

PATIENT GROUP DIRECTION For supply of

**Levonorgestrel 1500 microgram Tablets
by Registered Pharmacists**

Issue Date: February 2011

PGD expiry date: February 2013

Please check with the clinical lead, medicines management team or PCT website www.cambridgeshirepct.nhs.uk for the most recent version of the PGD before proceeding.

Names and signatures of the multidisciplinary group, which drew up this PGD

NAME	DESIGNATION/TITLE	SIGNATURE	DATE
Dr Lynne Gilbert	Associate Specialist in Sexual and Reproductive Health	Signed on	
Kelvin Rowland-Jones	Principal Pharmacist MMT, Cambs PCT, and Community Pharmacist	Signed on	

Approved by	Senior Medicines Management Team	
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Signatures for Ratification

NAME	DESIGNATION/TITLE	SIGNATURE	DATE
Christine Macleod	Medical Director	Signed On	
Sue Ashwell	Chief Pharmacist	Signed On	

Authorisation of Employer (if not employed by Cambridgeshire PCT)

NAME	DESIGNATION/TITLE	SIGNATURE	DATE

Each registered practitioner authorised to supply and/or administer medication under this PGD must have read, understood and signed this version of the PGD and completed the agreement to practice form before attempting to work according to it

Document Control Sheet

Rationale	To enable patients, presenting for emergency contraception to be treated in a consistent and timely manner by suitably trained pharmacists in community pharmacies within the PCT, without the need for a doctor's prescription
Documents replaced or superseded by this PGD.	<i>CP PGD2</i> For supply or administration of Post-Coital Contraceptive Pills by registered pharmacists: Cambridgeshire PCT Issued March 2010 Expiry March 2012
Development & Consultation:	Developed by the Cambridgeshire PCT Medicines Management Team in consultation with: Hina Patel - Community Pharmacist Tim Richards – Community Pharmacist
Dissemination	Community Pharmacies and Community Pharmacists Local Pharmaceutical Committee Family Planning services, GP Practices, Out of Hours services, for information
Accessibility	Cambridgeshire PCT website www.cambridgeshirepct.nhs.uk Cambridgeshire PCT Medicines Management Team offices
Implementation	Each registered pharmacist authorised to supply and/or administer medication under this PGD must have read, understood and signed it and completed the agreement to practice form before attempting to work according to it
Training	See PGD
Audit	See PGD
Review	The Clinical Lead Responsible for review of this PGD is: Principal Pharmacist MMT (Cambs PCT). Review should be initiated 3 months before the expiry date unless a review is required in response to a change to the medicine(s) covered by this PGD
Equality and Diversity	The Medicine Safety and Governance Group has carried out a Rapid Equality & Diversity Impact Assessment and concluded the document is compliant with the PCT Equality and Diversity Policy.

Standards for Better Health

Domain	How?
Safety	PGD documentation provides consistent approach to patient care. This document sets out the information specified in law as that required for a Patient Group Direction. Attention is drawn to professional guidelines on child protection and contact details for local child protection lead professionals. Professionals working under a patient group direction must fulfil the training requirements set out in it, and be working within their own competence.
Clinical & Cost Effectiveness	PGDs are evidence based. They allow the patient to be treated by the most appropriate health professional at the first point of contact.
Governance	PGD ensures standardisation of care. PGDs are a legal requirement for healthcare professionals (who are not independent prescribers) to be able to administer or supply medicines without a prescription. Practitioners working under the PGD must sign up to it and keep the specified records, thus providing an audit trail and accountability.
Patient Focus	Healthcare professionals respond to patients' needs in an appropriate and timely manner. It is specified that all aspects of the patients treatment, including any medicines supplied or administered are discussed with the patient Every patient is treated as an individual
Accessible & Responsive Care	Healthcare professionals respond to patients' needs in an appropriate and timely manner. The documentation allows specified healthcare professionals to supply or administer medicines without a prescription.
Public Health	In making emergency hormonal contraception more accessible this should aid in the reduction in the number of unwanted pregnancies. Health promotion is an integral part of the consultation

