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)Number 019

Supply and administration of ulipristal acetate 30mg tablet for emergency contraception in Suffolk as per the Community Pharmacy Sexual Health Service

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 1.2 July 2021	Minor amendments made to reflect local delivery including: - Specifying PGD applies to females aged 13 years and over only. - Added vomiting within 3 hours to inclusion criteria. - Added referral pathway for under 13's. - Exclusion added – refuses immediate consumption. - "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" – removed from patient advice
Version 22.0 March 2023	New national template

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

PGD DEVELOPMENT GROUP

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

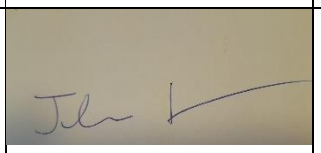
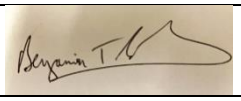
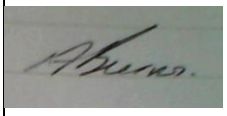
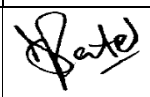
This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in October 2022.

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

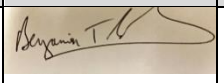
Name	Designation
Dr Cindy Farmer	Chair General Training Committee, Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee, FSRH
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron 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 (Working Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

PGD DEVELOPMENT

Name	Job title and organisation	Signature	Date
Tania Farrow	Chief Officer Suffolk Local Pharmaceutical Committee		28/02/2023
Alison Amstutz	Head of Drugs and Alcohol and Sexual Health Public Health and Communities Directorate, Suffolk County Council		28/02/2023
Julien Hersh	Health Improvement Lead-Sexual Health (and Drugs & Alcohol) Public Health and Communities Directorate Suffolk County Council		28/02/2023
Ben Solway	Senior Doctor		28/02/2023
Nettie Burns	Clinical G o v e r n a n c e L e a d , Public Health and Communities Directorate Suffolk County Council		28/02/2023
Dipti Patel	Consultant Pharmacist		20/02/2023

PGD AUTHORISATION

Name	Role	Job title and organisation	Signature	Date
Ben Solway	**Senior Doctor**	General Practitioner, PGD advisor SCC		28/02/2023
Dipti Patel	**Senior Pharmacist**	Consultant Pharmacist		20/02/2023
Stuart Keeble	**Person signing on behalf of Suffolk County Council**	Director of Public Health, Suffolk County Council		28/02/2023

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment or agreement within a community pharmacy service in Suffolk. 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 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 Patient Group Directions – elearning for healthcare (e-lfh.org.uk) The healthcare professional must have completed training in safeguarding children and vulnerable adults (level 2 safeguarding or the equivalent), including updates, and must be aware of Suffolk safeguarding processes. Information on Suffolk Safeguarding can be found here; https://www.suffolk.gov.uk/care-and-support-for-adults/protecting-people-at-risk-of-abuse/adult-abuse-and-safeguarding/. Update training should be completed at least every two years
Competency assessment	The registered healthcare professional operating under this PGD • Must complete the CPPE declaration of competence for emergency contraception

	(https://www.cppe.ac.uk/services/docs/emergency%20contraception.pdf)
	• Must be able to satisfy the requirements of the self-declaration of qualifications and competence to deliver sexual health services according to the following CPPE programmes:
	  ○ Sexual Health in Pharmacies
	  ○ Safeguarding Children and Vulnerable adults
	• Are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
	• Must have read and understood the context and content of this PGD.

