



PATIENT GROUP DIRECTION (PGD) FOR		
PGD 219 (S)	LEVONORGESTREL 1500 microgram Tablet (e.g. LEVONELLE®) Sexual Health. Patients aged 13 years and older	POM

**YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS
PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT**

PROFESSIONALS TO WHICH THIS PGD APPLIES:

Community Pharmacists

Nursing and Midwifery Council (NMC) Registered Nurse or Health and Care Professions Council (HCPC) registered Emergency Care Practitioner working within

- Derbyshire Integrated Sexual Health service (DISH)
- The community as a nurse for children and young people
- Minor Injury Unit (MIU)

CLINICAL CONDITION	
Indication	Prevention of pregnancy from unprotected sexual intercourse (UPSI) e.g. no contraception or failed condom / barrier method. See Appendix 1 - FSRH Emergency Contraception Guidelines, Table 1: 'Indications for emergency contraception following potential failure of hormonal and intrauterine methods of contraception'.
Inclusion criteria	<p>Age 13 and over:</p> <p>Client (females of child bearing potential) requesting post coital contraception due to UPSI in whom there are no contraindications.</p> <ul style="list-style-type: none"> • UPSI also includes: <ul style="list-style-type: none"> ○ Missed contraceptive pills (Appendix 2) ○ Condom failure ○ Significant drug interaction ○ Late contraceptive injection ○ Implant overdue for change ○ Any other suspected compromise of regular method of contraception <p><u>For licensed use</u></p> <ul style="list-style-type: none"> ○ Clients presenting between 0-72 hours after UPSI Note: Clients presenting between 0-72 hours after UPSI and at high risk of pregnancy near ovulation can be offered Ulipristal Acetate (UPA) SEE alternative PGD <p><u>Use outside of product licence</u></p> <ul style="list-style-type: none"> • UPSI within the previous 72-120 hours • Previous use of oral emergency contraception (OEC) within the current menstrual cycle or UPSI greater than 120 hours – please refer to Appendix 3 (FSRH Algorithm 2: decision making algorithm for oral emergency contraception) • >14 weeks since last progestogen injection • BMI > 26 or weight > 70kg - – see caution/ needs further advice section for more information



	<ul style="list-style-type: none"> Concurrent use of enzyme inducing medication e.g. carbamazepine, eslicarbazepine, nevirapine, oxcarbazepine, phenytoin, phenobarbital, primidone, ritonavir, St John's Wort, topiramate and above all, rifabutin and rifampicin. <p>This list is not exhaustive – always check drug interactions in latest version of British National Formulary (BNF)</p>
Exclusion criteria	<ul style="list-style-type: none"> Under 13 years of age Confirmed pregnancy <ul style="list-style-type: none"> Suspected pregnancy or doubt about last menstrual period (LMP), <u>unless pregnancy test (PT) carried out that day is negative</u> Ulipristal (UPA) taken in the last 5 days Hypersensitivity to Levonorgestrel Acute porphyria Severe liver disease <p>Always explain reason for exclusion and action to be taken.</p>
Cautions/Need for further advice	<p>Potential drug interactions with:</p> <ul style="list-style-type: none"> <u>Enzyme inducing medication</u> may reduce the efficacy of Levonorgestrel - double dose Levonorgestrel needed. e.g. carbamazepine, eslicarbazepine, nevirapine, oxcarbazepine, phenytoin, phenobarbital, primidone, ritonavir, St John's Wort, topiramate and above all, rifabutin and rifampicin) <p>Ciclosporin and theophylline – theoretical risk of toxicity</p> <p>This list is not exhaustive – always check drug interactions in latest version of BNF.</p> <p>BMI > 26 or weight > 70kg Levonorgestrel effectiveness may be reduced. Needs UPA or double dose of Levonorgestrel. Consider IUD if within timescale.</p> <p>Breastfeeding Levonorgestrel is secreted into breast milk, but in small amounts not thought to be harmful. Potential exposure of an infant to Levonorgestrel can be reduced if the woman takes the tablet immediately after breast feeding.</p> <p>Use of UPA in last 5 days Levonorgestrel may not be effective and may also interfere with efficacy of UPA taken in last 5 days – consider repeat UPA or emergency IUD if within timescale.</p>
Action if patient declines or is excluded	Refer urgently to DISH service or to client's GP and record in notes/record sheet.



DRUG DETAILS	
Name, Form & Strength of Medicine	Levonorgestrel 1500 microgram tablet
Route/Method	Oral
Dosage/Frequency	<p>Patients BMI < 26 and weighing 70kg or less OR on no interacting medication (see Appendix 6)</p> <ul style="list-style-type: none"> One Levonorgestrel 1500 mcg tablet to be taken orally Ideally client to take tablet at end of consultation If there are concerns that the client may be pregnant, carry out a pregnancy test (PT) and if negative supply the tablet. If unable to carry out a PT immediately, supply test and tablet and inform the client to take tablet if PT is negative. Give client 'Information on Pregnancy Test' leaflet (Appendix 5) If vomiting occurs within 3 hours of Levonogestrel intake, another tablet should be taken. <p>Patients BMI >26 OR weighing > 70 kg OR on interacting medication (see Appendix 6). Use outside of product licence as described below:-</p> <ul style="list-style-type: none"> If treatment with rifampicin / rifabutin within the last 3 months, supply 2 tablets to be taken together. Give client MHRA leaflet 'Levonorgestrel emergency contraception: important information for women taking other medicines' (Appendix 6). If client is currently taking, or has taken in the last 4 weeks other enzyme inducing medication, supply 2 tablets to be taken together. Give client MHRA leaflet: 'Levonorgestrel emergency contraception: important information for women taking other medicines' (Appendix 6). If client has BMI >26 (or body weight >70kg) supply 2 tablets to be taken together. If vomiting occurs within 3 hours of Levonogestrel intake and client is taking enzyme inducing medication or BMI >26 (or body weight >70kg), another TWO tablets should be taken together.
Quantity	<p>1 single dose tablet (repeat dose of 1 tablet if vomits within 3 hours i.e. total of TWO tablets)</p> <p><u>Use outside of product licence</u></p> <p>If taking enzyme inducing medication or BMI >26 (or body weight >70kg), single dose of TWO tablets (repeat dose of TWO tablets if vomits within 3 hours i.e. total of FOUR tablets)</p>
Total Daily Dose	Variable according to dose and vomiting. Either 1500mcg (1 tablet), 3000mcg (2 tablets), or 6000mcg (4 tablets)
Duration of treatment	One dose to be taken at once, unless vomiting occurs within 3 hours when another dose should be taken
Advice to patient/carer	<p>Give client:</p> <p>a. Give client MHRA leaflet 'Levonorgestrel emergency contraception: important information for women taking other</p>



medicines' (Appendix 6).