1. Staff Authorised to supply the medicine under the PGD	
1.1 Professional qualification	Member of the Royal Pharmaceutical Society of Great Britain (RPSGB) Practising community pharmacist
1.2 Specialist qualifications, training, experience and competence that must be achieved relevant to the clinical conditions and medicines used	<p>Each pharmacist must:</p> <ul style="list-style-type: none"> • Complete the latest CPPE distance learning pack on Emergency Hormonal Contraception (EHC). • Attend a training workshop organised by Cambridgeshire PCT OR have completed the two CPPE packages: Safeguarding Children and Patient Group Directions and provided the PCT with the certificate for successful completion <p>In addition all authorised pharmacists must demonstrate an appropriate level of understanding and knowledge with regards to:</p> <ul style="list-style-type: none"> • Assessment of the patient and appropriate issue of EHC. • The medication, therapeutic use, side-effects, interactions and storage and handling requirements. • The pharmacist must have read, understood and signed up to this PGD. <p>A copy of the Agreement to Act under this PGD (see page 11) will be retained by the Cambridgeshire PCT Medicines Management Team.</p>
1.3 Continuing Professional Development Requirements (CPD)	<ul style="list-style-type: none"> • The pharmacist must complete an annual audit of service provision and return a competency assessment to the PCT. • A record of attendance will be kept by the PCT. • All registered pharmacists must maintain a record of training and competence in their CPD record. • All registered pharmacists are professionally accountable and must work within their competence. • The practitioner should be aware of any changes to the recommendations for the medicines listed and changes to national guidance. • It is the responsibility of the individual to maintain and improve their professional knowledge and skills in this area of practice.
1.4 Documents to be read in conjunction with this PGD	<ul style="list-style-type: none"> • Latest CPPE distance learning pack on Emergency Hormonal Contraception. • RPSGB Guidance on Child Protection • Cambridgeshire PCT Patient Group Direction Policy • Faculty of Family Planning and Reproductive Health Centre, Guidance on Emergency Contraception, April 2006 (www.ffprhc.org.uk/)
2. Clinical condition or situation to which this Patient Group Direction applies	
2.1 Clinical condition/situation	<p>Women requesting oral emergency hormonal contraception (EHC) following:</p> <ul style="list-style-type: none"> • unprotected sexual intercourse (UPSI) where no contraception has been used • actual, or potential, failure of a contraceptive method.
2.2 Inclusion criteria	<ul style="list-style-type: none"> • Women of child bearing age who require emergency contraception within 72hours of unprotected sexual intercourse (UPSI) or failure of a contraceptive method. • Women of child bearing age who require emergency contraception after 72hours (but less than 120 hours) of unprotected sexual intercourse (UPSI) or failure of a contraceptive method. This is an unlicensed indication and one which should only be considered if the woman cannot or will not be referred to a medical practitioner for assessment for an IUD insertion. IUD insertion is the recommended first –line treatment and should be offered first. Concerns about the efficacy of the Levonelle should be explained before Levonelle can be supplied. • Levonelle ® 1500 is not recommended in children. Very limited data are available in women under 16 years of age. Levonelle ® 1500 is not licensed

	<p>for women under the age of 16. However, it is a very safe drug with very few contra-indications. If clinically indicated in a woman under the age of 16 it may be given in strict accordance with the Fraser Guidelines – see Appendix 3. For children under 13 Fraser Guidelines still apply, but please see Appendix 2.</p> <p>The wider safeguarding context for children and young people should also be considered. See Appendix 2.</p> <p>-----</p> <ul style="list-style-type: none"> • If after discussing the 2 options for emergency contraception, the patient decides she wants the most effective method, i.e. a copper IUD then the patient can be given Levonorgestrel in addition - particularly if she presents more than 24 hours after unprotected sex or is taking liver enzyme inducers. An IUD is indicated if all instances of unprotected sexual intercourse this cycle are within the last 5 days or if not, the woman • presents within 5 days of the likely date of ovulation based on her shortest cycle length.
<p>2.3 Exclusion criteria</p>	<ul style="list-style-type: none"> • Pregnancy– if in doubt perform pregnancy test before supplying emergency contraception. (See 2.4b below.) • Unexplained overdue menstrual bleeding* • Unprotected intercourse more than 120 hours previously. (See 2.4c below) • Hypersensitivity to levonorgestrel or to any of the tablet excipients. • Severe hepatic dysfunction • Porphyria • Patients with acute exacerbations of severe malabsorption syndromes (e.g. Crohn’s disease), as this might impair the efficacy of levonorgestrel • Patient not deemed competent when assessed against Fraser guidelines (see Appendix 3) • Unexplained or unusual vaginal bleeding. • Levonelle® 1500 contains 142.5mg lactose. Women with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should be referred. <p>* If a full coital and menstrual history and/or pregnancy test have been performed at the correct interval and pregnancy from earlier UPSI has been excluded; then EHC may be given under this PGD.</p> <p>NB: Patients taking liver enzyme inducing drugs are not excluded from this PGD (e.g. Carbamazepine, Griseofulvin, Oxcarbazepine, Phenytoin, Phenobarbitone, Primidone and other Barbiturates, Topiramate, Rifabutin, or Rifampicin, St John’s Wort, some antivirals used in HIV treatment, e.g. Ritonavir, Nelfinavir, and Nevarapine ;).</p> <p>However the dose should be increased to 2 tablets Levonelle® 1500, taken together, but explain to patient that this is outside the SPC. See Section 3.4 of this PGD.</p>
<p>2.4 Actions to be taken regarding care of excluded patients</p>	<ul style="list-style-type: none"> • Excluded patients should be referred as soon as possible to a registered medical practitioner, i.e. GP, Family Planning Clinic or out of hours service (OOH). • If unprotected intercourse also occurred more than 21 days previously, pregnancy can be excluded by a negative pregnancy test. If it occurred more recently, the result would not be conclusive and the patient should be referred. • If the only unprotected intercourse within this cycle occurred less than 120

