



POLICY DOCUMENT

**Patient Group Direction for the Supply of levonorgestrel
for
Emergency Hormonal Contraception
by
Community Pharmacists**

Approved by:

**Leicester City Council
Clinical Governance Board
Leicestershire and Rutland
County Councils Clinical
Governance Board**

Commencement date:

1st. April, 2015

Expiry Date:

31st. March 2018

**Directorate responsible
for Review:**

**Public Health (Leicester City,
Leicestershire and Rutland
County Councils)**

PGD Number:

LLRPGD001

Due Regard

The Council's commitment to equality means that this PGD has been screened in relation to paying due regard to the general duty of the Equality Act 2010 to eliminate unlawful discrimination, harassment, victimisation; advance equality of opportunity and foster good relations.

This document has been assessed to ensure that no one receives less favourable treatment on the protected characteristics of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

It is judged that it is not proportionate (equality relevant) in respect of this PGD as it specifically enables identified registered pharmacists to supply and administer medicines in accordance with national guidelines. Due regard has been given in respect of accessibility (larger print, Braille etc), including the provision of information or advice in an alternative language and consideration of patient carers and family members for support.

Patient Group Direction for the supply of levonorgestrel 1500 micrograms for Emergency Hormonal Contraception by designated community pharmacists across Leicester, Leicestershire and Rutland

Premises

From registered pharmacy premises which have been approved for this service by Leicester City Council, Leicestershire County Council or Rutland County Council.

The EHC service is provided alongside a Chlamydia Screening Service.

Staff Characteristics

Qualifications	<ul style="list-style-type: none">• Registered Pharmacist currently on the practicing section of the pharmaceutical register held by the General Pharmaceutical Council that have completed the required training for accreditation and competency• Practitioners must hold a current and up to date Enhanced Disclosure and Barring Service check <p>ALL HEALTHCARE PROFESSIONALS MUST BE AUTHORISED BY NAME UNDER THIS DIRECTION BEFORE USING IT.</p>
Method of Competency assessment	<p>Pharmacists applying (or re-applying) to be on the Approved Provider List will have declared themselves competent using the CPPE Declaration of Competence for Community Pharmacy Services Emergency Contraception and will undertake to keep themselves up to date.</p> <p>Each Council will approve pharmacies to provide the service in that locality and pharmacy providers, at the request of the commissioner, will be required to provide evidence to confirm that pharmacists have the necessary skills and competencies in accordance with the requirements of the contract.</p> <p>Before commencing the delivery of this service, all providers must have attended at least one face to face local CPPE training event.</p>

Specialist competencies or qualifications	<p>The pharmacist must be competent to assess a client's capacity to understand the nature and purpose of the treatment in order to give or refuse consent.</p> <p>Evidence of completion of approved CPPE training packages listed below and successful completion of their associated e-assessment.</p> <ul style="list-style-type: none"> • CPPE's e-learning on Contraception • CPPE's e-learning on Emergency Hormonal Contraception • CPPE's e-learning on Safeguarding children and vulnerable adults. (e.g. CPPE online competence assessment) on EHC. • The CPPE e-assessments must be completed successfully every 3 years. <p>The practitioner must also attend a local workshop session, organised and delivered by the Integrated Sexual Health service.</p>
Frequency of Competency review	<p>Three yearly</p>
Accountability for competency assessment	<p>Pharmacists will self-declare using the CPPE Declaration of Competence for Community Pharmacy Services – Emergency Contraception</p>
Accountability for staff involved in using the PGD	<p>Pharmacists using the PGD are accountable to the Responsible Pharmacist and the Superintendent Pharmacist of the Pharmacy in which they are providing pharmaceutical services. The Responsible Pharmacist is responsible for the correct implementation of the PGD.</p>
Continuing training & education	<p>The practitioner should be aware of any change to the recommendations for levonorgestrel. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.</p> <p>CPPE e-learning and e-assessment training refresh on Safeguarding children, young people and vulnerable adults module every 3 years; evidenced by satisfactory completion of e-assessment.</p> <p>The practitioner must attend a local workshop session, organised and delivered by the Integrated Sexual Health Service as a refresh every 3 years.</p>

Referral Arrangements and Audit Trail

Additional Facilities and Referral Arrangements

The client must always be advised to talk to her GP or Integrated Sexual Health Services across Leicester, Leicestershire and Rutland, regardless of whether a supply is made. Where the circumstances are outside the PGD, or where there are medical concerns, or if the client wishes it, the client should be referred to a GP or the Integrated Sexual Health Service clinics using the Client Referral Form.

Records/audit trail

Records should be made on the Client Record Sheet (Appendix 2)

Ongoing Monitoring	
Method of auditing adherence to PGD	Adherence to the PGD will be monitored through the data submissions and mystery shopping/audit exercise
Frequency of audit	Annually
Accountability for audit and monitoring	Respective Consultant lead in Public Health at each local authority

Supply of levonorgestrel 1500 micrograms for Emergency Hormonal Contraception, by designated community pharmacists across Leicester, Leicestershire and Rutland.

Clinical Condition	
Indication	Clients presenting to a community pharmacy requesting Emergency Hormonal Contraception (EHC) who, following appropriate assessment, are at risk of pregnancy.

