

## PATIENT GROUP DIRECTION (PGD)

The supply of Levonorgestrel 1.5mg Tablets for Emergency Contraception (LNG-EC) by community pharmacists working within the boundaries of East Sussex County Council (ESCC)

Version 4

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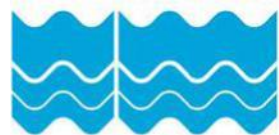
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Community pharmacists using this PGD must ensure that it is formally approved and signed by a pharmacist, medical lead and governance lead for the organisation with legal authority, so that this document meets legal requirements for a PGD.

The pharmacist must be authorised by name, under the current version of this PGD before working according to it.

CHANGE HISTORY	
Version/Date	Change details
Version 4	Updated Summary of Product Characteristics (SmPC) Updated Faculty of Sexual and Reproductive Healthcare (FSRH) guidance Updated National Institute for Health and Care Excellence (NICE) Guidance

PGD comes into effect	1 <sup>st</sup> April 2022
PGD Review date	1 <sup>st</sup> April 2023 or earlier in the light of significant changes in best practice
PGD Expiry date	31 <sup>st</sup> March 2024



This PGD template has been developed by the following healthcare professionals on behalf of ESCC:

NAME/ROLE	SIGNATURE	DATE
Doctor Dr Karen Skinner		22/4/2022
Pharmacist Janet Rittman		14/3/22
Clinical Governance Lead		

Short Life Working Group Membership

Name	Designation
Janet Rittman*	Pharmacist
Dr Karen Skinner	Doctor
Tony Proom	Strategic Commissioning Manager - Sexual Health

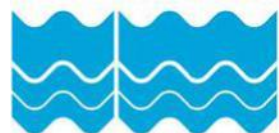
\* Core working group members and PGD signatories

**ORGANISATIONAL APPROVAL**

The PGD is not legally valid until it has had the relevant organisational approval.

Patient Group Direction Authorised by:		
TITLE /ORGANISATION	SIGNATURE	DATE
Darrell Gale Director of Public Health East Sussex County Council		22/04/2022

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

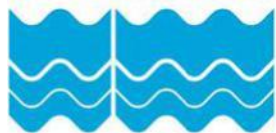


with the General Pharmaceutical Council (GPhC) Standards for Pharmacy Professionals and Pharmaceutical Society of Northern Ireland (PSNI) Code of Ethics for Pharmacists.

No PGD can envisage every clinical situation. Pharmacists are expected to exercise professional judgement and discretion. In any situation where there is a concern a doctor must be consulted.

Individual practitioners must declare that they have read and understood the Patient Group Direction and agree to supply/administer medicines listed only in accordance with the PGD within the specified start and expiry dates. The original copy, signed by all those concerned, should be kept in a designated place within the pharmacy, and be readily accessible for reference and audit purposes.

The pharmacist must work within the service specification agreed between the contracted pharmacy and the commissioning organisation.



Patient group direction effective from 1<sup>st</sup> April 2022

**HEALTHCARE PROFESSIONALS AUTHORISED TO SUPPLY UNDER THIS PGD**

ESCC authorises the use of this document by accredited community pharmacists who are working within the boundaries of **East Sussex County Council**

**DECLARATION:** I am a registered pharmacist, employed

Name of Pharmacy	
Address	
Post Code	

**Characteristics of Staff**

**I have read this Patient Group Direction (PGD) and confirm that:**

**Qualifications**

I am registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society of Northern Ireland (PSNI)

**Specialist qualifications and competencies**

I am competent to provide the Community Pharmacy Emergency Hormonal Contraception to a individuals aged 25 and under and Chlamydia Screening Public Health Local Service Agreement (PHSLA) because:

1. I have completed the accreditation and training requirements detailed in the Community Pharmacy EHC to individuals aged 25 and under and Chlamydia screening PHSLA
2. I have completed the Emergency Hormonal Contraception Declaration of Competence (DoC) on the Centre for Pharmacist Postgraduate Education (CPPE) website <https://www.cppe.ac.uk/services/declaration-of-competence>
3. I have completed the mandatory CPPE Safeguarding Children and Vulnerable Adults e-learning and passed the associated level 2 assessment.
4. I have reviewed my competency to operate under this PGD using the [NICE Competency Framework for health professionals using patient group directions](#)
5. I am aware of local safeguarding policies and contact information.
6. I have reviewed the local policies and documentation for this service and references associated with this PGD.
7. I am aware that it is my responsibility to keep up-to-date with changes to the recommendations for this medicine and acknowledge any limitations to my knowledge or competence. I will complete continuing professional development



as defined by the GPhC or PSNI and take part in an audit as detailed in the service specification.

