# Document Control

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| **Title: Protocol for the provision of Emergency Hormonal Contraception by community pharmacists in the Devon County Council (DCC) and Torbay Council areas** |
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| 1 | July 2018 | Original | Approved DTC - July 2018 |
| 2 | August 2018 |  | Substitution of ‘Roaccutane’ with ‘isotretinoin’ –to reflect the fact that Roaccutane is not the only brand of isotretinoin available (page 6). |
|  |  |  | Removal of the line: ‘If emergency contraception is supplied, then the pharmacist and individual should sign only when the pharmacist is confident that the person understands the information given’ (page 7) (only electronic records are kept). |
| 3445 | August 2018April 2021April 2021June 2024 | Final | Removal of the sentence ‘concomitant use of drugs that increase gastric PH’, from list of contraindications to UPA (page 10)Removal of the wording severe liver disease, breast cancer, or malabsorption syndromes- as examples of medical conditions (last paragraph on page 10).Updated contact names and email addressesAdditional explanation of oral EC efficacyValproate pregnancy prevention programme citedAdditional comments advising referral for onward contraceptionAddition of reference to Lapp lactase deficiency in ‘History’ medical history.Approved at Devon Sexual Health Governance 21/04/2021Contact details for clinics and condom provider updated.Update to section regarding medical history and intolerances.Inclusion of medroxyprogesterone acetate, subdermal implant and levonorgestrel intrauterine device within persons usual method of contraception.Efficacy of levonorgestrel emergency contraception updated. |
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2. Ulipristal Acetate PGD
3. Protocol for the provision of Emergency Hormonal Contraception
4. Public Health Service specification for the provision of Emergency Hormonal Contraception
 |
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# Purpose

The purpose of this document is to detail the process for the management of and the provision of emergency contraception (EC) via PGD to a person aged 13- 24 years old who attends a community pharmacy requesting EC

# Presenting/Complaint

The person requests EC following an episode of unprotected sex or concern that their contraceptive method may have failed.

# History

The need for EC should be assessed as per flow chart- appendix A.

Exclude current pregnancy.

Exclude delivery of a baby within the last 21 days.

Ascertain:

**The person’s usual method of contraception**. Avoid use of Ulipristal Acetate (UPA) if any use of progestogen (including contraceptive, HRT, Levonorgestrel EC, Norethisterone, medroxyprogesterone acetate) in last 7 days or recently expired contraceptive implant or levonorgestrel intrauterine device.

Pill errors can be complicated- avoid use of UPA, give levonorgestrel (LNG) and consider referral for PCIUD/specialist advice.

**Previous use of EC this menstrual cycle**. UPA should not be given if use of LNG in the preceding 7days and LNG should not be given with in the 5 days following use of UPA. Repeat dosing can be given in a cycle as long as UPA is followed by UPA and LNG followed by LNG. Repeat dosing should alert pharmacist to the need for reliable contraceptive method and signposting or referral should be made to local sexual health services.

**The person’s medical history**- specifically do they have severe asthma requiring use of oral corticosteroids currently, severe liver disease, severe renal disease, active acute porphyria, LAPP lactase deficiency, lactose or galactose intolerance or breast cancer? Seek specialist advice.

**The person’s medication usage:**

UPA should not be used if current use or use in the last 28 days of any enzyme inducing medication and the dose of LNG should be doubled in this situation.

Enzyme inducing drugs – check BNF. Examples include, primidone, phenobarbital/phenobarbitone, phenytoin, carbamazepine, esclicarbazepine, oxcarbazepine, topiramate, rifampicin, rifabutin, Griseofulvin, ritonavir and other drugs used to treat HIV (seek specialist advice), modafinil, Aprepitant, Bosentan and herbal preparations containing St John’s wort.

Ciclosporin – Note risk of toxicity with LNG.

Drugs that increase gastric PH may affect UPA.

Anticoagulants – warfarin and phenindione may be affected by LNG. Advise INR (international normalised ratio) to be checked 3 days after use LNG.

