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

PATIENT GROUP DIRECTION (PGD)

For Community Pharmacists

Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception

Version Number 2.0

Change History	
Version and Date	**Change details**
Version 1.0 March 2020	New template
Version 1.1 January 2021	(DCHS update) Updated in line with FSRH Statement – 17 November 2020 Addition of acute porphyria to exclusion criteria
Version 2.0 March 2023	SPS: Updated template (no clinical changes to expired V1) DCHS update: removed covid advise. Added local safeguarding information.

This PGD is hosted by Derbyshire Community Health Services (DCHS) on behalf of Local Authorities and NHS commissioned services who are not appropriate authorising organisations.

PGD DEVELOPMENT GROUP	
Date PGD template comes into effect:	1st March 2023
Review date	September 2025
Expiry date:	28th February 2026

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in October 2022.

This section MUST REMAIN when a PGD is adopted by an organisation.

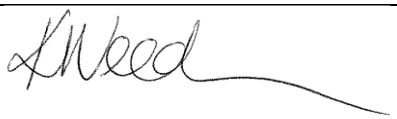
Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Associate Specialist
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	NHS North East London ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins (Woking Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS

PATIENT GROUP DIRECTION DEVELOPMENT WORKING GROUP
This PGD has been agreed by doctors, and/or expert clinical practitioners, pharmacist and representative healthcare professionals from the trust stated below for use by Community Pharmacists contracted by Derbyshire Community Health Services to provide emergency contraception services in Derbyshire.

PATIENT GROUP DIRECTION AUTHORISATION

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

Position of signatory	Name	Signature	Date
Director of Nursing, AHPs & Quality	Michelle Bateman		28/02/2023
Head of Medicines Management	Kate Needham		28/02/2023
Medical Director	Dr Ben Pearson		28/02/2023
Lead Clinician	Dr Ade Apoola		28/02/2023

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medication(s) listed only in accordance with the PGD.

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy. Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or as advised in the RCN training directory. Individual has undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training – eLfH PGD elearning programme The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix G) or complete a self-declaration of competence for emergency contraception. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD – if any training needs are identified these should be addressed and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular non-hormonal contraception has been compromised or used incorrectly.
Criteria for inclusion	Any individual presenting for emergency contraception (EC) between 0 and 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly *(Appendix B, C and D).* No contraindications to the medication. Informed consent given.
Criteria for exclusion	• Informed consent not given. • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • This episode of UPSI occurred more than 120 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 120 hours. • Known pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period). • Less than 21 days after childbirth. • Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD). • Known hypersensitivity to the active ingredient or to any component of the product – see Summary of Product Characteristics • Use of levonorgestrel (LNG-EC) or any other progestogen in the previous 7 days (i.e. hormonal contraception, hormone replacement therapy or use for other gynaecological indications). • Concurrent use of antacids, proton-pump inhibitors or H_2-receptor antagonists including any non-prescription (i.e. over the counter) products being taken. • Severe asthma controlled by oral glucocorticoids. • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping. • Acute porphyria.
Cautions including any relevant action to be taken	• All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider. • Ulipristal acetate (UPA-EC) is ineffective if taken after ovulation. • If individual vomits within three hours from ingestion, a repeat dose may be given. • Body Mass Index (BMI) >26kg/m2 or weight >70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC.

	• Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of UPA-EC is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed. • Breast feeding – advise to express and discard breast milk for 7 days after UPA-EC dose. • The effectiveness of UPA-EC can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs for 5 days after UPA-EC. UPA EC is generally not recommended in a missed pill situation. See section 'Written information and further advice to be given to individual'. • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. • If the individual has not yet reached menarche consider onward referral for further assessment or investigation.
Safeguarding	**Gillick Competence:** **Guidance for Providing Advice and Treatment to Young People** *(Appendix F)* Clients aged < 16 years should be assessed for Gillick competence following the Under 18 Checklist. Refer to social care as per safeguarding procedures – **if aged under 13 must be referred.** **Refer to:** East Midlands Children and Young People's Sexual Health Service (EMCYPSAS). Access to the 24-hour service can be gained through 0800 183 0023. (If any reservations discuss with Child Protection Unit or Community Paediatrician on call) **Safeguarding:** Consider completing the Derby and Derbyshire 'Spotting the Signs' Child at Risk of Exploitation (CRE) Assessment Proforma. Additional local training for enhanced provision (CHC, POP and Injectable Contraception) and local CPPE training will incorporate both the CRE Toolkit and Gillick Competence. Safeguarding Forms and Assessments (ddscp.org.uk) Where there are any safeguarding concerns refer to local policies for safeguarding adults and children and/or seek advice from the safeguarding lead/team in the organisation. Community Pharmacists refer to: Starting Point/Call Derbyshire on 01629 533190. OR Derby City First on 01332 641172 / 01332 786968 (under 18 years) depending on location. Document the concern and outcome in the healthcare record.

