University Hospitals of Derby and Burton NHS Foundation Trust

Derbyshire Community Health Services NHS Foundation Trust

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)

Supply and/or administration of levonorgestrel 1500micrograms tablet(s) for emergency contraception in Integrated Sexual Health Services (ISHS) Urgent Treatment Centres (UTCs) Community Nursing for Children and Young People

Derbyshire Community Health Services

Version Number 2.0

Change History	
Version and Date	**Change details**
Version 1 March 2020	New template
Version 1.1 November 2020	Addition of acute porphyria to exclusion criteria
Version 2.0 March 2023	Updated template (no clinical changes to expired V1)

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)
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

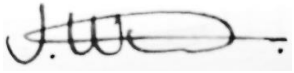
ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS

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 within Integrated Sexual Health Services (ISHS)
University of Derby and Burton Teaching Hospitals Foundation Trust (UHDBFT) Trust and Derbyshire Community Health Services Foundation Trust (DCHSFT)

PATIENT GROUP DIRECTION AUTHORISATION

PGD approved by PGD Working Group on *19th January 2023*

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

Position of signatory	Name	Signature	Date
Deputy Chief Nurse	Jo Wain		19/02/2023
Head of Medicines Management	Kate Needham		19/02/2023
Medical Director	Dr Ben Pearson		19/02/2023
Lead Clinician	Dr Ade Apoola		19/02/2023

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 medications(s) listed only in accordance with the PGD.

REVIEWED FOR DCHS BY:		
Date	**Name**	**Position**
December 2022	Sharon Boden Dr Ade Apoola	Quality & Training Lead ISHS Consultant

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. For advice on additional local training requirements, see section 4: Characteristics of DCHS Staff
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) 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 contraception has been compromised or used incorrectly.
Criteria for inclusion	• Any individual presenting for emergency contraception (EC) between 0 and 96 hours following UPSI or when regular contraception has been compromised or used incorrectly. • 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 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. • 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). • 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 ulipristal acetate (UPA-EC) emergency contraception in the previous 5 days. • 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. • UPA-EC can delay ovulation until closer to the time of ovulation than levonorgestrel (LNG-EC). Consider UPA-EC if the individual presents in the five days leading up to estimated day of ovulation. • LNG-EC is ineffective if taken after ovulation. • If individual vomits within three hours from ingestion, a repeat dose may be given. • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them - see dose frequency section.

	• Body Mass Index (BMI) >26kg/m^2 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. If LNG-EC is to be given see dosage section. • 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 LNG-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. • 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. **Safeguarding:** 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. Document the concern and outcome in the healthcare record. DCHS: Safeguarding adults and children policies on DCHS SharePoint. DCHS Safeguarding Team: 01773 850000. East Midland's Children and Young People's Sexual Assault Service (EMCYPSAS): 0800 183 0023 (24-hour service). • If the individual has not yet reached menarche consider onward referral for further assessment or investigation.
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	Levonorgestrel 1500 micrograms tablet (N.B. this is equivalent to 1.5mg levonorgestrel)
Legal category	P/POM
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: ○ use between 72 and 96 hours post UPSI ○ consideration of increased dose for individuals with BMI over 26kg/m2or weight over 70kg ○ increased dose for individuals using liver enzyme inducing agents ○ severe hepatic impairment ○ individuals with previous salpingitis or ectopic pregnancy ○ lapp-lactase deficiency ○ hereditary problems of galactose intolerance ○ glucose-galactose malabsorption Note some products may be licenced only for certain age groups (e.g. 16 years and over) – supply of these products outside the licensed age groups is permitted under this PGD. 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 local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management 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 pharmacy/Medicines Management. 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	• Levonorgestrel 1500mcg (1 tablet) to be taken as soon as possible up to 96 hours of UPSI. • **Dose for those individuals taking enzyme inducing medicines or herbal products:** An individual who requests LNG-EC whilst using enzyme-inducing drugs, or within 4 weeks of stopping them, can be advised to take a total of 3mg levonorgestrel (two 1500mcg tablets) as a

	single dose and within 96 hours of UPSI. **Note** the effectiveness of this regimen is unknown. • **Dose for those individuals with a body mass index of more than 26kg/m^2 or who weigh more than 70kg:** An individual who requests LNG-EC with a body mass index of more than 26kg/m^2 or who weighs more than 70kg can be offered a total of 3mg LNG-EC (two 1500mcg tablets) as a single dose and within 96 hours of UPSI. **Note** the effectiveness of this regimen is unknown.