	<p>hours (5 days) or, if not, the patient presents within 5 days of the expected ovulation based on shortest cycle length, the patient can be referred for insertion of an intra-uterine device (which has a much lower failure rate anyway). There is limited data that Levonelle may have some effectiveness between 72 and 120 hours after unprotected sex, although this is outside the licensing.</p> <p>The patient should be provided with relevant information leaflets, such as details of Family Planning Clinics/ Young Persons' Clinics.</p>
2.5 Consent	<ul style="list-style-type: none"> • The proposed treatment including the risks, benefits and side effects must be explained to the patient /guardian. • The patient should be asked to sign the confirmation on Appendix 3. • If the patient prefers to remain anonymous, record that consent has been obtained.
2.6 Actions for patients who do not wish to receive care under this PGD	<ul style="list-style-type: none"> • Refer urgently to GP, Family Planning clinic or OOH. • They should be warned that the delay in starting treatment might compromise its efficacy. • Patient should be provided with relevant information leaflets, such as details of family planning clinic.
3. Medicine to be supplied under this Patient Group Direction	
3.1 Name, strength and form of medicine(s)	Levonorgestrel 1500microgram tablet (Levonelle® 1500)
3.2 Legal Status	POM
3.3 ▼Black triangle	NO Black triangle drugs (see BNF) are newly licensed medicines that are closely monitored by the MHRA. All suspected reactions should be reported using yellow cards (see below Adverse Drug Reactions)
3.4 PGD covering use outside terms of Summary of Product Characteristics (SPC)?	<p>Levonelle® 1500 is not licensed for women under 16 years of age.</p> <p>The use of 2 x Levonelle® 1500 tablets if the patient is taking enzyme-inducing drugs (see Section 2.3 above) is an unlicensed indication. However, this is the recommendation in the current BNF.</p> <p>Use between 73 and 120 hours after UPSI EHC may be considered for use between 73 and 120 hours after UPSI, but women should be informed of the limited evidence of efficacy and that such use falls outside the licence of the product.</p> <p>If >72 hours but <less 120 hours from UPSI, advise that the option of an insertion of an IUD is the recommended first –line treatment but that EHC is supported by evidence from a World Health Organisation trial. Use of EHC does NOT stop a woman from having the IUD fitted as well but may ensure some protection whilst more effective protection is sought.</p> <p>Use more than once in a cycle The product SPC advises against this because of the possibility of disturbance of the cycle. However, use more than once is supported by guidance from the Faculty of Sexual and Reproductive Healthcare.</p> <p>Explain to patient that advice differs from patient information leaflet and the reason for this</p>

3.5 Route/ Method of administration	Oral
3.6 Dose	<p>One tablet should be taken as soon as possible, preferably within 12 hours, and no later than 120 hours after unprotected intercourse.</p> <p>Levonorgestrel 1500micrograms can be used at any time during the menstrual cycle unless menstrual bleeding is overdue and the possibility of an early pregnancy cannot be excluded</p> <p>Note: If vomiting occurs within three hours of taking the tablet, the patient should return (or visit her GP, family planning clinic or OOH service) and a second tablet taken immediately.</p>
3.7 Frequency	<ul style="list-style-type: none"> • Maximum of two tablets for one episode (The second tablet may be given only if the patient returns because they have vomited within 3 hours of taking the first tablet OR if patient is taking a liver enzyme inducing drug as specified in Section 2.3 above) • A subsequent request for the repetition of the treatment should be based on a new assessment of the patient
3.8 Interactions with other medicines See also any interactions listed as exclusions	<ul style="list-style-type: none"> • Enzyme inducing drugs (see Section 2.3 above) • Ciclosporin. Levonorgestrel may increase the risk of ciclosporin toxicity. Caution advised. • Anticoagulants. Levonorgestrel may antagonize the anticoagulant effect of coumarins. EHC can be provided but the woman should be advised to have an early check of her INR and encouraged to inform her GP. • See SPC or current BNF
3.9 Caution	<p>Acute episode of Inflammatory Bowel Disease</p> <p>Active Inflammatory Bowel Disease (Crohn's disease, Ulcerative Colitis) may affect the absorption of EHC. Women whose disease is active should be advised that insertion of an IUD would be the most effective emergency contraception and referred accordingly.</p> <p>EHC should be provided even if an IUD is planned unless there are exclusions.</p>
3.10 Potential adverse reactions/ side effects	<p>Very common (>1/10):</p> <ul style="list-style-type: none"> • Nausea • Bleeding not related to menses • Low abdominal pain • Fatigue <p>Common(>1/100)</p> <ul style="list-style-type: none"> • Dizziness • Headache • Delay of menses more than 7 days • Irregular bleeding and spotting • Diarrhoea • Vomiting • Breast tenderness
3.11 Instructions on identifying and managing	<ul style="list-style-type: none"> • Advise patient on management of the adverse effect • Report any serious ADR to the patient's medical practitioner as soon as possible if clinically relevant.

