North Yorkshire County Council

Targeted Primary Care Sexual Health Service Provided in Community Pharmacies Service Specification

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1. Introduction

This Service Specification will contribute to the overall delivery of the local Sexual Health System. Providers delivering these services are will have close working relationships with other pharmacies, GPs and the local Integrated Sexual Health Service (known as YorSexual Health). They will have a good understanding of other provision in their area. They will know who to contact within YorSexual Health for specialist support and advice, and to access local training.

The services will be commissioned as one basket of services.

2. Outline of the targeted primary care sexual health services provided in community pharmacies

The targeted primary care sexual health services described in this Specification are commissioned as a 'basket' of services from Providers. This means that Providers are contracted to deliver all the services in the basket – they cannot opt to deliver individual elements. The services to be provided are:

1) The provision of free emergency hormonal contraception (EHC) to service users aged 13 years to 24 years.
2) Provision of Chlamydia screening kits to under 25 year olds (as part of the NCSP)
3) Free condoms to under 25 year olds
4) Provision of sexual health information to service users

3. Service Objectives

The specific objectives of the Service to be delivered by the Provider are:

- To increase the awareness, especially among young people, of the availability of free emergency contraception for 13 to 24 year olds from pharmacies.
- To improve access to emergency contraception and provide informed advice and support to complement existing sexual health services and provide a signposting service into YorSexual Health as required.

- To increase the appropriate use of EHC by women aged 13-24 years who have had unprotected sex to help contribute to a reduction in the number of unplanned pregnancies or terminations in the client group.
- To improve access to 'self-administered' Chlamydia screening kits.
- To promote the use of Chlamydia screening kits and increase the number of test samples returned for analysis.
- To promote the use of condoms and encourage safe sex practice.
- To promote Double Dutch[1] method of using two forms of contraception against pregnancy and STI's.
- To increase knowledge and understanding of sexual health issues.
- To raise awareness and facilitate access to other sexual health and related services.

This 'basket of services' will contribute to delivery of the following indicators which are monitored by the Commissioner to measure the effectiveness of delivery of the local sexual health system.

- The rate of sexually transmitted infections (STIs) diagnoses in clinic attendees
- The rate of STIs diagnoses in young people attending clinics
- The Chlamydia diagnostic rate for those aged 15-24
- The rate of late HIV diagnoses
- The rate of under 18 conceptions
- The number of abortions
- The number of under 18 abortions

4. Evidence base

4.1 Emergency Hormonal Contraception (EHC)

According to the government's Sexual Health Framework, around 50% of all pregnancies are unplanned. The government's ambition is to reduce unintended pregnancies among all women of fertile age through increased knowledge and awareness of all methods of contraception and improved

[1] *Double Dutch method is the use of hormonal contraception combined with use of barrier method – condoms male or female*

access to these methods, including emergency hormonal contraception (EHC), for women and their partners. The Sexual Health Framework concludes that "emergency contraception is a safe and effective way of preventing unwanted pregnancy when regular methods have failed or have not been used."[2]

Women presenting for EHC are clearly indicating that they do not wish to become pregnant, despite being at risk of pregnancy following unprotected sexual intercourse (UPSI). Although the copper intrauterine device (IUD) is recognised by healthcare professionals as the most effective method of emergency contraception[3], over 95% of women who present after UPSI do not opt for an IUD as a method of emergency contraception.[4] [5]

4.2 Chlamydia screening for under 25 year olds (as part of the National Chlamydia Screening Programme (NCSP))

Chlamydia is the most common bacterial sexually transmitted infection, with sexually active young people at highest risk. As Chlamydia often has no symptoms and can have serious health consequences (e.g. pelvic inflammatory disease, ectopic pregnancy and tubal factor infertility) opportunistic screening remains an essential element of good quality services for young people[6].