- b. 'Information on Emergency Contraception' leaflet (final Appendix) and discuss content including:
- If client is likely to be ovulating or likely to be near ovulation she is at higher risk of pregnancy. Inform client about higher efficacy of both emergency IUD (including timescale for fitting) and UPA and ensure she is signposted to services
 - Method of administration
 - Mode of action: primarily inhibition or delay of ovulation. Not abortifacient
 - Alteration in timing of next menses. Advise to return for PT if next menses is delayed by >7 days or is much shorter or lighter than usual.
 - Possible side effects (usually mild or none): nausea, breast tenderness, headaches, dizziness or tiredness
 - What to do if vomiting occurs within 3 hours of administration
 - If client chooses UPA she should be advised to obtain and take it that day in which case she should NOT take Levonorgestrel. Supply client with the Levonorgestrel to take later in the day if she is unable to access UPA and give her the 'Taking Levonorgestrel at Home' letter (Appendix 7)
 - Contraception for present cycle and future use
 - If client has missed contraceptive pill(s) advise to:
 - continue taking contraceptive pills
 - use condoms for the next 2 days if POP
 - use condoms for the next 7 days if COC. Omit pill-free interval if less than 7 pills left in pill packet
 - have PT 4 weeks after taking the Levonorgestrel (*whether or not has had a withdrawal bleed*)
 - If OEC following quickstart implant, client needs to use condoms for 7 days and have a PT in 4 weeks
 - Sexually transmitted infections (STI) risk. Advise or sign post for STI screening. If available offer chlamydia screening if under 25 years and advise repeat screening in 2 weeks.
 - If there are concerns that client may be pregnant and has to take PT and tablet away with her, advise client:
 - To take PT as soon as possible
 - To take tablet if PT is negative
 - That taking the tablet if PT is positive will not terminate the pregnancy
 - Need to visit GP or ISHS if PT is positive to discuss future care.

Use outside of product licence

- If client is taking / has taken enzyme inducing medication within the last 4 weeks (if rifampicin / rifabutin then within the last 3 months)
- Provide client with MHRA leaflet 'Levonorgestrel emergency contraception: important information for women taking other medicines' (Appendix 6).
- Inform client that OEC may be less effective. Rifampicin and rifabutin are particularly strong enzyme inducers and clients taking these should be strongly encouraged to have an IUD.
- If client is taking Ciclosporin, inform her that Levonorgestrel may



	alter the Ciclosporin level and she should review Ciclosporin dose with GP.
Advice to staff	<p>Where use is outside the product licence, it is recommended that the client should be informed and advised that OEC may be less effective. Rifampicin and Rifabutin are particularly strong enzyme inducers and clients taking these should be strongly encouraged to have an IUD.</p> <p>If client is taking Ciclosporin, she should be informed that Levonorgestrel may alter the Ciclosporin level and the client should review Ciclosporin dose with her GP.</p> <p>All clients must be informed of higher efficacy of having an IUD fitted, especially if:</p> <ul style="list-style-type: none"> • Client is mid menstrual cycle and / or over 72 hours since UPSI • Levonorgestrel is being used outside of product licence <p>Women should be informed if they are at higher risk of failure, patient should be informed about availability of UPA and where to obtain it. The timescale for EC IUD fitting and where this can be carried out should be written on the client information leaflet (final Appendix).</p> <p>EC is not needed when a woman is less than 3 weeks postnatal, has had a 3rd trimester loss of pregnancy within the last 3 weeks, or is fully breastfeeding and amenorrhoeic and child is less than 6 months old. However if the client is very anxious, EC may be supplied.</p> <ul style="list-style-type: none"> • Always consider the possibility of abuse / safeguarding issues and if there are concerns obtain client contact details if possible. • If the client is under 16 and Fraser competent http://www.fpa.org.uk/factsheets/under-16s-consent-confidentiality supply of OEC should be made. However if the child is under 13 years of age, or if there are Safeguarding concerns, current Safeguarding guidelines MUST be followed including a referral to the Safeguarding Team. Adult Child safeguarding http://www.derby.gov.uk/health-and-social-care/safeguarding-children/ • If you have a concern about Safeguarding Adults, e.g. sexual exploitation or abuse then contact the Lead Named Nurse Safeguarding Adults in the first instance or call the Service Manager for Adult Social Care on Call Derbyshire. safeguarding http://www.derby.gov.uk/health-and-social-care/safeguarding-adults-at-risk/safeguarding-vulnerable-adults/
Record	<p>Community pharmacists and non-DISH practitioners</p> <ul style="list-style-type: none"> • Complete either all sections of client record sheet (Appendix 4) or electronic record • Client record sheets to be retained in client's file or in confidential file for all OEC consultation records • For electronic record the following must be recorded as a minimum: <ul style="list-style-type: none"> ○ Date of FFLMP or withdrawal bleed (WTB) and whether normal and at expected time ○ Date and time of <u>all</u> UPSI since LMP or missed pills /



	<p>progestogen injection and hours since first UPSI this cycle</p> <ul style="list-style-type: none"> ○ Either cycle length and current day of cycle or current pill / pill free day if on COC ○ PT result if appropriate ○ Current illness and medication ○ If under 16 – confirmation that Fraser Competent ○ Last date for emergency IUD insertion, whether high risk of failure of OEC and whether info given re UPA ○ Dose and form issued (batch details and expiry date) and whether taken in clinic ○ Whether issued on PGD or prescribed ○ Name and designation of staff administering medication. <p>DISH Nurses</p> <ul style="list-style-type: none"> • History: <ul style="list-style-type: none"> ○ <u>Essential</u> – History re recent UPSI, dates all UPSI since LMP, date LMP, menstrual history, details of missed pills/late progestogen injection or any other suspected compromise of regular method of contraception ○ Sexual and social history and STI risk assessment • Last date for emergency IUD insertion, whether high risk of failure of OEC and whether info given re UPA • Significant current and past medical history and medications • Details of any adverse drug reaction and actions taken • Under 16 checklist if appropriate • Discussions and outcome – re PGD, under 16s or any other concerns • Dose and form administered (batch details and expiry date) • State whether taken in clinic or issued to client • Signature, name and designation of staff who administered or supplied the medication.
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CHARACTERISTICS OF STAFF	
Qualifications	<p>A community pharmacist or registered practitioner working within DISH, in MIU or in the community who:</p> <ul style="list-style-type: none"> • Has completed emergency contraception training • Has regular updating e.g. Centre for Pharmacy Postgraduate Education (CPPE) courses, update sessions from DISH.
Additional local training	<ul style="list-style-type: none"> • Has undertaken the local training programme on the process, responsibilities and scope of PGDs • Has undertaken local training based on the use of PGDs and has been authorised by their line manager to undertake the clinical assessment of a patient leading to the identification of those suitable for management under the PGD • Within a pharmacy there must be facilities for private and confidential counselling of the clients. It must meet the following three criteria: <ul style="list-style-type: none"> ○ Is a designated area where both patient and professional can sit down ○ Talking can be carried out at normal volume, without being overheard by visitors or staff carrying out their normal activity ○ Be a designated area for confidential consultations, distinct from general public areas of the Pharmacy.