Action to be taken if the individual is excluded or declines treatment	Explain the reasons for exclusion to the individual and document in the consultation record. Record reason for decline in the consultation record. Offer suitable alternative emergency contraception or refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, strength & formulation of drug	Ulipristal acetate 30mg tablet
Legal category	P
Route of administration	Oral
Off label use	Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes off-label use in the following conditions: • Lapp-lactase deficiency • Hereditary problems of galactose intolerance • Glucose-galactose malabsorption • Severe hepatic impairment Medicines should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the manufacturer must be consulted. Where drugs have been assessed by the registered healthcare professional operating under this PGD in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with the registered healthcare professional operating under this PGD. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	• One tablet (30mg) as a single dose taken as soon as possible up to 120 hours after UPSI.

Duration of treatment	• A single dose is permitted under this PGD.
	• If vomiting occurs within 3 hours of UPA-EC being taken a repeat dose can be supplied under this PGD.
	• Repeated doses, as separate episodes of care, can be given within the same cycle. Please note:
	  ○ If within 7 days of previous LNG-EC offer LNG-EC again (not UPA-EC)
	  ○ If within 5 days of UPA-EC then offer UPA-EC again (not LNG-EC)

Quantity to be supplied	Appropriately labelled pack of one tablet.

Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org Refer also to FSRH guidance on drug interactions with hormonal contraception file://rlbuht.lan/userdata/jjenkins/Downloads/drug-interactions-with-hormonal-contraception-5may2022.pdf
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org The following side effects are common with UPA-EC (but may not reflect all reported side effects): • Nausea or vomiting • Abdominal pain or discomfort • Headache • Dizziness • Muscle pain (myalgia) • Dysmenorrhea • Pelvic pain • Breast tenderness • Mood changes • Fatigue • The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception.
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report any adverse reactions via organisation incident policy.
Written information and further advice to be given to individual	• All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception. • Ensure that a patient information leaflet (PIL) is provided within the original pack. • If appropriate provide a Pregnancy Testing Leaflet *(Appendix E).* • If vomiting occurs within three hours of taking the dose, the individual should return for another dose. • Explain that menstrual disturbances can occur after the use of emergency hormonal contraception. • Provide advice on ongoing contraceptive methods, including how these can be accessed. • Repeated episodes of UPSI within one menstrual cycle – the dose may be repeated more than once in the same menstrual cycle should the need occur. • In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal

	contraception for 5 days following UPA-EC use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. • Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern. • Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs. • There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception. • Advise to consult a pharmacist, nurse or doctor before taking any new medicines including those purchased.
Advice / follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. • Pregnancy test as required (see advice to individual above). • Individuals advised how to access on-going contraception and STI screening as required.

Records	**Using the Oral Emergency Contraception Patient Record Form** *(Appendix A)*
	Record:
	• The consent of the individual and
	  ○ If individual is under 13 years of age record action taken
	  ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken
	  ○ If individual over 16 years of age and not competent, record action taken
	• Name of individual, address, date of birth
	• GP contact details where appropriate
	• Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight
	• Any known medication allergies
	• Name of registered health professional operating under the PGD
	• Name of medication supplied
	• Date of supply
	• Dose supplied
	• Quantity supplied
	• Advice given, including advice given if excluded or declines treatment
	• Details of any adverse drug reactions and actions taken
	• Advice given about the medication including side effects, benefits, and when and what to do if any concerns
	• Any referral arrangements made
	• Any supply outside the terms of the product marketing authorisation
	• Record that administered/supplied via Patient Group Direction (PGD)

	Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references (accessed September 2022)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017 (Amended March 2000) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ • Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines

APPENDIX A

Oral Emergency Contraception (OEC) Provided by Community Pharmacists

Patient Record - All sides to be completed

Date: ..... **Time:** .....