Name	GPhC/PSNI registration number	Signature	Date

**Signature of Authorising Pharmacist or Pharmacy Manager**

**Date**

.....

.....

**Name of Authorising Pharmacist or Pharmacy Manager**

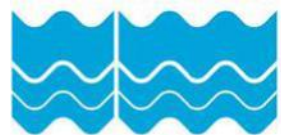
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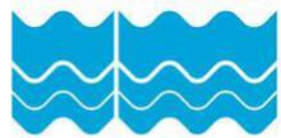
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<p><b>1. Clinical condition or situation to which this PGD applies</b></p>	<p>The supply of levonorgestrel 1.5mg tablet for emergency contraception (LNG-EC) to be taken as soon as possible after unprotected sexual intercourse (UPSI) or contraceptive failure preferably within 12 hours and no later than after 72hrs (may also be used between 72-96 hours after UPSI - off label)</p>
<p><b>1.1 Criteria for inclusion</b></p>	<ul style="list-style-type: none"> <li>• Any individual <b>13 to 25 years of age</b> presenting for emergency contraception (EC) preferably within 12 hours and no later than after 72 hours (may also be used between 72-96 hours after UPSI but efficacy decreases with time, off label use between 72-96hrs - see section 2.4). For guidance refer to the <b>Faculty of Sexual and Reproductive Healthcare (FSRH) Decision-making Algorithms for Emergency Contraception</b> in the following document Page ix. FSRH Guideline Emergency Contraception March 2017 (Amended December 2020) <a href="http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf">http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf</a></li> <li>• The individual has no contraindications to the medication.</li> <li>• Individuals 26 years of age or over who cannot easily obtain EC from another NHS source without undue delay (exceptional circumstances only)</li> <li>• Contraception has been used incorrectly or has been compromised. For further information refer to the Summary of Product Characteristics (SmPC) of individual products or Faculty of Sexual and Reproductive Healthcare (FSRH) March 2017 (Updated December 2017) FSRH Guideline Emergency Contraception. <a href="http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf">http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf</a></li> <li>• All options for emergency contraception discussed and the individual prefers the hormonal method and declined 1<sup>st</sup> line ulipristal</li> <li>• The individual has taken LNG-EC but has vomited the tablet within 3 hours of taking. The new dose must still be within 72 hours (96 hours off label) of the first UPSI of that episode.</li> <li>• Must be able to give <b>informed consent</b> to treatment. Informed consent is the process by which a patient learns about and understands the purpose, benefits, and potential risks of a treatment and then agrees to receive the treatment.</li> <li>• <b>If the individual is under 16 years old</b>, they must be assessed as Fraser Competent (see Appendix 1) or if not assessed as Fraser Competent accompanied by one or both parents, or a legal guardian and consents to the treatment being given.</li> <li>• Consents to consultation and medication supply by a pharmacist without referral to a doctor.</li> </ul>



