Patient Group Direction
For the administration of Levonorgestrel 1500micrograms
by Pharmacists, for Emergency Hormonal Contraception

1. Authorisation

This specimen Patient Group Direction (PGD) template has been produced by the Primary Care Pharmacy Group to assist NHS boards. NHS boards should ensure that the final PGD is considered and approved in line with local clinical governance arrangements for PGDs.

The qualified health professionals who may administer levonorgestrel 1500micrograms under this PGD can only do so as named individuals. **It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure** familiarity with the marketing authorisation holder's summary of product characteristics (SmPC) for all medicines administered in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation.

Administration of the medicine has to be by the same practitioner who has assessed the patient under the PGD.

Signatures of those developing the Patient Group Direction

Job Title	Name	Signature	Date
Doctor	Dr Olga Diaz-Morales	**Signed by Dr Olga Diaz-Morales**	**11/3/15**
Pharmacist	Carole Smith	**Signed by Carole Smith**	**12/3/15**
Nurse			

Approved on behalf of **NHS Forth Valley by**

Medical Director – Tracey Gillies Signature Signed by Tracey Gillies Date 9/4/15

Director of Pharmacy- Gail Caldwell Signature Signed by Gail Caldwell Date 9/4/15

Clinical Governance Lead–Tracey Gillies Signature Signed by Tracey Gillies Date 9/4/15

Date Approved 24/2/15

Effective from 9/4/15 Review Date December 2017

2. Management of the National Patient Group Direction (PGD)

The original signed copy should be held by the NHS Board.

This PGD must be read, agreed to, signed and a copy retained by all pharmacists involved in its use. A copy of the signature sheet should be sent to the NHS Board.

3. Application

This PGD covers the supply of levonorgestrel 1500micrograms tablet for use as emergency hormonal contraception by female patients who are aged 13 years or over, provided none of the exclusion criteria listed below apply.

4. Clinical Situation

Indication	Patient presenting in person at the community pharmacy requesting emergency contraception for their own use within 72 hours of unprotected sexual intercourse (UPSI).
Inclusion Criteria	Patient is aged 13 years or over. Unprotected sexual intercourse/contraception failure within the last 72 hours. Unprotected sexual intercourse/contraception failure within the last 72 hours where patient has vomited within 2 hours of taking a dose of levonorgestrel for emergency hormonal contraception. Patient gives their consent to providing the relevant clinical information to the pharmacist after pharmacist has assessed their capacity to consent (see under Staff).
Exclusion Criteria	Patient is aged 12 years or under. **The Child Protection Team must be contacted for children of 12 years and under, who present having had sexual intercourse.** Patient who the pharmacist has assessed as not being competent to consent. Unexplained vaginal bleeding. Patient has had unprotected sex more than 72 hours ago. Levonorgestrel should not be given to pregnant women. Previous unprotected sexual intercourse in current menstrual cycle. Patient used levonorgestrel for emergency hormonal contraception in current menstrual cycle. (If patient has vomited within 2 hours of

	taking a dose of levonorgestrel, dose can be repeated. Refer to Inclusion Criteria.) Severe hepatic dysfunction. History of salpingitis or ectopic pregnancy. Severe malabsorption syndromes e.g. severe diarrhoea, Crohns disease. Porphyria. Hypersensitivity to levonorgestrel or any of the tablet ingredients/ excipients (potato starch, maize starch, colloidal silica anhydrous, magnesium stearate, talc, lactose monohydrate). Patients who have delivered a baby within last 3 weeks (EHC not required in these circumstances). Patient does not agree to share relevant clinical information or there is no valid consent. Patients with hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption as contains 142.5 mg lactose.
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	The available data are limited and not robust enough to support with certainty the conclusion of decreased contraceptive effect with increased bodyweight/BMI. In order to maximise the likelihood that Levonorgestrel will work, it is important that it is taken as soon as possible after unprotected intercourse.
Action if Excluded	All excluded patients should be referred to Sexual Health Service or GP practice. Direct referral process contained within the Unscheduled Care Folder should be used during out of hours period. If unprotected sex was within the last 5 days (120 hours) the patient may be suitable for IUD (intrauterine device) insertion or use of Ulipristal. Assessment or referral should be made in a suitable timeframe to allow this to happen.
Action if Patient Declines	Patient should be advised of the risks of the consequences of not receiving treatment. Record outcome in Patient Medication Record if appropriate and