Provision of Chlamydia screening in primary care provides the opportunity for young people not necessarily in contact with sexual health services to receive testing. The aim of this service in primary care is to increase the uptake of screening and treatment (if appropriate) for Chlamydia by young people and thus help contribute to a reduction in the prevalence of the infection and its medical complications.

4.3 Free condoms to under 25 year olds

Condoms can be expensive and, when buying them, young people are often embarrassed to ask for advice. In this context the distribution of condoms to young people is an effective and practical way of preventing further unplanned pregnancies and sexual infections.

Providing condoms can also provide useful opportunities for sexual health promotion in safe and informal settings.

Used consistently and correctly, male condoms are up to 98% effective in preventing pregnancy and female condoms up to 95% effective. In general evidence supports the use of condoms to reduce the risk of STI transmission; however, even with correct and consistent use, transmission may occur.

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[2] *Department of Health. A framework for sexual health improvement in England. March 2013.*
[3] *The Health and Social Care Information Centre. NHS contraceptive services: England, 2011/12. Lifestyles statistics. 31 October 2012.*
[4] *Department for Children, Schools and Families and the Department of Health. Teenage pregnancy strategy: beyond 2010. February 2010.*
[5] *Can we reduce costs and prevent more unintended pregnancies? A cost of illness and cost-effectiveness study comparing two methods of EHC. Thomas, C.M and Cameron, S. BMJ Open 2013;**3**:e003815 doi:10.1136/bmjopen-2013-003815 http://bmjopen.bmj.com/content/3/12/e003815.full*
[6] *http://www.chlamydiascreening.nhs.uk*

4.4 Provision of sexual health information

It is important that young people and adults are able to make informed and responsible decisions, understand issues around consent and the benefits of stable relationships and are aware of the risk of unprotected sex. It is important that women are able to access the full range of contraception to avoid unwanted pregnancy.

5. Service description

The specific requirements which need to be undertaken by Providers delivering this service are:

5.1 Provision of EHC

Providers will discuss individual need for emergency contraception and inform women about the different methods with regard to efficacy, adverse effects, interactions, medical eligibility and need for additional contraceptive precautions.

The Provider will supply EHC, when appropriate, to service users aged 13 years to 24 years inclusive, in line with the requirements of the Patient Group Directions (PGDs) see appendices 1-3. This will be either EllaOne or Levonelle as per the algorithm.

Where a supply of EHC is not appropriate, advice and signposting to the service user's local GP or the specialist sexual health service will be provided as soon as possible.

Service users who have exceeded the time limit for EHC will be informed about the possibility of the use of a Copper Intrauterine Device (Cu-IUD) and will be signposted to either their GP or specialist sexual health service as soon as possible.

All service users will be made aware that the Cu-IUD is more effective than EHC.

5.2 Chlamydia screening service to under 25 year olds (as part of NCSP)

The Provider will work with YorSexual Health to promote and supply free Chlamydia testing kits to all under 25's attending the pharmacy for EHC. Test kits will be provided by YorSexual Health, along with specimen pots and patient information. For ordering information see https://www.yorsexualhealth.org.uk/yor-sexual-health-professionals/condoms-and-chlamydia-tests/chlamydia-tests/

The Provider will inform the service user about how to use the kit, what happens afterwards, i.e. how results are provided, what will happen if a positive result is obtained (treatment and partner notification services).

The Provider will inform the service user that YorSexual Health will provide results to service users, discuss treatment options, and manage the partner notification service.

5.3 Free Condom service

The Provider will sign up to and implement the free condom service that is managed and resourced by YorSexual Health (complying with the governance and training requirements stipulated by YorSexual Health). For further details see here https://www.yorsexualhealth.org.uk/yor-sexual-health-professionals/condoms-and-chlamydia-tests/

The Provider will supply condoms and lubricants to under 25s attending for EHC (using the ordering process run by YorSexual Health) together with supplying information about sexual health and contraception and local services.