**Allergy history:** including previous adverse reactions to any of the ingredients in UPA/LNG

**Is the person currently breast feeding?** Breast feeding should not occur for 7 days following use of UPA.

# Assess safeguarding needs for all persons and Gillick competency as per Fraser guidelines for all persons <16 years of age and as per locally agreed safeguarding training and standards. Give EC as per PGD boundaries but refer to MASH/GP/Devon Sexual Health if there are any concerns. Examination

**Assess the person’s weight and BMI**. The dose of LNG should be doubled if BMI >26 and/or weight >70kg. UPA is unaffected by weight.

**An initial pregnancy test** should be recommended to exclude current pregnancy if there has been repeated use of EC, menstrual irregularities, repeated pill errors. Refer onto GP or Devon Sexual Health for further advice.

# Treatment Pathway

Advise all persons that the fitting of a **copper intrauterine device** (PCIUD or “coil”) is the most effective method of EC. Signpost to Devon Sexual Health if the person is keen to consider a PCIUD BUT please give oral EC anyway in case and IUD cannot be fitted or the person changes their mind.

Advise all persons that if they have already ovulated with in this cycle oral EC may not work. Give oral EC anyway but a PCIUD fitting may be preferable.

Advise that the use of a **reliable method of contraception** is more effective at preventing pregnancy than repeated use of EC. Hormonal methods of contraception can be started/restarted immediately after use of LNG and on the 6th day following UPA. Signpost to GP or sexual health services for provision of ongoing method of contraception. Direct to Devon Sexual Health website for further information (http://devonsexualhealth.co.uk/)

Advise **condom use** until a reliable method of contraception becomes effective. Signpost to local condom provision online via Doink website.

( <https://www.sh.uk/services/condoms/devon-and-torbay>)

Advise a **pregnancy test, 3 weeks after use of EC**- bleed patterns can be unreliable following EC or when using hormonal methods contraception and cannot be relied on to exclude pregnancy.

Advise repeat dose of EC if they vomit within 3 hours of taking EC. Ensure it is the same type of EC as explained above.

Offer an opportunistic Chlamydia screening test and kit as part of the emergency contraception consultation**.** If it is not appropriate at the time, ensure that the person has details of how to access a test at another time, direct the individual to Devon Sexual Health website https://www.devonsexualhealth.nhs.uk/which includes details of local services. You may also provide signpost them to freetest.me for postal testing via national chlamydia screening programme (https://www.freetest.me/chlamydia/devon)

Use of emergency contraception does not replace the necessary precautions against sexually transmitted infections (STIs). Direct the individual to the Devon Sexual Health website (https://www.devonsexualhealth.nhs.uk/) which includes details of local services.

**Supply EC as per pathway and Patient Group Direction..**

Guidance on failed contraception and circumstances where emergency contraception is indicated should be obtained from:

* The most recent version of the BNF;
* Other sources where necessary e.g. the Faculty of Sexual and Reproductive Healthcare guidance and the individual product Summary of Product Characteristics;
* Devon Sexual Health Professional Helpline – 01392 284960 or 01271 341569

The pharmacist is required to keep up to date with the latest guidance regarding appropriate indications for emergency contraception.

# Discharge Pathway

The pharmacist is required to keep up to date with the latest guidance regarding appropriate indications for emergency contraception.

Signpost all persons to Devon Sexual Health or GP for on-going contraceptive provision.

Persons attending for multiple repeat doses of EC please provide EC on each occasion but refer to Devon Sexual Health services.

**Teratogenic drugs**. If use of teratogenic drugs (check BNF but common drugs are sodium valproate and isotretinoin) the person must be made aware that pregnancy must be avoided and exclusion of pregnancy with a pregnancy test at 3 weeks following use of EC is paramount. Please refer to Devon Sexual Health or GP for a reliable contraceptive method.

Further actions for pharmacists dispensing valproate drugs are detailed in the national valproate pregnancy prevention programme:

*https://www.gov.uk/drug-safety-update/valproate-pregnancy-prevention-programme-actions-required-now-from-gps-specialists-and-dispensers*

**Complete the PharmOutcomes documentation and electronic record of consultation**

The pharmacist should record the consultation in accordance with local service specifications and any agreed electronic reporting mechanisms, including time and date of consultation.

All records should be retained for 8 years (in adults) or until 25th birthday in a child (age 26 if the record is made when the young person was 17). All records must be retained securely to maintain confidentiality.