<p>Adverse Drug Reactions (ADRs)</p>	<ul style="list-style-type: none"> Use the Yellow Card System to report serious adverse drug reactions directly to the Committee on Safety of Medicines (MHRA). Guidance on the use of the Yellow Card System and Yellow Cards are available in the current BNF
<p>3.12 Advice to patient</p>	<p>Each patient should be advised as follows:</p> <ul style="list-style-type: none"> Explain the treatment to the patient. Obtain consent as per 2.5 above. All patients are to be given the medication together with its enclosed information leaflet and any other relevant information leaflets regarding methods of contraception, sexually transmitted infections (STIs) and family planning clinic opening times. Warn patient that Levonelle[®] 1500 can fail and she may still become pregnant (see efficacy, below). Therefore she should seek further advice if menstruation is late, missed or lighter than usual. Stress the need to abstain from sexual intercourse or to consistently and carefully use a reliable barrier method until she is protected by another method of contraception. In the case of vomiting or severe diarrhoea within 3 hours of taking the dose she should either return for a further dose, or go to her GP, Family Planning Clinic or out of hours medical service, to consider either a further dose (with an anti-emetic if appropriate) or the insertion of a copper IUD. Emergency contraception does not provide protection against pregnancy for the rest of the menstrual cycle. Other contraceptive methods will be needed. Levonelle[®] 1500 is only for occasional use and it should in no instance replace a regular contraceptive method. If EHC is needed due to missed oral contraceptive pills, then the patient should be advised to continue taking her normal oral contraceptive for the remainder of the cycle. COC users should also be advised to use a barrier form of contraception for the next seven days. POP users should be advised to use a barrier form of contraception for the next two days after restarting the pill. A pregnancy test is advised 3 weeks after the latest episode of unprotected sexual intercourse Patients who are breastfeeding should be advised that very small amounts of levonorgestrel may appear in the milk. This is not thought to be harmful but if the patient is concerned then tablets should be taken immediately after a breast feed. Taking the tablet well before the next feed reduces the amount of active ingredient the baby will take in with the breast milk. Only 1 course in any single menstrual cycle is advised because of the possibility of disturbance of the cycle, except in the case of vomited tablets: Repeated episode(s) of unprotected sexual intercourse should usually be referred to a registered medical practitioner, for consideration of repeat supply of Levonelle[®] 1500 or fitting of a copper IUD. The pharmacist must reassess the patient and use their professional judgement before agreeing to a repeated supply within the cycle. See GP if any lower abdominal pain occurs, as ectopic pregnancy may continue despite the occurrence of uterine bleeding. The absolute risk of this is likely to be low, but this is a potentially life-threatening complication. Patient should be encouraged to consider if she is at risk of STI. Further advice can be obtained from her GP, Family Planning Clinic or GUM clinic. Advice should be given on the use of a barrier method to protect against sexually transmitted infection. Women should be advised that Chlamydia is the most common STI diagnosed in GUM clinics and prevalence is highest amongst sexually active young men and women, especially those aged less than 25 years. Untreated infection can have serious long-term consequences long-term consequences, particularly for

	<p>women, in whom it can lead to pelvic inflammatory disease (PID), ectopic pregnancy and tubal factor infertility. Since many infections are asymptomatic a large proportion of cases remain undiagnosed, although infection can be diagnosed easily and effectively treated. Chlamydia screening is currently carried out across England as part of the National Chlamydia Screening Programme (NCSP). Patients should be offered or signposted for screening where appropriate.</p> <p>Efficacy - The most effective form of emergency contraception is the copper IUD, (though this may not be the most appropriate choice for some very young patients or those at high risk of STIs). This should be discussed as an option, especially with those at high risk of pregnancy and those presenting 72 hours or more after UPSI. Even if a patient considers referral for an IUD assessment, emergency hormonal contraception may still be supplied under this patient group direction as appropriate. Efficacy of EHC has been found to decrease dramatically with time</p> <ul style="list-style-type: none"> • 24 hour or less = 95% of pregnancies prevented • 25 - 48 hours = 85% of pregnancies prevented • 49 - 72 hours = 58% of pregnancies prevented <p>Levonelle® 1500 may have some effect 72-120 hours after UPSI but this is outside the SPC. If unlicensed use is indicated then the women should be informed of the limited evidence of efficacy and that such use falls outside the licence of the product.</p> <p>Mode of action - Uncertain but thought to mainly inhibit ovulation and ovum transport and possibly to prevent implantation</p> <p>Foetal effects - No evidence that this method of contraception has any teratogenic effects but every pregnancy has a 1/50 overall chance of foetal abnormality</p> <p>Side effects - As detailed above</p>
3.13 Follow up	Patients should be told to go to their GP or the Family Planning Clinic if their next menstrual period is late, missed or lighter than usual or if there is any unusual pain. They should be advised to carry out a pregnancy test if they do not have a period within 2 weeks of their due date, if possible, in order to inform the consultation.
3.14 Storage and Handling	Store in original container.