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 in individuals aged 13 years of age or older after unprotected sexual intercourse (UPSI) or regular non-hormonal contraception has been compromised or used incorrectly.
Criteria for inclusion	• Any individual 13 years of age or older presenting for emergency contraception (EC) between 0 and 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly. • No contraindications to the medication. • Informed consent given.
Criteria for exclusion	• Informed consent not given. • Is under 13 years of age (These patients must be referred to their GP or the local sexual health clinic. The registered pharmacist should endeavour to support and assist the child in accessing this service. This may include the registered pharmacist contacting the service and arranging an appointment on the child's behalf. A safeguarding referral should also be made, and confirmation of referral documented on PharmOutcomes). • 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. • Refuses immediate supervised consumption of ulipristal tablet. • 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 . 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. 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 ulipristal dose. • The effectiveness of ulipristal 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 ulipristal. 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. This should be recorded using the 'sexual health referral for under 13's' template on PharmOutcomes. • 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 on PharmOutcomes. • Offer levonorgestrel 1500 mcg tablet if clinically appropriate – refer to PGD number 015. • Record reason for decline in the consultation record on PharmOutcomes. • Advise the patient regarding the risk of pregnancy and document the advice on PharmOutcomes. • 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. • Patients under 13 years of age must be referred to their GP or the local sexual health clinic and the referral should be documented on the 'sexual health referral for under 13's' template on PharmOutcomes. The registered pharmacist should endeavour to support and assist the individual in accessing this service. This may include the registered pharmacist contacting the service and arranging an appointment on the individual's behalf.

3. Description of treatment

Name, strength & formulation of drug	Ulipristal acetate 30mg tablet
Legal category	P – Pharmacy medicine
Route of administration	Oral - to be taken immediately under supervision of the registered pharmacist.
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 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	• One tablet (30mg) as a single dose taken as soon as possible up to 120 hours after UPSI or failure of contraceptive method.
Duration of treatment	• A single dose is permitted under this PGD. • If vomiting occurs within 3 hours of UPA-EC being taken AND UPSI or failure of contraceptive method is still within the previous 120 hours, a repeat dose can be supplied

	under this PGD.
	• Repeated doses 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
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.

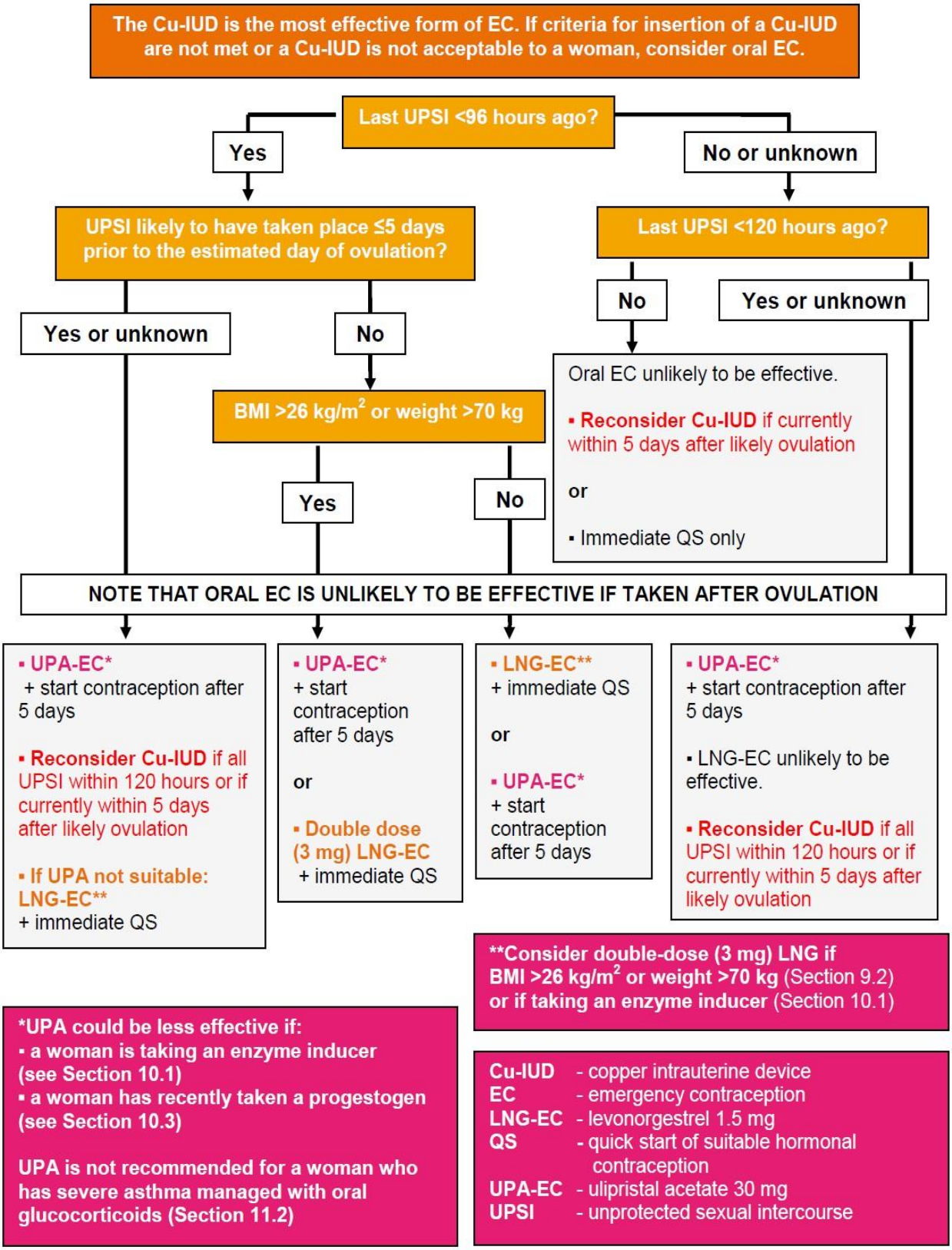
Written information and further advice to be given to individual	• All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception. • Ensure that a patient information leaflet (PIL) is provided within the original pack. • If 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	Records should be kept using the emergency contraception template on PharmOutcomes, record:
	• The consent of the individual and
	  ○ If individual is under 13 years of age record action taken on PharmOutcomes
	  ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken on PharmOutcomes.
	  ○ If individual over 16 years of age and not competent, record action taken on PharmOutcomes
	