Duration of treatment	• A single dose is permitted under this PGD.
	• If vomiting occurs within 3 hours of LNG-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. • Two tablets can be supplied for individuals taking enzyme inducing drugs and/or individuals with a BMI of more than 26kg/m^2 or who weigh more than 70kg.
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
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 LNG-EC (but may not reflect all reported side effects): • Nausea and vomiting are the most common side effects. • Headache, dizziness, fatigue, low abdominal pain and breast tenderness, diarrhoea. • The FSRH advises that bleeding patterns may be temporarily disturbed and spotting may occur, but most individuals will have their next menstrual period within seven days of the expected time
Management of and reporting procedure for adverse reactions	• Healthcare professionals and individuals 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 individual's medical record. • Report any adverse reactions via organisation incident policy.
Written information and further advice to be provided	• All methods of emergency contraception should be discussed including efficacy. 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 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. • Individuals using hormonal contraception should restart their regular hormonal contraception immediately. 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	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 findings where relevant e.g. weight • Any known drug 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/off-label • Recorded that 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. Characteristics of DCHS Staff

Qualifications	A registered nurse working within ISHS who is deemed competent by their clinical line manager and authorised by their professional lead to undertake the clinical assessment of a patients leading to the identification of those suitable for management under this PGD. A registered nurse or registered paramedic working within a UTC setting or a registered nurse working in a community service for children and young people who has undertaken the emergency contraception initial training and updates provided by ISHS, and is deemed competent by their clinical line manager to undertake the clinical assessment of a patients leading to the identification of those suitable for management under this PGD.
Additional Local Training	Has undertaken the local training programme on the process, responsibilities and scope of PGDs. Has undertaken local training based on the use of this PGD.

	Has undertaken training in recognition of and treatment of anaphylaxis including basic life support in the 12 months. Has undertaken Safeguarding Children Level 3 training in the last 12 months. Has undertaken Safeguarding Adults Level 2 training in the last 3 years.
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.

5. 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/ • FSRH CEU Statement Response to Edelman 2022 (August 2022) https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-statement-response-to-edelman-2022-august-2022/ • 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 – registered health professional authorisation sheet

PGD Name/Version: 219(S) Levonorgestrel 1500 microgram tablets 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 Service Manager who is responsible for the safe storage of the records.

APPENDIX B

https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/

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]

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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