Inclusion criteria

- Emergency hormonal contraception within 96 hours of unprotected sexual intercourse (UPSI) – please note that use beyond 72 hours is outside of the product licence:
 - Clients over 16 years of age and under 25 years of age
 - Clients under 16 years of age who have been assessed as Fraser competent (see appendix 4 and cautions on page 9)
- Client gives their consent to providing the relevant clinical information to the pharmacist after pharmacist has assessed their capacity to consent (see under Staff Characteristics; Client Record Sheet (appendix 2)). Clients who are on the Combined Oral Contraceptive (COC) pill who present within 96 hours of UPSI after missing an active pill as per the guidance from the Faculty of Sexual and Reproductive Healthcare (FSRH) guidance (see Appendix 3):
<http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf>
- Clients who are on the progestogen only pill (POP) other than desogestrel and present within 96 hours of UPSI after taking any pill within the last 3 days which is 3 hours or more late as per the guidance from the Faculty of Sexual and Reproductive Healthcare (FSRH) guidance:
<http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf>
- Clients who are taking the POP containing desogestrel and present within 96 hours of UPSI after taking the pill more than 12 hours late as per the guidance from the Faculty of Sexual and Reproductive Healthcare (FSRH) guidance:
<http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf>
- Clients who have experienced failure of barrier method of contraception.
- If client wishes to use IUDs for EC, give levonorgestrel (as long as meets criteria of this PGD), but refer to GP or Integrated Sexual Health Services across Leicester, Leicestershire and Rutland for consideration of IUDs insertion
- Previous UPSI within same cycle and treated with levonorgestrel
- Vomiting within 2 hours of taking levonorgestrel EHC. Note that this advice differs from the SPC.

PLEASE NOTE THAT THIS IS NOT AN EXHAUSTIVE LIST.

Exclusion criteria	<ul style="list-style-type: none"> • Clients under 16 years who are not considered to be Fraser competent • Known hypersensitivity to levonorgestrel • Established pregnancy • Client has had a baby in the last 3 weeks (EHC not required in these circumstances) • Known acute active porphyria • No valid consent obtained from client • Clients aged 25 years and over (please consider OTC supply)
Action if patient declines or is excluded	<p>Discuss reason for exclusion with client.</p> <p>Clients aged 25 years and over may be eligible to purchase EHC.</p> <p>Clients excluded under this PGD are to be referred for further assessment to a registered medical practitioner (e.g. their own GP) or the nearest accessible alternative Integrated Sexual Health Service clinic offering contraceptive services. The advice given should be documented in the client's record sheet (and Patient Medication Record if appropriate).</p> <p>If UPSI was within the last 5 days (120 hours) the client may be suitable for IUD (intrauterine device) insertion or ulipristal acetate (EllaOne) and referral should be made to either the Integrated Sexual health Services or the patient's own GP in a suitable timeframe to allow this to happen</p> <p>Where care is declined by the client, document refusal in client's clinical records.</p> <p>Ensure the client is signposted to different services in the area e.g. Integrated Sexual Health Service Clinic, general practitioner</p> <p>Advise the client that GP practices <u>may</u> provide contraceptive services to patients meeting certain criteria.</p> <p>It is important to warn the client that a delay in starting treatment will compromise its efficacy.</p> <p>If any doubt about exclusion, telephone the Integrated Sexual Health Services on 0116 295 1208 (9am - 7.30pm Mon-Fri and 9 - 1.30pm Sat) or contact the client's own GP for advice with the client's consent.</p>

Cautions/Need for further advice

If in doubt about cautions, refer to or telephone the Integrated Sexual Health Service on 0116 295 1208 (9am - 7.30pm Mon-Fri and 9 - 1.30pm Sat) or contact the client's GP.

Please refer to the current BNF edition for further information.

Cautions	Advice/Actions	Comments
Clients aged 13 years or under	<ul style="list-style-type: none"> Consider supply of levonorgestrel, if Fraser competent. (see appendix 4) There is a duty to seek further advice and onward referral to address child protection issues. The Child Protection Team must be contacted for clients aged 13 or under who present having had sexual intercourse. 	Please see Appendix 6 for referral pathways and contact details.
Clients currently taking enzyme inducing drugs or have stopped within the last 28 days.	<ul style="list-style-type: none"> May be offered 3000 microgram dose of levonorgestrel (this is not based on evidence or within product licence but on expert clinical judgment of balance of risks and benefits) 	Advise to consider IUD as preferred option.
Breastfeeding	<ul style="list-style-type: none"> FSRH recommends breast-feeding clients can use progesterone only emergency contraception without restriction. 	Unprotected sexual intercourse or contraceptive failure before day 21 postpartum is not an indication for emergency contraception (regardless of method of feeding).
Repeated use in same cycle	<p>Advise client:</p> <ul style="list-style-type: none"> She may be pregnant (consider pregnancy test as appropriate) Repeated use disturbs menstrual cycle Consider IUD as preferred alternative Levonorgestrel EHC will not interrupt a pregnancy (there is no epidemiological data to indicate that 1500 micrograms levonorgestrel has an adverse effect on the foetus) If UPSI was within 12 hours of previous levonorgestrel dose, further EHC not required. 	Please see Appendix 3 for further advice.
Vomiting	If the request is due to an episode of vomiting which has occurred within 2 hours of taking the dose, a replacement supply may be issued.	Ensure replacement supply remains within 96 hours of the episode of UPSI.
Episodes of UPSI over 72 hours	Consider options if UPSI occurred between 72 hours and 120 hours e.g. levonorgestrel, out of license up to 96 hours or referral for ulipristal or IUD up to 120 hours.	
Previous UPSI more than 96 hours earlier within the same cycle and no emergency contraception used	Consider supply of levonorgestrel (subject to clinical judgment). Consider pregnancy test.	Please note that there is no epidemiological data to indicate that 1500micrograms of levonorgestrel has an adverse effect on the foetus.
Previous UPSI within the same cycle and treated with ulipristal	Consider providing levonorgestrel and referral for IUD.	Ulipristal possibly reduces contraceptive effect of progestogens. It is not known if ulipristal reduces efficacy of levonorgestrel EHC. Ulipristal should not be taken repeatedly in the same menstrual cycle.