Place of Consultation *(or Pharmacy stamp)* .....

.....

PATIENT DETAILS

Name: ..... **Age:** ..... **Postcode:** .....

If Patient under the age of 16 refer to Fraser Guidelines and consider 'Spotting the Signs' CRE Risk Assessment

GP DETAILS *(If given)*

Name: ..... **Surgery:** .....

DETAILS OF UNPROTECTED SEXUAL INTERCOURSE (UPSI)

Date and Time of UPSI: ..... LMP:.....

Hours since UPSI: ..... hours

Other UPSI since last menstrual period (LMP) ☐ **Yes** ☐ **No**

If yes, give details: .....

.....

CURRENT CONTRACEPTION *(Circle as appropriate)*

COC / CHC Patch / POP / Condoms / IUD / IUS / Implant / Injection / None /

Other *(Specify):* .....

If recently missed Pill(s) *(Details)*: .....

.....

If condom failure *(Details):* .....

If recently stopped Pills – Date last Pill taken: .....

If Implant fitted over 3 years ago – Date fitted: .....

Is Injection overdue? ☐ **Yes** ☐ **No** Date of last injection: ..... weeks since last injection: .....

Type *(Circle):* Depo Provera / Sayana Press / Noristerat

OTHER MEDICATIONS AND ALLERGIES

Allergies: ☐ **Yes** ☐ **No** *If yes, details:* .....

Other Medication? .....

..... Liver Enzyme Inducing? ☐ **Yes** ☐ **No**

MENSTRUAL HISTORY

COMPLETE EITHER (a) OR (b) AS APPROPRIATE

(a) For Patients not taking Oral or Patch Combined Hormonal Contraception (COC/CHC)

Date of last menstrual period (LMP) – (First day of bleeding): .....

Current day of cycle: ..... Usual cycle length: ..... days

(b) For Patients taking COC or CHC

Date of last withdrawal bleed (WTB): ..... *(first day)*

Current day is: ☐ Pill/patch day **or** ☐ Pill/patch-free day

COMPLETE FOR ALL PATIENTS

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 Patient to carry out at Home?

PERSONAL CHARACTERISTICS, REPRODUCTIVE & MEDICAL HISTORY - LEVONORGESTREL

1. Consent not given	☐ **Yes** ☐ **No**
2. Individuals under 16 years and assessed not competent using Fraser Guidelines	☐ **Yes** ☐ **No**
3. Individuals 16 years and over and assessed as lacking capacity to consent	☐ **Yes** ☐ **No**
4. This episode of UPSI occurred more than 96 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 96 hours	☐ **Yes** ☐ **No**
5. Known or suspected pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period since UPSI)	☐ **Yes** ☐ **No**
6. Less 21 days after childbirth	☐ **Yes** ☐ **No**
7. Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD)	☐ **Yes** ☐ **No**
8. Known hypersensitivity to active ingredients or to any component of the product	☐ **Yes** ☐ **No**
9. Use of ulipristal acetate emergency contraception in the previous 5 days	☐ **Yes** ☐ **No**