Additional competency requirements for Pharmacists	<ul style="list-style-type: none"> It is the responsibility of the pharmacist to ensure that they have received training and are competent in all aspects of issuing OEC under this PGD Pharmacists will have completed all of the criteria listed for the declaration of competency (DoC) system for emergency contraception via CPPE. The PSNC website (psnc.org.uk) contains information on how to complete this process Derby City Council may request to inspect these records Pharmacists will be responsible for reassessing their competence to deliver this service.
Continuing training & education	The practitioner should be aware of any change to the recommendations for the medicines listed. 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

REFERRAL ARRANGEMENTS AND AUDIT TRAIL

Referral arrangements	See Advice to patient/carer section above
Records/Audit Trail	Document in patient's notes/Treatment card, PGD record on either electronic or paper systems and complete PGD Record Form.

ADDITIONAL INFORMATION

References	<ul style="list-style-type: none"> Faculty of Sexual and Reproductive Healthcare, Guideline Emergency Contraception (March 2017) https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/ Faculty of Sexual and Reproductive Healthcare, Response to new data on quick-starting hormonal contraception after use of Ulipristal Acetate 30 mg for emergency contraception, September 2015 Faculty of Sexual & Reproductive Healthcare, UK Medical Eligibility Criteria for Contraceptive Use, 2016 https://www.fsrh.org/standards-and-guidance/documents/ukmec-2016/ The family planning association: Under 16s consent and confidentiality (Fraser). http://www.fpa.org.uk/factsheets/under-16s-consent-confidentiality Faculty of Sexual & Reproductive Healthcare, Clinical Effectiveness Unit: Quick Starting Contraception, September 2010. Faculty of Sexual & Reproductive Healthcare, Clinical Effectiveness Unit: Drug Interactions with Hormonal Contraception, January 2011 Faculty of Sexual & Reproductive Healthcare, Clinical Standards Committee: Statement on the prescription, administration or supply of Contraceptive Medicines for use outside the terms of their references, December 2009 British National Formulary http://www.bnf.org Summary of product characteristics http://emc.medicines.org.uk MHRA 2016 Levonorgestrel-containing emergency hormonal contraception: advice on interactions with hepatic enzyme inducers and contraceptive efficacy. https://www.gov.uk/drug-safety-update/levonorgestrel-containing-emergency-hormonal-contraception-advice-on-interactions-with-hepatic-enzyme-inducers-and-contraceptive-efficacy. Adult safeguarding http://www.derby.gov.uk/health-and-social-care/safeguarding-adults-at-risk/safeguarding-vulnerable-adults/
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	<ul style="list-style-type: none"> Child safeguarding http://www.derby.gov.uk/health-and-social-care/safeguarding-children/
Drug Interactions	Comprehensive lists of drug interactions are not described in each PGD and only most significant are listed. For further information please refer to the BNF.
Side effects	Comprehensive lists of side effects are not described in each PGD and only most significant are listed. For further information please refer to the current BNF or SPC.
Yellow Card Scheme	Adverse drug reactions should be reported directly via the Yellow Card Scheme run by the MHRA and the Commission on Human Medicines (CHM). For guidance and to report online click the link http://yellowcard.mhra.gov.uk/ Yellow Cards and completion information are also available at the back of the BNF.

THIS PGD WAS DEVELOPED BY:

Name	Position
Dr Jackie Abrahams	Lead Doctor, DISH
Dr Amanda Smith	Associate Specialist, DISH
Janet Beardsley	Workforce Practice Facilitator, DISH


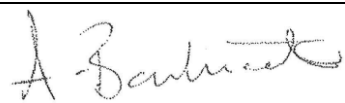

Review

Date & Comments	Name	Position
July 2017. Updated:- <ul style="list-style-type: none"> Age Indications Inclusion/ exclusion criteria Advice Appendices 	Dr Nathani	Lead Clinician DISH
	Janet Beardsley	Workforce Practice Facilitator, DISH
	Anna Braithwaite	Chief Pharmacist DCHS

PATIENT GROUP DIRECTION AUTHORISATION

PGD approved by PGD Steering Group on (May 2017)

This PGD is authorised for use on behalf of DCHS by the following signatories:

Position of signatory	Name	Signature	Date
Director of Quality & Chief Nurse	Carolyn White		30/08/2017
Head of Medicines Management	Anna Braithwaite		30/08/2017
Medical Director	Rick Meredith		30/08/2017



Appendix 1



4.3 Women using hormonal contraception incorrectly

✓ Women who do not wish to conceive should be offered EC after UPSI if their regular contraception has been compromised or has been used incorrectly.

EC may be indicated if contraception has been used incorrectly or has been compromised (e.g. by concomitant use of enzyme-inducing drug or vomiting). [Table 1](#) outlines situations in which EC is indicated because of likely failure of hormonal or intrauterine contraception. This is a guide only; there are too many variables relating to incorrect use of contraception to provide advice for every situation.

Table 1: Indications for emergency contraception following potential failure of hormonal and intrauterine methods of contraception (see [Section 13.2](#) for clarification)

Method	Situation leading to possible contraceptive failure	Indication for EC
Hormonal methods of contraception	Failure to use additional contraceptive precautions when starting the method	UPSI or barrier failure during time that additional precautions required as indicated within CEU guidance.
Combined hormonal transdermal patch or combined hormonal vaginal ring	Patch detachment/ring removal for >48 hours Extension of patch-free or ring-free interval by >48 hours	EC is indicated if patch detachment or ring removal occurs in Week 1 and there has been UPSI or barrier failure during the hormone-free interval (HFI) or Week 1. If the HFI is extended, a Cu-IUD can be offered up to 13 days after the start of the HFI assuming previous perfect use (see Section 13.2.1). If CHC has been used in the 7 days prior to EC, the effectiveness of UPA-EC could theoretically be reduced. Consider use of LNG-EC (see Section 10.3).
Combined oral contraceptive pill (monophasic pill containing ethinylestradiol)	Missed pills (if two or more active pills are missed)	EC is indicated if the pills are missed in Week 1 and there has been UPSI or barrier failure during the pill-free interval or Week 1. If the pill-free interval is extended (this includes missing pills in Week 1), a Cu-IUD can be offered up to 13 days after the start of the HFI assuming previous perfect use (see Section 13.2.1). If COC has been taken in the 7 days prior to EC, the effectiveness of UPA-EC could theoretically be reduced. Consider use of LNG-EC (see Section 10.3).

