

NHS Derby City and NHS Derbyshire County

Controlled Document

Reference: C100

Approval Date: June 12

Expiry Date: May 14

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

PATIENT GROUP DIRECTION (PGD) FOR		
NO. C100	LEVONORGESTREL 1500 microgram Tablet (LEVONELLE®)	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 Professions Council (HPC) registered Emergency Care Practitioner working within

- Derbyshire Contraception and Sexual Health Service (C&SH) Service
- Walk in Centre (WIC) or Minor Injury Unit (MIU)
- The community as a nurse for children and young people

CLINICAL CONDITION

Indication	Prevention of pregnancy from unprotected sexual intercourse (UPSI) e.g. no contraception or failed condom / barrier method If missed pills, patch or ring see Appendix 1 and Sexual Health Service Guidelines on Missed Pills, Patch or Ring and use of Emergency Contraception.
Inclusion criteria	Client requesting post coital contraception due to unprotected sexual intercourse (UPSI) in whom there are no contraindications. <ul style="list-style-type: none"> • Unprotected sexual intercourse also includes; <ul style="list-style-type: none"> ○ Missed pills (Appendix 1) ○ Condom failure ○ Significant drug interaction ○ Late contraceptive injection ○ Implant overdue for change <p>For <u>licensed use</u> all UPSI since last menstrual period (LMP) must have been within the preceding 72 hours</p> <p><u>Use outside of product licence¹</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 • Several episodes of UPSI within current cycle and no use of OEC within this menstrual cycle but presenting within 5 days of ovulation <ul style="list-style-type: none"> ○ Up to Day 19 of a regular 28 day menstrual cycle ○ Up to day 15 of an extended pill free interval ○ Up to 14 weeks and 5 days since last Depo-Provera injection • Severe malabsorption syndrome • Concurrent use of enzyme inducing medication e.g.

	<ul style="list-style-type: none"> ○ Carbamazepine, griseofulvin, oxcarbazepine, phenytoin, primidone, other barbiturates, ritonavir, topiramate, rifabutin, rifampicin and St John's Wort <p>This list is not exhaustive – always check drug interactions in latest version of BNF</p> <p>Guidance for providing advice and treatment to young people under 16 is given in advice section later and in Appendix 3.</p>
Exclusion criteria	<ul style="list-style-type: none"> • Confirmed pregnancy • Suspected pregnancy or doubt about last menstrual period, <u>unless pregnancy test carried out that day is negative</u> • 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: Enzyme inducers e.g. carbamazepine, griseofulvin, oxcarbazepine, phenytoin, primidone and other barbiturates, ritonavir, topiramate, rifabutin, rifampicin or St John's Wort – may reduce the efficacy of levonorgestrel - double dose levonorgestrel needed. <u>Ciclosporin</u> and <u>Theophylline</u> – Theoretical risk of toxicity. <u>Warfarin</u> and <u>Phenindione</u> - change in INR (re-check INR) This list is not exhaustive – always check drug interactions in latest version of BNF</p> <p>Severe Malabsorption (eg Crohn's disease, severe coeliac disease) - Needs double dose levonorgestrel. Discuss with C&SH doctor or prescriber if concerns</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 breast-feeding woman takes the tablet immediately after feeding.</p>
Action if patient declines or is excluded	Refer urgently to CSHS/CASH Service or to patient's GP and record in notes/record sheet

DRUG DETAILS	
Name, Form & Strength of Medicine	Levonorgestrel 1500 microgram tablet
Route/Method	Oral
Dosage/Frequency	<ul style="list-style-type: none"> • One tablet to be supplied. • Ideally patient to take tablet at end of consultation. • If there are concerns that the person may be pregnant, then carry out a pregnancy test and if negative supply the medication. If unable to carry out a test immediately, supply a test and the medication informing the patient to take the tablet if the test is negative. Give information leaflet (Appendix 5) <p><u>Use outside of product licence</u></p> <ul style="list-style-type: none"> • If the patient is currently taking, or has taken in the last 4 weeks, enzyme inducing medication, or is suffering from severe malabsorption syndrome (see above and BNF), 2 tablets to be supplied and taken together • Treatment with Rifampicin/Rifabutin within the last three months, 2 tablets to be supplied and taken together.

