

APPENDIX A

LOCALLY COMMISSIONED SERVICE SPECIFICATION

Service Specification	Emergency Hormonal Contraception and Condom Distribution in Community Pharmacy
Service	Sexual Health
Authority	Public Health Lead
Provider Representative	Community Pharmacies
Authority Details: Name Address Email Telephone Number	Public Health Lead Civic Centre York Street Twickenham TW1 3BZ
Period	1st April 2015 – 31st March 2016
Date of Review	September 2015

1. Population Needs

1.1 Background

Levonorgestrel (Levonelle® 1500) is a progesterone contraceptive designed to be used for the occasional emergency when sexual intercourse has taken place without protection or when protection has failed (e.g. burst condom). Emergency hormonal contraception (EHC) is not a substitute for regular contraceptive use as it is less effective and provides no protection from HIV or sexually transmitted diseases. However it is a safe and effective way of preventing accidental pregnancy after unprotected intercourse. A 1998 World Health Organisation (WHO) trial demonstrated that Progestogen-only emergency contraception, prevented 86% of expected pregnancies when treatment was initiated within 72 hours of unprotected sex, this increased to 95% when treatment commenced in the first 24 hours¹.

The provision of EHC to young women plays an important role in the prevention of pregnancy group, because of the nature of their sexual activity which can be unplanned and sporadic.

Community Pharmacy (C.P.) provide an excellent opportunity to access young people due to their high street location; long opening hours and non medical setting, enabling young people to more readily access services that are convenient and accessible to them. For this reason C.P.'s play an increasing role in the delivery of sexual health services. The 2008 Pharmacy White Paper² sets out specific proposals on the contribution that pharmacies can make to sexual health services nationally.

¹ Faculty of Family Planning and Reproductive Health Care, Clinical Effectiveness Unit (2006)

² Pharmacy in England: building on Strengths Delivering the Future - 2008

2. Key Service Outcomes

2.1 Outcomes

To improve the sexual and emotional health and wellbeing of young people in the London Borough of Richmond upon Thames, whilst reducing the rates of unwanted pregnancy in the borough.

To establish a holistic sexual health service in C.P., whilst addressing health inequities and improving outcomes for young people whatever their circumstance.

3. Scope

3.1 Aims and objectives of service

Aims

The aim of the service is to provide free EHC through C.P. by Patient Group Direction (PGD) to girls and young women aged 13 - 24 years of age following unprotected sex / failed contraception in the last 72 hours.

The primary aims of this Locally Commissioned Service are to:

- Help provide easy and swift access to free EHC
- Offer Chlamydia screening after unprotected sexual intercourse to every request for EHC
- Strengthen the network of sexual health services in the community
- Improve access to mainstream contraceptive and sexual health services in the target group, especially those who are hard to engage
- To provide sexual health services in a safe and confidential environment

Objectives:

- To strengthen and increase access to EHC in a safe and confidential environment
- To provide prompt and convenient access to consistent, equitable and high quality sexual health care and advice without the need to wait and see a doctor or nurse
- To improve choice and access to EHC
- Increase knowledge of EHC, contraception generally and sexual health services
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- Improve access to information and advice relevant to improving the health and health literacy in young people
- To de-stigmatise Chlamydia infection and raise awareness of safer sexual practices
- To increase access to free condoms
- To increase understanding - and raise awareness - of the importance of screening for sexually transmitted infections (STI's) in young sexually active service users
- To support health professionals through improve referral and signposting to Contraceptive and sexual health (CASH) services, GUM

clinics and other services in the community

3.2 Service description/pathway

This specification will continually be reviewed in line with national recommendations in order to ensure adherence with best practice, and national and local requirements.

3.2.1 EHC provision

The pharmacist will assess the suitability of the person to receive free EHC, in line with the inclusion and exclusion criteria detailed in the PGD for Levonelle (appendix 2 and assess young people under 16 or and adult deemed an 'adult at risk' for Fraser competency. When a young person is judged not to be competent in line with the Fraser ruling, they should be referred to GUM or GP (*liaise with the Safeguarding Team first*). Where appropriate a supply will be made. However if, in the pharmacist's professional opinion, they feel that supply is not appropriate a referral should be made to GUM/CaSH.