[continued on next page]



Method	Situation leading to possible contraceptive failure	Indication for EC
Combined hormonal contraception, progestogen-only pill and progestogen-only implant	Failure to use additional contraceptive precautions whilst using liver enzyme-inducing drugs or in the 28 days after use	EC is indicated if there is UPSI or barrier failure during, or in the 28 days following, use of liver enzyme-inducing drugs. Offer a Cu-IUD (unaffected by liver enzyme-inducing drugs) or a double dose (3 mg) of LNG-EC. UPA-EC is not recommended with liver enzyme-inducing drugs.
Progestogen-only pill	Late or missed pill (>27 hours since last traditional POP or >36 hours since last desogestrel-only pill)	EC is indicated if a pill is late or missed and there has been UPSI or barrier failure before efficacy has been re-established (i.e. 48 hours after restarting). Timing of ovulation after missed pills cannot be accurately predicted. A Cu-IUD is therefore only recommended up to 5 days after the first UPSI following a missed POP (see Section 13.2.1). If POP has been taken in the 7 days prior to EC, the effectiveness of UPA-EC could theoretically be reduced. Consider use of LNG-EC (see Section 10.3).
Progestogen-only injectable	Late injection (>14 weeks since last injection of DMPA)	EC is indicated if there has been UPSI or barrier failure: <ul style="list-style-type: none"> ▶ >14 weeks after the last injection ▶ within the first 7 days after late injection Timing of ovulation after expiry of the progestogen-only injectable is extremely variable (see Section 13.2.1). A Cu-IUD is only recommended up to 5 days after the first UPSI that takes place >14 weeks after the last DMPA injection. The effectiveness of UPA-EC could theoretically be reduced by residual circulating progestogen. Consider use of LNG-EC (see Section 10.3).
Progestogen-only implant	Expired implant	See Section 13.2.2 .
Intrauterine contraception (Cu-IUD and LNG-IUS)	Removal without immediate replacement; partial or complete expulsion; threads missing and IUC location unknown	If UPSI has occurred in the 5 days (the duration of sperm viability in the upper genital tract) prior to removal, perforation, partial or complete expulsion. Depending on the timing of UPSI and time since IUD known to be correctly placed, it may be appropriate to fit another Cu-IUD for EC.

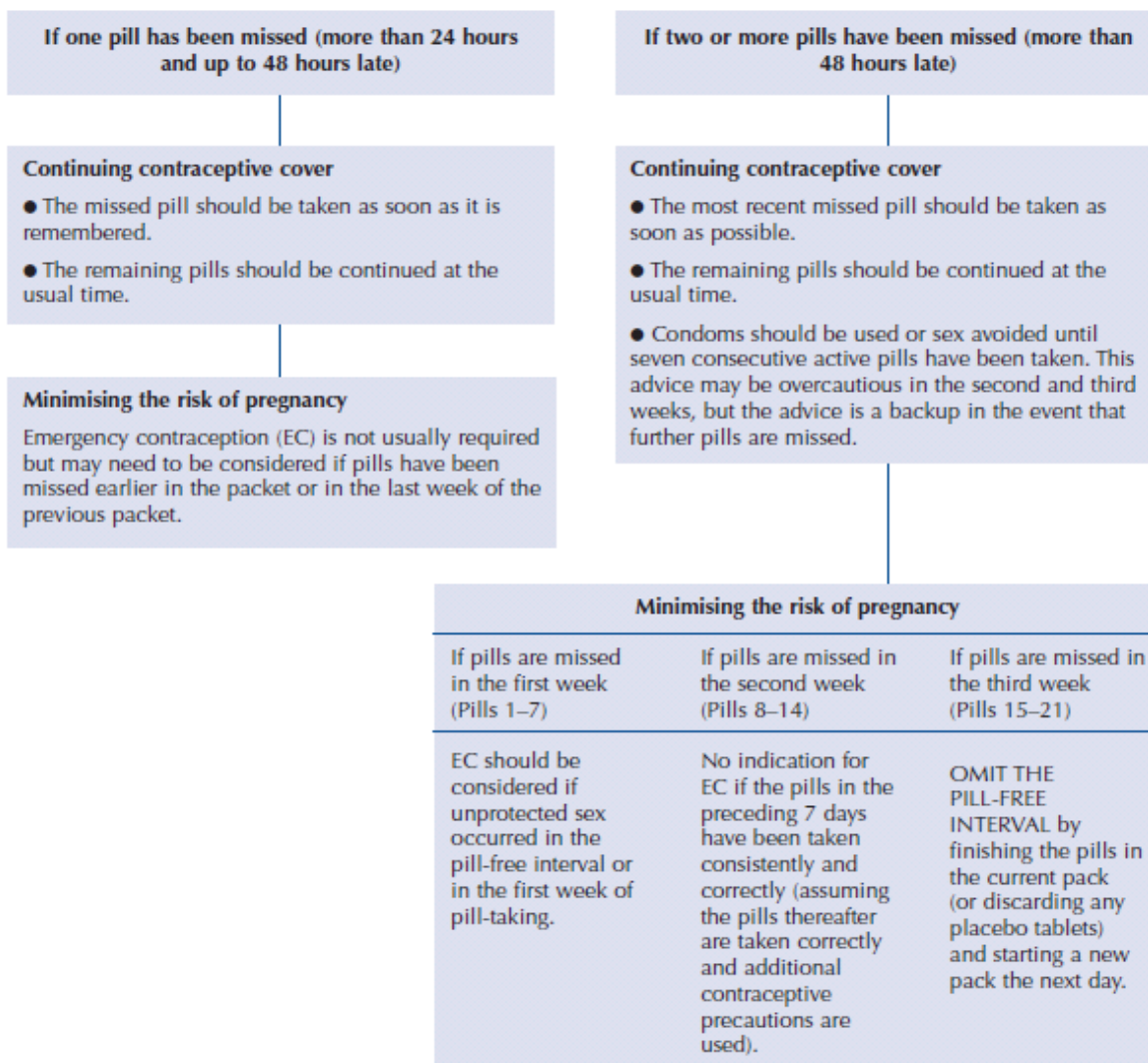
CEU, Clinical Effectiveness Unit; CHC, combined hormonal contraception; COC, combined oral contraception; Cu-IUD, copper intrauterine device; DMPA, progestogen-only injectable: depot medroxyprogesterone acetate; EC, emergency contraception; HFI, hormonal-free interval; IMP, progestogen-only implant; IUC, intrauterine contraception; LNG-EC, levonorgestrel for EC; LNG-IUS, levonorgestrel-releasing intrauterine system; POP, progestogen-only pill; UPA-EC, ulipristal acetate for EC; UPSI, unprotected sexual intercourse.