<p>Quantity</p>	<ul style="list-style-type: none"> One (retreatment with second dose if vomits within 2 hours) <p><i>Use outside of product licence</i> If taking enzyme inducing medication or malabsorption, quantity will be TWO tablets (total of 4 tablets if vomits within 2 hours)</p>
<p>Total Daily Dose</p>	<ul style="list-style-type: none"> One (2 to be taken if vomits within 2 hours) <p><i>Use outside of product licence</i> If taking enzyme inducing medication or malabsorption, dose will be TWO tablets (total of 4 tablets if vomits within 2 hours)</p>
<p>Duration of treatment</p>	<p>To be taken at once</p>
<p>Advice to patient/carer</p>	<p>As per client information leaflet including:</p> <ul style="list-style-type: none"> Method of administration. Side effects – usually mild or none – can cause nausea, breast tenderness, headaches, dizziness or tiredness. What to do if vomiting occurs within 2 hours of administration. How it works. Failure rate and option of emergency intra-uterine device (EC IUD) - including timescale for fitting. If aged ≤ 35 and higher risk failure of EC - (ie UPSI between ovulation minus 6 days and ovulation plus 2 days) - give information about higher efficacy of Ulipristal and where to obtain it Possibility of early or late onset of next period. Clients should be advised that if they do not experience a normal period within 4 weeks of using levonorgestrel they should be followed up by their GP, the CSHS/CASH service or their school nurse so that pregnancy can be excluded. Contraception for present cycle and future use. If OEC following missed pills, continue taking pills – need condoms for 2 days (POP) or 7 days (COC) – omit pill free interval (PFI) if less than 7 pills left in current COC strip. Clients should be advised to have tests for sexually transmitted infection if appropriate. (If new or casual partner should wait 2-3 weeks) If there are concerns that person may be pregnant and has taken pregnancy test with them to carry out <ul style="list-style-type: none"> Need to be informed that they need to take the tablet if the result of the pregnancy test is negative Taking the tablet if the test is positive will not terminate the pregnancy. <p>Need to visit GP or CSHS/CASH service if test is positive to discuss future care</p>
<p>Advice to staff</p>	<ul style="list-style-type: none"> 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. If patient is taking Warfarin they should be advised to have their INR checked 3 days after OEC If client is taking Ciclosporin, they should be informed that Levonorgestrel may alter the Ciclosporin level and the client should review Ciclosporin dose with their GP <p>All clients must be informed of higher efficacy of EC IUD, especially if</p> <ul style="list-style-type: none"> Client is mid menstrual cycle and /or over 48hours since UPSI

	<ul style="list-style-type: none"> • OEC is being used outside of product licence <p>Women should be informed if they are at higher risk of failure and if aged 35 or under should be informed about availability of Ulipristal and where to obtain it</p> <p>The timescale for EC IUD fitting and where this can be carried out should be written on the client information leaflet</p> <p>OEC <u>not needed</u> when;</p> <ul style="list-style-type: none"> • Woman is <u>fully</u> breastfeeding and amenorrhoeic and child is less than 6 months old • Woman is <i>less than</i> 3 weeks post-natal or had a 3rd trimester miscarriage within the last 3 weeks <p>However if the client is very anxious, OEC may be supplied and will not cause harm.</p> <p>See Appendix 3 for information and advice on clients under the age of 16. Always consider the possibility of abuse/child protection issues and if there are concerns obtain client contact details if possible.</p> <p>If the client is under 16 and Fraser competent, supply of OEC should be made. However if the client is under 13 years of age, or if there are Child Protection concerns, guidelines in Appendix 3 MUST be followed. The Client should also be informed that their details will be passed to members of the Safeguarding Children service in the first instance or to the CSHS/CASH service if Safeguarding Children service is unavailable, (unless informing them of this intention will put them in further danger) and these services may get in contact with them. See Appendix 3 for contact details</p>
<p>Record</p>	<p>Pharmacists and WIC/MIU and Community Nurses</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 a 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 last menstrual period (LMP) or withdrawal bleed (WTB) and whether normal and at expected time ○ Date and time of <u>all</u> UPSI since LMP or missed pills/depo injection and hours since first UPSI this cycle ○ Either cycle length and current day of cycle or current pill/pill free day if on COC ○ Pregnancy test result if appropriate ○ Current illness and medication ○ If age under 16 – confirmation that Fraser Competent ○ Last date for emergency IUD insertion, whether high risk failure of OEC and whether info given re Ulipristal ○ 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>CASH Nurses</p> <ul style="list-style-type: none"> • History - <u>Essential</u> – History re recent UPSI, dates all UPSI since LMP, date LMP, menstrual history, details of missed pills/late Depo if relevant. <ul style="list-style-type: none"> - Sexual and social history and STI risk assessment • Last date for emergency IUD insertion, whether high risk failure of OEC and whether info given re Ulipristal • Current illness and medication • Details of any adverse drug reaction and actions taken • Under 16 checklist if appropriate • Discussions and outcome – re PGD, under 16's or any other