Service users will self-refer and may also be referred by other healthcare professionals including other C.P. not participating in the scheme. The pharmacists will:

- Supply EHC to women aged 13 – 24 years old of age and according to the inclusion and exclusion criteria and procedures detailed in the EHC PGD and EHC guidelines (appendix 2)
- Take Levonelle 1500 from CP contractor's own stock - to be reimbursed by the Authority
- The service user would normally be expected to take EHC on site and should be provided with the means to do this comfortably, under the supervision of the accredited pharmacist e.g. given a cup of water to take the tablets in the consultation area. However the pharmacist should use their professional discretion in those situations where the service user indicates they do not wish to take the medication immediately. In this case EHC must be labelled according to the PGD for the service user to take away

3.2.2 Chlamydia screening

Offer a Chlamydia screen to all service users requesting EHC and encourage them to re-test in six weeks due to the incubation period – for payment details refer to Chlamydia screening service specification.

3.2.3 Information

As good case management the pharmacist is required to reassure confidentiality and with every EHC provision must treat and counsel the patient separately from accompanying partners. Interviews should include advise on (to include but not limited to);

- Information about ongoing contraception including LARC and condom use
- Re-test in six weeks
- Chlamydia screening and re-testing annually and on change of sexual partner if sooner
- Sexual health promotion

- Suggest a full sexual health screen at GUM
- Give information on the C-card scheme and provide two free condoms with each EHC provision – see point 3.2.5

3.2.4 Data – Refer to the Chlamydia Treatment LCS

3.2.5 Free condoms – Refer to the Chlamydia Screening LCS

3.3 Population covered

- Females between 13 and 24 years of age

3.4 Any acceptance and exclusion criteria and thresholds

3.4.1 Criteria for acceptance

Females between 13 and 24 years of age presenting for EHC within 72 hours of unprotected sexual intercourse and who meet the criteria set out in the PGD for Levonelle. The service is open to any young woman using C.P. in Richmond. There is no requirement for service users to be registered with a Richmond G.P or resident in the borough.

3.4.2 Exclusion from EHC provision

In line with the Levonelle PGD and to include:

- Known or suspected pregnancy
- Under 16 years old and assessed as not competent using Fraser guidelines
- Under 13 years old
- Hypersensitivity to any constituent of the POEC
- More than 72 hours since this episode of unprotected sexual intercourse
- Declined to be treated under PGD
- Supply of EHC to a third party is not permitted

3.4.3 Service users falling outside the criteria for the EHC provision

Anyone who falls outside the Levonelle PGD/criteria should be immediately referred to GUM or Contraception and Sexual Health (CASH) services. Levonelle, One Step can be sold over the counter if the service user doesn't want to be referred.

3.5 Interdependencies with other services

- GUM, CaSH services G.P. (referral of young people deemed not Fraser competent)
- The CSO for supply of Chlamydia screening kits and managing results

- Service users should be advised to be screened for Chlamydia annually – or at change of partner if sooner. They should be made aware of the free online testing service at <http://www.freetest.me/>
- The London C-card scheme <http://www.comecorrect.org.uk/> - free condoms for under 25 year olds provided to C.P. by LBRuT – distribution to be logged through the c-card web site in order to audit supplies.
- Service users should be made aware of the web site <http://www.gettingiton.org.uk/> which gives up to date information on sexual health services in South West London and www.freetest.me for online Chlamydia testing kits.