Severe hepatic dysfunction	Consider discussion with Integrated Sexual Health Service or GP.	
Known breast cancer	Consider discussion with Integrated Sexual Health Service or GP.	
Severe malabsorption syndromes i.e. Crohn's	Consider discussion with Integrated Sexual Health Service or GP.	
Possible pregnancy: <ul style="list-style-type: none"> • Vague menstrual history • Last menstrual period late/abnormal/different 	Consider pregnancy test.	Please note that there is no epidemiological data to indicate that 1500 micrograms of levonorgestrel has an adverse effect on the foetus.
Clients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption	Consider alternative method.	
Client given birth in last 3 weeks	EHC <u>not</u> required.	

Interactions

Please note that there are specific drugs which require the dose to be altered.

The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers, and these medications can reduce the efficacy of levonorgestrel. Clients currently (or within last 28 days) of taking enzyme-inducing drugs for example barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing hypericum perforatum (St. John's Wort), rifampicin, anti-retrovirals, rifabutin, griseofulvin (should be supplied with and take TWO tablets (3000micrograms) as soon as practical after UPSI (and not later than 96 hours). [This dose is unlicensed but is endorsed by the Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit; although IUD is the preferred method]

If unsure, consult Appendix 1 of the current British National Formulary, or the SPC for the product being used (www.medicines.org.uk).

Consider referring clients taking cyclosporin, tacrolimus or anti-coagulants to the Integrated Sexual Health Services across Leicester, Leicestershire & Rutland on **0116 295 1208 (9am – 7.30pm Mon-Fri and 9am – 1.30pm Sat)** or patient's own GP.

Supply of levonorgestrel for Emergency Hormonal Contraception

Drug Details

Name, form & strength of medicine	Levonorgestrel 1500 micrograms tablet
Route/Method	Oral administration
Licensing/Use of label	The following are uses outside of the terms of the Product Licence: <ul style="list-style-type: none"> • Under 16 years of age • Used more than once in a cycle • Double dosing when woman taking enzyme-inducing drugs but endorsed by Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit
Dosage	<p>This PGD allows administration outside of the Product Licence only in the above circumstances. The client must be advised that it is being recommended as an unlicensed indication for levonorgestrel not included in the Summary of Product Characteristics (SPC)</p> <p>One 1500 microgram tablet should be taken as soon as possible, preferably within 96 hours after UPSI</p> <p>If the client is using liver enzyme-inducing medication (see interacting medicines), or within 28 days of stopping them, then TWO tablets of levonorgestrel 1500micrograms should be taken as the single dose (total dose 3000micrograms levonorgestrel) as soon as practical after UPSI (and not later than 96 hours). Client must be advised that this is an unlicensed indication for levonorgestrel not included in the Summary of Product Characteristics (SPC) but is endorsed by the Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit. Client must give consent to use outside of product license.</p> <p>The client should be encouraged to take the dose whilst in the pharmacy.</p>
Frequency	<p>May be given within the 96 hour subject to the cautions timeframe on each occasion, for more than one episode of UPSI within a cycle.</p> <p><u>Vomiting</u></p> <p>A replacement dose can be provided under this PGD as soon as possible (within the 96 hour post UPSI timeframe) if the client has vomited the first dose within 2 hours (NB this is different to the recommendations in the SPC)</p>
Duration of treatment	Single dose

Maximum or minimum treatment period	Single dose per episode
Quantity to supply/administer	<p>1 x 1500 microgram levonorgestrel tablet – as a single dose</p> <p><i>If taking liver-enzyme inducing drugs</i> 2 x 1500 microgram tablet (3000microgram) – as a single dose if patient is also taking a liver-enzyme inducing drug or within 28 days of stopping a liver enzyme inducing drug</p> <p><i>The client should be encouraged to take the dose whilst in the pharmacy.</i></p>
Action to take if drug interactions identified	Please read cautions on page 8 and check BNF and SPC.
Side effects	<p>Always refer to the current BNF and Summary of Product Characteristics (SPC) available from: www.medicines.org.uk.</p> <p>The most common adverse effects are:</p> <ul style="list-style-type: none"> • Nausea • Vomiting • Breast tenderness • Headache • Dizziness • Fatigue <p>Temporary disturbance of menstrual bleeding pattern (if menstrual bleed is more than 7 days overdue, pregnancy should be excluded (by taking a pregnancy test))</p> <p>Advise client to contact the Integrated Sexual health Services across Leicester, Leicestershire & Rutland or their own GP if they experience any adverse effects (see Appendix 6 for contact details).</p> <p>Use the Yellow Card system to report adverse drug reactions (ADRs) directly to the Medicines and Healthcare Products Regulatory Agency (MHRA). Yellow cards (and guidance) are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk.</p> <p>Report all significant ADRs to patient’s own GP (with patient consent).</p>