The following will be recorded in accordance with local service specifications and any agreed electronic reporting mechanisms:

* Batch number and expiry dates
* The date and time of supply/administration
* The name of the person administering/supplying the medication.
* Whether the medication was witnessed as taken within the pharmacy.

**Confidentiality:**

All pharmacists and their supporting staff must respect their duty of confidentiality and information should not be disclosed to any third party without the individuals consent. This duty of confidentiality applies equally to patients who are less than 16 years of age ***providing that safeguarding issues have been addressed***. Pharmacists should be aware of their obligations under their appropriate Code of Conduct/Ethics.

# Documents Consulted to Prepare This Protocol

Faculty of Sexual and Reproductive Healthcare CEU Clinical Guidance on Emergency Contraception. March 2017 (amended July 2023)

Faculty of Sexual and Reproductive Healthcare UKMEC 2016

Faculty of Sexual and Reproductive Healthcare CEU Guidance on Drug interactions with hormonal contraception. May 2022).

Faculty of Sexual and Reproductive Healthcare CEU Clinical Guidance, Contraception after Pregnancy. 2017 (amended October 2020).

Fraser Guidelines/Gillick Competency (Gillick v West Norfolk and Wisbech Area Health Authority 1985 All ER 402-437)

Health Authority 1985 All ER 402-437)

Safeguarding Children Devon County Council:

<https://www.devonchildrenandfamiliespartnership.org.uk/>

 Safeguarding Children Torbay Council:

 <http://www.torbaysafeguarding.org.uk/>

Safeguarding Adults Devon County Council:

<https://new.devon.gov.uk/devonsafeguardingadultsboard/>

Safeguarding Adults Torbay Council:

<https://www.torbayandsouthdevon.nhs.uk/services/safeguarding-adults/>

Domestic Violence and Sexual Abuse Devon County Council:

<https://new.devon.gov.uk/dsva/>

Domestic and Sexual Violence Torbay Council:

<http://www.areyouok.co.uk/directory/torbay-domestic-abuse-service/>

**Appendix A - Is emergency contraception required?**

Has the person had a baby in the last 21 days?

 YES

No emergency contraception required

 NO

Is the person known to be pregnant?

 YES

Do not give EHC but the person may be eligible for PCIUD, refer to Sexual Health Services

 NO

Has the person had USI within the last 5 days/120 hours

 NO

 YES

 NO

Is UPA contraindicated?

(see list appendix A)

Is LNG contraindicated?

 YES

 NO

 YES

Has the person taken enzyme inducers within 28 days as per BNF or weight over 70kg/BMI over 26?

Refer to Sexual Health Services

Give UPA. It is licensed if USI within 5 days. May be given off label if previous episodes of USI that cycle and may be given if Previous use of UPA in this cycle

 NO

Has the person had UPA within the last 5 days?

YES

Give single dose LNG

Do not give LNG, refer Sexual Health Services

 YES NO

Give double dose LNG

**ADVICE ON GIVING UPA**

1. If the person vomits within 3 hours they need a further dose of UPA
2. Delay restarting hormonal contraception or any other progestogens (HRT/Norethisterone/LNG) for at least 5 days. Use condoms until chosen method becomes effective
3. Advise a pregnancy test in 3 weeks
4. Advise STI screen or chlamydia screen in 2-3 weeks
5. Consider safeguarding issues for all under 18-year olds and Fraser competency for 13-16-year olds
6. Advise overall pregnancy rate after use of UPA is approximately 1-2% BUT this is dependent on the timing of UPSI in relation to ovulation and once ovulation has occurred UPA will be ineffective.
7. Advise the person that PCIUD is the best method of emergency contraception and give them the contact details of Sexual Health Services

**ADVICE ON GIVING LNG**

1. If the person vomits within 3 hours they need a further dose of LNG
2. The person may immediately start or resume taking hormonal contraception with extra precautions until the chosen method becomes effective
3. Advise a pregnancy test in 3 weeks
4. Advise STI screen or chlamydia screen in 2-3 weeks
5. Consider safeguarding issues for all under 18-year olds and Fraser competency for 13-16-year olds
6. LNG is thought to be approximately pregnancy rate is approximately 0.6-2.6% if given within 72hrs of a single episode of UPSI but this is dependent on the timing of UPSI in relation to ovulation and once ovulation has occurred LNG will be ineffective.
7. Advise the person that PCIUD is the best method of emergency contraception and give them the contact details of Sexual Health Services