PERSONAL CHARACTERISTICS, REPRODUCTIVE & MEDICAL HISTORY – ULIPRISTAL ACETATE

1. Consent not given	☐ **Yes** ☐ **No**

2. Individuals under 16 years and assessed not competent using Fraser Guidelines	☐ **Yes** ☐ **No**
3. Individuals 16 years and over and assessed as lacking capacity to consent	☐ **Yes** ☐ **No**
4. This episode of UPSI occurred more than 120 hours ago **Note:** UPA-EC may be used again if a woman has already received UPA-EC earlier in the cycle. The GDG recommends LNG-EC should not be taken in the 5 days after UPA-EC. It is recommended that if a woman requests EC for further UPSI within 5 days of taking UPA-EC, a Cu-IUD is offered if appropriate. Alternatively, UPA-EC can be given again.	☐ **Yes** ☐ **No**
5. Known pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period since UPSI)	☐ **Yes** ☐ **No**
6. Less 21 days after childbirth	☐ **Yes** ☐ **No**
7. Breastfeeding and less than 6 weeks post-partum	☐ **Yes** ☐ **No**
8. Not breastfeeding and 3-6 weeks post-partum with other risks for venous thromboembolism (VTE)	☐ **Yes** ☐ **No**
9. Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD)	☐ **Yes** ☐ **No**
10. Known hypersensitivity to the active ingredient or to any component of the product	☐ **Yes** ☐ **No**
11. Use of levonorgestrel or any other progestogen in the previous 7 days (i.e. hormonal contraception, hormone replacement therapy or use for other gynaecological indications).	☐ **Yes** ☐ **No**
12. Severe asthma controlled by oral glucocorticoids	☐ **Yes** ☐ **No**
13. Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping	☐ **Yes** ☐ **No**

OEC excluded if YES to any of the above

1. Unexplained vaginal bleeding ☐ **Yes** ☐ **No**
   If YES, **OEC not excluded -** supply and advise Patient to consult GP/Sexual Health Service
2. Taking an enzyme inducer medication consider double-dose (3mg) Levonorgestrel
3. BMI > 26kg/m^2 or Weight > 70kg consider double-dose (3mg) Levonorgestrel

Patient Weight: ..... kg **Patient Height** ..... cm **Patient BMI**: .....

UNDER 16	☐ **Yes**	☐ **No**	UNDER 13	☐ **Yes**	☐ **No**
GILLICK COMPETENT	☐ **Yes**	☐ **No**	CHILD PROTECTION CONCERNS	☐ **Yes**	☐ **No**

Contact Details if under 13 or Child Protection concerns
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)

(Address, School and Mobile Number if possible) .....

.....

Referral to East Midlands Children's and Young People's Sexual Assault Service (EMCYPSAS)?
☐ **Yes** ☐ **No**

OEC Patient Information Leaflet supplied	Patient Consent Obtained	Emergency IUD Explained
☐ **Yes** ☐ **No**	☐ **Yes** ☐ **No**	☐ **Yes** ☐ **No**

Patient at Higher Risk of Failure of OEC *(ie between ovulation minus 6 and ovulation plus 2)* ☐ **Yes** ☐ **No**

OEC supply ☐ **Yes** ☐ **No** **Licensed / Unlicensed / Not Supplied** *(circle which)*
(Refer to flow chart if necessary)

Information given about Ulipristal (EllaOne) / Levonorgestrel ☐ **Yes** ☐ **No**

☐ **Last Date for IUD insertion - on or before** ..... , **OR**
☐ **TOO LATE for Emergency IUD**

Other concerns or any additional advice given: .....

.....

.....

RECORD OF ISSUE

Drug Name: .....

Time Taken:..... **OR** ☐ **Taken Away**

Batch No: ..... **Expiry Date***:* .....

Follow Up *(if arranged):* .....

Pharmacist *(Please PRINT name):* .....

Pharmacist Signature: .....

APPENDIX B

FSRH

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]

APPENDIX B (cont.)

FSRH

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: ▶ >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 C