Advice to patient/carer

- Refer to BNF and SPC information
- Advise client to read Manufacturer's Patient Information Leaflet
- If vomiting occurs within 2 hours of taking the tablet, client should return to pharmacy for replacement supply or seek medical assistance.
- All clients should be advised to have a pregnancy test 3 weeks after Emergency Contraception regardless of circumstances.
- Please supply and advise client to read Patient Information Sheet (Appendix 1)

Arrangements for medicine supply	<p>The levonorgestrel should be dispensed from the community pharmacy stock labelled and recorded on the Patient Medical Record system.</p> <p>The client should be given a Patient Information Sheet (see Appendix 1) as well as the Manufacturer’s Patient Information Leaflet for the levonorgestrel.</p> <p><i>The client should be encouraged to take the dose whilst in the pharmacy.</i></p>
Storage requirements	<p>The usual community pharmacy storage of medicines requirements apply.</p>
Follow up	<p>There is generally no need for routine follow-up but advise to see GP or Integrated Sexual Health Service or have a pregnancy test if normal period has not come by 7 days after its expected date. Patients taking EHC while on hormonal contraception should be advised to have a pregnancy test after 3 weeks regardless of any bleeding. This can be obtained from GP or Integrated Sexual Health Service or purchased.</p> <p>Advise of need to use appropriate barrier contraception for rest of present cycle if any possibility of further exposure to risk of pregnancy.</p> <p>All clients should be advised to have a pregnancy test 3 weeks after Emergency Contraception regardless of circumstances.</p> <p>Encourage client to put arrangements in place for further contraceptive advice and sexually transmitted infection (STI) prevention if needed.</p> <p>Client to seek medical advice if risk of STI has occurred.</p> <p>If patient reports assault or rape, refer as appropriate (see Appendix 6 for contact details).</p> <p>If client wishes to use IUD for EC, give levonorgestrel (as long as meets criteria of this PGD) but refer to GP or Integrated Sexual Health Service for consideration of IUD insertion.</p>

Referrals

Medical:

An appropriate prescriber eg GP or Integrated Sexual Health Service should be referred to in the following situations:

- If client requires ulipristal for EC
- If client wishes to use IUD for EC

Clients should be advised to seek medical attention promptly:

- If any lower abdominal pain occurs because this could signify an ectopic pregnancy
- If, in 3 to 4 weeks, the subsequent menstrual bleed is abnormally light, heavy or brief, or is absent, or if the client is otherwise concerned
- If there is any doubt as to whether menstruation has occurred, a pregnancy test should be performed at least 3 weeks after UPSI

Safeguarding:

If under 16, consider need for possible child protection process including awareness of Child Sexual Exploitation.

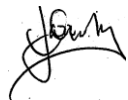

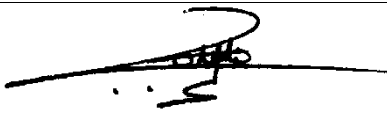
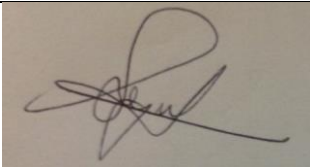

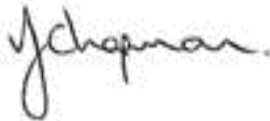
Please note that it is a mandatory requirement to refer those under the age of 13 years who present having had sexual intercourse.


If client discloses allegation of rape, please refer as appropriate.

This patient group direction must be agreed to and signed by all health care professionals involved in its use.

Leicester City Council, Leicestershire County Council and Rutland County Council will hold the original signed copy.

The PGD must be easily accessible in the clinical setting


PATIENT GROUP DIRECTION WORKING GROUP		
NAME	POSITION	SIGNATURE
Dr. Jasmine Murphy	Consultant in Public Health (Leicester City Council)	
Dr. Mike McHugh	Consultant in Public Health (Leicestershire and Rutland County Councils)	
Mr. Emeka Oloto	Consultant in Sexual and Reproductive Health (Staffordshire and Stoke on Trent NHS Partnership Trust)	
Sejal Gohil	Chair of Leicester, Leicestershire and Rutland Local Pharmacy Committee and CPPE Tutor	
Satyan Kotecha	Community Pharmacist and member of Leicester, Leicestershire and Rutland Local Pharmacy Committee	
Vanessa Chapman	Acting Director, Trent Medicines Information Centre, University Hospitals of Leicester NHS Trust	

PATIENT GROUP DIRECTION CONTRIBUTORS		
Name	Position	Signature
Liz Rodrigo	Public Health Principal (Leicester City Council)	


Janet Hutchins	Senior Public Health Manager (Leicester and Rutland County Councils)	
Dr. Madhusree Ghosh	Specialty Registrar (Sexual and Reproductive Health) Staffordshire and Stoke on Trent NHS Partnership Trust	

This PGD is approved for use within the area covered by Leicester City Council, Leicestershire County Council and Rutland County Council.

PGD Authorisation and Adoption by Leicester City Council

Director of Public Health Leicester City Council	Name Rod Moore
	Signature 
	Date 25 March 2015

PGD Authorisation and Adoption by Leicestershire and Rutland County Councils

Director of Public Health Leicestershire and Rutland County Councils	Name Mike Sandys
	Signature 
	Date 26 March 2015

Responsibility for updating the PGD

Leicester City Council, Leicestershire County Council and Rutland County Council	Public Health commissioners will review the Service Specification to update the PGD.
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References

1. www.medicine.org.uk
2. http://www.fsrh.org/pages/clinical_guidance.asp
3. <http://pharmacyregulation.org/>
4. <https://www.cppe.ac.uk>
5. Best practice guidance for doctors and other health professionals in providing advice and treatment to young people on contraception, sexual and reproductive health.
http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4086960
6. <http://www.fsrh.org/pdfs/SpottingTheSignsCSEproformaA4.pdf>

Individual Authorisation

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY

Pharmacy Details	
Name	
Address	
Telephone Number	

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.