The Provider will comply with monitoring systems, standards, policies and procedures as designated by YorSexual Health and comply with the schemes policy around safeguarding and issuing contraception, particularly to under 16 year olds.

5.4 Provision of sexual health information

The Provider will provide a range of evidence based sexual health information tailored to meet the needs of different age groups on:

- How to prevent and/or get tested for STIs and how to prevent unwanted pregnancies.
- All methods contraception including LARCs[7],[8].
- How to get and use emergency contraception.
- Other reproductive issues and concerns.
- Where to access further information and guidance about sexual health services.

The Provider will ensure the full range of sexual health promotion information is available in the Pharmacy as well as providing appropriate information as part of the EHC consultation.

The Provider will advertise the EHC service that it offers, including advertising on its own website where this exists, as well as having a link to the website managed by YorSexual Health and NHS Choices.

The Provider will provide information in a range of formats and mediums to meet language and literacy needs[9,10].

[7] http://www.nhs.uk/Conditions/contraception-guide/Pages/contraception.aspx

[8] http://www.fpa.org.uk/contraception-help/your-guide-contraception

The Provider will engage in local targeted public health campaigns led by YorSexual Health to promote key sexual health messages and services, for example World Aids Day, HIV Testing Week.

6. Service delivery elements

The Provider will be expected to deliver services taking into account the following elements:

- Access
- Eligibility criteria
- Exclusion criteria
- Referral pathways
- Marketing & publicity
- Environment & premises
- Data management
- Workforce
- Clinical governance arrangements
- Safeguarding
- Confidentiality & consent
- Service User feedback
- Support from YorSexual Health
- Quality standards

6.1 Access

The Service delivered by the Provider will be available to any service user within the target age range.

The Provider will aim to ensure that the Service is always available whenever the pharmacy is open. The Provider must inform the Commissioner as soon as is practicably possible, if they are unable to meet this requirement for periods of over one week. If the Provider is unable to provide the service on a short-term basis e.g. due to sickness, they will be aware of and signpost to the nearest alternative Provider. All details are available here: https://www.yorsexualhealth.org.uk/contraception-and-pregnancy/emergency-contraception/

The Provider will ensure that reasonable effort is made to provide translating services for clients whose first language is not English.

[9] http://www.nhs.uk/aboutnhschoices/aboutnhschoices/aboutus/pages/languageshub.aspx
[10] http://www.easyhealth.org.uk/categories/health-leaflets

6.2 Eligibility Criteria

EHC will be made available free to women aged between 13 and 24 years.

Chlamydia screening kits will be provided to all young people under 25 years old attending for EHC.

Free condoms will be provided to all young people under 25 years old attending for EHC.

6.3 Exclusion Criteria

Services not funded:

- Service Users excluded from the Patient Group Directions (PGD) criteria will be referred by the Provider to another local service that will be able to assist them, as soon as possible, e.g. GP, YorSexual Health, or will be invited to purchase the Pharmacy medicine product if the exclusion from supply via the PGD is only due to an administrative matter, e.g. age range determined by the Commissioner.

Refusal of service provision

The Provider has the right to refuse service provision:

- To users who are unsuitable for treatment under the conditions of this Service Specification.

- For any unreasonable behaviour deemed unacceptable to the Provider, it's Staff, or the named professional clinically responsible for the care of the service user.

6.4 Referral pathways

The Provider will work within recognised referral pathways and signpost service users to other services, including:

- YorSexual Health
- Termination services
- Sexual Assault Referral Centres (SARCs)
- HIV Specialist Services
- A&E
- GP's
- Healthy Child Programme team
- Substance misuse services
- Mental health services

- Other services within the sexual health system

6.5 Marketing and Publicity

The Service delivered by the Provider will be appropriately marketed and publicised, including within their own premises and on the YorSexual Health website.

The Provider is responsible for ensuring that information about the service they provide is accurate and kept up to date on the YorSexual Health website, to ensure details of their service are widely available to the public and professionals.