Appendix 2

CEU STATEMENT

MISSED COMBINED ORAL CONTRACEPTIVE PILLS (COCs): CEU ADVICE FOR HEALTH PROFESSIONALS

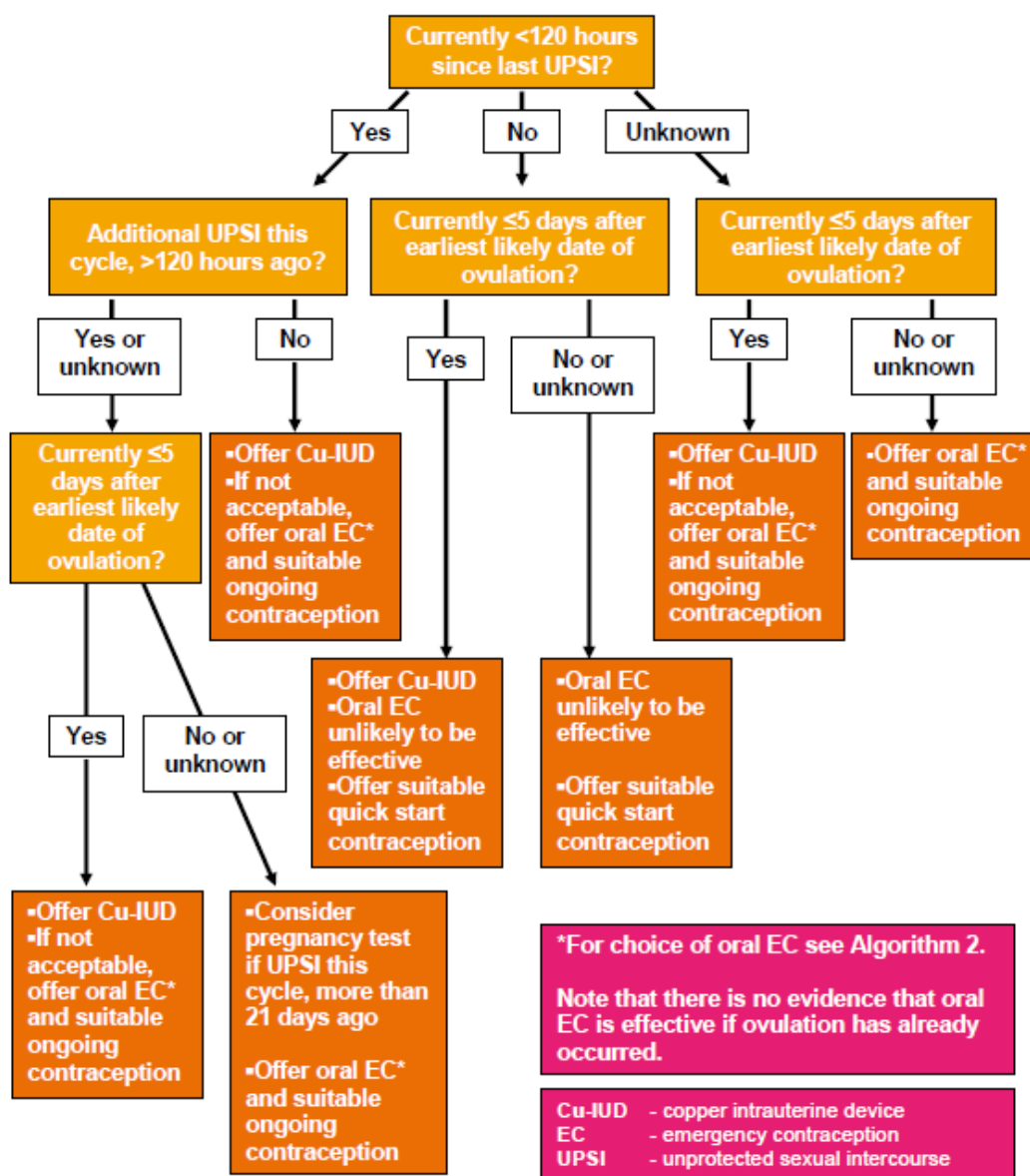


References

- 1 Faculty of Family Planning and Reproductive Health Care. Missed pills: new recommendations. *J Fam Plann Reprod Health Care* 2005; **31**: 153–156.
- 2 World Health Organization. *Selected Practice Recommendations for Contraceptive Use* (2nd edn). 2004. <http://whqlibdoc.who.int/publications/2004/9241562846.pdf> [Accessed 24 November 2010].
- 3 Medicines and Healthcare products Regulatory Agency (MHRA). *Combined Oral Contraceptives (The Pill): When to Start Taking the Pill, and Missed Pill Advice*. MHRA UK Public Assessment Report, May 2011. <http://www.mhra.gov.uk> [Accessed 12 May 2011].