3.6 Any activity planning assumptions

N/A

4. Applicable Service Standards

In addition to the Chlamydia Treatment LCS

4.1 Applicable national standards

The C.P. should refer to the following standards and guidelines for the delivery of the EHC service:

- [Individual pharmacists must complete and submit the CPPE Personal Declaration of Qualifications and Competence to deliver EHC Service³ \(renew every three years\).](#)

4.2 Applicable local standards – refer to the Chlamydia Treatment LCS

4.2.1 Summary of information required to deliver the service before it can start – in addition to the Chlamydia Treatment LCS

C.P. Requirements

- Must be accredited by the Authority to provide EHC

³ https://www.cppe.ac.uk/services/docs/ec_wgll.pdf

- Must commit appropriate staffing levels to support the delivery of the service and identify a pharmacist EHC lead.
- There are adequate stock levels of Levonelle

Staff Competencies – in addition to the Chlamydia Treatment LCS

- The named EHC lead will be required to carry out tasks in line with the Chlamydia screening lead.

4.2.2 Training – In addition to the Chlamydia Treatment LCS's

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CPPE Programmes, Workshops and Assessment Training/Learning for EHC

- Emergency Contraception e-Learning Programme - and assessment
- Contraception Open Learning Programme - and assessment

Please note that the cost to cover staff whilst in training is not included.

4.2.3 Safeguarding – Refer to the Chlamydia Treatment LCS Safeguarding, Safeguarding Adults, Safeguarding Children

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4.2.4 Complaints – Refer to the Chlamydia Screening LCS

4.2.5 Incidents Requiring Reporting – Refer to the Chlamydia Screening LCS

4.2.6 Information Governance – Refer to the Chlamydia Screening LCS

4.2.7 Post Payment Validation – Refer to the Chlamydia Screening LCS

5. Quality Outcome Indicators / Data Submission

Quality Outcomes Indicators	Threshold	Method of Measurement	Consequence of breach	Data to be Submitted (√)	Method for data submission
Online system to be completed accurately	100%	Details of service user to be taken from service user at EHC provision	No payment and performance monitoring meeting called by commissioner	Service users name Post code Date of birth Attendance date Reason for attendance Referrals/signposting If service user is under 13 years of	Online system to be completed at the time of treatment (or within 48hrs)

				age record action taken Name of medication, number of tablets supplied, batch number and expiry dates Refusal of treatment by the service user and reason Refusal of treatment by pharmacist and reason Safeguarding action How the service user knew of the service visited Chlamydia screen	
Completed, dated and signed Fraser competency forms to be submitted for under 16 year olds and adults deemed an adult at risk. Provide only if competent	100%	Pharmacist to complete form giving information about service user producing sample. Form to be signed and dated by service user. If the service user is accompanied by a responsible adult they should also sign and date form.	No payment and performance monitoring meeting called by commissioner	Monthly forms to be securely submitted to the LBRuT Public Health	Completed Fraser competency form for be sent securely to Public Health

Please note that any costs relating to data collection and submission are included within the service price

6. Prices 1st April 2015 – 31st March 2016

Chlamydia screening payments in line with the Chlamydia Screening Service Specification

Basis of Contract	Unit of Measurement	Price	Thresholds	Expected Annual Contract Value
Consultation and condom provision	per service user		None	N/A
Supply of one Levonelle in addition to	one 1500mg tablet		None	N/A

consultation fee				
Supply of two Levonelle in addition to consultation fee	Two 1500mg tablets – when service user using enzyme inducing drugs/within four weeks of stopping		None	N/A

7. Reporting and Payment

Locally Commissioned Services Reporting and Payment Schedule

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- Public Health commissioners will have 3 working days (from the last day of data received) to verify the data according to iPharmPro system.
- On the 3rd working day commissioners will submit verified data to the London Borough of Richmond upon Thames Finance Department for payment.
- Payment to the provider will be made within 30 days from receipt of validated data.
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The table below summarises these key dates.