Please note:

Listed above are the interactions with commonly used medicines and the main side effects. If the patient is taking a medicine not listed above or reports other possible side effects refer to the current BNF, Patient Information Leaflet or electronic medicines compendium <http://www.medicines.org> or seek advice from pharmacist or medicines information department.

4. Facilities and supplies that must be available	
4.1 Medicine to be stocked	Levonorgestrel tablets 1500 micrograms Levonelle® 1500 microgram tablet
4.2 Reporting incidents	<ul style="list-style-type: none"> • Incidents and near misses must be reported using the Cambridgeshire PCT Incident Reporting form (DATIX) which should be forwarded to the Risk Manager as soon as possible. This can be found at http://www.cambridgeshirepct.nhs.uk/default.asp?id=648 • Support for community pharmacists to complete incident reports is available from the Medicines Management Team on 01223 725276 • AND via employer's critical incident reporting system.
4.3 Other	<ul style="list-style-type: none"> • Current BNF

requirements	<ul style="list-style-type: none"> Supplies of relevant Patient Information Leaflets Details of local Family Planning Clinics and Genito-Urinary Medicine Clinics.
5. Records to be kept for audit purposes	
5.1 Patient details	<ul style="list-style-type: none"> Complete the details in Appendix 3 in indelible ink.
5.2 Records of clinical circumstances	<ul style="list-style-type: none"> Complete the details in Appendix 3 in indelible ink.
5.3 Records of supply	<ul style="list-style-type: none"> Complete the details in Appendix 3 in indelible ink.
5.4 Audit	<ul style="list-style-type: none"> Annual audit must be carried out by the clinical lead <ol style="list-style-type: none"> Clinical practice audit <ul style="list-style-type: none"> Each practitioner operating under this PGD will record for the purposes of audit, details of the consultation on the assessment form (Appendix 3). The application of the PGD by each practitioner will be reviewed for FIVE patients with a NHS Cambridgeshire MMT pharmacist and any area issues for development of knowledge or competence identified and addressed. Supply system audit, including record keeping <ul style="list-style-type: none"> Regulations require that there is a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient by patient basis. The health professional responsible for the supply must make the issue directly to the patient only. <p>The EC Labelling and Leaflet Directive applies to all medicines supplied under the Patient Group Direction. The pack should be labelled with the following information:</p> <ul style="list-style-type: none"> The address of the clinical area where supply is made 'Keep out of reach of children' Directions for use The name of the patient or patient ID number Date of supply <p>The patient information leaflet (PIL) from the package must be provided to each patient on every occasion, in addition to verbal advice.</p>

6. References

- HSC 2000/026, 9th August 2000 Patient Group Directions.
- Levonelle® 1500 Summary of Product Characteristics. Bayer plc <http://emc.medicines.org.uk/> last updated 2nd November 2009
- Joint Formulary Committee. British National Formulary Number 60. London: British Medical Association / Royal Pharmaceutical Society of Great Britain, September 2010
- <http://www.homeoffice.gov.uk/documents/children-safer-fr-sex-crime?view=Binary> Children and Families: safer from sexual crime, The Sexual Offences Act 2003
- <http://www.ffprhc.org.uk/admin/uploads/ServiceStandardsonObtainingValidConsent.pdf> Faculty Statement on obtaining consent in sexual health services, June 2007.
- <http://www.ffprhc.org.uk/admin/uploads/ServiceStandardsRecordKeepingAdd07.pdf> Faculty Statement on Record Keeping, Appendix 8 May 2007
- Royal Pharmaceutical Society of Great Britain. Guidance on Child Protection. August 2007, available at <http://www.rpsgb.org/pdfs/childprotectguid.pdf>

- Faculty of Family Planning and Reproductive Health Care, Faculty Statement from the CEU on a New Publication: WHO Selected Practice Recommendations for Contraceptive Use Update, Missed pill: new recommendations, April 2005. <http://www.ffprhc.org.uk/>
- FFPRHC Guidance on Emergency Contraception April 2006
- Faculty of Family Planning and Reproductive Health Care, Faculty Statement from the CEU on Levonelle® 1500 and the use of liver enzyme inducing drugs, November 2005.
- Journal of Family Planning and Reproductive Health care 2003:29(2)
- Health Records, Guidance for Maintenance and Storage, Cambridge City and South Cambridgeshire PCTs, April 2005.

