Northamptonshire Healthcare
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

By Authorised Registered Community Pharmacists

Working in Primary Care settings, accredited to provide Emergency Contraception by Northamptonshire Healthcare NHS Foundation Trust

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)

Reference Number: PGD 178 Levonorgestrel 1500 micrograms (Community Pharmacists)
National template valid from: 1st August 2023
Approved by NHFT: 20th July 2023 by Chair's actions
Review date: September 2025
Expiry date: 28th February 2026

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:	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.

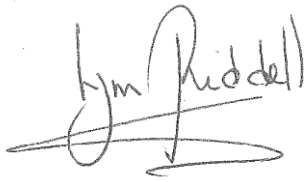
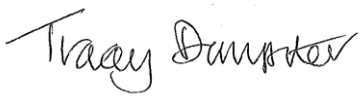
Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory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

NHFT ORGANISATIONAL AUTHORISATIONS

Title of PGD: Supply and/or administration of levonorgestrel 1500micrograms tablet(s) for emergency contraception	
Review and implementation of National PGD template	**Expiry date of previous version:** 31st July 2023
Clinical areas in which the PGD will be / is used Community Pharmacies authorised by NHFT to supply levonorgestrel for emergency contraception	
Directorate Adults, Children's & Ambulatory Directorate **Service** Specialist Ambulatory Services in the Ambulatory, Therapy & Diabetes Services Stack	**Department** Northamptonshire Integrated Sexual Health & HIV Service (NISHH)
Details and declaration of the PGD Workgroup The Lead Author confirms that a PGD is legal and appropriate. The following have reviewed and support this proposal for development of the PGD and agree to be a co-author once the proposal is approved.	
Job title & name of post holder	**Signature and date**
Lead Author (Registered Health Professional) **Dr Ros Phillips GP and Contraceptive Lead**	 27.06.23
Lead Practitioner. *As senior registered health professional representing the staff group, I confirm that use by the group of health professionals described in this PGD is appropriate and within their competence* **Selina Reynolds, Senior CRH Nurse**	 28.06.23
Consultant / Senior Doctor **Dr Anna McKendry, Consultant Lead, NISHH Contraceptive Services**	 27.06.23
Directorate Pharmacist **Vijay Patel, HIV Specialist Pharmacist**	 27.06.23

Service Governance Approval

- The following managers have responsibility for service provision, governance (clinical and legal), and financial support of the service delivered under the PGD.
- and confirm they authorise use of the new / reviewed PGD in their specialty

Job title & name of post holder	**Signature and date**
Clinical Lead **Lynn Riddell**	 28.06.23
Clinical Director **Mr George Flanagan**	 04.07.23
Head of Service **Tracey Dempster**	 06.07.23
Appointed Practitioner in Charge **Selina Reynolds, Senior CRH Nurse Ashwood Centre**	 28.06.23

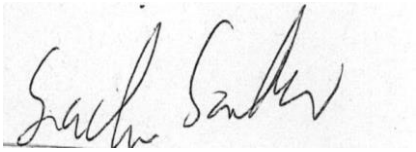
Clinical Executive / Directorate Governance Approval

The Clinical Executive / Directorate has agreed that a PGD is the most appropriate route to provide this clinical activity and has reviewed and supports operation of this PGD

Date approved by Directorate meeting: 14/07/2023

Deputy Medical Director
Dr Sachin Sankar

Signature



Authorised on behalf of NHFT by **Julie Shepherd, Chief Nurse**	**Signature and date**  25.07.2023