Reporting period	Data submission cut-off date	Commissioner verification cut-off date	Finance processing
	<i>Online submission</i>	<i>PH commissioners to verify provider data (3 working days from cut-off date)</i>	<i>Processed within 30 days from commissioner verification date</i>
2014-15			
Qtr. 4 1 Jan 2015 – 31 Mar 2015	Tuesday 7 April 2015	Friday 10 April 2015	Sunday 10 May 2015
2015-16			
Qtr. 1 1 Apr 2015 – 30 Jun 2015	Tuesday 7 July 2015	Friday 10 July 2015	Sunday 9 August 2015
Qtr. 2 1 Jul 2015 – 30 Sep 2015	Wednesday 7 October 2015	Monday 12 October 2015	Tuesday 10 November 2015

Qtr. 3 1 Oct 2015 – 31 Dec 2015	Friday 8 January 2016	Wednesday 13 January 2016	Friday 12 February 2016
Qtr. 4 1 Jan 2016 – 31 Mar 2016	Thursday 7 April 2016	Tuesday 12 April 2016	Thursday 12 May 2016
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APPENDIX 1

EHC Guidelines

Certain information will need to be obtained by the pharmacist in order to be sure that EHC is safe for the woman to take.

Key questions / information to obtain

1. Is the service user under 16 years of age or deemed adult at risk?

If yes, ensure their Fraser Competency is assessed and refer on if not competent or there are any safeguarding concerns.

2. Is the service user under 13 years of age?

If yes, see safeguarding information and refer.

3. Is the consultation with the service user?

Supply to someone else (i.e. third parties) should normally only be carried out in exceptional circumstances.

4. Has there been unprotected sex / intercourse within the last 72 hours?

The efficacy of EHC decreases with time and will only be effective if taken within 72 hours of unprotected sex. An IUD can be fitted up to 120 hours (5 days) after unprotected sex or within 5 days of expected ovulation. Service users who may need an IUD must be referred on as a matter of urgency.

5. Is it possible that the service user is already pregnant?

Is your period late? If so, how late?

Was your last period shorter or lighter than usual?

Was your last period unusual in any other way or different from normal?

Since your last period, have you had unprotected sex at any time before this occasion?

Pregnancy is a contraindication to taking EHC and service users should be referred. In addition, pharmacists should be aware that there are some conditions, for example, Chlamydia infection, which can cause bleeding between periods and therefore could be confused with pregnancy or miscarriage. Any service user who answers 'yes' to any of the questions should be considered for referral.

6. Has EHC been used since the last period?

More than one course of EHC can be taken safely within the same menstrual cycle, but a service user may need to seek advice about more reliable methods of contraception and advised about cycle disruption.

7. Are any medicines or pills being taken, including over the counter or herbal remedies?

Some medicines and herbal remedies interfere with the dose of levonorgestrel required and service users will need to be referred e.g.:

Carbamazepine	Griseofulvin
Phenobarbital	Phenylbutazone
Phenytoin	Primidone
Rifabutin	Rifampicin
Ritonavir	St John's Wort
Ciclospirin	

8. Are there any problems that may affect absorption of EHC e.g. vomiting, severe diarrhoea, Crohn's disease?

The dose of Levonorgestrel may need to be changed if there are problems with absorption. Service users will need to be referred.

9. Are there severe liver problems?

Levonorgestrel containing EHC is not recommended in service users with severe hepatic dysfunction. Service users will need to be referred.

10. Has there previously been an allergy or other reaction to emergency contraception or levonorgestrel?

Allergy to Levonorgestrel is rare but is a contraindication to taking progestogen containing EHC.

Key Things to Raise When Recommending EHC

If a decision to supply EHC is taken, pharmacists should highlight the following points:

Emergency use: EHC is for emergency use after unprotected sex and is not as effective as using regular methods of contraception.

How to take: A single dose of 1.5 mg levonorgestrel based EHC (equating to 2 x 0.75 mg tablets) should be taken as soon as possible, preferably within 12 hours and no later than 72 hours (3 days) since unprotected sex.

Side effects: The most commonly reported side effect is nausea; some women may also vomit after taking EHC. Irregular bleeding and spotting may occur until the next period.

Vomiting: If the service user vomits within three hours of taking EHC, she should take another single dose of 1.5 mg levonorgestrel based EHC (equating to 2 x 0.75 mg tablets) immediately. They should be advised to contact their GP, contraception clinic or pharmacist if this happens for further advice and more tablets.

