




This Patient Group Direction (PGD) must only be used by registered Pharmacists who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction
For the supply and oral administration of
Levonorgestrel 1500mcgs
(Levonelle 1500)

By registered pharmacists for
Women requesting emergency contraception
In Northumberland, North Tyneside and Newcastle

Version number: NOT- 1. V1.

PGD Authorisation Group

Name	Job title and organisation	Signature	Date
Senior doctor Professor Eugene Milne	Director of Public Health, Newcastle City Council		2/1/2015
Senior pharmacist Anne Everden	Pharmacy Consultant to PH, North Tyneside and Northumberland County Council.		2/1/2015
Person signing on behalf of authorising body Karen Rowell.	PH Service Manager, Northumberland County Council		2/1/2015

Change History

Version number	Change details	Date
1	Update of PCT PGDs NOT -263-V3.1 (May 2013)	2/1/2015

Training and competency of registered Pharmacists

Requirements of registered Pharmacists working under the PGD	
Qualifications and professional registration	Registered with the General Pharmaceutical Council
Initial training	Must attend initial training prior to using the PGD
Competency assessment	<p>Pharmacists will have ;</p> <ul style="list-style-type: none"> • Successfully completed CPPE training on Emergency Hormonal Contraception training • Attended programme provided and accredited by Newcastle, North Tyneside and Northumberland Public Health Team • Appropriate indemnity insurance • Systems to protect confidential information • Awareness and understanding of the emergency contraception guidelines including advanced supply of Levonorgestel 1500mcg.
Ongoing training and competency	<ul style="list-style-type: none"> • Maintain knowledge and expertise and keep up to date with any changes in the use of POEC • Complete annual refresher e-learning and face to face training as appropriate

Copper IUD should always be the initial option for women who are requesting emergency contraception

Clinical Condition

Clinical condition or situation to which this PGD applies	Request for Emergency Contraception
Inclusion criteria	<p>Any female in her reproductive years. Fraser competent if under 16. Emergency Contraception up to 72 hrs after first episode of unprotected sexual intercourse (UPSI) that cycle including:</p> <ul style="list-style-type: none"> • Penetration without ejaculation or ejaculation on external genitals • Barrier method failure- cap or condom • Missed pill without alternative methods used- check missed pill guidelines • Medroxyprogesterone acetate (Depo- Provera®) injection overdue by two weeks (i.e. more than 14 weeks since last injection) • Potential intrauterine contraceptive device (IUD) failure, e.g. lost threads • Withdrawal method used • No method used • Following rape or sexual assault. <p>The patient is beyond 3rd day of spontaneous menstrual cycle unless menstrual cycle is short</p> <p>More than 21 days post- partum. Any UPSI after the 21st day should be assessed for risk.</p> <p>Following termination of pregnancy, consider the date of termination as the last menstrual period.</p>