1. Characteristics of staff

Qualifications and professional registration	Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions. Specifically: • Pharmacist registered with the General Pharmaceutical Council and working at a community pharmacy providing emergency contraception services in partnership with Northamptonshire Health Foundation Trust • Authorised by name by Northamptonshire Healthcare NHS Foundation Trust to work to this PGD • Hold a current and up to date Enhanced Disclosure and Barring Service Check
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. Local requirements: • Has completed CPPE learning programmes to provide necessary knowledge to underpin the provision of this service: • Emergency Contraception CPPE e-learning and e-assessment • Safeguarding Children and Vulnerable Adults CPPE e-learning and e-assessment • Pharmacist must declare themselves competent using the CPPE declaration of Competence for Pharmacy services for EHC Statement and sign. This is updated every 3 years. The declaration of competence must remain valid to continue using PGD. i.e. must be renewed if expires during duration of PGD • Contraception CPPE e-learning (recommended only / NOT mandatory) • Has confirmed competence and confidence around

	supply of levonorgestrel EHC under PGD • Where the learning programme provides pharmacists with an assessment or record of completion this must be kept by the pharmacist. • Understanding of Fraser competence assessment The above CPPE competencies to be updated to latest versions (where available) as soon as practically possible
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 declaration of competence must remain valid to continue using PGD. i.e. must be renewed if expires during duration of PGD
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. • 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 Refer also to FSRH guidance on drug interactions with hormonal contraception
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 (ie. Datix)
Written information and further advice to be provided	• 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. • 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 o If individual is under 13 years of age record action taken o If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. o 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 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 • 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. 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/ • 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 competency statement and authorisation form to act under this Patient Group Direction

PGD178: Supply & Administration of Levonorgestrel 1500 micrograms to female clients at risk of pregnancy (version 2.0). Valid from: 1st August 2023 Expiry: 28th February 2026

A register of all practitioners authorised to practice under this PGD is maintained by the service

Before signing this form, check that the PGD document has had the necessary authorisations on page 3. Without these, this PGD is not lawfully valid.

Original: to be retained by health professional as evidence of authority to practise under this PGD
Copy: to be submitted to the NHFT Appointed Practitioner in Charge for inclusion in the service register of Authorised PGD Practitioners

Registered health professional competency statement

Note: By signing the competency statement to practice under this PGD, you are indicating you agree to its contents and accept the responsibility and accountability that practice under this PGD entails and agree to practice only within the terms and conditions of the PGD.

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.

It is the responsibility of each individual to maintain his/her competency and ensure his/her authorisation does not lapse by arranging a competency review meeting with his/her authorising manager. **THE TRUST REQUIRES PRACTITIONERS TO BE RE-ASSESSED ANNUALLY.** Copies of the completed forms must be submitted to the Appointed Practitioner in Charge AFTER EACH RE-ASSESSMENT for continued inclusion in the service register of Authorised PGD Practitioners.

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 professional named above has declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of Northamptonshire Healthcare NHS Foundation Trust for the above named health care professionals who has signed the PGD competency statement to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Each individual working to a PGD should have their own signed copy, which they retain for their record; a copy should be kept on file by the service manager.

Appendix B – Details of premises participating in service

PHARMACY CONTRACTED TO DELIVER THIS SERVICE UNDER THE PGD	
NAME OF PHARMACY	
ADDRESS OF PHARMACY	
PHARMACY OCS CODE	

Any pharmacist working in this location who does not believe in his/her competence in this clinical area MUST NOT sign the PGD and will therefore not have the authorization to work under this Direction.

Each pharmacist must have the authority of the Contractor/Sub-contractor to deliver the Locally Commissioned Service "Provision of Emergency Hormonal Contraception to Female clients at risk of pregnancy" as well as being authorised to work to the PGD by Northamptonshire Healthcare NHS Foundation Trust..

The Contractor/Sub-contractor must list all the pharmacists who will be working under the PGD in each branch. A copy of the PGD will be kept in the branch together with this list.

It is the responsibility of the Contractor/Sub-contractor to ensure the pharmacist has:

- Provided evidence of eligibility to work to the PGD from Northamptonshire Healthcare NHS Foundation Trust e.g. up to date training requirements including a copy of the CPPE EHC Certificate and valid CPPE Declaration of Competence (this can be via Pharmoutcomes)
- Agreed to work within the terms and conditions of the PGD
- Agreed to work within the terms and conditions of the Service Specification

Appendix C – Details of Pharmacists who work in branch on a REGULAR basis

All pharmacists who work in the Pharmacy Branch on a **regular** basis and are signed up to the scheme must be indicated in the table below:

NAMED PHARMACISTS TO SUPPLY TREATMENT UNDER DIRECTIVE			
Name of Pharmacist	Signature of Pharmacist	Signature of Contractor (or authorised representative)	Date

Appendix D – Details of Pharmacists who work in branch on an OCCASIONAL basis

All pharmacists and locums who work in the Pharmacy Branch on a **occasional** basis and are signed up to the scheme must be indicated in the table below:

NAMED PHARMACISTS TO SUPPLY TREATMENT UNDER DIRECTIVE			
Name of Pharmacist	Signature of Pharmacist	Signature of Contractor (or authorised representative)	Date

Appendix E: Standing order for Levonorgestrel EHC PGD

Part 1 - To be completed by the Pharmacist:

- I consider myself competent to supply Levonorgestrel EHC under this PGD
- I have completed the following necessary CPPE Learning:
    - Emergency Contraception (CPPE 2016 or later e-learning) and completed the related e-assessment
    - Safeguarding Children and Vulnerable Adults (CPPE 2014 or later e-learning) and completed the related e-assessment

Signed the Self Declaration of Competence for Pharmacy Services for provision of Emergency Hormonal Contraception

- I will ensure that my self-declaration of competence remains valid for the duration of service provision
- Unless already completed, I will undertake the updated 2022 CPPE e-training and e-assessments for emergency contraception and safeguarding children and vulnerable adults within six months of signing this form. Evidence of completion will be supplied to NHFT.
- I will have the opportunity to attend a NHFT/CPPE organised training event to supplement my clinical knowledge of emergency contraception if required by NHFT
- I have submitted a copy of my CPPE Certificates and self-declaration of competence to Northamptonshire Healthcare NHS Foundation Trust
- I have read and understood the Patient Group Direction and agree to use it in accordance with the criteria described

Pharmacist Name: _____
Pharmacist GPhC Number _____
Signature: _____
Business Address: _____
Date: _____

Each individual working to a PGD should have their own signed copy, which they retain for their record

Part 2- To be completed by the Commissioner:

- The above named pharmacist is identified as being suitably qualified in the supply of Levonorgestrel EHC
- This pharmacist has confirmed competency in the supply of Levonorgestrel EHC according to this Patent Group Direction
- The above named pharmacist is hereby authorised to operate this PGD within any **accredited** Community Pharmacy

Authorised by:

Name: _____

Position: _____

Signature: _____

Date: _____

Return this completed signed agreement to:

Business Manager
Northamptonshire Integrated Sexual Health Service
Department of Integrated Sexual Health
Northampton General Hospital NHS Trust
Northampton
NN1 5BD

Tel: 03000 270110……
Email: sms.nish@nhs.net……

Guidance Notes

- Each pharmacist should complete and sign part 1 of the Standing Order
- Part 2 will be completed by an authorised person at Northamptonshire Healthcare Foundation Trust
- When parts one and two are completed and signed, the original will be kept by the Commissioner and a copy will be returned to the pharmacist
- A copy of the completed standing order should be kept in each pharmacy where a pharmacist provides the service, and **retained by the accredited pharmacist**

APPENDIX F: FRASER GUIDELINES COMPETENCY TEST

For clients who are believed to be under 16 years of age. Discussion with the young person should explore the following issues at each consultation. This should be fully documented and should include an assessment of the young person's maturity.

ASSESSMENT OF FRASER GUIDELINES COMPETENCY	**YES**	**NO**
The young person could understand the advice and had sufficient maturity to understand what was involved in terms of the moral, social and emotional implications		
The young person was encouraged, but declined, to inform or seek support from their parents or to allow the health professional to inform the parents that they are seeking sexual health advice		
The young person would be very likely to begin, or to continue having, sexual intercourse with or without sexual health advice and/or treatment		
That, without sexual health advice or treatment, the young person's physical or mental health, or both, would be likely to suffer		
That the young person's best interests required them to receive sexual health advice and/or treatment without parental consent		

Taking the above into account, the pharmacist or nurse should decide if the young person is competent to receive advice and treatment. The consultation is governed by the same terms of confidentiality whether or not the health professional considers the young person competent.