Ectopic pregnancy: If any severe lower abdominal pain occurs after taking this medicine the service user should refer to her doctor promptly as this could signify an ectopic pregnancy.

Continued contraception: EHC does not provide protection against pregnancy for the rest of the menstrual cycle. Other contraceptive methods are needed and should be discussed. Service users seeking EHC because they have missed one or more oral contraceptive should be advised according to the oral contraceptive they are taking. Full advice can be found in the BNF.

Breastfeeding: Small amounts of levonorgestrel may appear in breast milk. This should not be harmful to the baby, but women can be advised to take EHC immediately after a breast feed, thus reducing the amounts of levonorgestrel the baby may take in at the next feed.

Next period: EHC can alter the timing and type of bleeding of the next menstrual period, which may start early or late, but usually within three days of the expected time.

Follow up: Suggest follow up advice from a GP, practice nurse or contraceptive service approximately three weeks after taking EHC if the next period is light, more than 3 days late, or unusual in any way (to establish whether the service user is pregnant).

STIs: EHC does not protect against STIs, only condoms do this. Due to unprotected sex and STI risk a Chlamydia test must be taken and information leaflet on sexual health and STIs provided.

Local networks: Provide information on local services offering advance supplies, advice on contraception, sexual health, follow up care, testing and screening for STIs.

LONDON CONTRACEPTION AND SEXUAL HEALTH
PATIENT GROUP DIRECTION (PGD)



**PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF
PROGESTOGEN ONLY
EMERGENCY CONTRACEPTION (POEC)
LEVONORGESTREL 1.5mg tablet**
by
**COMMUNITY PHARMACISTS WORKING IN A COMMUNITY
PHARMACY contracted by the London Borough of
Richmond upon Thames**
Version Number 1.2

Change History	
Version and Date	1.2 01/03/2015
Version 1.2	New template. Updated SPC/BNF/NICE and other references Minor changes to text Amendments in line with FSRH guidelines (2014)

Organisations

Each organisation using this PGD must ensure that it is formally authorised by a pharmacist, a medical lead and a governance lead on behalf of the authorising organisation to ensure that this document meets legal requirements for a PGD.

Community pharmacists

Each community pharmacist using this PGD must ensure that it is formally authorised i.e. signed by a pharmacist, medical lead and governance lead of the commissioning organisation which has legal authority to do so, ensuring that this document meets legal requirements for a PGD.

This PGD must only be used by registered community pharmacists who have been named and authorised to do so. This will be a locally agreed arrangement between the commissioner and the provider.

The most recent and in date final signed version of the PGD must be used.

Pharmacists are responsible and accountable for ensuring that they work under the relevant PGD and correct Service Specification applicable to the area, and commissioner, where they are working.

Version No: 1.2
Approving Organisation Name:
Approval Committee Name:
Date of authorisation:

Expiry date: 31/01/2018
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**LONDON CONTRACEPTION AND SEXUAL HEALTH
PATIENT GROUP DIRECTION (PGD)**

**PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF PROGESTOGEN ONLY
EMERGENCY CONTRACEPTION (POEC) LEVONORGESTREL 1.5mg TABLET**



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Authorisation and Signatures	To be added by approving organisation
Individual authorisation to supply Levonorgestrel 1.5mg using this PGD	To be added by approving organisation

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PATIENT GROUP DIRECTION (PGD)**

**PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF PROGESTOGEN ONLY
EMERGENCY CONTRACEPTION (POEC) LEVONORGESTREL 1.5mg TABLET**



DRUG NAME /STRENGTH/FORM Levonorgestrel 1.5mg tablet

CLINICAL CONDITION TO WHICH THIS DIRECTION APPLIES	Emergency contraception
INCLUSION CRITERIA	Any individual presenting for emergency contraception following unprotected sexual intercourse (UPI) or failed contraceptive method and who has no contraindications to the medication
EXCLUSION CRITERIA (I.E. SITUATIONS NOT COVERED BY THE PGD)	<p>Personal Characteristics & Reproductive History</p> <ul style="list-style-type: none"> • Known or suspected pregnancy • Under 16 years of age and assessed as not competent using Fraser guidelines • 16 years of age and over and assessed as not competent to consent using local safeguarding guidelines • Known hypersensitivity to any constituent of the progestogen only emergency contraception (POEC) • More than 72 hours since this episode of unprotected sexual intercourse