**CONTRAINDICATIONS TO UPA (1)**

1. Use of any progestogen in the previous 7 days (including all hormonal contraception, HRT, Norethisterone and Levonorgestrel (EHC)
2. Enzyme inducers in past 28 days as per BNF
3. Severe asthma requiring oral glucocorticoids
4. Breast feeding
5. Severe liver or kidney disease

If you have any concerns about suitability for any emergency contraception, e.g. in certain medical conditions or concomitant use of any drugs, refer to PGD initially and (or) contact Devon Sexual Health Services for advice.

**Appendix B**

**Training and Accreditation Standards for Community Pharmacists in the Devon and Torbay area (excluding Plymouth)**

Community pharmacists in the Devon County Council and Torbay Council area who wish to become accredited to deliver emergency hormonal contraception to people aged 13-24 yrs., must be registered with the General Pharmaceutical Council (GPhC) and meet the following standards as a minimum:

* Completion of the online CPPE **emergency contraception** **learning** and **assessment** module (2023- the reference number of these modules changes annually).
* Completion of the online CPPE **Level 2 safeguarding children and safeguarding adultslearning** and **assessment** modules (released 2022 - the reference number of these modules changes annually).
* Attend a locally approved training event organised by Devon Sexual Health
* Evidence of a DBS check as per organisational requirements[[1]](#footnote-1)

The CPPE sexual health in pharmacies self-learning package is currently recommended but not compulsory.

**Locally approved training event delivered by Devon Sexual Health**:

This session will include the following:

* The protocol for the provision of Emergency Hormonal Contraception by community pharmacists in the Devon and Torbay areas.
* How to make the best of the conversation with a young person
* Consent issues and assessing Fraser competence in young people and vulnerable young adults; being alert for areas of safeguarding concern and appropriate referral
* Promotion of sexual health in the pharmacy environment
* Chlamydia screening and the role of the pharmacist and proactively offering an opportunistic Chlamydia Screening Kit
* The role of Devon Sexual Health in managing positive results
* Recording and inputting information to PharmOutcomes (paperless record keeping).

**Counter Top Chlamydia Screening Kits for young people aged 16-24**:

In a small number of cases pharmacists may only wish to provide counter top kits only for remote pick up by young people aged 16-24. The pharmacist will be expected to attend the locally approved training event delivered by Devon Sexual Health.

**Refresher and Update Training**:

Pharmacists are responsible for identifying their own learning needs and recording their Continuing Professional Development (CPD) in accordance with current GPhC standards. To remain accredited to provide Emergency Hormonal Contraception in the Devon and Torbay areas pharmacists are required to:

* Update specified CPPE learning and assessment modules in accordance with personal learning requirements
* Attend a 3-yearly refresher of the locally approved training delivered by Devon Sexual Health.

**USEFUL INFORMATION**

**For details of the Devon and Torbay *locally approved training event* and *how to obtain a supply of Chlamydia Screening Kits*, contact the Devon Sexual Health Chlamydia Screening Administrator on 01392 284965 or by email at** **ndht.CSO@nhs.net****.**

**List of local pharmacies in Devon and Torbay providing emergency contraception:**

[**http://devonsexualhealth.co.uk/images/pharmacies-providing-emergency-contraception.pdf**](http://devonsexualhealth.co.uk/images/pharmacies-providing-emergency-contraception.pdf)

**List of local contraception and sexual health clinics in Devon and Torbay:**

[**http://devonsexualhealth.co.uk/clinics**](http://devonsexualhealth.co.uk/clinics)

**Devon Sexual Health Professional Helpline:**

01392 284960 or 01271 341569

1. The Devon and Torbay contract for the provision of pharmacy based public health services states that: *the Applicant, as employers, confirm that they will ensure that all pharmacists and supporting staff are fit for the purposes for which they are employed i.e. suitably qualified and appropriately trained and vetted for the roles that they are undertaking (for example DBS checks as per organisational requirement). For more information see* [*https://www.gov.uk/government/organisations/disclosure-and-barring-service*](https://www.gov.uk/government/organisations/disclosure-and-barring-service). [↑](#footnote-ref-1)