	<p>Patient has received progestogen only emergency contraception (POEC) but has vomited within TWO hours- offer a repeat dose of Levonorgestel 1500mcg, provided she is still within 72 hours of UPSI.</p> <p>If it is longer than 72 hours since UPSI, Levonorgestel 1500mcg may be considered, but women should be informed of limited evidence of efficacy, that such use is outside the produce license. Use Cu IUD or ulipristal if possible.</p> <p>Patient who may not need POEC on medical grounds on the basis of failed contraception but show extreme anxiety about conceiving.</p>
Exclusion criteria	<p>IUD is the more effective appropriate method and should be discussed with the patient before referral to a doctor.</p> <p>Other exclusions:</p> <ul style="list-style-type: none"> • Hypersensitivity to any of the ingredients in the preparation or patient has previously experienced any severe clinical problems with hormonal contraception • Unexplained vaginal bleeding • Current breast cancer • Several liver disease or current hepatocellular jaundice • Acute porphyria • During a sickle cell crisis • Patient not deemed to be competent or requests to see a doctor • Pregnancy (where pregnancy is suspected, a pregnancy test should be performed) <p>Ulipristal acetate (ellaOne®) is recommended by APC as the preferred drug treatment option for post coital contraception for patients who present between 72-120 hours following unprotected intercourse and when an IUD is unacceptable. See PGD NoT-2.V1.</p>
Cautions (including any relevant action to be taken)	<p>A history of active or poorly controlled intestinal malabsorption disease, e.g. Crohn's Disease because this may impair the efficacy of Levonorgestel.</p> <p>The effectiveness of levonorgesterel is reduced in women taking liver enzyme inducing drugs (and possibly for 4 weeks after stopping); a copper intra-uterine device should be offered instead or the dose of levonorgesterel should be increased to a total of 3mg taken as a single dose (unlicensed dose-advise women accordingly) within 72 hours of UPSI. This is recommended by the Faculty of Sexual health and Reproductive Healthcare and seen as standard practice but is outside the product license. Enzyme inducing drugs include: barbiturates, primidone, phenytoin, carbamazepine, phenylbutazone, St John's Wort, rifbutin, griseofulvin, rifampicin or ritonavir. See BNF for full list of affected drugs.</p> <p>Ciclosporin metabolism is inhibited by progestogens (increase plasma concentration). Women who are taking ciclosporin may wish to consider use of non-hormonal methods of contraception such as IUD, but hormonal methods could be considered after consultation with the patients consultant (FFPRHC 01/09/06)</p> <p>Note- commonly used antibiotics do not interfere with POEC. There is no need to increase the dose for emergency contraception if the patient is taking antibacterials that are not enzyme inducers.</p> <p>If there are symptoms of PID- Refer to a doctor</p>
Arrangements for referral for medical advice	<p>If the patient is under 13 years of age discuss with doctor</p> <p>Patient self refers.</p> <p>Refer to a doctor within the contraception and sexual health service if medically indicated or at patient's request.</p>

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Action to be taken if patient excluded	Refer for fitting of an emergency Cu-IUD if patient wishes. Consider use of ellaOne For other exclusions, refer to clinic doctor (or doctor on call). Document advice given.
Action to be taken if patient declines treatment	As above

Details of the medicine

Name, form and strength of medicine, include ▼ for black triangle medicines	Levonorgestrel 1500mcg tablets
Legal category	POM
Indicate any off-label use (if relevant)	Unlicensed- one tablet between 72-120 hours after UPSI only if other treatments are unacceptable. Unlicensed- increased dose two tablets (3mg) if the patient is taking Liver enzyme inducing drug (see BNF and FFPRHC guidance for list of affected drugs)
Route/method of administration	Orally
Dose and frequency	Single administration One tablet as soon as possible after UPSI. A dose of two tablets if the patient is taking liver enzyme inducing drugs (Unlicensed use FFPRHC 2012). Administration while in the pharmacy should be encouraged and supported, although this is voluntary.
Quantity to be administered and/or supplied	Medication will be supplied in pre-packed labelled single dose boxes containing 1 tablet, if patient not consuming on the premises
Maximum or minimum treatment period	One tablet single dose within 72 hours of UPSI Second dose if first dose vomited within two hours Unlicensed- one tablet between 72-120 hours after UPSI only if other treatments are unacceptable. Unlicensed- increased dose two tablets (3mg) if the patient is taking Liver enzyme inducing drug (see BNF and FFPRHC guidance for list of affected drugs)
Adverse effects	Headaches, nausea and altered bleeding patterns are the most common side effects. Less than 1% of women experience vomiting. Breast tenderness, low abdominal pain and dizziness are less common. Please refer to SPC or current BNF (http://www.bnf.org.uk) for full details. Use the Yellow Card System to report adverse drug reactions directly to the CSM.
Records to be kept	Complete record of consultation for emergency contraception which includes; <ul style="list-style-type: none"> • Patients name, date of birth, postcode and consent given • Reason for requesting emergency contraception • Previous use of POEC • Estimated day of ovulation • Day in cycle of UPSI • Time since first UPSI (within 72 hours/within five days/within five days of ovulation). • Relevant medical history • LMP normal/abnormal (pregnancy test if indicated) • Recent menstrual cycle any symptoms described by the patient • Risk of STI and referral to GUM (if indicated) • Dose and form administered/supplied