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LONDON CONTRACEPTION AND SEXUAL HEALTH PATIENT GROUP DIRECTION (PGD)

PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF PROGESTOGEN ONLY EMERGENCY CONTRACEPTION (POEC) LEVONORGESTREL 1.5mg TABLET

	<ul style="list-style-type: none"> • Emergency post coital intrauterine device (IUD) should always be considered as a more effective alternative when emergency contraception is required. • In an instance where the emergency copper bearing IUD is appropriate and acceptable, continue to supply and signpost to appropriate health service provider • If under 13 years of age follow local safeguarding policy • Consider Ulipristal if the individual presents between 72 and 120 hours post UPSI. • If individual vomits within two hours from ingestion, a repeat dose may be given • The dose may be repeated more than once in the same menstrual cycle should the need occur • If community pharmacist has any clinical concerns , discuss with appropriate health service provider • Provide written advice on ongoing contraceptive methods • Interacting medicines –see current British National Formulary (BNF) for interactions • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them
ACTION IF EXCLUDED	<ul style="list-style-type: none"> • Refer to appropriate health service provider • Discuss /offer alternative emergency contraceptive method • Document all actions taken
ACTION IF PATIENT DECLINES TREATMENT	<ul style="list-style-type: none"> • Record the refusal in the individual's medical record. • Signpost/refer to appropriate health service provider with information about further options

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**PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OF PROGESTOGEN ONLY
EMERGENCY CONTRACEPTION (POEC) LEVONORGESTREL 1.5mg TABLET**

DRUG DETAILS	
NAME, FORM & STRENGTH OF MEDICINE	Levonorgestrel 1.5mg tablet
ROUTE/METHOD	Oral
LEGAL CATEGORY	Prescription Only Medicine/Pharmacy only Medicine
USE OUTSIDE THE TERMS OF THE MARKETING AUTHORISATION	<p>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)</p> <p>This includes off-label use (s):</p> <ul style="list-style-type: none"> • supply to individuals under 16 years of age • use more than once in menstrual cycle • increased dose when taking enzyme inducing medication. <p><i>(from Faculty of Sexual and Reproductive Healthcare (2012) Emergency contraception, see references)</i></p>
QUANTITY	Original pack of one tablet (or two original packs if taking enzyme inducing medication)
DOSAGE/FREQUENCY	<ul style="list-style-type: none"> • A single tablet to be taken within 72 hours of unprotected sexual intercourse (UPSI) • Repeated episodes of UPSI may be treated within one menstrual cycle provided each treatment is within 72 hours of the most recent UPSI. <p>Dose for those individuals taking enzyme inducing medicines or herbal products</p> <p>An individual who requests levonorgestrel whilst using enzyme-inducing drugs or within 4 weeks of stopping them, should be advised to take a total of 3 mg levonorgestrel (two 1.5 mg tablets) as a single dose and within 72 hours of UPSI</p>
DURATION OF TREATMENT	Single dose
MAXIMUM OR MINIMUM TREATMENT PERIOD	Single dose

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EMERGENCY CONTRACEPTION (POEC) LEVONORGESTREL 1.5mg TABLET**

<p>SIDE EFFECTS</p> <p>Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these is of vital importance. Patients should be actively encouraged to report any suspected adverse reaction, particularly to black triangle medicines.</p>	<p>This list may not represent all reported side effects of this medicine.</p> <p>Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for further information</p> <p>Side effects may include;</p> <p>Common side effects</p> <ul style="list-style-type: none">• Nausea• Low abdominal pain• Fatigue• Dizziness• Headache• Diarrhoea/vomiting• Breast tenderness <p>Bleeding patterns may be temporarily disturbed and spotting may occur, but most women will have their next menstrual period within seven days of the expected time.</p> <p>In the event of untoward or unexpected adverse reactions:</p> <ul style="list-style-type: none">• If necessary seek appropriate emergency advice and assistance• Document in the individual's medical record.• Complete incident procedure if adverse reaction is severe (refer to local organisational policy)• Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0800 100 3352 or online at www.yellowcard.mhra.gov.uk. <p>The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.</p>
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EMERGENCY CONTRACEPTION (POEC) LEVONORGESTREL 1.5mg TABLET**