6.6 Environment and premises

The Provider will be able to provide a private consulting area where confidentiality can be assured.

6.7 Data management

The Provider must:

- ensure all data management systems comply with Data Protection and Caldicott requirements.
- generate a monthly monitoring report of service user attendances and interventions delivered for payment and performance purposes to be submitted via a system provided by the Commissioner
- maintain full patient records.

6.8 Workforce

Provision of EHC

The workforce delivering this Service on behalf of the Provider will have the necessary skills and competence to deliver the services in this specification.

The Provider must complete a declaration of competence for EHC. This is a nationally recognised framework for Pharmacists to assess their competencies across of range of services. Pharmacists should register on the CPPE website: www.cppe.ac.uk/sp/sp4pop.asp?pid=189&ID=203 [11].

Each pharmacist delivering the service on behalf of the Provider must complete their Declaration of Competence Certificate (DOC) for EHC before they can provide this Service (a three month grace period is a 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

[11] http://www.cppe.ac.uk/sp/sp6.asp?PID=191&ID=205 currently DOC training is available on EHC and Chlamydia screening.

viewer facility via the *Profile* section of the *My CPPE* page to allow access by the Commissioner.

Each pharmacist delivering the Service on behalf of the Provider should sign a copy of the PGDs and retain a copy of the PGD for their reference. The lead pharmacist will maintain the master copy of the PGDs that will include the full signatures of all pharmacists signed up to the PGD. The lead pharmacist delivering the Service on behalf of the Provider is required to let the commissioner know which pharmacists have signed the PGDs.

All pharmacists delivering this Service on behalf of the Provider are also required to attend a one off face to face training event provided by YorSexual Health with input from the Commissioner's Medicines Management Advisory Service. This event will cover the local PGDs, Chlamydia screening, condom distribution and 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.

For Locums

- Providers who employ locum pharmacists must ensure that all locums employed by the Providers have a completed DOC and signed a copy of the local PGDs. Long term locum pharmacists working within the area will attend a face to face training at their earliest convenience.

Non-pharmacists may not be accredited nor are they allowed, by law, to supply via the PGDs. Providers should inform the Commissioner as soon as possible in situations where an accredited Pharmacist will no longer be available to provide the Service.

Chlamydia screening service

The Provider will ensure their staff are familiar with the chlamydia screening programme information provided by YorSexual Health (detailed here https://www.yorsexualhealth.org.uk/yor-sexual-health-professionals/condoms-and-chlamydia-tests/chlamydia-tests/). This will ensure staff are appropriately equipped to deliver a chlamydia screening service, in accordance with the latest NCSP standards.

Chlamydia treatment is outside the scope of this Service Specification.

Condom distribution service

The Provider will ensure all pharmacists delivering the service on behalf of the Provider participate in the free training provided by YorSexual Health to ensure that staff meet the requirements set by the service.

6.9 Clinical governance arrangements

The Provider will have a nominated lead for clinical governance and have a named lead for sexual health (this may be the same person) and will link with YorSexual Health.

The Provider will comply with current national regulations and directions on confidentiality and disclosure of information on sexual health and then follow the new statutory Code of Practice on Confidentiality once published.

The Provider will comply with Caldicott requirements on information governance.

The Provider will have robust systems in place for managing incidents and comply with policies and procedures set out by the Commissioner for reporting incidents including serious untoward incidents.

6.10 Safeguarding

The safety and wellbeing of children, young people and vulnerable adults is paramount. The Provider will ensure that all Staff (including administrative staff) are compliant with child protection and Children and Adult Safeguarding Policies. For example, the Provider shall ensure all Staff are aware of and trained to a level appropriate to their role in accordance with the *Safeguarding Children and Young People: roles and competences for health care staff Intercollegiate Document, March 2014*[12] and abide by national and local guidance and legislation on safeguarding (children and adults). Staff employed by the Provider will be competent in joint working with safeguarding teams and Designated Health Professionals, i.e. Designated Nurse and Designated Doctor for Child Protection/Safeguarding Children (see link www.safeguardingchildren.co.uk/section-2-procedures.html for further information regarding Designated Health Professionals).