Note to Authorising Managers:

Authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

Pharmacists should sign the table and keep their personal copy of this document.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD.

I also declare that I am aware that I have an obligation to keep my practice and knowledge up to date and to respond to any changes that affect the content of this PGD and any changes in the use of PGDs in general.

Name of Professional	Signature	GPhC No	Authorising Manager/ Superintendent (if appropriate)	Date

Progestogen Only Emergency Hormonal Contraception – levonorgestrel

Levonorgestrel is a type of emergency contraception. There are two other types; ellaOne tablet and IUD (copper coil). The pharmacist will have discussed these options to help you to decide what is suitable and best for you.

You have been provided with a medicine containing levonorgestrel. If you have any serious medical problems, or are taking, or have recently stopped taking any medicines, please make sure that you discuss these with the pharmacist, to ensure that this type of emergency contraception is safe for you.

Please let the pharmacist know of any medication you are taking, including over the counter medicines, herbal medicines or recreational drug use.

Please read this information and the information provided with your medication carefully and do not hesitate to speak to the pharmacist if you have any questions.

1. How to take the pills

You have been given one tablet levonorgestrel 1500mg (unless you are on certain medication which requires a dose of 2 tablets). Please take the medication now.

2. What to do if you feel sick

If you are sick (vomit) within two hours of taking the tablet, please contact the pharmacy you initially visited as soon as possible for a further supply. If the pharmacy you originally visited is not open, you may go to another pharmacy offering the service and explain the circumstances for a replacement supply. Pharmacies offering the service are listed on

www.leicestersexualhealth.nhs.uk

Contact would need to be made with the Pharmacy to find specific opening times.

If this is not possible, you should seek alternative medical advice (your GP practice or the Integrated Sexual Health Service) urgently. Contact 0300 124 0102, visit www.leicestersexualhealth.nhs.uk or call 111 for information of your nearest service.

If you vomit later than two hours, the levonorgestrel will have already been absorbed into your system so you will not need a replacement dose.

3. What happens next

Your next period may arrive earlier, on time or later than usual. It can also be lighter or heavier than normal. You may have some irregular bleeding before your next period; this can range from spotting to being quite heavy.

Do take a pregnancy test to make sure that you are not pregnant if you:

- feel pregnant or
- if you haven't had a normal period within three weeks of taking levonorgestrel.

Free pregnancy testing is available at the integrated sexual health service and from a range of places if you are under 19 years. Visit www.leicestersexualhealth.nhs.uk for further details.

If you have any sudden or unusual abdominal pain or irregular bleeding in the next few weeks, these could be signs of an ectopic pregnancy. Although this is not common, it is very serious so you should seek urgent medical advice.

Levonorgestrel is very effective if taken as soon as possible after unprotected sexual intercourse but it will not prevent pregnancy in every case. If you do become pregnant despite taking levonorgestrel, there is no evidence that it will harm the pregnancy.

3. Future Contraception

This dose of levonorgestrel will not protect you against pregnancy if you have unprotected sexual intercourse in the future.

If you forgot to take your regular contraceptive pills, you should take them as soon as possible.

You should also use condoms as well as your usual contraception for the next 7 days for the combined pill, for the next two days with progestogen-only pill or for the next 9 days for Qlaira. If you are not sure which type of pill you usually take, please ask your pharmacist.

If you are planning to start the pill, it will be helpful to see your doctor or sexual health service soon as you may be offered a 'quick start' rather than waiting until your next period.

Emergency contraception does not protect against sexually transmitted infections, however condoms reduce the risk Chlamydia is the most common sexually transmitted infection (STI) in 15-24 year olds and it often does not have any symptoms. Chlamydia can be detected by a simple test and is easily treated. The Pharmacist will have offered you a chlamydia screening test and you are encouraged to take this test. If you think you are at risk of other STIs or would like a chlamydia test you should contact the sexual health service.

Emergency contraception is not as effective as using other regular methods of contraception. For confidential information & advice about contraception, please see your doctor or visit the integrated sexual health service.

Contact 0300 124 0102 or www.leicestersexualhealth.nhs.uk for information of your nearest service.

Appendix 2



Client Assessment and Record Form for supply of levonorgestral for Emergency Hormonal Contraception - to be used in conjunction with the approved PGD

Client Details

Name	Address (not mandatory)	Postcode	D. O. B. Age.
<p>Ethnicity (circle which applies)</p> <p>White: British Irish Eastern European Other</p> <p>Asian/Asian British: Indian Pakistani Bangladeshi Other</p> <p>Black/Black British: African Caribbean Other</p> <p>Mixed</p> <p>Other</p> <p>Not Stated</p>			

This is a confidential service.

Whatever your age, you have a right to confidential advice.

We will not give information to anyone (even if you are under 16) – including parents, other family members, care workers, school or your doctor, without your permission.

The only reason that we may have to consider passing on confidential information without your permission, would be to protect you or someone else from serious harm. We will always try to discuss this with you first.

Any information about you will be stored securely.