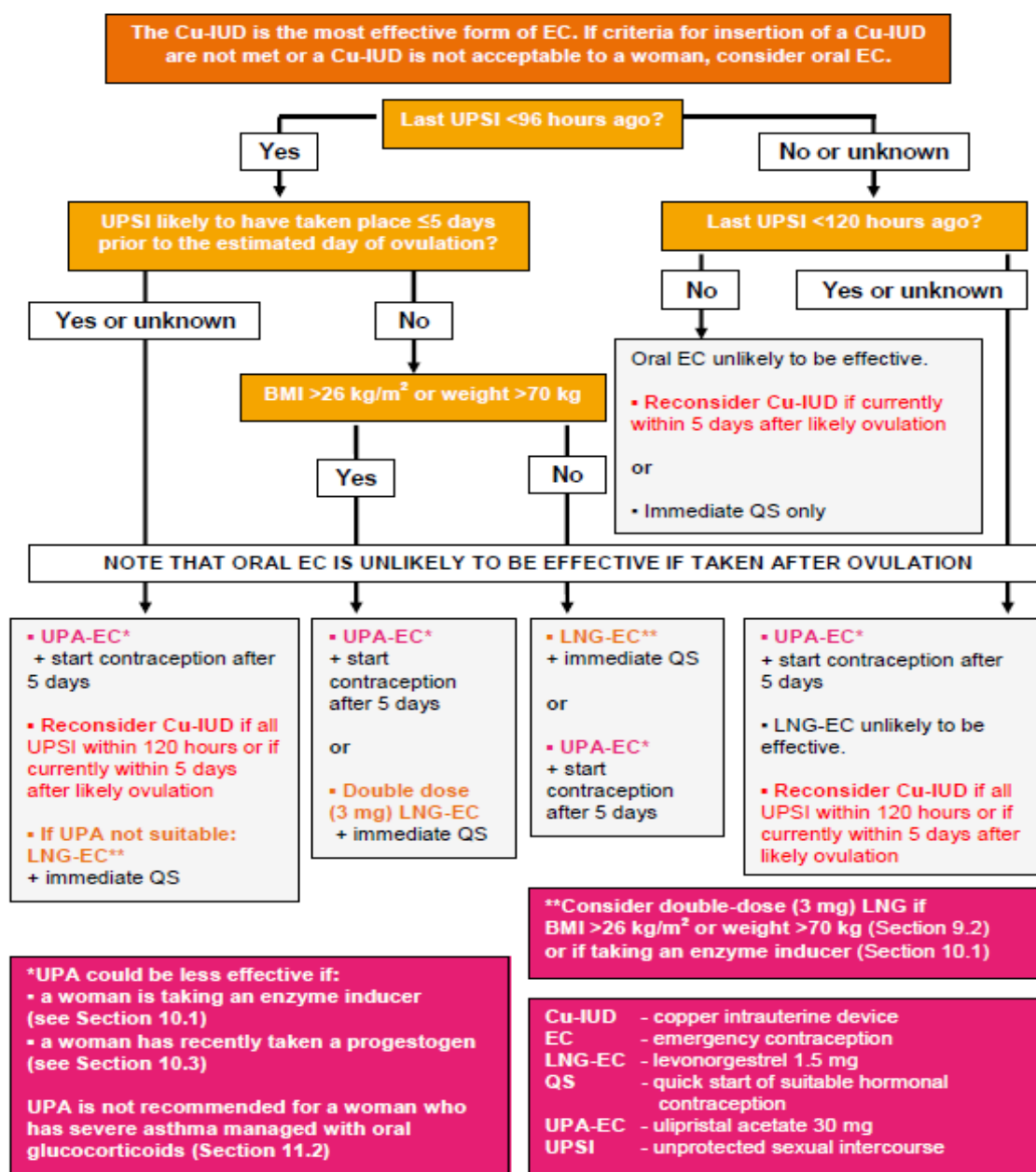


Algorithm 1: Decision-making Algorithm for Emergency Contraception (EC):
Copper Intrauterine Device (Cu-IUD) vs Oral EC





Algorithm 2: Decision-making Algorithm for Oral Emergency Contraception (EC):
Levonorgestrel EC (LNG-EC) vs Ulipristal Acetate EC (UPA-EC)



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Appendix 4

Oral Emergency Contraception (OEC) Provided by Community Pharmacists or Nurses

Client Record - Both sides to be completed

Date _____ Time _____

Place of Consultation (or Pharmacy stamp)

CLIENT DETAILS

Name: _____ Age: _____ Postcode: _____

If Client under the age of 16 refer to Fraser Guidelines and other issues

GP DETAILS (If Given)

Name: _____ Surgery: _____

DETAILS OF UNPROTECTED SEXUAL INTERCOURSE (UPSI)

Date & Time of UPSI _____ Hours since UPSI _____ Other UPSI since last menstrual period (LMP) **YES/ NO**
If **yes** give details _____

CURRENT CONTRACEPTION (circle as appropriate)

COC / POP / Condoms / IUD / Implanon / Injection / None / Other (specify) _____

If recently missed pill(s) - details: _____

If recently stopped pills-date last pill taken: _____ If Implant fitted over 3 years ago-date fitted _____

If Injection overdue - state Depo or Noristerat and date last injection: _____

OTHER MEDICATION? _____ Liver Enzyme Inducing? **YES/NO**

MENSTRUAL HISTORY

COMPLETE EITHER (a) or (b) AS APPROPRIATE

a) For Clients not taking Combined Oral Contraception (COC)

Date of Last Menstrual Period (LMP) (First day of bleeding) _____

Current day of Cycle _____ Usual cycle length _____

b) For Clients taking COC

Date last Withdrawal Bleed (WTB) _____ Current pill day or pill free day _____
(First day) (state whether pill day or pill free day)

**COMPLETE FOR ALL CLIENTS**LMP / WTB UNUSUAL? **YES/NO**PERIOD / WTB OVERDUE? **YES/NO**

If LMP or WTB unusual or overdue - was Pregnancy Test (PT) Negative / Positive / Given to Client to carry out at Home

MEDICAL HISTORY

1. Active/Severe Liver Disease **YES / NO** Hypersensitivity to OEC **YES / NO** Porphyrria **YES / NO**

OEC excluded if YES to any of the above

2. Unexplained vaginal Bleeding **YES / NO** If YES, **OEC not excluded** - supply and advise client to consult GP/Sexual Health service

3. BMI > 26kg/m² or Weight > 70Kg consider dose-dose (3mg)

4. Taking an enzyme inducer medication consider dose-dose (3mg)

UNDER 16

YES/NO

UNDER 13

YES/NO

FRASER COMPETENT

YES/NOCHILD PROTECTION CONCERNS **YES/NO****Contact Details if under 13 or Child Protection concerns**

(Address, School and Mobile Number if possible)

OEC Client Information Leaflet supplied

Emergency IUD Explained

YES / NO**YES / NO**

Client at Higher Risk of Failure of OEC
(ie between ovulation minus 6 and ovulation plus 2)
YES / NO

OEC supply
Licensed / Unlicensed / Not Supplied
(refer to flow chart if necessary)

Information given about Ulipristal (EllaOne) **YES / NO**

Last Date for IUD insertion - on or before

Too late for Emergency IUD (either enter date or circle 'too late') Other concerns or any additional advice given

Record of issue _____ **Time taken** _____ / **Taken away** _____
(Drug name, (circle as appropriate)
Batch no and Expiry date) _____

Follow up (if arranged) _____
Nurse / Pharmacist name (Please PRINT) _____

Nurse / Pharmacist signature _____

Appendix 5

INFORMATION ON THE PREGNANCY TEST

Date _____

This information is to be given to clients who have been given a pregnancy test to do at home. The test is to be carried out BEFORE taking the emergency contraceptive pill (Levonelle®).

If the test is **NEGATIVE**:

- Take the emergency contraceptive pill as soon as possible
- If you do not have a completely normal period within the next 4 weeks you should contact your GP or a Your Sexual Health Matters clinic for a repeat test and further advice. To book an appointment at a Your Sexual Health Matters clinic contact the Central Booking Line on 0800 3283383.

If the test is **POSITIVE**:

- You should NOT take the tablet
- A positive test means that you became pregnant at least 2 weeks ago and taking the emergency contraceptive pill will not change this
- Contact the Central Booking Line on 0800 3283383 to book an appointment at a Your Sexual Health Matters clinic, or speak to your GP, especially if you do not want to continue with the pregnancy.

Your nearest Your Sexual Health Matters clinic is

NAME of the Pharmacist / Nurse who gave you this letter:.....

ADDRESS (or stamp) of the premises where you were seen by the Pharmacist / Nurse:

.....

Booking and information line: 0800 328 3383 Website: www.yoursexualhealthmatters.org.uk

This service is funded by Derbyshire County Council, Derby City Council and delivered by Derbyshire Community Health Services NHS Foundation Trust.



Derby City Council



DERBYSHIRE
County Council
Improving life for local people



Appendix 6



Medicines & Healthcare products
Regulatory Agency



Levonorgestrel emergency contraception: important information for women taking other medicines

Some medicines, or herbal remedies that contain the ingredient St John's wort, might reduce how well levonorgestrel emergency contraception works.

What you need to do

Tell the doctor, pharmacist, or nurse if you are currently taking a medicine to treat any of the following, or you have used one in the past 4 weeks:

- epilepsy (eg, medicines called barbiturates, primidone, phenytoin, or carbamazepine)
- tuberculosis (eg, rifampicin, rifabutin)
- HIV (eg, ritonavir, efavirenz)
- a fungal infection (eg, griseofulvin)
- or if you have taken any herbal remedies that contain the ingredient St John's wort (scientific name *Hypericum perforatum*)

If you are taking any medicines or herbal remedies and are not sure if they might affect levonorgestrel emergency contraception check with your doctor, pharmacist, or nurse.