<p>ADVICE TO INDIVIDUAL</p>	<ul style="list-style-type: none"> • Provide Manufacturer's Patient Information Leaflet (PIL) and discuss • Explain mode of action, side effects, benefits and how to take the medication • Explain that the intra-uterine device (IUD) is considered a more effective method of emergency contraception and signpost to an appropriate healthcare provider after supply of POEC, where appropriate and acceptable • Advise that the medicine should be taken immediately • Advise about the risks of the medication including failure rates and serious side effects and actions to be taken • Advise on what to do if vomits within two hours of taking the pill(s) • Advise availability of ulipristal if the individual presents between 72 and 120 hours post UPSI • Provide a copy of the FPA leaflet on emergency contraception http://www.fpa.org.uk/media/uploads/helpandadvice/contraception-booklets/emergency-contraception-your-guide.pdf • Offer condoms and advice on safer sex practices and possible need for screening for sexually transmitted infections • Discuss ongoing contraception and provide written advice on methods • Advise a pregnancy test three weeks after treatment especially if period is delayed or abnormal, or if using hormonal contraception which may affect bleeding pattern • Ensure the individual has contact details of local contraceptive /sexual health services
<p>FOLLOW UP</p>	<ul style="list-style-type: none"> • Individual to attend appropriate health service provider if period is delayed, absent or abnormal or if she is otherwise concerned • Individual to attend appropriate health service provider for ongoing contraception and STI screening as required • Pregnancy test as required (see advice to individual)

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RECORDS	<p>The authorised community pharmacist must ensure the following is documented in the individual's medical record:</p> <ul style="list-style-type: none">• Individual's name, address and date of birth• GP contact details if registered• Attendance date• Reason for attendance• Relevant past and present medical history, including drug history• Any known allergy• The consent of the individual• If individual is under 13 years of age, record action taken• If individual is under 16 years of age document competency, using Fraser guidelines• If individual is 16 years of age and over and not competent, record action taken• Relevant examination findings (where appropriate)• Inclusion or exclusion from PGD• A statement that supply or administration is by using a PGD• Advice given about the medication including side effects, benefits, and when and what to do if any concerns• Details of any adverse drug reactions and what action taken• Any administration outside the terms of the product marketing authorisation• Record the name/brand, dose of the medication and quantity supplied• Record batch number and expiry date according to local policy or national guidelines• Any referral arrangements• Record follow up and/or signposting arrangements• Any other relevant information that was provided to the individual• Name and signature (which may be an electronic signature) of the community pharmacist supplying the medicine
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EMERGENCY CONTRACEPTION (POEC) LEVONORGESTREL 1.5mg TABLET**