Recommended actions after incorrect use of combined oral contraception

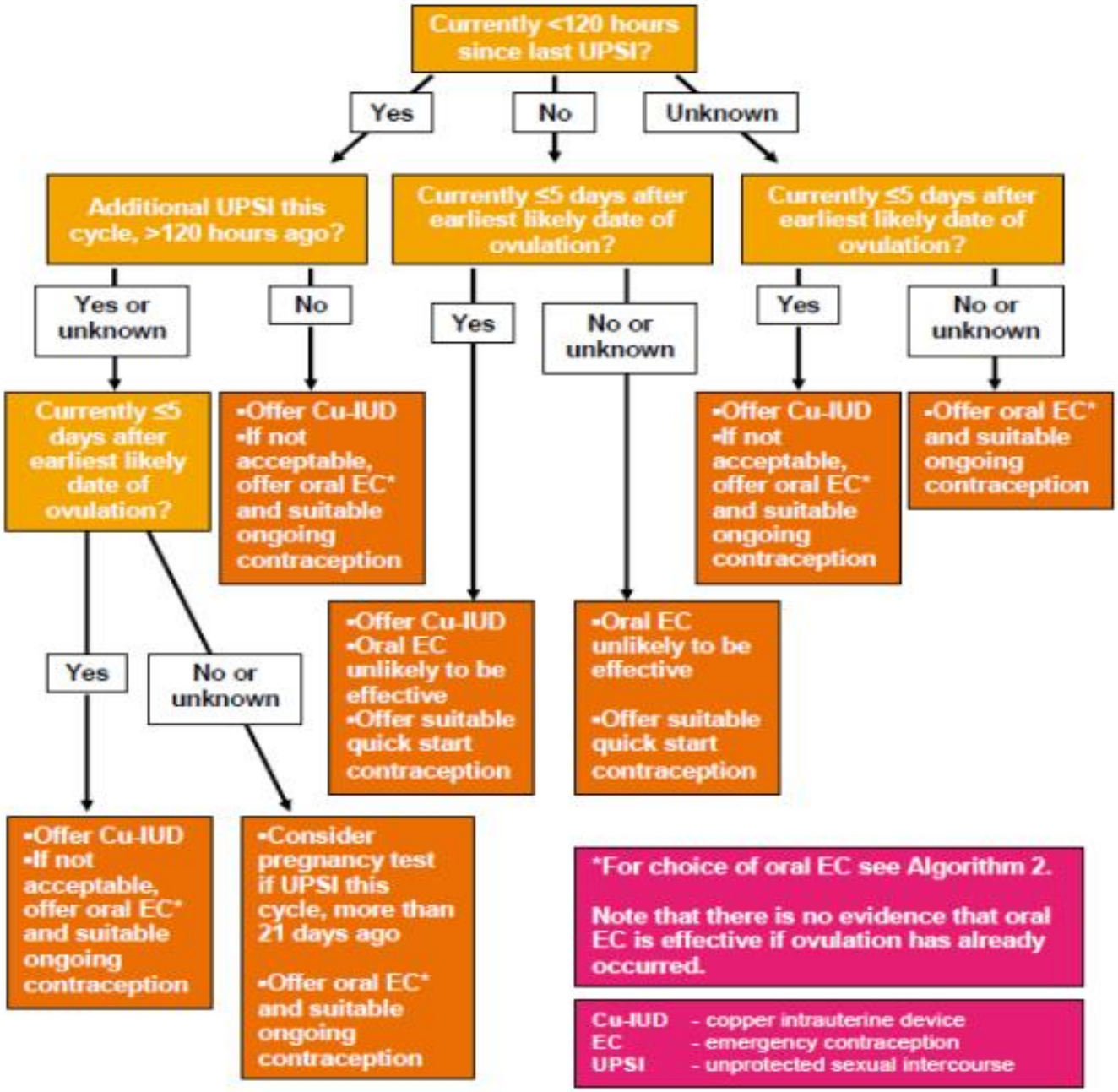
FSRH CEU Guidance: Recommended Actions after incorrect Use of Combined Hormonal Contraception (e.g. late or missed pills, ring and patch) (March 2020, amended July 2021) - Faculty of Sexual and Reproductive Healthcare