	<p>concerns</p> <ul style="list-style-type: none"> • Dose and form administered (batch details and expiry date) • State whether taken in clinic or issued to client <p>Signature, name and designation of staff who administered or supplied the medication</p>
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CHARACTERISTICS OF STAFF	
Qualifications	<p>A pharmacist or NMC registered nurse working within CSHS/CASH Service, in MIU or in the community who:</p> <ul style="list-style-type: none"> • Has undertaken emergency contraception training provided by the CSHS/CASH Service and passed the post course assessment • Has regular updating (e.g. CPPE courses, update sessions from the CSHS/CASH Service)
Additional local training	<p>Has undertaken the local training programme on the process, responsibilities and scope of PGDs.</p> <p>Has undertaken local training based on the use of each PGD (above) 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.</p> <p>Within a Pharmacy there must be facilities for private and confidential counselling of the clients. It must meet the following three criteria</p> <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.
Continuing training & education	<p>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</p>

REFERRAL ARRANGEMENTS AND AUDIT TRAIL	
Referral arrangements	See Advice to patient/carer section above
Records/Audit Trail	In line with Trust policy

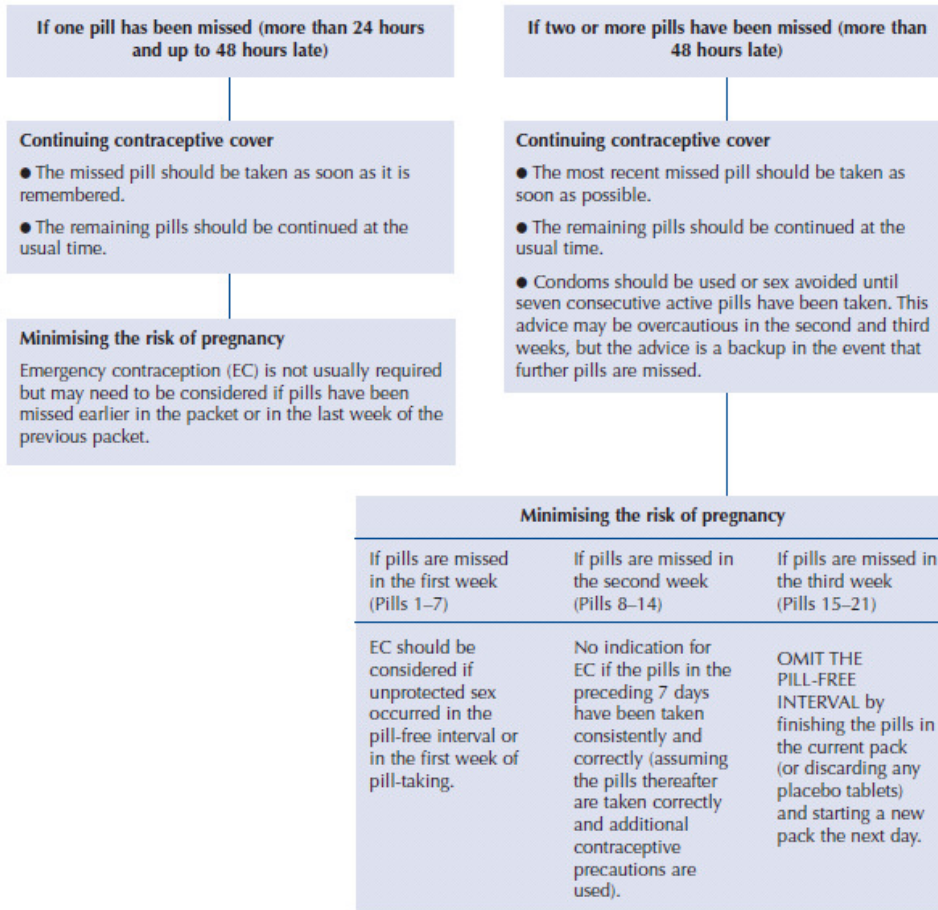
ADDITIONAL INFORMATION	
References	<ul style="list-style-type: none"> ○ Faculty of Sexual & Reproductive Healthcare, Clinical Effectiveness Unit: Emergency Contraception, August 2011 (Updated January 2012) ○ DCHS, Sexual Health Service Guideline for Missed Pills, Patch or Nuvaring and Use of Emergency Contraception ○ Faculty of Sexual & Reproductive Healthcare, UK Medical Eligibility Criteria for Contraceptive Use, UKMEC 2009 ○ 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 ○ Summary of Product Characteristics
Drug Interactions	<p>Comprehensive lists of drug interactions are not described in each PGD and only most significant are listed. For further information please refer to</p>