Confidentiality discussed with client	Y/N
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Client History

Details of current requirement for Emergency Contraception (tick all that apply)				
No contraception	Condom failure	Missed pill		
Vomited levonorgestrel dose	Other – please state			
How long ago was UPSI (hours)?				
Current regular method of contraception				
Condom	Pill (specify type)	IUD/S	None	Other (specify)
If missed Pills, give details:				
Menstrual cycle				
Day of cycle	Usual cycle length (days)	Regular Y/N	Has client had levonorgestrel or ulipristal since the LMP? Y/N	
Inclusion Criteria				
UPSI occurred within previous 72 hours? (Or within time judged to be clinically appropriate in relation to Cautions section of PGD) Y/N	Where a client has vomited the dose of levonorgestrel, was this within 2 hours of ingestion? Y/N	Have all options for Emergency Contraception been explained and the client prefers levonorgestrel? Y/N	Missed pills are in the timescales that cause loss of protection? Y/N	
Exclusion/Caution criteria (including follow up action)				
Criteria	Y/N	Recommended follow up	Follow up taken (please detail)	
Clients aged 13 years or under		<ul style="list-style-type: none"> Consider supply of levonorgestrel, if Fraser competent. There is a duty to seek further advice and onward referral to address child protection issues. <p>The Child Protection Team must be contacted for children aged 13 or under who present having had sexual intercourse.</p>		
Clients currently taking enzyme inducing drugs or have stopped within the last 28 days.		May be offered 3000 microgram dose of levonorgestrel (this is not based on evidence or within product licence but on expert clinical judgment of balance of risks and benefits)		
Breastfeeding		FSRH recommends women can use progesterone-only emergency contraception without restriction.		
Repeated use in same cycle		<p>Advice client:</p> <ul style="list-style-type: none"> She may be pregnant (consider pregnancy test as appropriate) Repeated use disturbs menstrual cycle Consider IUD as preferred alternative Levonorgestrel EHC will not interrupt a pregnancy (there is no epidemiological data to indicate that 1500 micrograms levonorgestrel has an adverse effect on the foetus) If UPSI was within 12 hours of previous levonorgestrel dose, further EHC not required. 		

Criteria	Y/N	Recommended follow up	Follow up taken (please detail)
Vomiting		If the request is due to an episode of vomiting which has occurred within 2 hours of taking the dose, a replacement supply may be issued (see appendix 3).	
Episodes of UPSI over 96 hours		Consider options if UPSI occurred between 72 hours and 120 hours e.g. levonorgestrel, out of license up to 96 hours or referral for ulipristal or IUD up to 120 hours.	
Previous UPSI more than 96 hours earlier within the same cycle and no emergency contraception used		Consider supply of levonorgestrel subject to clinical judgement. Consider pregnancy test.	
Previous UPSI within the same cycle and treated with ulipristal		Consider providing levonorgestrel and referral for IUD.	
Severe hepatic dysfunction		Consider discussion with Integrated Sexual Health Service or GP.	
Known breast cancer		Consider discussion with Integrated Sexual Health Service or GP.	
Severe malabsorption syndromes i.e. Crohn's		Consider discussion with Integrated Sexual Health Service or GP.	
Possible pregnancy: <ul style="list-style-type: none"> • Vague menstrual history • Last menstrual period late/abnormal/different 		Consider pregnancy test.	
Clients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption		Consider alternative method.	
Client given birth in last 3 weeks		EHC <u>not</u> required.	
Known acute porphyria		Do not provide. Refer to Sexual Health Service asap.	
Know hypersensitivity to levonorgestrel		Refer to GP or integrated sexual health service	
Client Over 25 years of age		Offer purchase of OTC supply. Refer to GP or Integrated sexual health services	

Patient Competence & Confidentiality (Fraser Guidelines apply)

If under 16 years old, client must be assessed to be competent using Fraser Guidelines (Appendix 4) and give verbal consent.

Criteria for Competence (for supply all answers must be 'yes')	Yes	No
Does the client understand the advice that she has been given?		
Has the client been encouraged to discuss the situation with her parent/guardian?		
Is the client's physical and/or mental health likely to suffer unless she receives emergency contraceptive treatment?		
Is providing contraceptive advice and treatment in the client's best interest?		

If the answer to any of the above is no then the client must be referred to her GP or the local Sexual Health Service as a matter of priority so that treatment may still take place within the necessary timeframe.

<p>Have any safeguarding, including child sexual exploitation, concerns been identified?</p> <p>Suggested areas to consider:</p> <ul style="list-style-type: none"> • age difference between couple and age of partner • where they met partner (internet/position of trust/via peers) • how long they have been together • appears frightened of partner • any learning disability • understanding of abuse/coercion/exploitation • existing social worker <p>Has a safeguarding referral been made YES/NO</p>
<p>Detail here any additional information relevant to your decision to supply levonorgestrel to this young person</p>

Action taken

Supply of levonegestrel	Y/N	Dosage (please specify)
Batch Number	Expiry Date	
Comments:		
If supply is not given, please detail reason & onward referral action taken.		
Patient consent given to share information with GP or Integrated Sexual Health Service (if required). Y/N		

Advice/Follow up Check List (tick to confirm discussed/actioned)

Effectiveness, including failure rate <input type="checkbox"/>	Side Effects <input type="checkbox"/>	Action if vomit within 2 hours <input type="checkbox"/>	Next period may be early/late <input type="checkbox"/>
Return if further UPSI <input type="checkbox"/>	Pregnancy test in 3 weeks <input type="checkbox"/>	If levonorgestrel EHC fails: not harmful to pregnancy <input type="checkbox"/>	Encourage contact GP Sexual Health clinic for regular contraception <input type="checkbox"/>
Medication taken on premises <input type="checkbox"/>	Manufacturer's patient information leaflet and Patient Information Sheet (Appendix 1) issued <input type="checkbox"/>	Chlamydia screen offered & STIs discussed <input type="checkbox"/>	Condom/information pack issued <input type="checkbox"/>

Confirmation and Consent

The stated action was based on the information given to me by the client.