APPENDIX D

FSRH

Decision-making Algorithms for Emergency Contraception

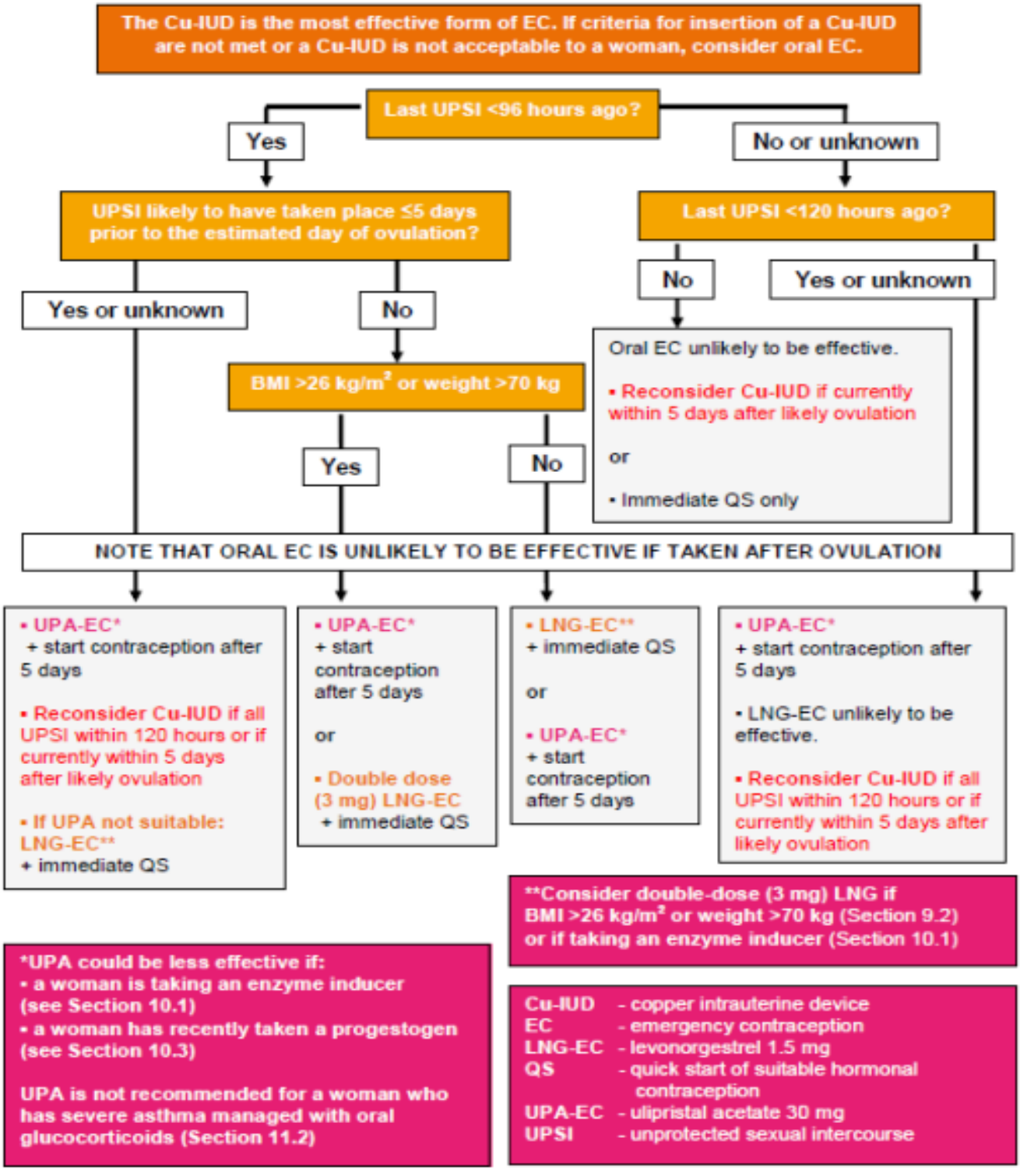
Algorithm 1: Decision-making Algorithm for Emergency Contraception (EC): Copper Intrauterine Device (Cu-IUD) vs Oral EC



APPENDIX D (cont.)

FSRH

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 E

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 (e.g. Levonelle®/Ulipristal).

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 who gave you this letter: .....

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

.....

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

APPENDIX F

Guidance for Providing Advice and Treatment to Young People

NB: However great the concerns – if a young person is Gillick 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 person's best interest to receive contraceptive /safe sex advice and treatment without parental consent

Gillick Competence

Gillick 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 "Gillick 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 "Gillick 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**.

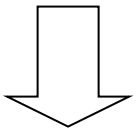
This means that they are the ideal people to contact if there is a young person that you are concerned about but do not feel there are sufficient concerns to make a referral to Social Care necessary. If you know what school they attend, the Child Health Office can put you in touch with the appropriate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

Derbyshire Child Health Office (South and North Derbyshire and Derby City): 01332 868909

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

Low/Moderate Concern
E.g., 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

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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

Appendix G – registered health professional authorisation sheet

PGD Name/Version: PGD 136(S) Ulipristal acetate 30mg v2.0
Valid from: March 2023 **Expiry:** 28th February 2026

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Derbyshire Community Health Services for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

PGD Authorisation Forms shall be maintained and retained by the Pharmacy Manager who is responsible for the safe storage of the records.