	• 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
	• Recorded that administered/supplied via 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 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 - March 2017 (Amended March 2020) 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
Decision-making Algorithm for Emergency Contraception (EC): Levonorgestrel EC (LNG-EC) vs Ulipristal Acetate EC (UPA-EC)



Reference Number: PGD 019
Valid from: 01/03/2023
Review date: September 2025
Expiry date: 28/02/2026

Appendix B
The Fraser guidelines

The court recognised that certain girls under the age of 16 have a right to consent to medical treatment. They feel that the doctor or healthcare professional should, of course, always seek to persuade a girl to tell her parents that she is seeking contraceptive advice and the nature of the advice she is to receive, and should seek to persuade her to agree to the doctor or healthcare professional informing her parents. There may well be cases where a girl refuses either to tell her parents herself or permit the doctor or healthcare professional to do so. In such cases, the doctor or healthcare professional will be justified in offering care without the girl's parent's consent or even their knowledge, providing s/he is satisfied having considered the Fraser guidelines.

The Fraser guidelines refer to the guidelines set out by Lord Fraser in his judgement of the Gillick case in the House of Lords (1985). Fraser guidelines originally just related to contraceptive advice and treatment but, following a case in 2006, they now apply to decisions about treatment for sexually transmitted infections and termination of pregnancy. Lord Fraser stated that a doctor [or healthcare professional] could proceed to give advice and treatment "provided he is satisfied in the following criteria:

1. that the girl (although under the age of 16 years of age) will understand his [or her] advice;
2. that he [or she] cannot persuade her to inform her parents or to allow him [or her] to inform the parents that she is seeking contraceptive advice;
3. that she is very likely to continue having sexual intercourse with or without contraceptive treatment;
4. that unless she receives contraceptive advice or treatment her physical or mental health or both are likely to suffer;
5. that her best interests require him [or her] to give her contraceptive advice, treatment or both without the parental consent."

NB. The possibility of sexual abuse can be emotionally difficult for staff. Remember to deal with the presenting problem. This applies to all treatment of under 16 year olds.

Appendix C - Registered health professional authorisation sheet

PGD Name/Version **Valid from:** **Expiry:**

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 _____ [insert name of organisation] 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.