	Appendix 1 of 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, Contraception and Sexual Health Services
Dr Amanda Smith	Associate Specialist, Contraception and Sexual Health Services
Jonathan Chapweteka	Quality / Professional Lead, Contraception and Sexual Health Services

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

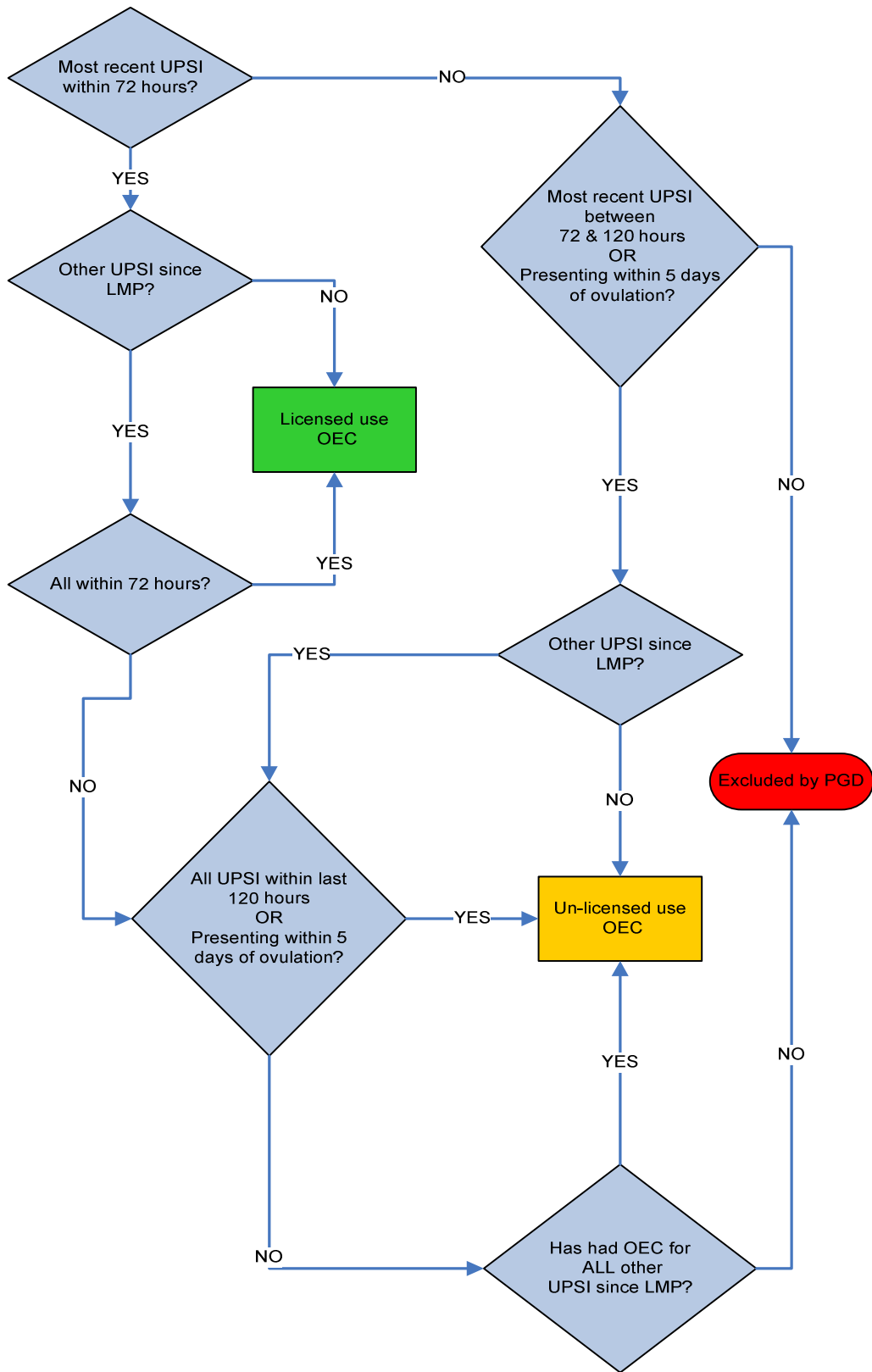


References

- 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].

PGD OEC - Flowchart

Appendix 2



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 under13)

The Derby and Derbyshire Safeguarding Children Procedures - Section 14.10

"In working with young people, it must always be made clear to them from the outset, that absolute confidentiality cannot be guaranteed, and that there may be some circumstances where the needs of the young person can only be safeguarded by sharing information with others."

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 PCT's (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.

Central Child Health Office (South Derbyshire and City)
Central Child Health Office (North Derbyshire)

01332 868818
01246 514584

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

Child Protection Unit	01332 888080 ext 88385 (Derby City)
(Mon - Fri 9am - 5pm)	01773 599410 (Derbyshire)
On call Community	01332 340131 (Royal Derby)
Paediatrician	01246 277271 (Chesterfield Royal)

SOCIAL CARE CONTACT NUMBERS

Tel: 01332 641172 (Derby City)
08456 058058 (County) Can be used 24 hours 7 days a week

OUT OF HOURS (Derby City) 01332 786968
(Do not use Mon - Fri 9am - 5pm)

NHS Derby City and NHS Derbyshire County