Pharmacist / Nurse Name: ……

Pharmacist / Nurse Signature: …… Date:……

Client Name : ……

Client Signature: …… Date:……

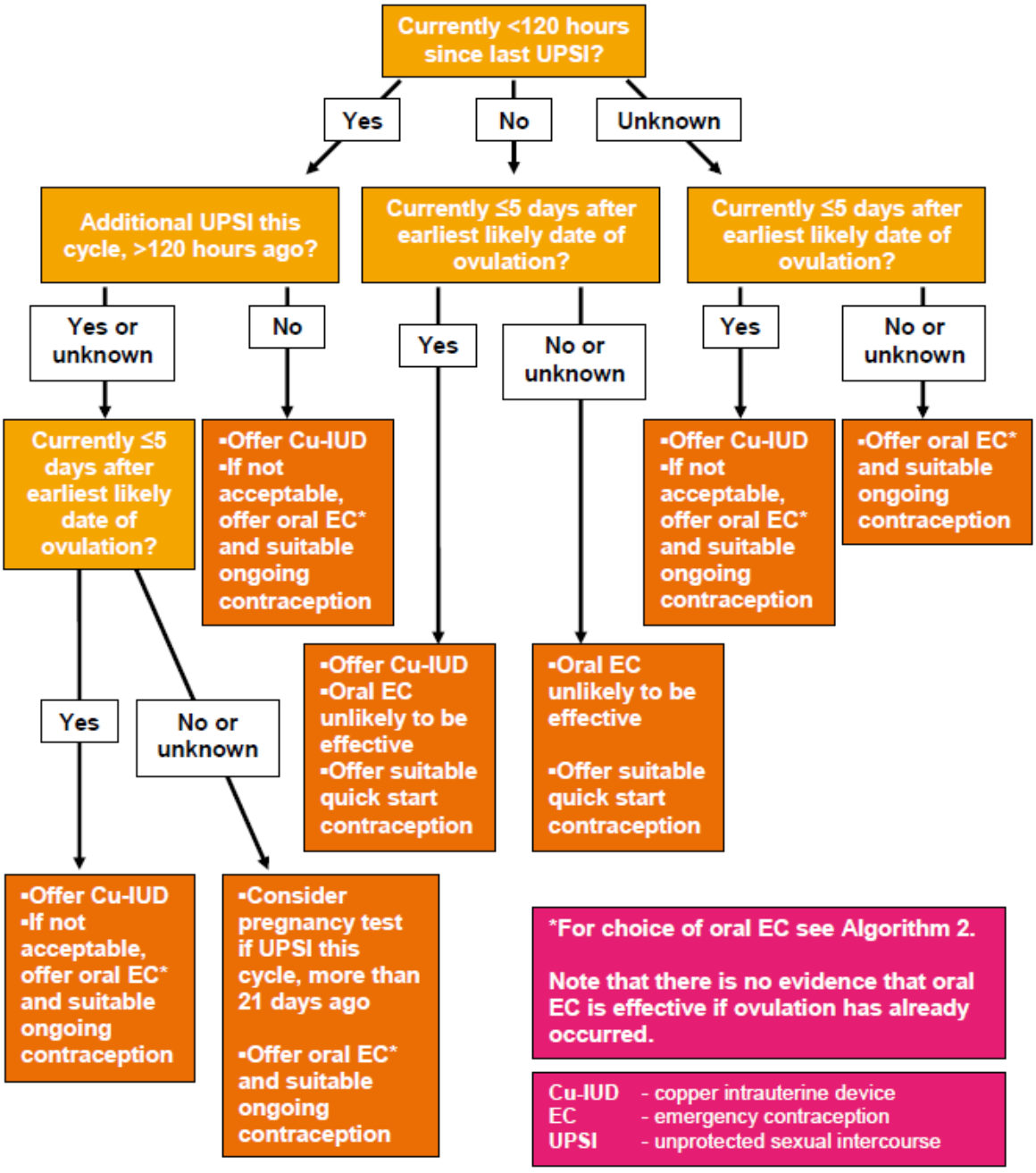
When a young person is judged not to be Fraser competent they should be referred.