The client has consented to use of levonorgestrel outside of product license.

Name of Pharmacist.....

Signature of Pharmacist.....

GPhC number Date.....

PHARMACY STAMP

Robust systems must be in place to meet the legal requirements of the Data Protection Act 1998 and the safeguarding of personal data at all times.

Appendix 3

Additional Guidance for Pharmacists

1. Repeat Supply within the Same Cycle:

➤ Vomited Tablets

If the dose of levonorgestrel has been vomited within 2 hours of ingestion, the dose may be repeated if it can still be taken within 96 hours of the UPSI. The efficacy of LNG has been demonstrated up to 96 hours; between 96 and 120 hours its efficacy is unknown. Use of LNG beyond 72 hours is outside the product licence.

Note that this differs from the recommendation in the SPC and in the patient information leaflet. A further supply should be provided and the client advised to take the replacement as soon as possible. Anti-emetics may be advised and the tablet should be taken with food.

The pharmacy should use clinical judgment regarding this.

If the replacement dose would be later than 96 hours after the unprotected intercourse, referral to a GP or Sexual Health Services is indicated.

2. Recommendations for use of EHC in missed pills with potential failures of combined oral contraceptives (COC)

The critical time for loss of contraceptive protection is when a combined oral contraceptives (COC) is omitted at the *beginning* or *end* of a cycle (which lengthens the pill-free interval).

If a woman forgets to take a pill, it should be taken as soon as she remembers, and the next one taken at the normal time (even if this means taking 2 pills together). A missed pill is one that is 24 or more hours late; for women taking *Qlaira*® or *Zoely*®, see BNF. If a woman misses only one pill, she should take an active pill as soon as she remembers and then resume normal pill-taking. No additional precautions are necessary.

If a woman misses 2 or more pills (especially from the first 7 in a packet), she may not be protected. She should take an active pill as soon as she remembers and then resume normal pill-taking. In addition, she must either abstain from sex or use an additional method of contraception such as a condom for the next 7 days. If these 7 days run beyond the end of the packet, the next packet should be started at once, omitting the pill-free interval (or, in the case of *everyday* (ED) pills, omitting the 7 inactive tablets).

A missed pill for a woman taking *Qlaira*® or *Zoely*® is one that is 12 hours or more late; for information on how to manage missed pills in women taking *Qlaira*® or *Zoely*®, refer to product literature.

Emergency contraception is recommended if 2 or more combined oral contraceptive tablets are missed from the first 7 tablets in a packet and unprotected intercourse has occurred since finishing the last packet.

3. TRADITIONAL POPs-missed pills

The following advice is recommended:

'If you forget a pill, take it as soon as you remember and carry on with the next pill at the right time. If the pill was more than 3 hours (12 hours for desogestrel) overdue you are not protected. Continue normal pill-taking but you must also use another method, such as the condom, for the next 2 days.'

The Faculty of Sexual and Reproductive Healthcare recommends emergency contraception if one or more progestogen-only contraceptive tablets are missed or taken more than 3 hours (12 hours for desogestrel) late and unprotected intercourse has occurred before 2 further tablets have been correctly taken.

4 Use of Contraception after taking levonorgestrel

Use of a barrier method should be recommended (e.g. condom) until the next menstrual period starts, if no other contraception is used.

Please see above re missed COC pills, (except Qlaira) i.e. the woman should continue taking tablets as normal, using **additional protection (barrier) for 7 days**. If there are less than seven pills remaining in the packet, the woman should continue with the next pack omitting the seven-day break or placebo tablets, if taking ED pills.

Please see above re missed POP pills, if using the POP the woman should continue taking tablets as normal, using **additional protection (barrier) for 2 days**. Additionally, it may be advisable to have a pregnancy test 3 weeks after UPSI.

If using Qlaira the woman should continue taking tablets as normal, using **additional protection (barrier) for 9 days**.

Appendix 4

The Fraser Guidelines in practice

If a client is believed to be under the age of 16 the pharmacist should:

- Assess the maturity of the client in terms of understanding any advice given
- Encourage the client to involve her parents
- Consider the effect on the physical or mental health of the client if advice or treatment is withheld
- Make a decision as to whether the client's best interests require the provision of contraceptive advice or supplies or both without parental consent

Where the pharmacist does not consider a young person meets the Fraser Guidelines a supply of levonorgestrel may not be provided. The pharmacist should recommend (and assist where necessary) the client to attend their GP or the Integrated Sexual Health Service.

Fraser Competence – Clients Under 16 Years

The Gillick ruling in 1985 established the current legal position in England and Wales, which states that people under the age of sixteen are legally able to consent on their own behalf to medical or dental procedures or treatment.

In considering the provision of advice or treatment on contraception, doctors and other professional staff need to take special care not to undermine parental responsibility and family stability. The doctor or health professional should therefore, always seek to persuade the young person to tell their parents or guardian (or other person in *loco parentis*) or to let the doctor inform them, that contraceptive advice is being sought and the nature of any advice or treatment that is given.