REFERENCES	<p>Manufacturers' Summaries of Product Characteristics</p> <ul style="list-style-type: none"> • Levonelle 1500 microgram tablet ;Summary of Product Characteristics Updated 23-Sep-2014 Bayer plc; accessed 30.092014 https://www.medicines.org.uk/emc/printdocument?documentId=16887 • Upostelle 1500 microgram tablet :Summary of Product Characteristics Updated 05-Nov-2013 Consilient Health Ltd: accessed 30 9.2014 : https://www.medicines.org.uk/emc/print-document?documentId=28337 • Levonelle One Step: Summary of Product Characteristics Updated 22-Nov-2013 Bayer plc accessed 30 9.2014 https://www.medicines.org.uk/emc/print-document?documentId=15227 • Isteranda 1.5 mg of levonorgestrel. Summary of Product Characteristics Updated 3rd Dec 2014 Sandoz Limited http://www.medicines.org.uk/emc/medicine/29571 • Boots Emergency Contraceptive 1.5 mg Tablet Summary of Product Characteristics Updated 21-Nov 2013 THE BOOTS COMPANY PLC: accessed 30 9.2014: https://www.medicines.org.uk/emc/print-document?documentId=24057 • Emergency Contraceptive Consilient 1500 microgram tablet Summary of Product Characteristics Updated 05-Nov-2013 Consilient Health Ltd Accessed 30.09.2014 https://www.medicines.org.uk/emc/print-document?documentId=28338 • Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press <http://www.medicinescomplete.com/> [Accessed on 10.12.2014] • National Institute for Health and Care Excellence (2013). Patient Group Directions. Medicines Practice Guidelines 2 http://www.nice.org.uk/guidance/mpg2 • Faculty of Sexual and Reproductive Healthcare (2012) Emergency Contraception. http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf • Faculty of Sexual and Reproductive Healthcare (2009) UK Medical Eligibility Criteria for Contraceptive Use; http://www.fsrh.org/pdfs/UKMEC2009.pdf <p>See next page</p>
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**LONDON CONTRACEPTION AND SEXUAL HEALTH
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EMERGENCY CONTRACEPTION (POEC) LEVONORGESTREL 1.5mg TABLET**

References continued	<ul style="list-style-type: none">• Faculty of Sexual and Reproductive Healthcare(2011) Drug interactions with hormonal contraception (updated January 2012) http://www.fsrh.org/pdfs/CEUGuidanceDrugInteractionsHormonal.pdf• Faculty of Sexual and Reproductive Healthcare (2010) Antiepileptic drugs and contraception: CEU Statement January 2010 http://www.fsrh.org/pdfs/CEUStatementADC0110.pdf• Faculty of Sexual and Reproductive Healthcare (2013) Update on newer antiepileptic and antiretroviral drugs http://www.fsrh.org/pdfs/CEUstatementUpdateNewerAntiepilepticAntiretroviralDrugs.pdf
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**LONDON CONTRACEPTION AND SEXUAL HEALTH
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STAFF CHARACTERISTICS	
<p>The named community pharmacist authorised to supply and/or administer medications under the PGD must meet the following criteria:</p>	<p>THE COMMUNITY PHARMACIST MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT</p> <p>Registration</p> <p>The community pharmacist must be registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society of Northern Ireland (PSNI)</p> <p>Specialist qualifications and competencies</p> <ul style="list-style-type: none"> • Has successfully completed the CPPE PGD e-learning programme or can provide evidence that they have achieved the competency levels specified in NICE Competency Framework for Health Professionals using Patient Group Directions http://www.nice.uk/mpc/goodpracticeguidance/GPG2.jsp • Has had the training which enables them to make a clinical assessment in order to establish the contraceptive need and supply the medicine according to this PGD • Can satisfy the requirements of self declaration of qualifications and competence to deliver Emergency contraceptive services according to the CPPE Programme for <ul style="list-style-type: none"> ○ Emergency Hormonal Contraception ○ Safeguarding children and vulnerable adults <p>or</p> <ul style="list-style-type: none"> • Can provide evidence of competencies achieved through other local training which delivers the equivalent knowledge. <p>and</p> <ul style="list-style-type: none"> • Pharmacists must ensure that the pharmacy where they are providing the service is contracted for this service • Have a current contract of employment with <u>(insert name of organisation here)</u>: <p>See next page</p>

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STAFF CHARACTERISTICS continued	Maintenance of competencies <ul style="list-style-type: none">• Has demonstrated that they are competent to provide the service• The pharmacists should ensure she/he is aware of any changes to the recommendations for this medication• Is familiar with current FSRH clinical guidelines on emergency contraception
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An up to date list and signatures of registered community pharmacists who are authorised to practise under this PGD is kept in Twickenham Civic Centre by the responsible Consultant in Public Health.

Practitioners not listed are not authorised to practise under this PGD.

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