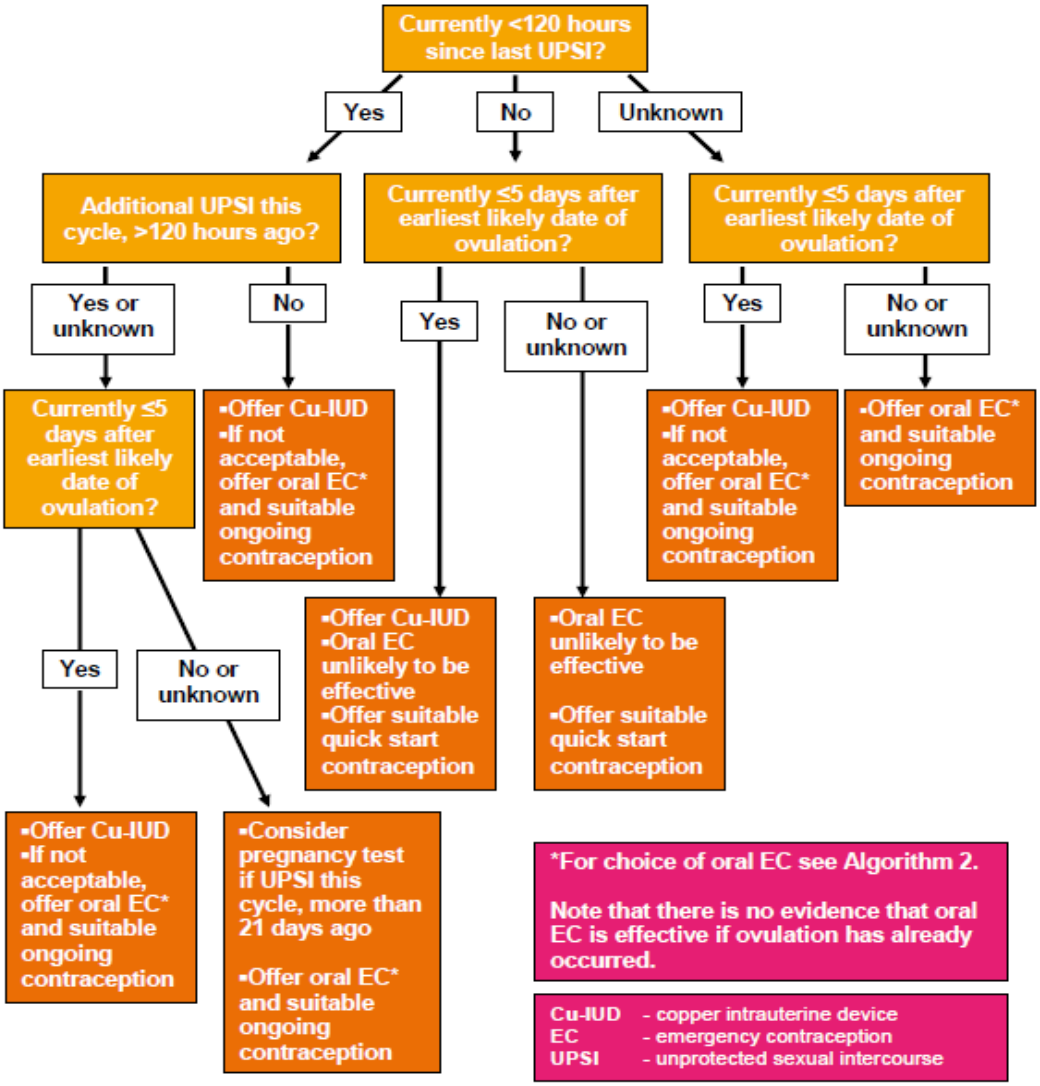
FSRH CEU Guidance: Recommended Actions after incorrect Use of Combined Hormonal Contraception (e.g. late or missed pills, ring and patch) (March 2020, amended July 2021) - Faculty of Sexual and Reproductive Healthcare