The Provider shall consider the government's guidance as set out in the document *Working Together to Safeguard Children: A guide to interagency working to safeguard and promote the welfare of children (DfE March 2013)*[13].

The Provider shall comply with the North Yorkshire Safeguarding Adults and Safeguarding Children Board's policies and procedures including best practice guidance with regard to child sexual exploitation, sexual abuse and neglect. These can be found at the following webpage links:
North Yorkshire Safeguarding Children Board
(www.**safeguardingchildren**.co.uk)

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[12] RCPCH (2014) *Safeguarding Children and Young people: roles and competences for health care staff Intercollegiate Document March 2014* *www.rcpch.ac.uk/sites/default/files/page/Safeguarding%20Children%20-%20Roles%20and%20Competences%20for%20Healthcare%20Staff%20%2002%200%20%20%20(3)_0.pdf*

[13] Department for Education (2013) Working Together to Safeguard Children: A guide to interagency working to safeguard and promote the welfare of children. www.gov.uk/government/uploads/system/uploads/attachment_data/file/281368/Working_together_to_safeguard_children.pdf

North Yorkshire Adults Safeguarding Board (http://www.nypartnerships.org.uk/index.aspx?articleid=17008)

When working with Service Users under the age of 16, the Provider shall adhere to the Department of Health's guidance document *Best practice guidance for doctors and other health professionals on the provision of advice and treatment to young people under 16 on contraception, sexual and reproductive health (DH 2004)*[14].

The Provider shall comply with their specific responsibilities and safeguarding protocols relating to young people aged 13-15 years and for those under the age of 13 years.

The Provider shall have robust child protection and adult safeguarding policies and procedures. The Provider shall have a named lead for safeguarding covering both children and adults.

The Provider shall ensure compliance with the Mental Capacity Act where clinicians have contact with young people aged 16-17, those with learning difficulties or where there is impairment in decision making.

6.11 DBS checks

All pharmacists delivering this service on behalf of the Provider are to be DBS checked. The Provider must confirm all pharmacists delivering this service have been DBS checked.

6.12 Confidentiality and consent

The Provider will provide service users with privacy and ensure that consultations are confidential.

People have a right to confidentiality regardless of where they access services from for reproductive and sexual health issues. The Provider will provide clear information to their service users explaining confidentiality, and the reasons why confidentiality may be broken. The Provider is expected to obtain consent for information to be shared with health professionals for the purposes of treatment and prevention. The Provider will be compliant with the FSRH Standard Statement[15] on Confidentiality and be young people friendly (e.g. "You're Welcome"[16]).

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[14] Department of Health (2004). *Best Practice Guidance for Doctors and other Health Professionals on the Provision of Advice and Treatment to Young People Under 16 on Contraception, Sexual and Reproductive Health* http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/publicationspolicyandguidance/DH_4086960

[15] www.fsrh.org/pdfs/ServiceStandardsConfidentiality.pdf

[16] https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-services

6.13 Service User Feedback

The Provider shall have in place a well-publicised feedback and complaints procedure which includes quality standards related to how complaints are dealt with and responded to.

6.14 Support from the Integrated Sexual Health Service (known as YorSexual Health)

Providers can expect clinical leadership from YorSexual Health and will receive the following:

a) Access to level 1 & 2 training provided by YorSexual Health as part of their free annual training programme. The training programme does not include backfill costs.

b) Free condoms and chlamydia test kits for under 25s attending for EHC.

c) A named local clinical sexual health lead who will provide support and respond to any queries related to the delivery of sexual health services.

Providers are to actively engage with YorSexual Health, and be part of the wider local sexual health system as well as promoting their local services.