	refer the patient to their general practitioner Direct Referral process contained within the Unscheduled Care Folder should be used during out of hours period.
Consent	Prior to the supply of levonorgestrel, consent must be obtained, preferably written, from the patient. Where a patient does not have capacity to consent then this may be provided by a parent, guardian or person with parental responsibility. Written and verbal information should be available in a form that can be easily understood by the person who will be giving the consent. Where English is not easily understood, translations and properly recognised interpreters should be used. Individuals (patient, parent, guardian or person with parental responsibility) should also be informed about how data on the supply will be stored, who will be able to access that information and how that data may be used.
Consent for under 16s	A patient under 16 years of age may give consent for the supply of EHC, provided she understands fully the benefits and risks involved. The patient should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the patient indicates that she wishes to accept the supply, supply should proceed, if the pharmacist deems the patient to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2(4) states that 'a person under the age of 16 years shall have legal capacity to consent on her own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending her, she is capable of understanding the nature and possible consequences of the procedure or treatment.' Legal advice from the NHS in Scotland states that if a healthcare professional has been trained and professionally authorised to undertake a clinical procedure which is normally that of a medical practitioner, then that health care professional can be considered to have the necessary power to assess the capacity of a child under the 1991 Act, for that procedure or treatment.

5. Description of Treatment

Name of Medicine	Levonorgestrel
Form/Strength	Tablet 1500 microgram (mcg)
Dosage	Female patients of 13 years and over – Take 1500micrograms as a single oral dose as soon as possible after coitus (preferably within 12 hours but no later than 72 hours after the event). If the patient is using an enzyme-inducing medication or has stopped taking such medication within the last 28 days (see interacting medications), then TWO tablets of levonorgestrel 1500micrograms should be taken as the single dose (total dose 3000micrograms levonorgestrel). This is an unlicensed indication for levonorgestrel not included in the Summary of Product Characteristics (SPC) but is a recommendation of the Faculty of Sexual and Reproductive Healthcare Clinical Guidance on Emergency Contraception. Patients taking enzyme inhibiting medication may experience adverse effects and may require additional monitoring (see interacting medications) If vomiting occurs within 2 hours of taking the original dose, another dose should be taken immediately.
Total Dose	1500micrograms (one tablet) as a single dose, or 3000micrograms (two tablets) as a single dose if patient also taking enzyme-inducing medication or has stopped taking such within last 28 days.
Duration of Treatment	Single oral dose, preferably within 12 hours but no later than 72 hours. If vomiting occurs within 2 hours of taking the original dose, another dose should be taken immediately.
Advice to Patient (verbal)	Advise women using liver enzyme-inducing drugs that an IUD is the preferred option. Discuss the mode of action, failure rate and possible effects on the foetus of levonorgestrel - See relevant SPC. There is no clinical data on effect on foetus by levonorgestrel but it should be avoided. If pregnancy is a possibility this should be excluded before supply is made.

	For patients who have missed their oral contraceptive pill, give advice based on the EHC e learning module developed by NES Pharmacy which can be found at https://www.portal.scot.nhs.uk./ or the Faculty of Sexual and Reproductive Health Statement on missed pills http://www.fsrh.org/pdfs/CEUStatementMissedPills.pdf If the patient is taking the oral contraceptive pill or using the contraceptive patch and emergency hormonal contraception is required, advise the patient to use a barrier method in addition to her usual method until she has taken the pill or applied the patch correctly for 7 consecutive days. (If taking Qlaira® - 9 days) If the patient is not using an oral contraceptive pill, a barrier method of contraception should be used until appropriate contraceptive advice from Sexual Health Service or GP is given. Highlight that the patient's next period may be early or late. Advise the patient that levonorgestrel may cause nausea and/or vomiting. If vomiting, or serious diarrhoea, occurs within two hours of taking the medication further advice should be sought immediately from the pharmacist, or other appropriate agency. Advise the patient that Levonorgestrel is an occasional method of contraception and must not be used as a replacement for a regular contraceptive method. Provide local information about how to access a local contraception service and contraceptive advice Advise the patient that they should consider being tested for a sexually transmitted infection and provide local information about where they can obtain that service. If the patient has not had their period within 5 days of their expected date of menstruation, abnormal bleeding occurs or pregnancy is suspected, they should be advised to attend the Sexual Health Service, GP or pharmacy (if pregnancy testing is provided) with a urine sample to confirm or exclude pregnancy. If patient is breast-feeding, advise levonorgestrel is not thought to be harmful *but potential exposure of their baby can be reduced if patient takes the dose immediately after feeding.* Requirements of oral anti-diabetics and insulin can change as a result of taking levonorgestrel therefore the patient with diabetes should be advised to monitor blood glucose levels closely. The available data are limited and not robust enough to support with certainty the conclusion of decreased contraceptive effect with