What happens now?

Your doctor, pharmacist or nurse will talk to you about whether this applies to medicines you have recently taken. If it does, you should either:

- see a doctor or nurse to have another type of emergency contraception called a copper intrauterine device or 'coil' inserted into the womb (this does not interfere with the action of other medicines);

or:

- take a double dose of levonorgestrel emergency contraception. The pharmacist will give you 2 packs, which should be taken together at the same time

Further information about levonorgestrel emergency contraception

Levonorgestrel is a hormonal type of emergency contraception. It can be used within 3 days (72 hours) after unprotected sex or failure of a usual contraceptive method.

Levonorgestrel emergency contraception may not prevent pregnancy every time. It works best the sooner it is taken—preferably within 12 hours.

Advice for women taking levonorgestrel emergency contraception:

- see your doctor or nurse for advice on effective ongoing contraception
- do a pregnancy test to ensure that you are not pregnant if your period does not come at the right time or if you suspect you could be pregnant
- if the test is positive and you are pregnant (even after taking levonorgestrel), see a doctor or nurse as soon as possible to ensure that you receive the best care
- read the leaflet that comes with levonorgestrel, which provides further information about this emergency contraception including any potential side effects
- if you think that you may have had a side effect after taking levonorgestrel, remember you can report it on a [Yellow Card](https://yellowcard.mhra.gov.uk/) (<https://yellowcard.mhra.gov.uk/>)



Appendix 7

IMPORTANT INFORMATION ABOUT THE EMERGENCY CONTRACEPTIVE PILL WHICH YOU HAVE BEEN GIVEN BY YOUR PHARMACIST / NURSE (Date.....)

TAKING LEVONORGESTREL 1500 MICROGRAM TABLET AT HOME

Your Pharmacist / Nurse has given you an emergency contraceptive pill called levonorgestrel 1500 microgram tablet to take at home in the event that:

- you are unable to attend a Your Sexual Health Matters clinic (see below) OR
- you are unable to get the other emergency contraceptive pill called ellaOne®.

The other emergency pill (ellaOne®) is available free of charge from YSHM clinics throughout Derby and Derbyshire – call the Central Booking Line on 0800 3283383 to arrange an urgent appointment.

At the appointment, a YSHM clinician will see you and give you an emergency pill. ellaOne® is a contraceptive intended to prevent pregnancy after unprotected sex or if you think your contraceptive method has failed.

ellaOne® contains the substance ulipristal acetate which acts by modifying the activity of the natural hormone progesterone which is necessary for ovulation to occur. As a result, ellaOne® works by postponing ovulation. This is why it is recommended for women who are closer to ovulation.

You should take ellaOne® as soon as possible after sex, and within a maximum of 5 days (120 hours). This is because the sperm can survive up to 5 days in your body after sex. ellaOne® is suitable for any woman of childbearing age, including adolescents.

Emergency contraception is not effective in every case. Of 100 women who take ellaOne® approximately 2 will become pregnant. ellaOne® is a contraceptive used to prevent a pregnancy from starting. If you are already pregnant, it will not interrupt an existing pregnancy.

DO NOT use ellaOne® together with another emergency contraceptive pill that contains Levonorgestrel. By taking them both together, you might make ellaOne® less effective.

If you get an appointment at a YSHM clinic then you must only take the ellaOne® that the clinic gives you. Your Pharmacist / Nurse has given you this Levonelle® tablet to take just in case you can't get to a YSHM clinic, in which case you need to take the tablet as soon as possible.

TAKING THE PREGNANCY TEST AT HOME (ONLY IF APPLICABLE)

If your Pharmacist / Nurse thinks you might be pregnant **and you can't get an urgent appointment with your GP or YSHM clinic**, they will give you a pregnancy test to do at home as well as the Levonelle® tablet. **The test is to be carried out BEFORE taking the tablet.**

- **If the test is NEGATIVE:**
 - Take the tablet as soon as possible
 - If you do not have a completely normal period within the next 4 weeks you should contact your GP or YSHM clinic for a repeat test and further advice.
- **If the test is POSITIVE:**
 - You should NOT take the tablet
 - A positive test means that you became pregnant at least 2 weeks ago and taking the emergency pill will not change this
 - Contact the Central Booking Line on 0800 3283383 for an appointment at a YSHM clinic, or speak to your GP, especially if you do not want to continue with the pregnancy. Your nearest YSHM clinic is.....

NAME of Pharmacist / Nurse who gave you this letter:.....

ADDRESS (or stamp) of the premises where you were seen by the Pharmacist / Nurse:

.....
.....
.....



Appendix 8

Guidance for providing Advice and treatment to Young People

NB However great the concerns – if a young person is Fraser Competent and needs Emergency Contraception - DO NOT DELAY ISSUING (even if aged under 13)

Derby and Derbyshire Safeguarding Children Boards' Information Sharing Agreement and Guidance for Practitioners 2015. 1.6.8 Working with Sexually Active Children and Young People Under the Age of 18

"Young people place great importance in confidentiality and may be concerned that their right to a confidential service is being removed. This guidance does not change the existing principle of confidentiality; however confidentiality has never been absolute and suitable support should be given to the young person."

Fraser Guidelines on providing advice and treatment

It is considered good practice for workers to follow the Fraser guidelines when discussing personal or sexual matters with a young person under 16. The Fraser guidelines give specific guidance on providing advice and treatment to young people under 16 years of age. These hold that sexual health services can be offered without parental consent providing that;

The young person understands the advice being given

The young person cannot be persuaded to inform or seek support from their parents, and will not allow the worker to inform the parents that contraceptive protection, for example: condom advice is being given

The young person is likely to begin or continue to have sexual intercourse without contraception or protection by a barrier method

The young person's physical or mental health is likely to suffer unless they receive contraceptive advice or treatment

It is in the young persons best interest to receive contraceptive /safe sex advice and treatment without parental consent

Fraser Competence

Fraser competence describes a child's capacity to give consent in more general terms and could relate to their competence to permit the sharing of confidential information. Each child and young person is an individual and their "Fraser competence" would depend on factors including their age, development and capacity to demonstrate an understanding of the issue under discussion and the concept of informed consent.

A young person of 16 or 17, or a child under 16, who has capacity to understand and make their own decisions, may give (or refuse) consent to sharing information. Practitioners should be mindful of their responsibilities to safeguard the child when considering the views of younger children or those where there are concerns about their capacity.

Practitioners need to take account of the views of a "Fraser competent" young person when considering the need to share confidential information with colleagues.

School Nurse Contact

The school nurses employed by the Trust (as opposed to those employed by the school) are bound by Health confidentiality guidelines and hold Child Health records for all children. **They have no obligation to share information with the school.**

This means that they are the ideal people to contact if there is a young person that you are concerned about but do not feel there are sufficient concerns to make a referral to Social Care necessary. If you know what school they attend, the Child Health Office can put you in touch with the appropriate school nurse.