Appendix G

FSRH

Decision-making Algorithms for Emergency Contraception

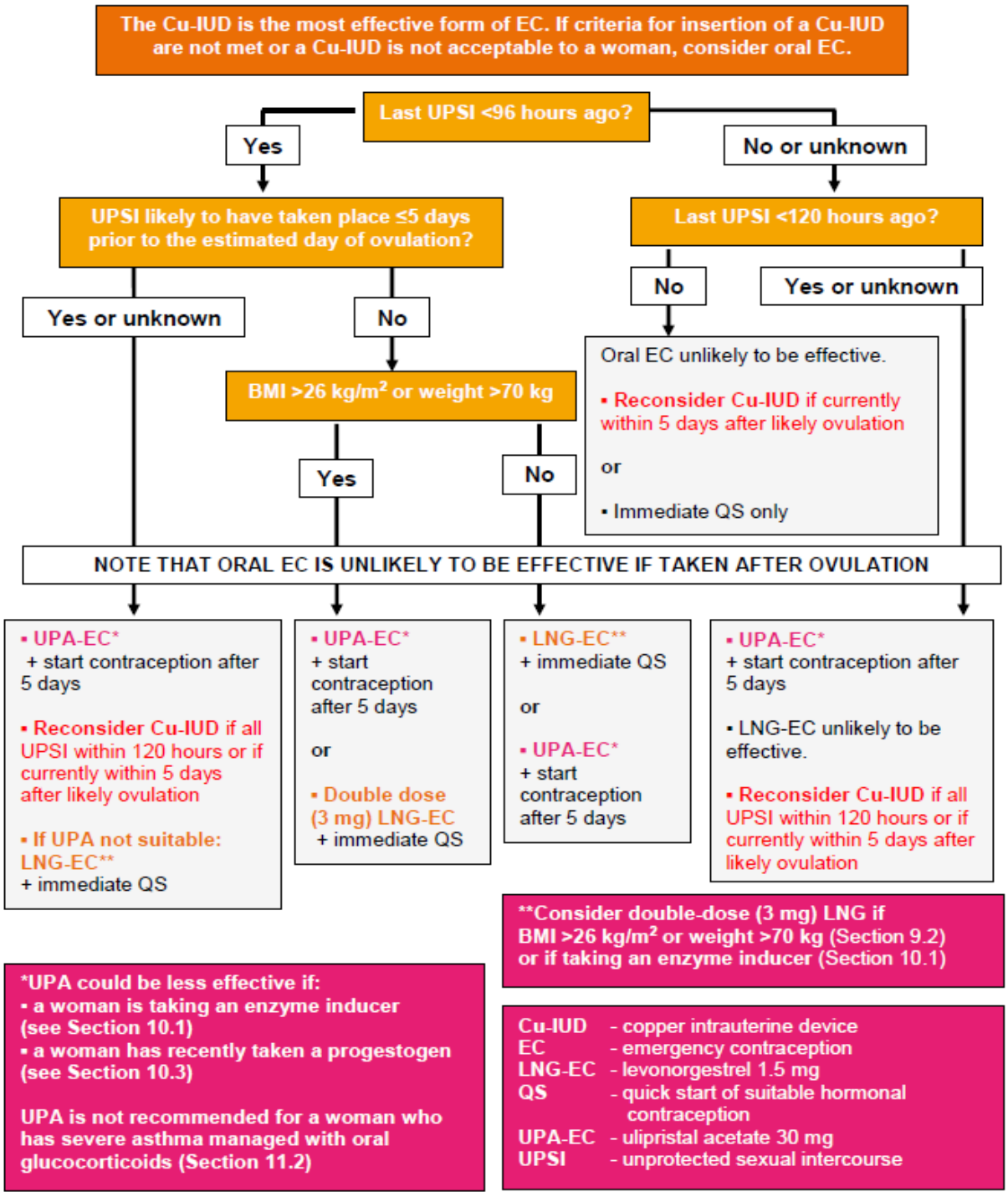
Algorithm 1: Decision-making Algorithm for Emergency Contraception (EC): Copper Intrauterine Device (Cu-IUD) vs Oral EC