	increased bodyweight/BMI
Patient Information (written)	1. Patient Information Leaflet provided with medication. 2. Written information about locally available contraception services and methods of contraception. 3. Written information about locally available services providing sexual health advice.
Documentation	The pharmacist must ensure maintenance of records for each supply (For example see appendix 1) and may be required to share information with appropriate parties in line with confidentiality protocols.
Follow-up	None required.
Storage requirements	Store in original container below 25^{o}C
Additional Information	***Reduced efficacy of Levonorgestrel*** The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers or use within the last 28 days, and these medications can reduce the efficacy of levonorgestrel. A full list is available in Appendix 1 of the relevant section of the British National Formulary, or in the SPC for the product being used. These include: Anticonvulsants: Barbiturates (including Primidone), Phenytoin, Carbamazepine, Topiramate. Anti-Fungal: Griseofulvin Herbal Medicines containing Hypericum perforatum (St. John's wort). Rifamycins: Rifampicin, Rifabutin Endothelin receptor antagonist: Bosentan ***Effect of Levonorgestrel on other medication*** Immunosuppressants: metabolism of ciclosporin reduced (increased plasma concentration). Increased risk of toxicity. Additional monitoring may be required. Caution is advised when prescribing for patients using the anticoagulant drugs, phenindione and warfarin. Anticoagulant effects may be altered following use. Additional monitoring may be required. Patients should be advised about potential drug

	interactions and attention should be paid to their anticoagulation monitoring.
Warnings including possible adverse reactions	Menstrual irregularities, nausea, low abdominal pain, fatigue, headache, dizziness, breast tenderness, vomiting. All adverse reactions (actual and suspected) will be reported to the appropriate medical practitioner and recorded in the appropriate place (e.g. the Minor Injury Record Sheet or the Allergies and Adverse Reactions section of the Patient Record). Where appropriate a Yellow Card Report will be forwarded to the Committee on Safety of Medicines. A supply of these forms can be found at the rear of the British National Formulary. Online reporting is available at http://yellowcard.mhra.gov.uk/
Patient Charges	None. Current NHS exemption is applicable. The Patient's CHI number should be recorded on the CPUS form where available
References	1. British National Formulary – Current edition 2. Faculty of Sexual and Reproductive Health Guidance CEU (August 2011, updated January 2012) "Emergency contraception". 3. Levonelle® 1500 microgram tablet SPC – Updated 15.2.2012 4. Upostelle 1500microgram tablet SPC – updated 15.3.2013 5. NES – Emergency Hormonal Contraception e learning module which can be found at https://www.portal.scot.nhs.uk./

Characteristics of staff authorised under the PGD

Professional qualifications	A person whose name is currently maintained on the register of pharmacists held by the General Pharmaceutical Council (GPhC) The pharmacist must maintain their own level of competence and knowledge in this area to provide the service.
Specialist competencies or qualifications	The practitioner should be competent to assess the person's capacity to understand the nature and purpose of the treatment in order to give or refuse consent.
Continuing education and training	The practitioner must be familiar with the SmPC for all medicines administered in accordance with this PGD. It is the responsibility of the individual to keep up to date with all aspects of practice in this area.

Audit Trail

Record/Audit Trail	The approved practitioner must ensure maintenance of records for each supply and may be required to share information with appropriate parties in line with confidentiality protocols.The information relating to the supply of medication of each individual must include as a minimum: • Patient's name and date of birth, • Dose, • Brand, batch number and expiry date of medicine, • Date given and by whom. All records must be clear and legible and, ideally, in an easily retrievable format. (see example proforma, Appendix 1) The patient's CHI number should be recorded on the CPUS form where available

NATIONAL PATIENT GROUP DIRECTION FOR SUPPLY OF LEVONORGESTREL 1500MCG TABLET BY PHARMACISTS, FOR EMERGENCY HORMONAL CONTRACEPTION

Individual Authorisation

This PGD does not remove inherent professional obligations or accountability

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. It is also your responsibility to ensure that all consultations with patients occur within a private and confidential area of the pharmacy.

I have read and understood the Patient Group Direction and agree to provide the levonorgestrel 1500mcg tablet only in accordance with this PGD.

I have read and understood the NHS Forth Valley Child Protection Guidelines for NHS staff working with sexually active under16s.

Name of Pharmacist .....

GPhC Registration Number .....

Normal Pharmacy Location .....

(if pharmacy locum please provide contact details) .....

Signature .....

Signature of Authorising Pharmacist on behalf of Employing Organisation

Name	Signature	Date

Note :
A copy of this agreement must be signed by each pharmacist who wishes to be authorised to use the PGD for Supply of Levonorgestrel 1500mcg by Community Pharmacists working in Forth Valley Pharmacies. Please return this form to Pharmacy Services, Euro House, Wellgreen Place, Stirling. FK8 2DJ, Fax: 01786-431199 and retain a copy in each pharmacy premises they wish to provide the medicine from. A copy of the PGD must also be available in the pharmacy for reference.