Dealing with Young People involved in Sexual Activity – Safeguarding or Child Protection Concerns

Low/Moderate Concern

Eg, no clear indication of abuse, but aspects cause you concern

Discuss with senior colleague

Refer as appropriate

High Concern

Young person under the age of 13

Power imbalance >than 5 year gap in age of partner

Disclosure of sexual abuse/rape

Multiple partners/reluctance to discuss age etc

Additional vulnerability for sexual exploitation eg:

going missing frequently

Domestic violence

Parental drug/alcohol or mental health concerns

Looked after child

Substance misuse/mental health problems

Learning / physical disability

Social Care involved



See young person alone for part of consultation

Discuss the limits of confidentiality in a manner they can understand:

Assess competence as per Fraser Guidelines

Listen carefully, reassure young person they are right to tell

Document concerns

Ensure you have the young person's contact details - including school attending

Discuss with senior member of staff

Obtain consent to share information (unless doing so will endanger the young person). Discuss with young person what you are concerned about, what you need to do, and what will happen.

Refer to social care as per safeguarding procedures - **if aged under 13 must be referred**

(if any reservations discuss with Child Protection Unit or Community Paediatrician on call)

Ensure young person has continued support

Refer to Derbyshire Safeguarding Procedures for further information

Useful Telephone Numbers

DCHST Safeguarding Service for Adults and Children (DCHST staff): 01773 850000

Derby City Safeguarding Unit: 01332 623700

On call Community Paediatrician: 01332 340131 (Royal Derby Hospitals switchboard) and 01246 277271 (Chesterfield Royal Hospitals switchboard)

SOCIAL CARE CONTACT NUMBERS:

Starting Point (Referrals – County): 01629 533190

Starting Point (Professional Advice Monday to Friday 8am to 6pm – County): 01629 535353

Derby City Social Care (Monday to Friday): 01332 717118

Derby City Social Care (Evenings and Weekends): 01332 711205

Emergency Contraception

To have an emergency coil (IUD) fitted please contact either:

- the Central Booking Line
0800 3283383 for an appointment with an Integrated Sexual Health Services clinic,
- or ask your GP if you can have one fitted at the surgery.

Your nearest clinic is:

.....

Telephone:

Sexually Transmitted Infections (STI)

Remember:

- STIs are very common
- Anyone who has unprotected sex is at risk of STIs.

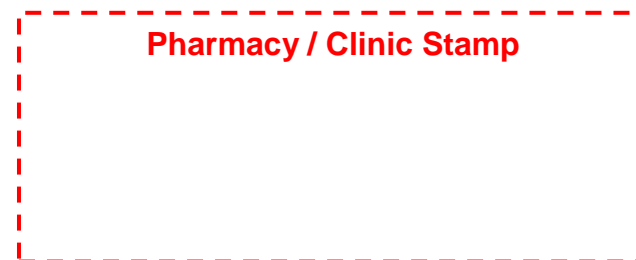
Not everyone knows they have an infection as they may not have any symptoms.

If you are worried that you may have been at risk of a sexually transmitted infection, you should contact your GP or Integrated Sexual Health Services on the Central Booking Line
0800 3283383

Emergency Contraception

For further information, contact any of the following:

- Your GP
- An Integrated Sexual Health Services clinic - for opening hours and locations telephone the Central Booking Line: **0800 3283383**
- The Pharmacist / Nurse who supplied this leaflet (see below)



Both Levonorgestrel and Ulipristal can be purchased from your local pharmacy – please ask your pharmacist for details.

Are we accessible to you? This publication is available in other formats (for example, large print, easy read, Braille or audio version) and other languages. For free translation and/or other formats please call **01246 515224** or email DCHST.communications@nhs.net

Information on Emergency Contraception

Clinic Booking Line: 0800 3283383

Integrated Sexual Health Services
www.yoursexualhealthmatters.org.uk



NHS 111 service operates a 24-hour nurse advice and health information service, providing confidential information on all aspects of healthcare.

For urgent health advice, telephone 111 or visit <http://www.nhs.uk/pages/home.aspx>

your
**sexual
health
matters**



Emergency Contraception

1) Emergency Pills:

- Levonorgestrel (Levonelle®)
- Ulipristal (ellaOne®)

These are hormonal methods, which should be taken within 5 days of unprotected sex (where no contraception has been used or when your usual method has failed).

How to take it

You have been given 1 tablet of Levonorgestrel (Levonelle®) / Ulipristal (ellaOne®) (**clinician to delete as appropriate**). The sooner treatment is started the better it works.

You should take the tablet as soon as possible

- If you are taking certain medicines or St John's Wort, you may require a higher dose of Levonorgestrel.
- You should avoid antacids (indigestion remedies) for 2 hours before and after Ulipristal.

If you are sick within 3 hours of taking Levonorgestrel tablet or Ulipristal tablet, you will need to take another one - available from here, your GP, or other Integrated Sexual Health Services clinics. For clinic opening times see Integrated Sexual Health Services website: www.yoursexualhealthmatters.org.uk

How it works

Oral emergency contraception works by delaying or stopping an egg being released (ovulation). It will not cause an abortion and there is no current evidence that it will affect a baby.

Failure Rate

This method does not always work. Its effectiveness depends on where you are in your menstrual cycle and how soon you take the emergency pill. **There is less chance of failure if there is no further sex until your next period.**

Are there any side effects?

The side effects are usually mild or none. You may experience nausea, vomiting, breast tenderness, headaches, dizziness or tiredness.

Your next period

This may come earlier or later than expected.

Follow up

It is **very important** to seek advice from your GP or an Integrated Sexual Health Services clinic if you have **an unusually light period or no period at all within the next 4 weeks**. Please take an early morning sample of urine with you for a pregnancy test.

Remember

If you have been given Levonogesterel following missed contraceptive pills, you should carry on taking them. You must also use condoms for the next 7 days and do a pregnancy test in 4 weeks.

If you have been given Ulipristal you must delay starting a hormonal method of contraception for the next 5 days because the Ulipristal will not be as effective. You must also use condoms

for the next 14 days and do a pregnancy test in 5 weeks.

2) Emergency Coil (IUD)

This is the MOST EFFECTIVE method of Emergency Contraception

If you are worried about failure of the emergency pill, you should consider having a coil fitted in the next few days.

(Pharmacist / Nurse to tick box below if it applies)

You are at higher risk of the emergency pill not working because you are in the middle of your cycle (when you release an egg – ovulate).

☐

You are at higher risk of the emergency pill not working because you have probably already ovulated and the pills will not be nearly as effective.

☐

An IUD can be fitted up to 5 days after the earliest time you could have released an egg (that means up to about 10 days before your next period is due), no matter how often you have had unprotected sex.

If your period is due in less than 10 days, an IUD can only be fitted if all unprotected sex since your last period has been in the previous 5 days.

You should be able to have an emergency coil fitted until:

(If not applicable, Pharmacist / Nurse to leave blank and explain why)

