PATIENT GROUP DIRECTION (PGD)
STFT PGD : STFT/176/2016

Drug Name: Levonelle 1500 Tablet (Levonorgestrel 1.5mg)	POM

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Clinical Condition	
Indication	Request for Emergency Contraception.
Inclusion criteria	Women aged 14 years and over, and in their reproductive years, presenting within 72 hours of Unprotected sexual intercourse (UPSI) or potential failure of a contraceptive method. Women aged less than 16 years must be assessed and considered to be Fraser competent. All under 18 years must be assessed for Child Sexual Exploitation (CSE) risks. Refer to Appendix 2 of the Specification. Potential failure of contraception includes [1,2]: • Women who have severe diarrhoea and/or vomiting which may have reduced the efficacy of oral contraception (see BNF)[2] • 'Failure to use additional contraceptive precautions when starting hormonal methods of contraception.' [1] • 'Failure to use additional contraceptive precautions (or barrier failure) to Combined Hormonal Contraception (CHC), Progestogen Only Pill (POP), Progestogen only implant, whilst using liver enzyme-inducing drugs or in the 28 days after use, e.g. concomitant use of enzyme-inducing rifamycins (such as rifabutin and rifampicin) and CHC. (EHC is not required when using combined hormonal contraception (CHC) with antibiotics that are not enzyme inducers.) Please see section entitled 'Precautions' for recommended action.' [1] • Non-compliance with dosage regime of hormonal contraceptives. i.e. delayed or missed pills, patches or rings. 'Late injection (>14 weeks since last injection of depo medroxyprogesterone acetate (DMPA) • or >10 weeks since norethisterone enanthate NET-EN) and UPSI during time that extra precautions were required.' [1] • Having reason to believe that a barrier method has failed. • Failed to use an additional barrier method of contraception when current methods have failed or been missed. • Can confirm that their intrauterine contraceptive device (IUCD)/IUS or Subdermal implant has expired, is not present, or displaced. This would indicate that their current method cannot be relied on, and she has not use additional contraception. [1] • Women who are taking oral contraception who have also

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	taken prescribed, or OTC, medication that is known to interact with their oral contraception (producing a reduced effect). • Women aged 14 years and over presenting within 72 hours of unprotected sexual intercourse who have vomited within three hours* of initial dose of Levonelle® 1500 tablet (Levonorgestrel 1.5mg) [1,3], and decline the offer of a Cu-IUD, but are still within the 72 hour window. *Use outside produce license-product license states within 3 hours, this PGD is based on Faculty or Sexual And Reproductive Health (FSRH) and BNF recommendations , and is consistent with good practice recommendations in the UK. Furthermore, following assessment, discussion and informed choice (including provision of information about efficacy, adverse effects, interactions, medical eligibility and contraindications, and additional contraceptive precautions), request ***Levonelle® 1500 tablet (Levonorgestrel 1.5mg)*** as the preferred emergency contraception method. [1]
Exclusion criteria	• UPSI more than 72 hours prior to presentation (***Levonelle® 1500 tablet (Levonorgestrel 1.5mg***) and not taken EHC previously if UPSI has occurred > 120 hours ago • Aged under 14 years • Aged under 16 years and not considered to be Fraser competent • Individuals aged 16 years and over and assessed as not competent to consent using local safeguarding guidelines unless under 18 and an appropriate adult can consent for them. • 'Known hypersensitivity to Levonorgestrel or any excipients contained within the product ***Levonelle® 1500 tablet (Levonorgestrel 1.5mg)***'. [4] • Known or suspected pregnancy. • Unexplained or unusual vaginal bleeding. • Young girls not having gone through menarche. • 'Previous history of ectopic pregnancy or of Salpingitis'. [4] • Taking drugs prescribed, OTC medication, or herbal remedies containing St John's wort [8] that is known to interact with Levonorgestrel or produce toxicity, e.g. possible inhibition of metabolism of cyclosporin producing toxicity. Refer to current BNF for list. • Severe hepatic dysfunction (including acute porphyria) [4] • Severe malabsorption syndromes (e.g. Crohn's disease). [4] • Trophoblastic disease. [4] • 'Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption'. [4] • Individual wishes to see a doctor.

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Cautions/Need for further advice	'All eligible women presenting between 0 and 120 hours of UPSI or within 5 days of expected ovulation should be offered a Cu-IUD because of the low documented failure rate'. [1] If client prefers IUCD, after advice about efficacy, then refer to Contraception & Sexual Health service or GP. However, if appropriate, still offer ***Levonelle® 1500 tablet (Levonorgestrel 1.5mg)*** to client. 'Women taking liver enzyme-inducing drugs (or who have stopped taking this medication within the last 28 days) should be advised that a Cu-IUD is the only method of EC not affected by these drugs.' [1] 'Women taking liver enzyme-inducing drugs, including post-exposure HIV prophylaxis after sexual exposure (or who have stopped within the last 28 days), and who decline or are not eligible for a Cu-IUD, should be advised to take a dose of 3 mg Levonorgestrel (two ***Levonelle® 1500 tablet (Levonorgestrel 1.5mg)***) as soon as possible within 120 hours of UPSI (outside the product licence). The efficacy of LNG after 96 hours is uncertain'. [1,5] Consider risks due to ovulation timing. When there is suspected sexually transmitted infection (STI) refer to Sexual Health Services or their own GP. Advice on Chlamydia screening service for under 25's. Provide information on any appropriate local 'condom supply schemes'. See supporting information file for specific information relating to services available locally. Refer to a GP or the Contraception & Sexual Health service, if medically indicated or at the patient's request.
Action if patient declines or is excluded	Refer to Contraception & Sexual Health service or GP. See supporting information file for specific information relating to services available locally. Document all action taken.

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Drug Details	
Name, form & strength of medicine	Levonelle® 1500 (Levonorgestrel 1.5mg tablet).
Is this product an antimicrobial?	**NO**
Route/Method	Oral
Dosage	**UPSI:** Single tablet (1.5mg) to be taken as soon as possible (provided dose is taken within 72 hours of unprotected sexual intercourse.) **UPSI and taking liver enzyme inducing medication:** If the patient does not want an IUCD inserted, recommended dosage is: Two tablets (3mg) to be taken as soon as possible within 72 hours of unprotected sexual intercourse (Unlicensed dosage). [1,5] See 'Precautions' section above for further information.
Frequency	Single dose (with possibility of second dose if vomiting occurs within 3 hours of first dose, providing that this second dose is still within the 72 hour window). Repeated episodes of UPSI may be treated within one menstrual cycle.
Duration of treatment	One dose
Maximum or minimum treatment period	One dose
Quantity to supply/administer	**UPSI:** One original pack containing one tablet (1.5mg). **UPSI and taking liver enzyme inducing medication:** Two original packs (total of 2 x 1.5mg tablets) See note above; 'Precautions'. POM pack should be supplied. OTC pack should not be supplied.

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Records to be completed	Records should be kept that will demonstrate; • Details of all drugs supplied for audit purposes. • Fraser guidance fulfilled for under 16. • If individual is under 14 years, record of action taken. • If individual is 16 years or over and not competent, action taken. • Evidence of counselling and future contraception needs explored. • Documentation of referral onward or advice sought. Records will be made on standard documentation. See supporting information pack for copies of documentation.

Side effects	**Relevant Warnings:**
	• Failure rate and efficacy.
	• Possible effects on menstrual cycle. Discuss what to do if period does not arrive/or is unusual (see management of adverse drug reactions (ADRs) below.
	• Seeking medical advice promptly if any lower abdominal pain occurs.
	• If taken more than once in a cycle that each subsequent dose would be less effective than the time before and would increase the effect on the menstrual cycle.
	
	Then explain/discuss the potential side effects, and the likelihood of them occurring (see below; adverse effects/reactions.
	
	Potential Adverse Effects/ Reactions:
	• Well tolerated, however common side effects include:
	  ○ Nausea and vomiting
	  ○ Diarrhoea, lower abdominal pain
	  ○ Breast tenderness
	  ○ Headache, Dizziness
	  ○ Menstrual irregularities
	  ○ Fatigue.
	
	Refer to Manufacturers SPC [4] for complete list of side effects and additional details (a copy of the most recent SPC, at the time of development of the PGD is included in the supporting information pack. Be aware that this may have been superseded. Current SPCs can be accessed via the electronic Medicine Compendium: http:///www.medicines.org.uk/emc.

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Advice to patient/carer	• Give patient information leaflet (PIL) and discuss as required. • Reason treatment required. • Mode of action. • Treatment administration. • Side effects and failure rates (as above). • When a pregnancy test is required. • What to do if vomiting occurs within 3 hours. (Advice may differ depending on timing of presentation with respect to 72 hour window). • Effective contraception. • 'After using emergency contraception it is recommended to use a barrier method (e.g. condom, diaphragm or cap) or abstain until the next menstrual period starts. The use of ***Levonelle® 1500 tablet (Levonorgestrel 1.5mg)*** does not contraindicate the continuation of regular hormonal contraception.' [4] • 'Women should be advised that oral EC methods do not provide contraceptive cover for subsequent UPSI and that they will need to use contraception or refrain from sex to avoid further risk of pregnancy.' [1]
Storage	Store in a locked Medicine cupboard (or refrigerator if applicable) as per manufacturers recommendations and Medicine Policy.
Follow up	• Refer to Contraception & Sexual Health service or GP if client experiences a missed or abnormal period. • When there is suspected sexually transmitted infection (STI) refer to Sexual Health services. • Advise on dual STI screening service for under 25's. • And advised any person who has had unprotected sexual intercourse to attend Sexual Health services for a full sexual health screen (testing for chlamydia , GC , HIV and STS) or see their GP. • Provide information on any appropriate local "condom supply schemes" • Provide contraception leaflet • Signpost to local contraceptive services. • Inform client that if there is an abnormal period and/or abdominal pain then they should contact their local sexual health services or see their GP. • See supporting information file for specific information relating to services available locally.

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Staff Characteristics	
Qualifications	Accreditation of pharmacists is conditional on successful completion of assessment (every 3 years) of the following Centre for Pharmacy Postgraduate Education (CPPE) e-learning and assessment packages: • Emergency Contraception • Contraception • Safeguarding Children and Vulnerable Adults. • Completion of a CPPE self-assessment and signed and dated Declaration of Competence (DoC) for community pharmacy emergency contraception services (hosted on www.cppe.ac.uk). This should indicate dates of successful completion of assessment of the above CPPE packages and a copy sent to the Council. The signed DoC must also confirm: • 'Pharmacist must have met or be **actively** working towards the Consultation Skills for Pharmacy Practice: Practice Standards for England, as determined by Health Education England.' [7] • Appropriate training for working under PGDs for supply/administration of medicines has been undertaken. • Competency in the use of PGDs (see NICE competency framework for health professionals using patient group directions). https://www.nice.org.uk/guidance/mpg2/resources • Current registration with the GPhC and date of annual registration. • Date of attendance (at least every 2 years) of a local workshop training session, which will cover local safeguarding arrangements and relevant Integrated Sexual Health Service pathways. Further requirements include: • Each practitioner must sign and date the current PGD and provide a copy of the signature sheet to South Tyneside NHS FT (Sexual Health lead) . Locums should sign the PGD for each shop they work in. STFT via Pharmoutcomes or other method will verify accreditation using the dates specified within the signed DoC statement – Emergency contraception. **Pharmacists must enable Pharmoutcomes to access their CPPE record.**

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	CPPE assessments must be reviewed at least every three years. If any of the CPPE assessment dates are older than 3 years, they will be considered expired and payment will not be made until an updated CPPE assessment and Declaration of Competence is evidenced. Providers must retain copies of their own or employees' certificates of accreditation and training at the premises where they offer the Service. The Provider will be required to comply with General Pharmaceutical Council Standards of Conduct, Ethics and Performance and demonstrate maintenance of knowledge, skills and competencies, with evidence of Continuing Professional Development, ideally via CPD entries on to the General Pharmaceutical Council Website www.uptodate.org.uk/home/welcome.shtml. The Provider shall ensure that each practitioner ensures their skills and knowledge are kept up to date prior to supplying under the PGD. Each pharmacy must have a Standard Operating Procedure in place which covers the supply of *Levonelle® 1500 tablet (Levonorgestrel 1.5mg* via this PGD. The Provider must ensure that supporting pharmacy staff are trained in dealing with patients in a patient-centred, user-friendly, confidential and non-judgmental manner when requesting EHC. Providers are expected to work towards implementing the Department of Health paper 'You're Welcome' Quality Standards. [6]
Specialist competencies or qualifications	• For Pharmacists: - General Pharmaceutical Council (GPhC)
Continuing training & education	Maintenance of knowledge, skills and competencies by engaging in continuing professional development. Each practitioner is accountable for ensuring their skills and knowledge is kept up to date prior to supplying under PGD. • 'Pharmacists are responsible for reassessing their competence to provide this service on an ongoing basis by responding to new guidance, standards and any relevant new learning programmes and assessment. In addition, you should complete the DoC system at least once every **3 years**. This should involve revisiting the self-assessment of

	competencies, reflecting on each competency and identifying personal learning needs to assure self-declaration again at this point. Where changes are introduced to the service, pharmacists will need to update themselves as part of their usual CPD.'

Referral Arrangements and Audit Trail	
Referral arrangements	Contraception & Sexual Health Service or GP See supporting information file for specific information relating to services available locally.
Records/audit trail	
References/Resources and comments	[1] FSRH (2012). Emergency Contraception. https://www.fsrh.org/documents/ceu-emergency-contraception-jan-2012/. *Accessed 15/9/16.* [2] BMA, RPS (2016). British National Formulary. https://www.medicinescomplete.com/mc/bnflegacy/current/PHP4869-combined-hormonal-contraceptives.htm. *Accessed 15/9/16* [3] BMA, RPS (2016). British National Formulary. https://www.medicinescomplete.com/mc/bnflegacy/current/PHP5027-levonelle-1500.htm?q=levonelle&t=search&ss=text&tot=2&p=2#PHP5027-levonelle-1500. *Accessed 15/9/16.* [4] Bayer (2014). SPC. Levonelle 1500 microgram tablet. https://www.medicines.org.uk/emc/medicine/16887. *Accessed 19/9/16.* [5] CEU (2016). CEU Statement: Use of double dose (3mg) levonorgestrel emergency contraception by women taking enzyme-inducing medications. https://www.fsrh.org/news/ceu-statement-use-of-double-dose-3mg-levonorgestrel-emergency/. *Accessed 6/9/16.* [6] DOH (2011). Quality criteria for young people friendly health services. https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-services. *Accessed 21/9/16.* [7] CPPE (2016). Specimen Declaration of Competence for Pharmacy Emergency Contraception Service. https://www.cppe.ac.uk/services/docs/ec_wgll.pdf. *Accessed 21/9/16.* [8] MHRA (2016). Levonorgestrel-containing emergency hormonal contraception: advice on interactions with hepatic enzyme inducers and contraceptive efficacy. https://www.gov.uk/drug-safety-update/levonorgestrel-containing-emergency-hormonal-contraception-advice-on-interactions-with-hepatic-enzyme-inducers-and-contraceptive-efficacy. *Accessed 27/09/16.*

South Tyneside NHS
NHS Foundation Trust

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This patient group direction must be agreed to and signed by all health care professionals involved in its use. The NHS Trust should hold the original signed copy. The PGD must be easily accessible in the clinical setting

Organisation	**SOUTH TYNESIDE NHS FOUNDATION TRUST**
Locality where PGD will be used	**South Tyneside Community Pharmacists**
Expiry Date	**29/09/2019**

PGD Developed by:	
Lead Doctor	Name: Dr Janet Gallagher Position: Lead Associate Specialist Signature: JGallagher Date: 30/9/16
Lead Nurse/Allied Health Professional	Name: Position: NOT APPLICABLE Signature: JGallagher Date: 30/9/16
Lead Pharmacist	Name: Graeme Richardson Position: Chief Pharmacist Signature: Date: 30/09/2016
Consultant Microbiologist (antimicrobials only)	Name: Position: N/A Signature: Date:

Organisational Authorisation	
Medical Director	Name: Dr Shahid Wahid Position: Medical Director Signature: S.WAHID Date: 29/9/16
Director of Nursing	Name: Louise Burn Position: Deputy Director of Nursing & Patient Safety Signature: LBurn Date: 29-9-16

Patient Group Direction Advisory Committee review		
Name	**Position**	**Date**
	PGD Approval Group	**29/09/2016**

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Individual Authorisation

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD. I confirm I have completed the competency training required to operate under this PGD

Name of Professional	Signature	Authorising Manager	Date