**AGREEMENT BY HEALTH PROFESSIONAL TO ACT
UNDER THE LEVONORGESTREL 1500 MICROGRAM TABLETS
BY REGISTERED PHARMACISTS
PATIENT GROUP DIRECTION**

I have read and fully understand the following documents:

1. The Patient Group Direction:
2. Dated: Expiry date:
3. BNF and SPC monographs for all drugs included in this PGD.
4. The NHS Cambridgeshire Patient Group Direction Policy

I agree to act within the terms of the Patient Group Direction and administer and/or supply medicines in accordance with the documents listed above.

I understand that my employer e.g. GP practice or NHS Cambridgeshire, is vicariously liable for acts and omissions by me during my employment with them.

I understand that failure to comply with the terms and conditions of the PGD, including the expiry date and limitations on practitioners, patients, drugs and indications may render me liable to disciplinary action by my employer e.g. GP practice or NHS Cambridgeshire under their performance and conduct arrangements.

NAME: *(block capitals)* (Health Professional)

SIGNATURE: (Health Professional)

POSITION:

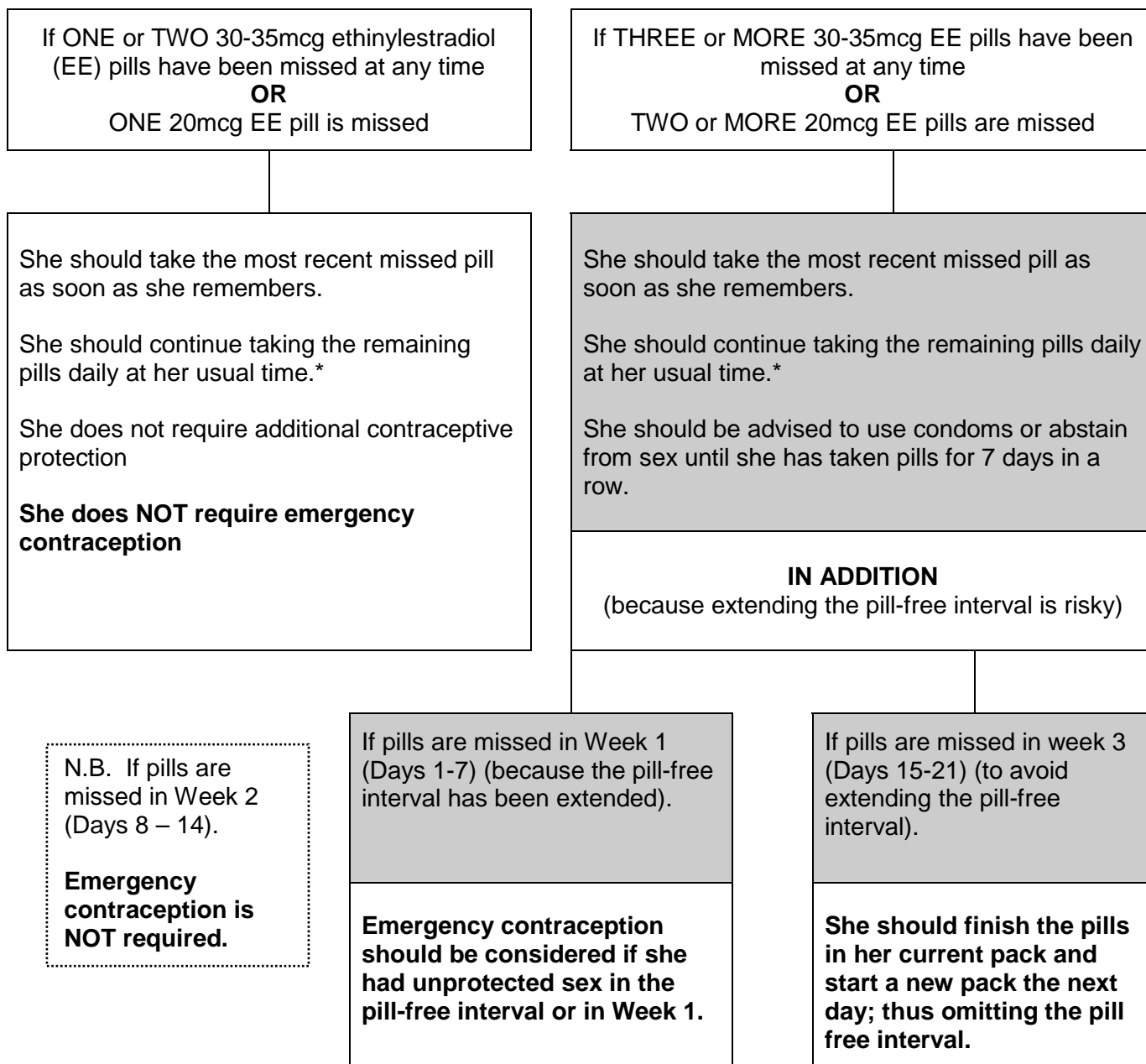
EMPLOYER:

SITE/PRACTICE:

DATE SIGNED:

The original must be filed in the health professional's personal file and a copy held by their manager or employer for the purposes of ensuring practice occurs only in accordance with the PGD and is only undertaken by approved practitioners.