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 (Appendix 3)

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

Active/Severe Liver Disease
YES/NO

Hypersensitivity to OEC
YES/NO

Porphyria
YES/NO

OEC excluded if YES to any of the above

Unexplained vaginal Bleeding
YES/NO

If YES, OEC not excluded - supply and advise client to consult GP/Sexual Health service

UNDER 16

YES/NO

UNDER 13

YES/NO

FRASER COMPETENT

YES/NO

CHILD 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

YES / NO

Emergency IUD Explained

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')

Chlamydia screen offered Yes / No / N/A Accepted / Declined (circle as appropriate)

Information given re LARC methods Yes / No (circle as appropriate)

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 _____

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 contraception pill (Levonelle 1500).

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 CSHS/CASH 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 contraceptive pill will not change this.
- Contact a Contraception and Sexual Health (CSHS/CASH) clinic for an appointment, or speak to your GP, especially if you do not want to continue with the pregnancy.

Your nearest CSHS/CASH clinic is

Telephone

Central Information Lines

Derby and Southern Derbyshire
Chesterfield and North Derbyshire

01332 888126
01246 235792

Pharmacist or Nurse (name or stamp)

AUTHORISED / ADOPTED FOR USE BY:

(Please amend / update the signature boxes as applicable)

DESIGNATION	NAME	SIGNATURE	DATE
Senior Doctor	Dr David Black		
Senior Pharmacist	Mr Steve Hulme		