not appropriate or safe.
	When it comes to contraception and sexual health, any information about sexual activity would be acted on regardless of whether the child is competent or not – because a child under 13 is not legally

	able to consent to sexual activity. **Under 16** If someone under 16 discloses information that raises concerns about their safety, the following needs to be considered: • If they are Gillick competent and disclosure is thought to be essential to protect them from danger, the healthcare professional *should* escalate concerns through safeguarding measures • If they aren't Gillick competent, the healthcare professional is *obliged* to escalate concerns through safeguarding measures • If it is both cases, the young person must be informed – unless doing would cause significant risk to their safety

3. Key references

Key references (accessed September 2022)	• 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 - March 2017 (Amended March 2020) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ • FSRH CEU Statement Response to Edelman 2022 (August 2022) https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-statement-response-to-edelman-2022-august-2022/ • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ • 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

Contact details:
Oxfordshire Sexual Health Service
• Telephone - 01865 231231
• https://www.sexualhealthoxfordshire.nhs.uk

Oxfordshire County Council commissioners of DAPL and PGD for EHC
- E-mail- publichealth@oxfordshire.gov.uk

GP Practice Finder
- https://www.nhs.uk/service-search/find-a-gp

School and College Health Nurse Service
- Telephone - 07920 470 529
- E-mail - Contraception.outreach@oxfordhealth.nhs.uk
- https://www.oxfordhealth.nhs.uk/school-health-nurses/

Appendix A – Registered Health Professional Authorisation Sheet

PGD Name/Version: PGD Levonelle April 2024
Valid from: 1st April 2024
Expiry: 31st March 2026

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 ******insert name of organisation* **below***

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.

Add details on how this information is to be retained according to organisation PGD policy.

[i] https://training.oscb.org.uk/elearning-detail/%3DETMyMTM/Level-1-Introduction-to-Safeguarding-2021-recommended-course-for-Volunteers
[ii] https://training.oscb.org.uk/elearning-detail/%3D%3DANwYTO/Emergency-Hormonal-Contraception-PGD-Training-for-Pharmacists