Exceptionally there will be cases where it is not possible to persuade the young person either to inform the parents or to allow the health professional to do so. In such cases, a doctor or other health professional would be justified in giving advice and treatment without parental knowledge or consent provided that the doctor or other health professional was satisfied that the Fraser Guidelines (often referred to as Gillick Competence) were met:

The Fraser Guidelines

1. The young person can understand the advice and has sufficient maturity to understand what is involved in terms of moral, social and emotional implications.
2. The young person cannot be persuaded to involve the parents, nor will they allow notification to the parent that contraceptive advice was being sought.
3. The young person will be very likely to begin or continue to have sexual intercourse with or without contraceptive treatment.
4. Without contraceptive advice or treatment the young person's physical and/or emotional health will be likely to suffer.

5. The young person's best interests require the health professional to give contraceptive advice and/or treatment without parental consent

Source: *The Fraser Ruling: Gillick v West Norfolk and Wisbech Area Health Authority (1985)*

Sexual Offences Act (2003) was made for prevention of sexual offences, and the protection of children from harm due to sexual acts. (<http://www.legislation.gov.uk/ukpga/2003/42/section/1>)

- The aim of the law is to protect the safety and rights of young people and make it easier to prosecute people who pressure or force others into having sex.
- Forcing someone to have sex is a crime.
- In England and Wales, under the law on Sexual Offences, the legal age for young people to consent to have sex is 16.
- In England, Wales and Northern Ireland those under the age of 13 years are considered unable to legally consent to sexual activity.
- Although the age of consent remains at 16, but the law should not be used to prosecute mutually agreed teenage sexual activity between two young people of a similar age, unless it involves abuse or exploitation.
- Under the Sexual Offences Act young people still have the right to confidential advice on contraception, condoms, pregnancy and abortion, even if they are under 16.
- The assessment of a young person's capacity to make a decision about contraception or medical treatment is a matter of clinical judgement guided by professional practice and local/national policy and is a legal requirement.
- Assumptions should not be made about an individual's capacity to consent based on age alone or disability

(Reference: SERVICE STANDARDS ON OBTAINING VALID CONSENT IN SEXUAL HEALTH SERVICES September 2014 Published by the Clinical Standards Committee, FSRH, (<http://www.fsrh.org/pdfs/ConsultationConsentServiceStandard.pdf>)

Appendix 5

Referral Proforma

Patient Group Direction – Emergency Contraception Referral by Community Pharmacist

Dear Doctor,

The named client below is considered to be unsuitable for issue of levonogestrel under the Leicester City, Leicestershire County & Rutland County Council's Patient Group Direction for Emergency Hormonal Contraception due to reasons provided below. Would you please provide the necessary advice regarding emergency contraception and/or on-going healthcare.

Clients name	
Date of Birth	
Date and time of consultation with Pharmacist	
Details of client history and reason for referral	
Date of first day of LMP and day of cycle	
Length of normal cycle	
Hours since UPSI	
Normal method of contraception	
Any safeguarding concerns identified? Any actions taken?	

Yours faithfully

Pharmacist name:

GPHC number:

Pharmacy address:

Telephone number:

Appendix 6

Contact details below are correct at time of production (February 2015)

LLR Sexual Health Service for appointments, advice, information for patients	0300 1240102 0800 318908	www.leicestersexualhealth.nhs.uk
LLR Sexual Health Service (Professional helpline)	0116 2951208 Available: Monday- Friday (9am -7.30pm) Saturday (9am – 1.30pm)	
Safer Sex project: pregnancy testing, condoms, advice & information for young people from range of local sites	Leicester City: LLR Sexual Health Service 0300 1240102 0800 318908 Leicestershire & Rutland (POP project): 01509 265197 POP text service: 07814877859	www.leicestersexualhealth.nhs.uk
Juniper Lodge: Sexual Assault Referral Centre (SARC)	0116 2733330	www.juniperlodge.org.uk
Rape Crisis	0116 2558852 0808 8029999	www.rapecrisis.co.uk
Leicester Constabulary Sexual Assault Unit (SIGNAL team/child abuse Investigation Unit)	Call 101 0116 222 2222	
Safeguarding If you think a child or young person is being abused or harmed, take action straight away. If you have concerns about a child or young person, help is available 24 hours a day, seven days a week.	Leicester City Council 0116 454 1004 It is expected that any professional/practitioner wanting to make a referral to Leicester City, will in the first instance ring the duty social worker and discuss the details of the referral. This can then be followed up by the referrer in writing and faxed. Leicestershire County Council 0116 305 0005 Please complete the electronic Agency Referral Form which is available at the following link:	

<https://forms.leics.gov.uk/AF3/an/default.aspx/RenderForm/?F.Name=r1c2j94jcs3>

The completed referral form should then be faxed to: 0116 305 0011

Postal address: Central Duty Service, Specialist Services, Children and Young People's Service, Leicestershire County Council, Eastern Annexe, County Hall, Glenfield, Leicestershire, LE3 8SR

Rutland County Council

01572 758407

Referrals to social care about children must be made in writing or confirmed in writing (by fax) after telephone contact is made.

Postal address: Rutland County Council, Childrens Duty & Assessments, Catmose, Oakham, Rutland, LE15 6HP

Police

Non emergencies, call 101

In emergencies, always dial 999

ChildLine

0800 1111

www.childline.org.uk

NSPCC

0808 800 5000

help@nspcc.org.uk

The Leicester City, Leicestershire and Rutland Local safeguarding Children Board procedures are available from:

www.lrsb.org.uk and www.lcitylscb.org