7. Service Delivery and Quality standards.

The Primary Care Service supplied by the Provider shall be delivered in accordance with the following:

- Service Standards for Sexual and Reproductive Healthcare (FSRH 2013)
- A Quality Standard for Contraceptive Services (FSRH, 2014)
- Service Standards for Consultations in Sexual and reproductive Health (FSRH, 2015)
- PH51 Contraceptive services with a focus on young people up to the age of 25: guidance (NICE, 2014)
- Clinical Guidance – Emergency Contraception (FSRH 2012)
- UK National Guideline on Safer Sex Advice (BASHH & BHIVA 2012)
- National Chlamydia Screening Programme Standards (7th Edition 2014)

Department of Health (2011). *You're Welcome: Quality Criteria for Young People Friendly Health Services* (http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126813

- Standards for the Management of Sexually Transmitted Infections (BASHH & MEDFASH 2014)
- Progress and Priorities - Working Together for High Quality Sexual Health (MEDFASH 2008)
- PH3 One to one interventions to reduce the transmission of sexually transmitted infections (STIs) including HIV, and to reduce the rate of under 18 conceptions, especially among vulnerable and at risk groups (NICE 2007)
- Recommended Standards for Sexual Health Services (MEDFASH 2005)
- Safeguarding children and young people: roles and competences for health care staff Intercollegiate Document March 2014 (RCPCH, 2014)

Relevant UK clinical guidance covering the specialities of Sexual and Reproductive Healthcare and Genitourinary Medicine can be found at www.fsrh.org and www.bashh.org. The Provider shall ensure the Primary Care Service reflect updates in guidance and recommendations as and when produced.

8. Finance information

Each Provider contracted to provide this service will receive the following fees:

- £15 per consultation (includes discussion and assessment for EHC, discussion about use and supply of chlamydia screening kit and condoms).
- Drug costs – currently Levonelle at £5.20 and EllaOne at £14.05
- Chlamydia £4.00 per returned test to lab

Where data is not submitted to the Commissioner by the due date each month, the Provider must notify the Commissioner of the reasons why this has occurred. In the case of late submission of performance data, the Provider will not receive payment for any data submitted more than eight weeks after the original submission date.

Appendix 1

PATIENT GROUP DIRECTION for the supply of ORAL EMERGENCY HORMONAL CONTRACEPTION (EHC)
by community pharmacists
(Levonorgestrel 1500micrograms x 1 tablet)

PATIENT GROUP DIRECTION
for the supply of
Levonorgestrel 1500micrograms as ORAL EMERGENCY HORMONAL CONTRACEPTION (EHC)
by accredited community pharmacists

Signed document for employees of primary care contractors to be retained by each contractor's Clinical Governance Lead

Patient Group Direction (PGD) for the supply of oral emergency hormonal contraception (levonorgestrel 1500 microgram as a Levonelle-1500® tablet) by accredited Community Pharmacists

IMPORTANT NOTES:

- ***UPSI*** *- For the purpose of this document (and appendices) unprotected sexual intercourse (UPSI) means sexual intercourse where the female is at risk of becoming pregnant. It may include situations where there has been a missed dose of the oral contraceptive pill or a failure in any barrier method of contraception.*
- **The Faculty of Sexual and Reproductive Healthcare (FSRH) state that the most effective form of EC is the copper intrauterine device (Cu-IUD). If the woman accepts Cu-IUD, refer to YorSexualHealth for emergency fitting and supply EHC in the meantime if conditions in the PGD are met.**