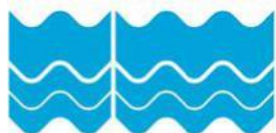
<p><b>1.2 Criteria for exclusion</b></p>	<p><b>Personal Characteristics &amp; Reproductive History</b></p> <ul style="list-style-type: none"> <li>• Age &lt;13 years or &gt; 25 years of age.</li> <li>• Informed consent not given</li> <li>• Individual under 16 years old assessed as lacking capacity to consent using the Fraser guidelines</li> <li>• If under 13 years of age follow local safeguarding policy.</li> <li>• Child Sexual Exploitation (CSE) concerns- refer to section 1.4</li> <li>• Safeguarding concerns- refer to section 1.4</li> <li>• More than 72 hours since this episode of UPSI, (96 hours off- label) Consider the supply of Ulipristal for emergency contraception (UPA-EC) (refer to Ulipristal PGD) if individual meets inclusion criteria and/ or copper intrauterine device (Cu-IUD)</li> <li>• Less than 21 days following childbirth.</li> <li>• Known or suspected pregnancy. If UPSI occurred &gt; 21 days ago and no or abnormal period advise individual to complete a pregnancy test before supplying EC.</li> <li>• Less than 5 days following abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.</li> </ul> <p><b>Medical history</b></p> <ul style="list-style-type: none"> <li>• Acute porphyria</li> </ul> <p><b>Medication History</b></p> <ul style="list-style-type: none"> <li>• Known hypersensitivity to any constituent of LNG-EC. Refer to Summary of product Characteristics (SmPC) <a href="https://www.medicines.org.uk/emc">https://www.medicines.org.uk/emc</a></li> <li>• Less than 5 days following ingestion of Ulipristal. Consider if another supply of UPA is appropriate -refer to UPA-EC PGD</li> <li>• Taking a medicine or herbal product that interacts with LNG-EC (see section 2.9). Refer to the British National Formulary (BNF) or the Faculty for Sexual and Reproductive Healthcare (FSRH) CEU guidance: Drug interactions with hormonal contraception <a href="https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/">https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/</a></li> </ul> <p><b>Please note:</b> It may be appropriate to supply individuals taking enzyme inducing drugs ( or within 4 weeks of stopping) with an increased dose of LNG-EC. Refer to section 2.5.</p> <p>It is imperative to contact the Sexual Health Service (SHS) for advice if the pharmacist has any concerns about supplying LGN-EC. Refer to the East Sussex Sexual Health website for contact information <a href="https://www.eastsussexsexualhealth.co.uk">https://www.eastsussexsexualhealth.co.uk</a></p>
<p><b>1.3 Cautions: Need for further advice or action to be taken</b></p>	<ul style="list-style-type: none"> <li>• A Copper intrauterine device (Cu-IUD) should always be discussed as a more effective option when emergency contraception is required. Cu-IUD can be inserted up to 5 days after first UPSI or up to 5 days after the earliest</li> </ul>



estimated date of ovulation (whichever is later). Onward referral should be made as appropriate. **LNG-EC should be provided even if a Cu-IUD is planned, unless it is to be fitted that day or there is an exclusion to it.**

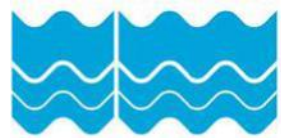
- LNG-EC is ineffective if taken after ovulation.
- Ulipristal acetate EC (UPA-EC) has been demonstrated to be effective for up to 120 hours after UPSI and should always be considered as first line for EHC.
- If UPA-EC (first line) is not appropriate then Levonorgestrel (LNG-EC) is licensed for EC up to 72 hours (up to 96 hours off label) after UPSI. The evidence suggests that LNG-EC is ineffective if taken more than 96 hours after UPSI.
- LNG-EC can be supplied if USPI earlier in the same cycle as well as within the last 72 hours (96 hours off label), as evidence suggests it does not disrupt an existing pregnancy and is not associated with fetal abnormality.
- A repeat dose of LNG-EC can be supplied in the same menstrual cycle should the need occur. Consider CU-IUD and signpost for sexual health and contraception advice.
- If individual is taking enzyme-inducing drugs (or herbal products) or has taken them in the last 28 days (includes prescribed and purchased medicines) – **see adjusted dosage recommendations in section 2.5**
- Individuals receiving post-exposure prophylaxis for sexual exposure to HIV (PEPSE). Refer to section 2.9.
- **Body Mass Index (BMI) greater than or equal to 26kg/m<sup>2</sup> or weighs 70kg (11 stone) or more**, individuals should be advised that although oral EC methods are safe, a high BMI may reduce effectiveness. A CU-IUD should be recommended as the most effective method of contraception. If CU-IUD is not accepted then either advise the individual to take a total dose of 3mg levonorgestrel (two 1.5mg tablets) as a single dose (off label indication) or consider Ulipristal 30mg tablet. Refer to section 2.5
- Severe malabsorption syndromes, such as Crohn's disease, or small bowel resection are likely to impair the efficacy of levonorgestrel. A CU-IUD should be recommended as the most effective method of contraception. Supply EC as appropriate and refer for CU-IUD accordingly if agreed
- If the individual has not yet reached menarche consider onward referral for further assessment or investigation.
- Breast feeding mothers are to be informed that limited evidence indicates that LNG-EC has no adverse effects on breastfeeding or on their infants. If concerns advise expressing milk before taking the tablet and no breast feeding for 8 hours.





<p><b>1.4 Action to be taken if the individual is excluded or declines treatment</b></p>	<ul style="list-style-type: none"> <li>• Signpost or refer to SHS or GP as soon as possible with information about further options, including referral to SHS for consideration of copper intrauterine device (Cu-IUD).</li> <li>• Individuals 26 years of age or older should be given the option to purchase EC over the counter (if appropriate) or be referred to the SHS or GP.</li> <li>• If pregnancy is suspected (i.e. If UPSI occurred &gt; 21days ago and no or abnormal period) supply free pregnancy test and ask individual to complete the test (as soon as possible as the supply of EC is time critical) before supplying EC or refer to SHS.</li> <li>• If exclusion is due to a drug interaction consider if UPA-EC could be supplied as an alternative to LNG-EC and/or refer for Cu-IUD.</li> <li>• <b>Safeguarding</b> (including child sexual exploitation) concerns identified at presentation should be referred to the East Sussex Safeguarding Children Partnership (ESSCP) <a href="https://www.esscp.org.uk">https://www.esscp.org.uk</a></li> <li>• Follow local safeguarding arrangements for vulnerable adults when appropriate <a href="https://www.eastsussexsab.org.uk/#">https://www.eastsussexsab.org.uk/#</a></li> <li>• Individuals who lack capacity to consent should be referred to SHS or GP for a Best Interest Assessment undertaken by an authorised prescribing practitioner <a href="http://www.legislation.gov.uk/ukpga/2005/9/contents">http://www.legislation.gov.uk/ukpga/2005/9/contents</a></li> <li>• If the individual declines treatment discuss implications and record the declination.</li> <li>• Document all actions taken.</li> </ul>
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2. Description of Treatment	
2.1 Name, strength & formulation of drug	Levonorgestrel 1.5mg Tablet
2.2 Legal status	Pharmacy only medicine (P) Prescription only medicine (POM)
2.3 Route of administration	Oral, with or without food. Taking with or after food may reduce the incidence of nausea and vomiting a known side effect.
2.4 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 <a href="#">Summary of Product Characteristics</a> (SmPC).
	This PGD includes off-label use in the following conditions: <ul style="list-style-type: none"> <li>• Use between 72 and 96 hours post UPSI</li> </ul>



- Increased dose for individuals with BMI over 26kg/m<sup>2</sup> or weight over 70kg and in individuals using liver enzyme inducing agent
- Severe hepatic impairment
- Individuals with previous salpingitis or ectopic pregnancy
- Lapp-lactase deficiency
- Hereditary problems of galactose intolerance
- Glucose-galactose malabsorption

LNG- EC is licensed for use within 72 hours of UPSI. Use of LNG-EC after 72 hours after UPSI is off-licence. Studies demonstrate a trend towards increasing pregnancy rates with increasing time between UPSI and LNG-EC.

Some studies have suggested that both LNG-EC and UPA-EC could be less effective in women who are overweight, obese or have higher body weight than those with normal or lower body weights. Refer to section 2.5.

FSRH guidance also states that pregnancy poses a significant risk in individuals with severe hepatic impairment and expert opinion suggests the use of a single dose of LGN 1.5mg is therefore acceptable.

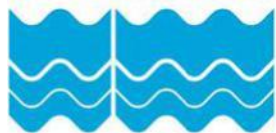
The absolute risk of ectopic pregnancy is likely to be low, as levonorgestrel prevents ovulation and fertilisation. FSRH guidance states that absolute numbers of ectopic pregnancies remain very small and LNG-EC reduces absolute risk of ectopic pregnancy by reducing pregnancy risk overall.

For further information regarding use outside product licence refer to the FSRH Guideline Emergency Contraception March 2017 (Amended December 2020)  
[http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception\\_11.pdf](http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception_11.pdf)

Drugs 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.
<b>2.5 Dose and frequency of administration</b>	<ul style="list-style-type: none"> <li>• A single 1.5mg tablet to be taken as soon as possible preferably within 12 hours and no later than 72 hours of unprotected sexual intercourse (UPSI) (96 hours off label).</li> <li>• <b>Dose for those individuals taking enzyme inducing medicines or herbal products:</b> An individual who requests levonorgestrel whilst using enzyme-inducing drugs, or within 4 weeks of stopping them, can be advised to take a total of 3mg levonorgestrel (two 1.5mg tablets) as a single dose and within 72 hours of UPSI (96 hours off label).</li> <li>• <b>Dose for those individuals with a body mass index of more than 26kg/m<sup>2</sup> or who weigh more than 70kg:</b> An individual who requests levonorgestrel with a body mass index of more than 26kg/m<sup>2</sup> or who weighs more than 70kg can be offered a total of 3mg levonorgestrel (two 1.5mg tablets) as a single dose and within 72 hours of UPSI (96 hours off label).</li> </ul>
<b>2.6 Quantity to be supplied</b>	<ul style="list-style-type: none"> <li>• Single dose – to be administered in the pharmacy or dispensed and appropriately labelled for the individual to take away.</li> <li>• Two tablets can be supplied for individuals taking enzyme inducing drugs and/or individuals with a BMI of more than 26kg/m<sup>2</sup> or who weigh more than 70kg.</li> </ul>
<b>2.7 Duration of treatment</b>	<ul style="list-style-type: none"> <li>• A single dose is permitted under this PGD.</li> <li>• If vomiting occurs within 3 hours of levonorgestrel being taken a repeat dose can be supplied under this PGD.</li> <li>• Repeated doses can be given within the same cycle. Please note:             <ul style="list-style-type: none"> <li>○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal)</li> <li>○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel)</li> </ul> </li> </ul>
<b>2.8 Storage of products</b>	Medicines must be stored securely according to national guidelines and in accordance with the SmPC.
<b>2.9 Drug interactions</b>	<p>A detailed list of drug interactions is available in the SmPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> or the BNF <a href="http://www.bnf.org">www.bnf.org</a></p> <p>Additional Sources of information include:</p> <ul style="list-style-type: none"> <li>• Stockley's Drug Interactions <a href="https://about.medicinescomplete.com/publication/stockleys-drug-interactions/">https://about.medicinescomplete.com/publication/stockleys-drug-interactions/</a></li> </ul>



	<ul style="list-style-type: none"> <li>Faculty for Sexual and Reproductive Healthcare (FSRH) CEU guidance: Drug interactions with hormonal contraception <a href="https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/">https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/</a></li> <li>For interactions with post-exposure prophylaxis for sexual exposure to HIV (PEPSE) regimes it is recommended to check with the online University of Liverpool HIV Drug Interactions Checker <a href="https://www.hiv-druginteractions.org/checker">https://www.hiv-druginteractions.org/checker</a></li> </ul> <p>If necessary access the individuals NHS Summary Care Record (SCR) (with consent) if they are uncertain about the medications they are taking.</p>
<p><b>2.10 Identification &amp; management of adverse reactions</b></p>	<p>A detailed list of adverse reactions is available in the SmPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> and BNF <a href="http://www.bnf.org">www.bnf.org</a></p> <p>The following side effects are common with levonorgestrel (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> <li>Nausea</li> <li>Lower abdominal pain</li> <li>Fatigue</li> <li>Dizziness</li> <li>Headache</li> <li>Diarrhoea/vomiting</li> <li>Breast tenderness</li> <li>Mood change</li> </ul> <p>Bleeding patterns may be temporarily disturbed and spotting may occur, but most women will have their next menstrual period within seven days of the expected time.</p>
<p><b>2.11 Management of and reporting procedure for adverse reactions</b></p>	<p>In the event of untoward or unexpected adverse reactions:</p> <ul style="list-style-type: none"> <li>If necessary seek appropriate emergency advice and assistance</li> <li>Document in the individual patient medication record and complete incident procedure if adverse reaction is severe (refer to local organisational policy)</li> <li>Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0800 100 3352 or online at <a href="https://yellowcard.mhra.gov.uk/">https://yellowcard.mhra.gov.uk/</a> The public</li> </ul>



	<p>can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.</p> <ul style="list-style-type: none"> <li>• Report any adverse reactions via organisation incident policy.</li> </ul>
<p><b>2.12 Written information and further advice to be provided</b></p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Explain mode of action, dosage, side effects, and follow-up advice. <b>Provide manufacturer’s patient information leaflet (PIL) and discuss content.</b></li> <li>• Advise individual to take the tablet with or after food. <b>If vomiting occurs within 3 hours, a second dose should be taken immediately. Advise individual to return to the pharmacy for a second dose or to contact the SHS.</b></li> <li>• Explain menstrual disturbances can occur after the use of emergency hormone contraceptives.</li> <li>• 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</li> <li>• Advise that LNG-EC will not protect against further UPSI later in the cycle. Recommend use of appropriate contraceptive methods and how these can be accessed. Supply condoms as needed.</li> <li>• Advise that after oral EC there is a pregnancy risk if there is further UPSI and ovulation occurs later in the same cycle.</li> <li>• Repeated doses of EC in the same cycle can be given if deemed appropriate.</li> <li>• Individuals presenting for repeat supplies of EHC should be referred to the SHS for additional support.</li> <li>• A pregnancy test is recommended 21 days after treatment especially if the next menstrual period is delayed by more than 7 days, is lighter or shorter than usual or is associated with abdominal pain that is not typical of the individuals usual dysmenorrhea</li> <li>• Individuals who start hormonal contraception after use of UPA-EC should be advised to have a pregnancy test at 3 weeks even if they have bleeding; bleeding associated with the contraceptive method may not represent menstruation.</li> <li>• A free pregnancy test can be issued to individuals under 26 years of age. <b>Individuals must be advised to go to SHS or GP if the pregnancy test is positive.</b></li> <li>• There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal <u>contraception.</u></li> </ul>



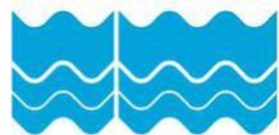
	<ul style="list-style-type: none"> <li>• Concurrent use of a barrier method should be encouraged and the risks of sexually transmitted infections (STIs) discussed. If appropriate provide a self-testing chlamydia /gonorrhoea test and explain how to use.</li> <li>• Discuss long term contraception options and refer individual to the Sexwise website <a href="https://www.sexwise.fpa.org.uk">https://www.sexwise.fpa.org.uk</a> to access further information.</li> <li>•</li> <li>• Give individual the opportunity to ask questions and address any concerns or queries.</li> <li>• Provide contact information for SHS or refer to website <a href="https://www.eastsussexsexualhealth.co.uk">https://www.eastsussexsexualhealth.co.uk</a></li> </ul>
<p><b>2.13 Advice/follow up treatment</b></p>	<ul style="list-style-type: none"> <li>• The individual should be advised to seek medical advice in the event of an adverse reaction.</li> <li>• The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned.</li> <li>• Advise individual to contact the SHS or GP 3 weeks after taking LNG-EC if the pregnancy test is positive or if the expected period is more than 7 days late.</li> <li>• Refer to SHS or GP for further advice about long term contraception and screening for sexually transmitted infections (STI).</li> </ul>

<p><b>3. Records</b></p>	<p>Record the consultation and clinical assessment as prompted on the Pharmoutcomes (PO) emergency contraception template, include additional notes on the PMR when necessary.</p> <p>Individuals should be made aware of the confidentiality policies for the service they are attending, including the circumstances in which confidentiality may need to be breached.</p> <p>The Pharmoutcomes template will record the following information:</p> <ul style="list-style-type: none"> <li>• Informed consent of the individual, including if Fraser Guidelines used and actions taken if individual not deemed competent to consent.</li> <li>• Safeguarding referral if relevant.</li> <li>• Individual's name, date of birth and first 3-4 characters of postcode i.e. TN34. This is a confidential service that can be accessed without a full address and GP notification.</li> <li>• Medical and medication history as prompted by PO.</li> </ul>
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	<ul style="list-style-type: none"> <li>• Any known allergy.</li> <li>• Date of supply.</li> <li>• Record the name of the medication, number of packs supplied with batch numbers and expiry dates.</li> <li>• Any advice given about the medication including side effects, benefits, how to take it and when, and what to do if any concerns.</li> <li>• Details of any adverse drug reactions and any action taken.</li> <li>• Any referral arrangements.</li> <li>• Any follow up arrangements.</li> <li>• Name of registered health professional operating under the PGD.</li> <li>• The consultation should be submitted on the PharmOutcomes system.</li> <li>• For adults all PGD documentation in a patient's clinical record must be kept for 8 years after the last entry.</li> <li>• For children all PGD documentation in a patient's clinical record must be kept until the child is 25 years old or for 8 years after a child's death.</li> </ul> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local <u>policy</u>.</p>
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<b>REFERENCES</b>	<ul style="list-style-type: none"> <li>• Faculty of Sexual and Reproductive Healthcare (FSRH) Clinical Guideline: Emergency Contraception (March 2017, amended December 2020) <a href="http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf">http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf</a></li> <li>• Faculty of Sexual and Reproductive Healthcare. UK Medical Eligibility Criteria (UKMEC) for Contraceptive Use; April 2016 (Amended September 2019) <a href="https://www.fsrh.org/standards-and-guidance/uk-medical-eligibility-criteria-for-contraceptive-use-ukmec/">https://www.fsrh.org/standards-and-guidance/uk-medical-eligibility-criteria-for-contraceptive-use-ukmec/</a></li> <li>• Faculty of Sexual and Reproductive Healthcare. Clinical Effectiveness Unit (CEU) guidance: Drug interactions with hormonal contraception (Jan 2017, last reviewed 2019) <a href="https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/">https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/</a></li> <li>• Faculty of Sexual and Reproductive Healthcare Clinical Guideline (April 2017): Quick starting contraception <a href="https://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017/">https://www.fsrh.org/standards-and-guidance/documents/fsrh-clinical-guidance-quick-starting-contraception-april-2017/</a></li> </ul>
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- Faculty of Sexual and Reproductive Healthcare: Clinical Effectiveness Unit guidance: Recommended Actions after Incorrect Use of Combined Hormonal Contraception (e.g. late or missed pills, ring and patch) ( March 2020, Amended 6 July 2021) <https://www.fsrh.org/documents/fsrh-ceu-guidance-recommended-actions-after-incorrect-use-of/>
- Faculty of Sexual and Reproductive Healthcare: Clinical Effectiveness Unit Statement: Response to Recent Publication Regarding Banh, et al. 17 November 2020
- <https://www.fsrh.org/standards-and-guidance/documents/fsrh-ceu-statement-response-to-recent-publication-regarding/?action=accept-all-cookies&module=privacy>
- Specialist Pharmacy Service: Patient Group Directions, Reproductive Health. Supply and/or administration of Levonorgestrel 1500 mcg tablet for emergency contraception: PGD template. <https://www.sps.nhs.uk/articles/supply-and-administration-of-levonorgestrel-1500micrograms-tablet-s-for-emergency-contraception-pgd-template/>
- National Institute for Health and Care Excellence (NICE) Patient Group Directions (March 2017) <https://www.nice.org.uk/Guidance/MPG2>
- British National Formulary (BNF) [www.bnf.org](http://www.bnf.org)
- Electronic Medicines Compendium <https://www.medicines.org.uk/emc>
- General Pharmaceutical Council Standards for Pharmacy Professionals. May 2017 [https://www.pharmacyregulation.org/sites/default/files/standards\\_for\\_pharmacy\\_professionals\\_may\\_2017\\_0.pdf](https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf)
- The Pharmaceutical Society of Northern Ireland (PSNI), The code of ethics for pharmacists in Northern Ireland. March 2016 <http://www.psn.org.uk/about/code-of-ethics-and-standards/>
- Centre for Postgraduate Pharmacist Education (CPPE). Declaration of Competence. <https://www.cppe.ac.uk/services/declaration-of-competence>



## Appendix 1

### Under 16s- Fraser Guidelines

In England, Wales and Northern Ireland, in order to provide contraception to young people under 16 years of age without parental consent, it is considered good practice to follow the Fraser Guidelines/criteria.

While the Fraser Guidelines below relate specifically to contraceptive advice or treatment, the principles are applicable to other sexual health services for young people under 16. A young person's age should not be a barrier to them accessing condoms.

Competence is demonstrated if the young person is able to:

Understand the treatment, its purpose and nature, and why it is being proposed  
Understand its benefits, risks and alternatives  
Understand in broader terms what the consequences of the treatment will be  
Retain the information for long enough to use it and weigh it up in order to arrive at a decision.

A young person is competent to consent to contraceptive advice or treatment if:

- The young person understands the professional's advice
- The professional cannot persuade the young person to inform their parents or allow the professional to inform the parents that they are seeking contraceptive advice.
- The young person is very likely to begin or continue having intercourse with or without the contraceptive treatment.
- Unless they receive contraceptive advice or treatment, the young person's physical or mental health or both are likely to suffer.
- The young person's best interests require the professional to give contraceptive advice, treatment or both without parental consent.

#### Reference

- Faculty of Sexual and Reproductive Healthcare Clinical Guideline: Contraceptive Choices for Young People Clinical Effectiveness Unit March 2010 (Amended May 2019)

<https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-young-people-mar-2010/>