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	<ul style="list-style-type: none"> • Batch and expiry date details • Advice given to patient (including side effects) • Signature of Pharmacist • Signature of patient • Medication the client is taking which will influence EHC provision • Referral arrangements (including self-care) <p>Input data onto appropriate data collection system (Pharmaoutcomes/Portal)</p>
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Patient information

<p>Written information to be given to patient or carer</p>	<p>Give following information leaflets:</p> <ul style="list-style-type: none"> • Product specific Patient Information Leaflet • Contraception & Sexual Health Service • Information on taking POEC • A leaflet on all contraceptive methods • A leaflet about sexually transmitted infections and genito-urinary services (if appropriate)
<p>Follow-up advice to be given to patient or carer</p>	<p>Explain why an emergency IUD is advised instead of Levonorgestrel 1500mcgs (Levonelle 1500) (more effective). Advise to take as soon as possible to improve efficacy. Advise to return if any concerns arise. Mode of action- uncertain but thought to inhibit or delay ovulation. Failure rate- This varies depending upon when in the cycle UPSI has occurred, the interval since UPSI. The failure rate increases with time. Warn that the patient may still become pregnant and should seek further advice if menstruation is delayed, lighter than normal or missed. Any abdominal pain, seek medical advice Emphasize that emergency contraceptives are not suitable for repeated use as they have a higher failure rate than regular oral contraception. Discuss on-going contraception.</p> <p>If under 13, consult with a doctor.</p> <p>Foetal effects- No evidence that this method of contraception has any teratogenic effects.</p> <p>Pharmacists should advise patients to attend GP or Family Planning Clinic if they do not have a routine form of contraception so that options can be discussed and a method established.</p> <p>Patients who present having missed one or more of their oral combined contraceptive tablets should be advised to continue taking their normal oral contraceptive for the remainder of the cycle. They should also be advised to use barrier methods of contraception for the next seven days. If these seven days run into a pill free interval (or placebo tablets of an ED pack), patients should be advised to omit the pill free interval (or placebo tablets) and start the next pack of pills immediately.</p> <p>A verbal warning should be given that the tablets may cause nausea and vomiting. If vomiting occurs within two hours of taking the tablets, further advice must be sought immediately. Give a contact telephone number- Contraceptive Services, or GP, A&E, Out of Hours Service if outside clinic hours. Offer condoms until the next period.</p>

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Appendices

Appendix A Key references

1. Summary of Product characteristics (SPC) Levonelle available at <http://www.medicines.org.uk> (accessed 10/11/2014)
2. Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit. Emergency Contraception (updated January 2012)(<http://www.ffprhc.org.uk>) (accessed 3/6/14)
3. Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit. Drug Interactions with Hormonal Contraception. (updated January 2012)(<http://www.ffprhc.org.uk>) (accessed 15/05/2014)
4. Current edition of BNF. (<http://www.bnf.org.uk>)









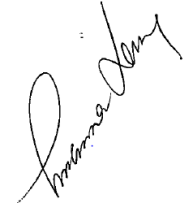
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Appendix B PGD Working Group.

Name	Job title and organisation	Signature	Date
Lead author- Karen Rowell	Public Health (PH) Service Manager, Northumberland County Council		2/1/2015
Lead doctor - Diana Mansour	Sexual Health Consultant , Newcastle Foundation Trust		2/1/2015
Lead pharmacist – Anne Everden	Pharmacy Consultant to PH, North Tyneside and Northumberland County Council.		2/1/2015
Representative of professional group using PGD- Ann Gunning	Community Pharmacy Development Lead, North of Tyne LPC		2/1/2015
Other members of the PGD working group			
Wendy Burke	PH Consultant, North Tyneside Council		2/1/2015
Karen Herne	PH Service Manager, Northumberland County Council		2/1/2015
Helen Robinson	Senior Public Health Specialist, Newcastle Council		2/1/2015
Vivienne O’Sullivan	Sexual Health Clinical Lead, Northumbria		2/1/2015
Susanna Leung	Healthcare NHS Foundation Trust (NHCT) (North Tyneside)		2/1/2015
	Sexual Health Clinical Lead, NHCT (Northumberland).		2/1/2015

Appendix C Health professionals' agreement to practise

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

Name of Pharmacist	Signature	Registration Number	Authorising Manager	Date