Advice for women missing combined oral contraceptives (30-35mcg and 20mcg ethinylestradiol formulations)



* Depending on when she remembers her missed pill she may take two pills on the same day (one at the moment of remembering and the other at the regular time) or even at the same time.

N.B. Shaded box indicates when emergency contraception indicated.

Adapted from Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. Faculty Statement from CEU on a New Publication: WHO selected Practice Recommendations for Contraceptive Use Update. Missed pills: new recommendations. Journal of Family Planning and Reproductive Health Care 2005; 31(2):153-155.

REQUESTS FOR CONDOMS/ CONTRACEPTION FROM CHILDREN AGED 12 AND UNDER

A statement from Safeguarding Children re children aged 12 and under will be added at a future date. In the interim local guidance from Cambridgeshire PCT is as follows:

If a child aged 12 or under requests levonorgestrel, Fraser Guidelines apply as above. In addition the practitioner concerned should discuss the case with their child protection lead. Advice MUST be sought from one of the child protection lead professionals listed below. The young person should be told that this discussion will take place.

"The law now makes it clear that sexual activity with a child under 13 is never acceptable, and that - regardless of the circumstances - children of this age can never legally give their consent" (ref "Children & Families: Safer from Sexual Crime " website

www.homeoffice.gov.uk/crime/sexualoffences/legislation/act.htm

CONTACT DETAILS OF CHILD PROTECTION LEAD PROFESSIONALS

Designated Doctor – Cambridgeshire	Dr David Vickers	01223 884167
Designated Nurse – Cambridgeshire	VACANT	
Named Nurse – Cambridgeshire	Barbara Cannon	01223 884159

Social Care Team (Social Services)		
Professionals	0345 045 0180	
Public	0345 045 5203	
Fax	01480 376748	
Email	Referralcentre.children@cambridgeshire.gov.uk	
Address	Cambridgeshire Direct, Children's Team, PO BOX 144, St Ives, Cambs PE27 9AU	
Out of hours Emergency Duty Team Tel	01733 234724	
Norfolk Out of hours Emergency Duty Team Tel	01603 638571	

Police Contact for Cambridgeshire	0345 456 456 4 (ask for child and domestic abuse unit)
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East Cambs & Fenland Area

Named GP for Child Protection	Dr Dee McCormack	01353 665511
Area Safeguarding Nurse	Melanie Sneath	01354 644316
Named Doctor for Child Protection (Fenland)	Dr Karina Hart, Community Paediatrician	01553 816358

Cambridge City and South Cambs Area

Area Safeguarding Nurse	Anthea Boulton	01223 884159
Named Doctor for Child Protection	Dr David Vickers	01223 884167

Hunts Area

Named Doctor	Dr Jill Challener, Consultant Paediatrician, Hinchingsbrooke Hos.	01480 416414
Area Safeguarding Nurse	Adrian Roberts	01480 418633

**ASSESSMENT FORM FOR EMERGENCY HORMONAL CONTRACEPTION
(LEVONELLE® 1500)**

Patient History		ID Number:	
Patient name (if known):		Age: If under 16years <input type="checkbox"/> 16 to 19 <input type="checkbox"/> 20 to 24 <input type="checkbox"/> 25 to 29 <input type="checkbox"/> 30 and over	
Date of consultation:		Time of consultation	
Post code (first 4 digits):		Date and time of UPSI:	
Date of Last Menstrual Period (LMP):		regular / irregular cycle (delete as applicable)	
Therefore day of cycle @ UPSI	 hours since UPSI	
Reason for seeking Emergency Contraception:		Usual method of contraception:	
Fraser Competence and Confidentiality			
<p>This section must be completed for all patients under 16 years of age or where competence is uncertain.</p> <p>Whilst it is permissible to offer young people confidential contraceptive advice they must be made aware that there can be occasions when this confidentiality may be broken and other agencies involved. This is usually if the professional suspects that someone is hurting or harming the patient. In some situations, such as where there is a discrepancy in age between a young patient (under 16) and their partner, concerns may be raised. For children under 13, see Appendix 2. If you are unsure, discuss the situation with a colleague or contact the designated Child Protection Nurse. It is probably not in the patient's best interests to withhold emergency contraception but record keeping should reflect details of the consultation.</p>			
Does the patient understand the advice given including potential risks and benefits?		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Has the patient been encouraged to involve her parents?		<input type="checkbox"/> Yes <input type="checkbox"/> No	
If unwilling to talk to parents/adult have the reasons been discussed		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Is the young person's physical or mental health likely to suffer unless she receives contraceptive treatment?		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Are these actions in the best interest of the patient?		<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p align="center">All the above areas must be fully discussed during the consultation. This should be documented and include an assessment of the patients maturity. If any question is answered no, the patient must be referred as below.</p>			
Inclusion Criteria			
<p>A Has the patient had unprotected sexual intercourse (UPSI) in this menstrual cycle? i.e.</p> <ul style="list-style-type: none"> ▪ No contraception used ▪ Barrier contraceptive failure (e.g. burst condom, displaced diaphragm) <input type="checkbox"/> Yes <input type="checkbox"/> No ▪ Oral contraceptive pill taken, but patient has missed dose(s) and meets the inclusion criteria for this situation (see separate notes) ▪ Other suspected contraceptive failure 			
B Since the LMP, has the patient had unprotected intercourse only within the last 120 hours?		<input type="checkbox"/> Yes <input type="checkbox"/> No	
C Use of both IUD and Levonelle discussed with the patient and hormonal method appropriate?		<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>To be eligible for supply of Levonelle® 1500 under this protocol, ALL answers to sections A, B and C must be <u>yes</u>. If NO is answered to any of these, the patient should be referred to a GP, Family Planning Service, OOH or A&E</p> <p>EHC may be considered for use between 73 and 120 hours after UPSI, but women should be informed of the limited evidence of efficacy and offered the alternative option of an IUD</p>			