Each authorised pharmacy practitioner should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

NHS Forth Valley

EXAMPLE EMERGENCY HORMONAL CONTRACEPTION PROFORMA

Appendix 1

Pharmacy Stamp

DATE _____ **CLIENT NAME** _____

CHI _____ **AGE** _____

If 13, 14, 15 YEARS OLD

EXPLAIN CONFIDENTIALITY AND LIMITS ☐

Who is with her? _____ Who knows she is here?

How old is partner? _____ Lives with family / friends / in care / homeless

Attends school? Y / N Concerns drugs/alcohol? Y / N

Concerns re assault/abuse Y / N

COMPETENT TO CONSENT Yes ☐

Not competent/ under 13 yrs old/ child protection issues ☐ REFER

Last Menstrual Period: NORMAL? Y / N CYCLE (Days) _ REGULAR? Y / N

PREGNANCY TEST NOT DONE ☐ NEGATIVE ☐ POSITIVE ☐

(Do test if period late or LMP unsure or LMP unusual)

CIRCUMSTANCES: UPSI ☐ CONTRACEPTIVE FAILURE ☐ OTHER: _____

WHEN WAS THE FIRST UPSI SINCE THE START OF HER LAST PERIOD OR SINCE HORMONAL METHOD FAILURE?

DATE _____ TIME

HOURS SINCE _____ > 72 hours since 1st UPSI - Refer

DAY IN CYCLE OF 1st UPSI _____

	NO	YES	
ANY EHC ALREADY THIS CYCLE	☐	☐	If already used EHC this cycle -Refer
SEXUAL ASSAULT?	☐	☐	If assault refer to local guidelines
PREVIOUS VOMIT WITH EHC	☐	☐	

MEDICAL HISTORY:

	NO	YES	
KNOWN ALLERGY TO LEVONORGESTREL	☐	☐	If YES Refer
SEVERE HEPATIC DYSFUNCTION	☐	☐	If YES Refer
SEVERE ABSORPTION DIFFICULTIES	☐	☐	If YES Refer
PORPHYRIA	☐	☐	If YES Refer
SEVERE MALABSORPTION SYNDROME	☐	☐	If YES Refer
UNEXPLAINED VAGINAL BLEEDING	☐	☐	If YES Refer
ON INTERACTING MEDICATION	☐	☐	If YES Consider referral
ENZYME INDUCING MEDICATION	☐	☐	If YES, refer for IUD or double dose EHC

CONCEPTION RISK for a 25 yr old after 1 episode of UPSI

Days 8-17	20-30% risk of pregnancy
Days 1-7 and >17	2-3% " " "

POSTCOITAL CONTRACEPTION OPTIONS

Levonorgestrel within 72 hours	97% reduction in expected pregnancies
Levonorgestrel 72 – 120 hours (off licence) - Refer	Efficacy unknown
Mifepristone 72 – 120 hours (off licence) - Refer	>85% " " " "
Ulipristal up to 120 hours - Refer	>98% " " " "
Copper IUD up to 120 hrs after UPSI / or 120hrs after predicted ovulation - Refer	>99% " " " "

(Refer to current BNF)

BOTH ORAL AND IUD EMERGENCY CONTRACEPTION DISCUSSED ☐

PLANNED TREATMENT

LEVONORGESTREL 1.5 mg as single dose (PGD supply) ☐

LEVONORGESTREL 3 mg single dose (enzyme inducers) (PGD supply – off licence) ☐

Referred for IUD : ☐
Referred for STI testing ☐
Referred for Contraceptive Advice: ☐

Too late for tablets but declines IUD or Ulipristal ☐

Too late for any EHC ☐

No EHC needed at all ☐

Details_____

CURRENT CONTRACEPTION

Patch ☐ COC ☐ POP ☐ injection ☐ implant ☐ IUD/S ☐

Other ☐ _____

Continue pills / patch + condoms too for 7 days ☐
Start pills / patch first day of next period ☐

ADVICE CHECKLIST

How to take tablets ☐
Action if vomits within 2 hours ☐
Next period may be early/late ☐
Return if further UPSI ☐

Failure rate ☐
Pregnancy test in 3 weeks unless normal period ☐
If Levonorgestrel EHC fails not harmful to pregnancy ☐
Contact GP/FP clinic for regular contraception ☐

May be light bleeding next few days, don't count as period ☐

SEXUALLY TRANSMITTED INFECTION

STI risk discussed ☐

14 day window period for Chlamydia, Gonnococcal & Trichomoniasis swabs ☐

3 month window period for Syphilis, Hepatitis B, C, HIV ☐

How/where to access STI tests or treatment if appropriate ☐

LEVONORGESTREL SUPPLY

BATCH NUMBER _____

EXPIRY _____

SIGNATURE OF PHARMACIST

_____

PRINT NAME _____ **DATE**