Appendix H

FSRH

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



Appendix I: Emergency Contraception Checklist

Details of current requirement for Emergency Contraception (tick all that apply)				
No contraception	Condom failure	Missed pills		
Vomiting levonorgestrel dose	Other- please state			
How long ago was UPSI (hours)?				
Current regular method of contraception				
condom	Pill (specify Type)	IUD/S	none	Other (specify)
If missed Pills, give details:				

Menstrual Cycle			
Day of Cycle	Usual cycle length	Regular Y/N	Has client had levonorgestrel or ulipristal since the LMP? Y/N

Inclusion Criteria			
UPSI occurred with previous 96 hours? Y/N	Where client has vomited the dose of levonorgestrel, was this within 3 hours of ingestion? Y/N	Have all options for emergency contraception been explained and the client prefers levonorgestrel? Y/N	Missed pills are in the timescales that cause loss of protection? Y/N
Any contraindications to levonorgestrel? Y/N	Informed consent given (including use of Fraser Guidelines if under 16yrs)? Y/N		

Exclusion /Caution Criteria (including follow up action)			
Criteria	Y/N	Recommended follow up	Follow up taken(please detail)
Clients aged under 13 years		• There is a duty to seek further advice and onward referral to address child protection issues **The Child Protection Team must be contacted for children aged under 13 years who present having has sexual intercourse**	

Clients currently taking enzyme inducing drugs or have stopped within last 28 days or weight >70kg or BMI over 26		Must be offered 3mg levonorgestrel (this is not based on evidence or within product licence but expert clinical judgement of balance of risks and benefits). Cu-IUD should be recommended as the most effective method of EC	
Breastfeeding		FSRH recommends women can use progesterone only emergency contraception without restriction	
Repeated use in same cycle		Advise client: • She may be pregnant (consider pregnancy test as appropriate) • Repeated use disturbs the menstrual cycle • Consider IUD as preferred alternative • Levonorgestrel EHC will not interrupt pregnancy (there is no epidemiological data to indicate that 1500micrograms levonorgestrel has an adverse effect on the foetus) • If UPSI was within 12 hours of previous levonorgestrel dose, further EHC is not required	
Criteria	Y/ N	Recommended follow up	Follow up taken(please detail)
Vomiting		If the request is due to an episode of vomiting which has occurred with 3 hours of taking the dose, a replacement supply may be issued	
Episodes of UPSI over 96 hours		Consider options if UPSI occurred between 72 hours and 120 hours e.g levonorgestrel out of license or referral for IUD or ulipristal up to 120 hours	
Previous UPSI more than 96 hours earlier within the same cycle and no emergency contraception used		Consider ulipristal/refer to GP/Integrated Sexual Health Service Consider pregnancy test	

Previous UPSI within the same cycle and treated with ulipristal		Consider referral for IUD or repeat dose of Ulipristal.	
Known breast Cancer		Refer to GP or Integrated Sexual Health service	
Possible Pregnancy -Vague menstrual history -last menstrual period Late/abnormal/different		Consider pregnancy test	
Client given birth in last 3 weeks		EHC not required	
Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD)		EHC not required	
Know acute porphyria		Do not provide- refer to GP or integrated Sexual Health service asap	
Known hypersensitivity to levonorgestrel		Refer to GP or Integrated Sexual Health service	

Counselling		
STI risk/Chlamydia screen Y/N	Methods of EHC Y/N	Failure rate Y/N
Instructions for use Y/N	Side effects Y/N	What to do if vomiting occurs Y/N
Timing of next period Y/N	Contraception for remainder of cycle Y/N	Future Contraception Y/N
Action Take		
Supply Levonorgestrel - to be taken in presence of pharmacist	Batch Number	Expiry date
Refer patient to:		

The above information is correct to the best of my knowledge. I have been counselled on use of EHC and understand the advice I have been given

Client's Signature date

Pharmacist Signature date