Exclusion Criteria	
D Has the patient used any form of emergency contraception within the current menstrual cycle?	<input type="checkbox"/> Yes <input type="checkbox"/> No
E If the last menstrual period (LMP) was more than four weeks ago - Does the LMP history of the patient fall into the exclusion criteria (2.3)	<input type="checkbox"/> Yes <input type="checkbox"/> No
F Is the patient pregnant or likely to be?	<input type="checkbox"/> Yes <input type="checkbox"/> No
G Did unprotected intercourse occur more than 120 hours ago?	<input type="checkbox"/> Yes <input type="checkbox"/> No
H Does the patient have severe liver disease?	<input type="checkbox"/> Yes <input type="checkbox"/> No
I Does the patient have active acute porphyria?	<input type="checkbox"/> Yes <input type="checkbox"/> No
J Has the patient had a previous allergic reaction to Levonorgestrol or any of its ingredients?	<input type="checkbox"/> Yes <input type="checkbox"/> No
K Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption (only applies to Levonelle®1500)	<input type="checkbox"/> Yes <input type="checkbox"/> No
L Acute episode of severe intestinal malabsorption syndrome e.g. Crohn's disease	<input type="checkbox"/> Yes <input type="checkbox"/> No
If the answer is yes to <u>any</u> of questions E to K – refer as above. Yes to L - EHC should be provided and the woman referred for IUD fitting as well for most effective emergency contraception	
M Please specify any other medications the woman is taking: Please specify any action taken regarding interacting drugs:	
Patient Counselling	
All the following subjects must be discussed with the patient before supply.	
The mode of action of Levonelle® 1500 and effects on menstrual cycle	<input type="checkbox"/> Yes <input type="checkbox"/> No
The failure rate with Levonelle® 1500 and other methods	<input type="checkbox"/> Yes <input type="checkbox"/> No
Possible adverse effects and side effects	<input type="checkbox"/> Yes <input type="checkbox"/> No
Possible effects on the foetus if pregnancy occurred	<input type="checkbox"/> Yes <input type="checkbox"/> No
How to take Levonelle® 1500	<input type="checkbox"/> Yes <input type="checkbox"/> No
Possibility of ectopic pregnancy	<input type="checkbox"/> Yes <input type="checkbox"/> No
Action to take if vomiting occurs	<input type="checkbox"/> Yes <input type="checkbox"/> No
Protection for rest of cycle	<input type="checkbox"/> Yes <input type="checkbox"/> No
Future contraception, including supply of leaflets	<input type="checkbox"/> Yes <input type="checkbox"/> No
STIs risk discussed, especially Chlamydia for the under 25's, and patient advised to seek advice as soon as possible,	<input type="checkbox"/> Yes <input type="checkbox"/> No
Recommend pregnancy test after three weeks or if next period is abnormal	<input type="checkbox"/> Yes <input type="checkbox"/> No
Scheme information leaflets provided	<input type="checkbox"/> Yes <input type="checkbox"/> No
Action Taken	
Please indicate the outcome of the consultation: Supplied Levonelle® 1500 / Referred to	
If supplied, record the following:	Batch Number: _____ Expiry Date: _____
Has the first dose been taken, supervised at the consultation: If no, please state reason:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Any further notes/advice given:	
Confirmation	
The above information is correct to the best of my knowledge. I have been counselled on the use of emergency contraception and understand the advice given to me.	
Patient signature:	Date:
The action specified was based on the information given to me by the patient, which, to the best of my knowledge is correct. All the information detailed above, and in the protocol for EHC, has been discussed with and given to the patient.	
Pharmacist signature:	Date: