North Yorkshire County Council
Health and Adult Services

Patient Group Direction (PGD) for the Supply of

LEVONORGESTREL 1500MCG TABLETS (Levonelle®) as Hormonal Emergency Contraception (EHC)

by Registered & Accredited Pharmacists to Individuals Accessing the NYCC EHC Service from Commissioned Community Pharmacies within North Yorkshire County Council (NYCC)

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

Direction Number: - **NYCC 2019/CP05**
Valid from: 1st August 2019
Review date: 1st May 2021
Expiry date: 30th September 2021

This patient group direction has been developed & produced by: -			
Title	Name	Signature	Date
Medicines Optimisation Pharmacist (Lead Author) (North of England Commissioning Support)	**Hira Singh** *(Senior Pharmacist)*		03/06/19
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Development also includes contribution from:
Alison Chorlton (YorSexualHealth Lead Nurse)
Emma Davis (Health Improvement Manager, NYCC)

This PGD has been approved for use in North Yorkshire County Council by:			
Title	Name	Signature	Date
Director of Public Health (North Yorkshire County Council Public Health)	**Dr Lincoln Sargeant** *(Authorising body Governance Authorisation)*		19/07/19

1. Clinical Condition or Situation to Which the Direction Applies

Indication (defines situation or condition)

- Female patients at risk of unwanted pregnancy requesting emergency hormonal contraception (EHC) within 72 hours of unprotected sexual intercourse (UPSI) or failed contraceptive method since last menstrual period

Objectives of care

- To prevent pregnancy (**NB. Advance supply is not included in this PGD)**

Inclusion criteria

(Only use those criteria that are specific to your authorised role & competence. Ensure appropriate consent has been obtained or a best interest decision is in place before commencing any supply).

Competent women aged 13-24 years old requesting EHC and one or more of the following criteria apply: -

1. Present within 72hrs of UPSI or potential failure of a contraceptive method listed in Table 1 and the client is either
   - aged 16 to 24 years (assess formerly if competence in doubt) **or**
   - aged 13, 14 or 15 years and considered to be Fraser competent by satisfying the assessment within the Fraser Guidance (see Appendix 1).

   Table 1- Possible failure of contraceptive methods include [1,2]:
   - Potential barrier method failure
   - Missed/delayed/failed combined contraceptive pill (COC)/patch or progesterone only pill (POP)- refer to missed pill guidance (appendix 2) and FSRH guidance
   - Late injection (>14 weeks since last injection of depo medroxyprogesterone acetate (DMPA) or >10 weeks since depo norethisterone enanthate (NET-EN) and UPSI during time that extra precautions were required.[1])
   - Severe gastrointestinal upset that may have affected contraceptive efficacy (see current BNF), including vomiting within 3 hours of taking a levonorgestrel EHC preparation [2]
   - Risk of conception whilst advised to avoid pregnancy, such as following administration of cytotoxic agents or potentially teratogenic drugs.
   - Failure to use additional contraceptive precautions when starting hormonal methods of contraception.[1]
   - Women who are taking oral contraception who have also taken prescribed, or OTC medication that is known to interact with their oral contraception (producing a reduced effect).
   - 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 CHC with antibiotics that are not enzyme inducers. Please also see section entitled 'Precautions' for recommended action.' [1]
   - 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 is not present, displaced, or expelled or subdermal implant has expired. [1] This would indicate that their current method cannot be relied on, and client has not used additional contraception.
2. Those who have vomited within 3 hours of taking Levonorgestrel Emergency Contraceptive pill (LNG-EC) & decline the offer of a Cu-IUD, providing the new dose is still within 72hrs of the UPSI that the previous dose was given for.
3. The client's medical history indicates prophylaxis is appropriate, (i.e. following assessment, discussion and informed choice (including provision of information about efficacy, adverse effects, interactions, medical eligibility and contraindications, and additional contraceptive precautions), they request Levonorgestrel 1500mcg as the preferred emergency contraception method [1]).

Inclusion criteria - continued

4. Is presenting within 72hours of UPSI and there has been an earlier episode of UPSI ≥120hours ago in the same menstrual cycle, whether oral EC was given or not. If the previous UPSI was > 21 days ago and the woman has had no period, there must be a negative pregnancy test i.e. pregnancy excluded before considering EC (refer to patient advice section **)
5. Women choosing to be referred for a Cu-IUD, where LNG-EC is clinically suitable and supply is not contra-indicated or excluded for reasons listed in the exclusion criteria.
6. Post-natal clients presenting within 72hours of UPSI and who are more than 21 days after delivery.

For further guidance on inclusion criteria see Patient advice section and Appendix 2

(Refer to the FRSH Emergency Contraception March 2017 guidelines for additional information).

Exclusion criteria (please also refer to current SPC and latest BNF)

Clients fulfilling one or more of the following criteria are excluded from supply under this PGD: -

- No valid consent /best interest decision in place;
- Where consumption of the dose would be over 72 hours since this episode of UPSI;
- The client is not present. (No third party supplies are permissible);
- Females aged 12 years and under or females aged 25 years or over;
- Female not satisfying the pharmacist's assessment for Fraser Competence (see Appendix 1);
- Where two previous episodes of UPSI have already been treated with a supply of LNG or UPA within this cycle;
- Relevant medical history is not provided by the client;
- A menstrual bleed is overdue;
- Post-natal clients presenting within 21 days after giving birth (USPI 21 days after delivery can lead to pregnancy);
- No menstrual period within the last 24 months;
- Known pregnancy or possibility of pregnancy i.e. last period absent, a current or recent positive pregnancy test**;
- Last menstrual bleed (period) in any way abnormal (different character, length or flow)**;
- Severe Liver disease;
- Any condition causing severe malabsorption e.g. Crohn's Disease[1];
- Patients who are currently experiencing severe diarrhoea &/or vomiting;
- If a further UPSI occurs within 12 hours of a dose of LNG, (further EHC treatment is not required);
- Where the consumption of LNG-EC would be within 5 days of a dose of Ulipristal (EllaOne) EHC;
- Patients who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy)[4];
- Is taking herbal remedies containing St John's Wort [8] or significantly interacting drugs or has done so in the last four weeks. See current BNF for full list of interacting drugs. **Also see cautions regarding enzyme inducing drugs;**
- Galactose intolerance, Lapp lactase deficiency or glucose galactose malabsorption;
- Any contraindication to levonorgestrel (Levonelle® 1500) **(see manufacturer's Levonelle 1500 SPC);**
- Known hypersensitivity to any ingredient, component or excipient of the tablet (refer to SPC);

Refer to current Summary of Product Characteristics (SPC) / BNF (current on-line version)/ latest BNF for full list of details

Cautions/Precautions

- There is an increased risk of pregnancy within the 5 days prior to ovulation and also, levonorgestrel efficacy may be reduced around the time of ovulation, increasing the risk of pregnancy. If this applies, consider referral for Cu-IUD or ulipristal (EllaOne) supply under Ulipristal PGD.
- Where the client is taking liver enzyme inducing drugs (e.g. carbamazepine, rifampicin, griseofulvin) for full details refer to BNF or SPC), they should be referred to YORSexualHealth https://yorsexualhealth.org.uk/ for Cu-IUD as the most effective method. Whether or not the patient accepts this offer, then the dose of LNG may be doubled to two tablets (3mg) taken as a single dose in line with BNF guidance (note that this is an unlicensed dose and clients should be advised accordingly). [1,5]
- **Breast feeding** – levonorgestrel (LNG) EHC is not known to be harmful, but potential exposure can be reduced if the woman takes the tablet immediately after feeding and avoids feeding for a further 8hrs (FSRH, page 19, section 12.3).
- Consider child protection issues in females aged 13-17yrs and any safeguarding issues in those aged 18 years and over.
- **Suspected pregnancy** – Levonorgestrel can still be given as there is no evidence that it is harmful in pregnancy.
- EC is indicated if there is UPSI or barrier failure during, or in the 28 days following use of liver enzyme-inducing drugs. Offer a Cu-IUD (unaffected by liver enzyme-inducing drugs) or a double dose (3 mg) of LNG-EC. UPA-EC is not recommended in this situation.
- Consider risks due to ovulation timing.
- When there is suspected sexually transmitted infection (STI), refer to YORSexualHealth services or their own GP.

Action if excluded

- If consumption of the dose would be beyond 72 hours since this episode of UPSI, refer to decision tree / consider supply of EllaOne (Ulipristal) under PGD
- If excluded for any other reason, refer to YorSexualHealth (family planning), GP or A&E immediately if emergency contraception considered necessary
- Ensure all actions/decisions are documented. If treatment is refused, this must be recorded on PharmOutcomes.

Circumstances in which further advice should be sought from a doctor and/or specialist

- Refer to the YORSexualHealth services or to GP if medically indicated or at the patient's request.
- If concerns identified regarding safeguarding issues follow local policy & contact safeguarding team for referral support.

Action if patient declines treatment

- Provide appropriate advice and refer to YORSexualHealth or GP.
- Record the refusal in the clinical record and document all other actions taken.

2. Description of treatment

Name, strength & formulation of drug

Levonorgestrel 1500mcg tablet (as Levonelle® 1500 manufactured by Bayer PLC)

Legal Status and Storage requirements:

POM – Prescription Only Medicine / **STORAGE**: Do not store above 25°C

Dosage /Dose range

1 x 1500mcg tablet:
Highest efficacy is achieved if the tablet is taken as soon as possible (no later than 72 hours) after UPSI.

For UPSI and taking enzyme inducing drugs or have taken these in the last 28 days (see also drug interactions) the standard dose may be doubled.
2 x 1500mcg tablets (3mg) taken as a single dose.
(This is an un-licensed dose but is recommended by the FSRH and is in line with the BNF. The client should be advised accordingly).

For women who have a BMI > 26kg/m^2 or weight >70kg
2 x 1500mcg tablets (3mg) taken as a single dose.
(This dose is un-licensed but is recommended by the FSRH (2017 guidance)).

Route/Method

Oral administration only

Frequency of Administration

One single treatment dose. The client should usually take the medicine whilst at the pharmacy.

- Repeated episodes of UPSI may be treated within one menstrual cycle (Maximum 2 separate episodes of UPSI in same cycle)

Maximum dose & number of treatments

Max. single treatment dose: -	**1 x 1500mcg tablet** or 2x1500mcg (3mg):- For those taking enzyme inducing drugs (see BNF/drug Interactions) **or** For those women who have a BMI > 26kg/m^2 or weight > 70kg
Maximum no. of treatments: -	Two separate episodes of UPSI within the same cycle. (See Frequency of Administration section above) (NB. LNG may be used more than once in a cycle even if there has been an earlier episode of UPSI outside the treatment window more than 72hours [1]).

Follow up treatment/action

- **A pregnancy test is recommended at three weeks' following EHC provision**
- When there is suspected STI, signpost to YorSexualHealth testing services if appropriate.
- Offer free condoms and chlamydia testing kit as defined in the service specification.
- 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.
- Advise 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.
- Record keeping – see section below.

Labelling

The packaging should be labelled in the manner of any prescribed medication and contain a manufacturer's patient information leaflet. Pre-printed labels should allow the client's name and date of dispensing to be added.

3. Further Aspects of Treatment

Drug Interactions (Please also refer to current BNF and manufacturers SPC for full details)

- The effectiveness of LNG is reduced in women taking enzyme-inducing drugs and for up to 4 weeks after stopping.
- Examples of enzyme inducing drugs include carbamazepine, griseofulvin, modafinil, nelfinavir, nevirapine, oxcarbazepine, phenytoin, phenobarbitone, primidone, ritonavir, St John's Wort, topiramate, rifampicin and rifabutin, ritonavir, but please refer to the current BNF Appendix 1 for a full list of drug interactions.

Women seeking EC who have used cytochrome P450 3A4 (CYP3A4) enzyme inducers (see below) within the last 4 weeks, should: -

- preferably use a non-hormonal emergency contraceptive - i.e., a copper intrauterine device
- if this is not an option, double the usual dose of levonorgestrel from 1.5 milligrams to 3 milligrams (i.e. 2 packs)

For these women:

- provide advice on highly effective ongoing contraception that is not affected by hepatic enzyme-inducing drugs (see guidance from the Faculty of Sexual and Reproductive Health: "Drug Interactions with Hormonal Contraception")
- advise them to have a pregnancy test to exclude pregnancy after use of levonorgestrel-containing emergency contraception
- advise them to seek prompt medical advice if they do become pregnant

Relevant Warnings & Potential Adverse Effects

Relevant Warnings: - (List not exhaustive. See also latest manufacturers SPC for full details & current BNF)

- Failure rate and efficacy. The risk of pregnancy is highest after UPSI that takes place during the 5 days leading up to and including the day of ovulation. Insertion of a Cu-IUD within 5 days of the earliest estimated date of ovulation is the only method of EC that is effective after ovulation has taken place.
- 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.
- Then explain/discuss the potential side effects, and the likelihood of them occurring (see below; adverse effects/reactions

Potential Adverse Effects/ Reactions: - (List not exhaustive. See also manufacturers SPC for full details & current BNF)

Well tolerated, however common side effects that some clients may experience include:

- **Nausea** – advise medication to be taken with food.
- **Vomiting** – provide clients with clear instructions for obtaining an extra tablet if vomiting occurs within 3hrs of dose being taken.
- **Other adverse reactions** include: breast tenderness, lower abdominal pain, headaches, dizziness, diarrhoea and fatigue. Bleeding patterns may be temporarily disturbed e.g. bleeding, spotting, delayed or early next period.

Use the yellow card system to report adverse drug reactions directly to the MHRA **(see BNF)**

Identification and Management of Adverse Drug Reactions

- Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected date. If the next menstrual period is more than 5 days overdue, pregnancy should be excluded. [4]

In the event of untoward or unexpected adverse reactions:

- If necessary seek appropriate emergency advice and assistance.
- Document in the Patient Record and inform GP. Complete local organisational incident procedure if appropriate.

Reporting Procedure of Adverse Effects

- See manufacturers Summary of Product Characteristics for details of all potential adverse reactions.
- Client to report any suspected ADRs believed to be associated with Levonelle® 1500 tablet (Levonorgestrel 1.5mg) to a Healthcare Professional (HCP) or directly using the Yellow Card system. NB. Clients and HCPs can log ADRs directly via the MHRA website (http://yellowcard.mhra.gov.uk/) or call free-phone 0808 100 3352 (10am to 2pm Monday-Friday only).

Advice to Patient (verbal or written)

Advice to all clients:

- Give advice on the options for emergency contraception (EC) as per the decision tree. Provide information and advice on LNG-EC, UPA-EC and the Cu-IUD to allow the client to make an informed choice regarding treatment (see decision tree). Advise client that the Cu-IUD is the most effective form of EC.
- Advise client to discuss sexual health matters & contraception with a suitable health care professional at their GP surgery or YorSexualHealth (leaflets available).
- Standard contraceptive methods are the first line in contraception. EC should only be used in emergencies. Whilst repeated doses of LNG can be given in 1 cycle, there is a risk of interruption of the menstrual cycle, hence repeated courses of EHC are not the best form of contraception.
- ** Advise that if they have had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with LNG-EC following the second act of intercourse may therefore be ineffective in preventing pregnancy. If menstrual periods are delayed by more than 5 days or abnormal bleeding has occurred at the expected date of menstrual period, or pregnancy is suspected for any other reason, pregnancy should be excluded.

Also, the patient must be given advice on:

- **Mode of action** - LNG-EC inhibits ovulation for the next 5 days until sperm from that episode of UPSI are no longer viable
- **Failure rate** - Research suggests LNG-EC prevents about 85% of expected pregnancies when tablet taken within 72hrs of UPSI.
  - LNG-EC is not effective when administered after ovulation.
- **Side effects** - Provide advice regarding vomiting or severe diarrhoea within 3 hours of taking the tablets.
- **Possible effects on foetus** - Limited data indicates no adverse effects but every pregnancy has a chance of foetal abnormality.
- **Risk of ectopic pregnancy** - Evidence is limited, but no evidence of adverse pregnancy outcomes or fetal abnormality, but every pregnancy has a chance of foetal abnormality. If LNG-EC has been taken in a cycle in which pregnancy is conceived, it should be reported to www.hra-pregnanct-registry.com. Inform patient to seek prompt medical advice if any abdominal pain occurs. NB. The rate of ectopic pregnancy when LNG EHC failed did not exceed that of the general population
- **Breast-feeding** – the drug does pass into breast milk but is not thought to be harmful. Exposure of infant to LNG can be reduced if the woman takes the tablet immediately after feeding and avoids nursing for at least 8hrs. The patient may express and discard for the next 8 hours if they wish. (See SPC and FSRH March 2017 Emergency Contraception guidance for more information)
- **Dose** - The dose should be taken under the supervision of the pharmacist.
- **Follow-up** – advise a pregnancy test 3 weeks after taking LNG-EC.
- **Contraception for the remainder of cycle** - Advise the client regarding abstaining from sexual intercourse or the use of barrier methods of contraception correctly and consistently until next period. EC does NOT provide contraceptive cover for the remainder of this menstrual cycle. Clients using oral contraceptives should restart their usual pill within 12hrs of talking Levonelle® 1500mcg.

  For women requiring emergency contraception because of missed pills, please refer to advice in Appendix 2.
- **Future contraception** – condoms are recommended until the start of the next menstrual cycle and for at least 2 weeks. There is no need to stop taking regular oral hormonal contraception (see Appendix 2 or 3). Discuss the need for reliable contraception for the future if necessary. After oral EC there is a pregnancy risk if there is a further UPSI & ovulation occurs later in the same cycle.
- **Risk of STI** - EHC does not replace necessary precautions against STIs. Advise screen for STI's after UPSI
- **Drug Interactions**: See patient advice in drug interaction section.
- **Informing the GP** - Request the client's permission to inform their GP that a supply of EHC has/has not been made.
- Explain the "**Out of Hours**" procedure.

Arrangements for Referral to Medical Advice

- Refer to YorSexualHealthservice as appropriate

Records

All details to be recorded on PharmOutcomes as detailed in the on line tool and be retained according to local, legal and professional obligations.

Records should be kept that will demonstrate;

- Confirmation that consent has been obtained;
- Details of all drugs, batch number; dose supplied and date administered for audit purposes.
- Confirmation that there are no contraindications; That side effects have been discussed; Support literature given (if applicable);
- Fraser guidance fulfilled for under 16; If not Fraser competent record action taken including safeguarding input;
- 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.

Additional Facilities

- Access to the current PGD and updated FSRH Emergency Contraception Guideline (March 2017);
- Access to the latest SPC and BNF.

Safeguarding Children & Adults

All staff should discuss any concerns that may undermine the safety of a vulnerable young person, including sexually active young people. Advice for Healthcare Professionals can be obtained by following the professional and training links through: www.safeguardingchildren.co.uk

To report or discuss a safeguarding concern please contact NYCC Customer Contact Centre on 01609 780780
For adults the email is Social.care@northyorks.gov.uk (Out of hours number for emergency duty team is 01609 780780)
For children the email is children&families@northyorks.gov.uk

In an emergency, contact North Yorkshire Police on 999

Multi-agency Safeguarding Children Procedures (including referrals forms and details of referral pathway) can be found at: www.safeguardingchildren.co.uk

References

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6. CPPE (2017). Specimen Declaration of Competence for Pharmacy Emergency Contraception Service. Version 18 (May 2017) https://www.cppe.ac.uk/services/docs/ec_wgll.pdf. Accessed 02/05/19.
7. 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 on 02/05/19.
8. NICE Good Practice Guidance 02 : Patient Group Directions Aug 2013
9. FSRH (April 2017). Quick Starting Contraception. https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/ Accessed on 03/05/19
10. Glasier AF, Cameron ST, Fine PM, *et al*. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. *Lancet* 2010; **375**:555–562.
11. FSRH (April 2019). Clinical Guideline - Overweight, Obesity and Contraception. Available at https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/contraception-for-specific-populations/overweight-and-obesity

4. Characteristics of Healthcare Professional using this PGD

Only those pharmacists that have been specifically authorised by their clinical lead/ supervisor/manager or by self-declaration may use this PGD for the indications defined within it. You may only supply or administer medicines under a PGD as named individuals.

Qualification/registration requirements

Currently registered with the General Pharmaceutical Council (GPhC) of Great Britain

Additional requirements (applies to all staff)

- 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
- Pharmacist with appropriate underpinning knowledge to competently undertake the clinical assessment of patients leading to treatment according to the indications listed in this PGD.
- Meet the workforce provision of EHC requirements as set out in the NYCC Service Specification for the "Targeted Primary Care Sexual Health Service Provided in Community Pharmacies."
- Pharmacists to complete their Declaration of Competence (DOC) Certificate for EHC and any required training as part of the DOC as defined by the CPPE. Pharmacists should register their DOC on the CPPE website (https://www.cppe.ac.uk/services/declaration-of-competence).
- Each pharmacist delivering the service on behalf of the Provider must complete their DOC Certificate for EHC before they can provide this Service (a three month grace period is in place). The DOC must be renewed every three years. The Provider must inform the commissioner when this DOC has been completed and when subsequent re-accreditation has been completed. This should be done by enabling the CPPE viewer facility via the *Profile* section of the *My CPPE* page to allow access by the Commissioner
- To attend a one off face to face training event provided by YorSexual Health that will cover cover the local PGDs, Chlamydia screening, condom distribution, other sexual health services available locally and safeguarding. Pharmacists employed by the Provider will attend a further training event if they, YorSexual Health or the Commissioner feel this would be useful to refresh knowledge.
- Accredited pharmacists will retain all training documentation.
- To have access to PharmOutcomes. Pharmacists must enable PharmOutcomes to access their CPPE record.
- The pharmacist must ensure that the pharmacy they are working in is an approved provider of EHC provision under PGD before making any supply under this PGD.
- By signing up to this PGD, the pharmacist accepts personal responsibility for working under it, understands the legal implications of doing so, and works within the scope of the PGD.
- It is the responsibility of the pharmacist to ensure that they have appropriate up to date knowledge of the medicine prior to its supply and to maintain this knowledge and keep up to date with relevant developments
- The Provider will be required to comply with GPhC 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.
- Each pharmacy must have a Standard Operating Procedure in place which covers the supply of Levonelle® 1500 tablets 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. [5]
- Medicine counter staff must be trained to refer requests for EHC to the pharmacist or a suitable alternative provider if the pharmacist is not present.
- The pharmacist is required to maintain own level of updating and competence with evidence of continued professional development and adhere continued training requirements as deemed necessary by your organisation or the authorising body. (NB. If not already trained, pharmacists are encouraged to undertake the FSRH's online course on conducting a contraceptive choices consultation, available at https://www.fsrh.org/education-and-training/fsrh-contraceptive-counselling-online-course/).

Individual Healthcare Professional Authorisation

This form can be used for the purpose of managing, monitoring and authorising the use of this Patient Group Direction by the named accredited pharmacist.

- **This page is to be retained by the individual healthcare professional/practitioner.**
- This PGD is to be read, agreed to and signed by the registered Healthcare Professional it applies to. Healthcare Professionals must be authorised by the person(s) named below before using the PGD. Pharmacists who do not have a clinical lead available to authorise them, will be required to authorise themselves, i.e. have the relevant Declaration of Competence in place.
- By signing this document, the pharmacist confirms that they understand the PGD, that they are competent to work under this PGD, that they will practice in accordance with the parameters of the PGD and accept full clinical responsibility for any decisions made with using this PGD).
- Patient Group Directions should be used in conjunction with reference to national or local policies, guidelines or standard text (e.g. manufacturers Summary of Product Characteristics) and DO NOT replace the need to refer to such sources.

Agreement by Pharmacist

I _____ (name of healthcare professional), consider that I am competent to supply oral emergency hormonal contraception (Levonorgestrel 1500mcg). I have completed the appropriate training, as recognised by NYCC, which will allow me to provide this service for up to **three years** from the date of the last NYCC accredited training session I attended.

I have read and understood the Patient Group Direction

Levonorgestrel 1500mcg tablet (Levonelle®1500) – Direction number: NYCC 2019/CP05

I agree to supply Levonorgestrel 1500mcg tablet(s) (Levonelle® 1500) in accordance with this PGD (NYCC 2019/CP05). I will maintain clinical records as defined by the PGD, PharmOutcomes and in line with recognised governance standards.

Signature of Healthcare Professional: - _____

Date signed: _____ GPhC Registration no.:_____

Full address: ……
……
……

Authorisation from Clinical Lead to use this PGD (where available/appropriate)**: -**

I agree that the above named healthcare professional is authorised to administer medicines in accordance with this PGD by:

Name of Clinical Lead: _____

Signature of Clinical Lead: _____ Date signed: _____

PGD Valid from: 1st August 2019	Review Date: - May 2021	**Expiry Date: - 30th September 2021**

APPENDIX 1

FRASER GUIDANCE (formerly known as GILLICK COMPETENCE)

In circumstances when it is believed that a client may be less than 16 years of age, the healthcare professional operating under this PGD will assess the client's 'Fraser Ruling' (formerly known as 'Gillick Competence'). Contraceptive advice and treatment can be offered to young people less than 16 years without parental consent provided that the health professional explored the following issues and has confirmed that the young person is able to meet all the Fraser criteria below.
The following protocol should be used to support explorative discussion with the client and to act as a record and assessment tool for the client's maturity.

Is the healthcare professional satisfied that:	**YES**	**NO**
The client understands the advice given?		
The client has been encouraged to involve her own parents or carers?		
You have adequately considered the possible effect on the physical or mental health of the young person should the advice or treatment to be withheld?		
The action is in the best interest of the young person?		

If the answer to any of these questions is no, then the patient is not Fraser competent and administration/supply must not be made.

The Sexual Offences legislation does not affect the duty of care and confidentiality of health professionals to young people under 16. Health professionals are not liable to prosecution when they are acting to protect a child or young person, for example, when providing contraception or sexual health advice to a child under 16. The right to confidential advice on contraception extends to all young people, including those under 13, but the duty of confidentiality is not absolute and the younger the person, the greater the concern should be about the possible existence of abuse or exploitation.

Comments by the Healthcare Professional operating under this PGD:
(if no comment than write ***'no comment'***)

Client's name: ……....

Client's signature: …… Date: ……

Healthcare Professional's name: ……

Health Professional's signature: …… Date: ……

APPENDIX 2 -

ADVICE for PROFESSIONALS SUPPLYING ORAL EMERGENCY HORMONAL CONTRACEPTION
(levonorgestrel 1500micrograms (Levonelle 1500))

Failure rate
Levonelle-1500® does not have as high a success rate as established methods of regular contraception, e.g. the pill or barrier methods, therefore the patient should not expect a 100% success rate. Levonelle-1500® prevents about 85% of expected pregnancies when the tablet is taken within 72 hours (3 days) of UPSI.

- The overall pregnancy rate amongst woman taking LNG-EC within 72hours of UPSI is about 0.6-2.6%. (p13.FSRH)
- LNG-EC effectively delays ovulation when taken before the beginning of the LH surge, but not thereafter, so has implications for choice of oral EC when a woman is likely to be close to ovulation. (Page 13. FSRH EC Guidance (2017)).
- There is an increase in pregnancy rates after taking LNG-EC in woman weighing >70kg or BMI>26kg/m^2, so a double dose of LNG-EC is recommended in these individuals.

Verbal advice on nausea and vomiting
The patient must be advised that the tablet may cause nausea and vomiting. If vomiting occurs within three hours of taking the dose, further advice must be sought immediately from a health professional. Taking with or after food can sometimes reduce side effects.

Guidance for a lost or vomited tablet: If the tablet has been lost, a further tablet may be supplied if this is considered appropriate. If the tablet is vomited within 3 hours of ingestion, the dose may be repeated provided that the dose is still within 72 hours of the first unprotected intercourse of that cycle. Anti-emetics may be advised. If the new dose would be later than 72 hours after the first unprotected intercourse of that cycle, referral for an IUCD may be indicated and the tablet should not be issued.

Supplementary Patient Information
The following advice leaflets are available for the patient:

- Manufacturer's patient information leaflet - essential
- Leaflet on methods of contraception and websites www.brook.org.uk and www.fpa.org.uk - advisable
- Leaflet on local sexual health services (YorSexualHealth) - advisable
- Leaflet on Out of Hours services - advisable

Follow-up Advice
Menstrual periods - If menstrual periods are delayed by more than 7 days or abnormal bleeding occurs or pregnancy is suspected the possibility of pregnancy should be considered.

Abnormal abdominal pain or heavy bleeding should be referred.

Ectopic pregnancy can occur should the prophylaxis fail. No difference to background risk. Seek pregnancy test if pregnancy suspected.

Foetal effects – There is no evidence that this method of contraception has any teratogenic effects (were conception to take place), however, pregnancy has a high overall chance of foetal abnormality (1 in 50).

Effective contraception - A visit to a GP or clinic about three weeks after completing a course of oral EHC should be recommended if there are any concerns of a possible pregnancy. It may be advisable for the client to seek advice earlier about ongoing contraception.

Adverse Drug Reporting (ADRs)
All ADRs, even if it is well recognised, should be reported using the CSM Yellow Card Scheme, either by a doctor, pharmacist or nurse. For supporting information see British National Formulary (BNF), which also contains yellow reporting cards. The client may need to be referred to their doctor.

Contraception
Emergency contraceptives are less effective than established regular contraceptive methods (e.g. pill or barrier methods) and should not be used as an alternative to regular contraception.
The requirement for emergency contraception (EC) should be assessed if there has been recent UPSI. If EC is indicated, the copper intrauterine device (Cu-IUD) should be considered first, as it is the most effective method of EC and provides ongoing contraception.

- After LNG-EC administration, CHC, POP, IMP (and DMPA) can be quick started immediately.
- After taking oral EC there is still a pregnancy risk if there is a further UPSI and ovulation occurs later in the same cycle.
- Additional contraceptive precautions (barrier or abstinence) are required until the quick started contraceptive method becomes effective.

- If a woman and her EC provider estimate that UPSI is unlikely to have occurred during her fertile period, she may consider the option of using LNG-EC with immediate start of hormonal contraception rather than UPA-EC with delayed start of hormonal contraception

Practising Safer Sex
Neither EHC nor oral contraceptive pills provide protection against sexually transmitted infections.

Audit trail
The health professional must keep a record of the consultation and outcome **(PharmOutcomes)** for an agreed period according to local, legal and professional obligations. It is also recommended that computerised patient medication records be kept where possible.

Informing the Patient's GP
It is not essential that the supply of oEHC is reported to the patient's GP, but the patient should be encouraged to give permission to inform her own GP of this supply **(see Appendix 4)**.

Missed Pills OR Accidental Lengthening of the Pill Free Interval
Women who do not wish to conceive should be offered EC after UPSI if their regular contraception has been compromised or has been used incorrectly. (Please also refer to section 4.3 of 2017 FSRH EC Guidelines)

a) Combined oral contraceptive pills (COC).
The critical time for loss of contraceptive protection is when a pill is omitted at the beginning or end of a cycle (which lengthens the pill-free interval).

If a woman forgets to take a pill, it should be taken as soon as she remembers, and the next one taken at the normal time (even if this means taking 2 pills together). If a woman misses only one pill, she should take an active pill as soon as she remembers and then resume normal pill-taking. No additional precautions are necessary.

If a woman misses 2 or more pills (especially from the first or last 7 in a packet), she may not be protected. She should take an active pill as soon as she remembers and then resume normal pill-taking. In addition, she must either abstain from sex or use an additional method of contraception such as a condom for the next 7 days. If these 7 days run beyond the end of the packet, the next packet should be started at once, omitting the pill-free interval (or, in the case of everyday (ED) pills, omitting the 7 inactive tablets).

Emergency contraception is recommended if 2 or more combined oral contraceptive tablets are missed from the first 7 tablets in a packet (i.e. in Week 1) **and there has been an UPSI or barrier failure during the pill-free interval or Week 1. Note Qlaira – missed pill that is 12 hours or more late: please refer to product literature. http://www.medicines.org.uk/emc/searchresults.aspx?term=qlaira&searchtype=QuickSearch**

In applying the 'missed pill rules', clinicians must remember that there comes a point when a woman has missed so many pills that she must be viewed as having stopped taking the pill. The Faculty of Sexual and Reproductive Healthcare considers that if a woman has missed more than seven consecutive pills, then she has stopped using COC, and the 'missed pill rules' cannot be applied.

CHC containing cyproterone acetate should not be quick started unless pregnancy can be reasonably excluded. Note: The Faculty of Sexual and Reproductive Healthcare (FSRH) offers updated advice for what EC is indicated following potential failure of hormonal and intrauterine methods of contraception (see Table1 page 5 of FSRH guidance: https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/).

b) Oral progestogen only contraceptive pills
The following advice is now recommended by the FSRH: -

- If you forget a pill, the missed pill should be taken as soon as remembered.
- If more than one pill has been missed, only one pill should be taken.
- The next pill should be taken at the usual time. This may mean that two pills are taken in 1 day.
- If the pill was more than 3 hours (12 hours for Cerazette®) overdue you are not protected.
- Continue normal pill-taking, but you must also use additional contraceptive precautions (condoms or avoidance of sex) for 2 days (48 hours) after restarting the POP.
- Emergency contraception is indicated if one or more progestogen-only contraceptive tablets are missed or taken more than 3 hours (12 hours for *Cerazette*®) late and UPSI has occurred within 48hours of restarting the POP, i.e. before 2 further tablets have been correctly taken – see link https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-pop-mar-2015/

c) Delayed application or detached patch

If a patch is partly detached for less than 24 hours, reapply to the same site or replace with a new patch immediately; no additional contraception is needed and the next patch should be applied on the usual 'change day'. If the patch remains detached for more than 24 hours or if the user is not aware when the patch became detached , then stop the current contraceptive cycle and start a new cycle by applying a new patch, giving a new 'day 1', an additional non-hormonal contraceptive must be used concurrently for the next 7 days of the new cycle.

EC is indicated if patch detachment occurs in Week 1 and there has been UPSI or barrier failure during the hormone-free interval (HFI) or Week 1. (See link https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/)

d) The Effect of Weight/BMI on the Effectiveness of EC

The effectiveness of LNG-EC could be reduced if a woman has a BMI >25 kg/m2 or weight >70 kg. It is recommended that either UPA-EC or a double dose (3 mg) of LNG-EC is given in this situation. It is unknown which is more effective.

APPENDIX 3 – Template Letter

PRIVATE AND CONFIDENTIAL

Date: *Pharmacy stamp:*

Dear Dr . . . . . .

Re: Client's name . . . . . .

Client's date of birth . . . . . .

Client's address . . . . . .

. . . . . .

. . . . . .

A. I am writing to inform you that the above patient was supplied with a course of levonorgestrel emergency hormonal contraception on ……..

B. I am writing to inform you that the above patient requested a course of levonorgestrel emergency hormonal contraception on ……. I was unable to supply the medication because

……

……

……

……
and I would therefore be grateful if you could see this patient as soon as possible.

Yours sincerely

Signed……

Name……..

GPhC Registration number…….... …….