APPENDIX D

FSRH

Decision-making Algorithms for Emergency Contraception

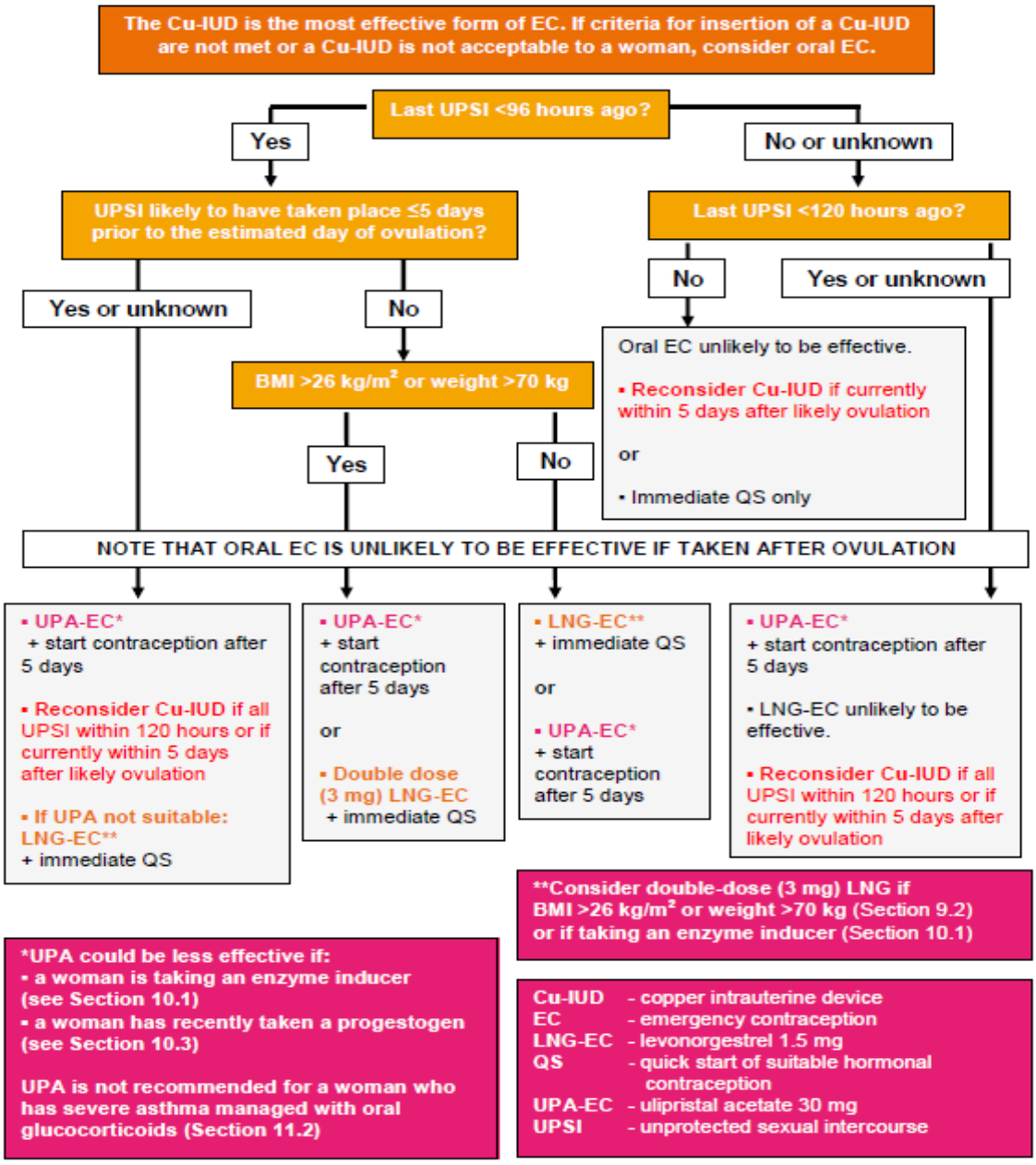
Algorithm 1: Decision-making Algorithm for Emergency Contraception (EC): Copper Intrauterine Device (Cu-IUD) vs Oral EC



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 F

Oral Emergency Contraception (OEC) UTC Nurses and Paramedics and Nurses in the Community

PATIENT RECORD – All pages to be completed

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

Place of Consultation .....

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. Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD)	☐ **Yes** ☐ **No**
8. Known hypersensitivity to the active ingredient or to any component of the product	☐ **Yes** ☐ **No**
9. 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**
10. Concurrent use of antacids, proton-pump inhibitors or H_2-receptor antagonists. 11. Severe asthma controlled by oral glucocorticoids	☐ **Yes** ☐ **No** ☐ **Yes** ☐ **No**
12. Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping	☐ **Yes** ☐ **No**
13. Acute porphyria	☐ **Yes** ☐ **No**

OEC excluded if YES to any of the above

1. Unexplained vaginal bleeding ☐ **Yes** ☐ **No**
   If YES, **OEC <u>not</u> 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 for any safeguarding concerns
DCHS Safeguarding Team 01773 850000
East Midland's Children and Young People's Sexual Assault Service (EMCYPSAS): 0800 183 0023 (24-hour service).

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

.....

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 *(i.e. 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**

Document any other concerns or additional advice given: .....

.....

.....

.....

RECORD OF ISSUE

Drug Name: .....

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

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

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

Issued by *(Please PRINT name):* .....

Signature: .....

APPENDIX G

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®**/Levonorgestrel**).

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 Nurse who gave you this letter: .....

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

.....

APPENDIX H

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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/)

APPENDIX I

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
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 Hospital 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