1. CLINICAL CONDITIONS FOR ORAL EMERGENCY HORMONAL CONTRACEPTION	
Title of Patient Group Direction:	Levonorgestrel 1500 microgram tablet (Levonelle-1500®) Emergency Hormonal Contraception by accredited community pharmacists
PGD valid from:	1 September 2015
Expiry Date:	31 August 2017
Clinical area where PGD applies	Accredited community pharmacists employed within an NHS community pharmacy within boundaries of North Yorkshire County Council (NYCC) in pharmacies that are commissioned to provide this EHC service.
Clinical condition to which PGD applies	Where emergency contraception is required; preferably within 12 hours, and no later than 72 hours, of the first episode of UPSI or failed contraceptive (missed pills/patches, failed condom/barrier method).
ADVANCE SUPPLY IS NOT INCLUDED IN THIS PGD	
Inclusion criteria	1. The female has decided to avoid risk of pregnancy in this instance 2. Previous UPSI within the last 72 hours and the client is either • aged between 16 and 24 ***or*** • aged 13, 14 or 15 and satisfies the operators assessment for the Fraser Guidance (see Appendix 1) 3. Previous UPSI within the last 72 hours due to possible failure of contraceptive method e.g. • Potential barrier method failure • Missed/failed combined contraceptive pill/patch • Missed/failed progesterone only pill • Medroxyprogesterone depot (Depo-Provera) > 89 days (12 weeks and 5 days) lapsed since the last injection • Severe gastrointestinal upset that may have affected contraceptive efficacy **(see current BNF)**, including vomiting within 3 hours of taking a levonorgestrel emergency hormonal

	contraception preparation • Risk of conception whilst advised to avoid pregnancy, such as following administration of cytotoxic agents or potentially teratogenic drugs 4. Vomiting within 3 hours of taking levonorgestrel emergency contraceptive pill 5. Previous UPSI in the same cycle and treated with levonorgestrel. If previous UPSI is 3 weeks ago or more and the woman has had no period, there must be a negative pregnancy test i.e. pregnancy excluded 6. The client's medical history indicates prophylaxis is appropriate 7. The client has agreed to complete the prophylactic course For further guidance on inclusion criteria see Appendix 2
Exclusion criteria (any one excludes)	• Exclude from supply under the PGD if consumption of the dose would be beyond 72 hours since any episode of UPSI since last menstruation • No third party supplies are permissible • Female aged under 13 years of age or over 24 years of age • Female aged 13, 14 or 15 who did not satisfy the pharmacist's assessment for the Fraser Ruling (see Appendix 2) • Relevant medical history is not provided by the client • A menstrual bleed is overdue (e.g. the female may already be pregnant). **BUT** *for post-natal clients before their first post-natal menstruation, UPSI more than 21 days after delivery can lead to pregnancy (EHC is not necessary in the first 21 days post-natally)* • No menstrual period within the last 24 months (12 months if over 50 years old) • Last menstrual period was abnormal in any way (timing or character) • Female has not consented to taking levonorgestrel 1500mcg • Unexplained vaginal bleeding • Current breast cancer • Severe liver disease • Acute active porphyria • Previous supply of emergency contraception within this cycle if the drug used was ulipristal (ellaOne). A further course of levonorgestrel may be supplied in the same cycle if levonorgestrel was taken for the previous episode of UPSI. ALSO, if the dose has been taken and vomited then a further supply of one tablet can be made under this PGD (see Appendix 3 or 4). • The female takes interacting drugs. See current BNF for full list of interacting drugs. **Please see cautions also regarding enzyme inducing drugs.** • Any condition causing severe malabsorption e.g. Crohn's disease • Galactose intolerance, Lapp lactase deficiency or glucose galactose malabsorption • History of severe clinical problems with hormonal contraception • Hypersensitivity to any component of the product

	• Any contraindication to levonorgestrel **(see manufacturer's Levonelle SPC)** • History of hydatidiform mole or trophoblastic disease
If client is excluded or declines (the service provider should offer to assist the client in this process)	• If consumption of the dose would be beyond 72 hours since 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 • If treatment is refused, this must be recorded on PharmOutcomes
Cautions	• **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. If this is not possible or appropriate, then the dose of levonorgestrel 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).
Advice to all clients	• Give advice on the options for emergency contraception (EC) as per the decision tree. Advise the client that the Cu-IUD is the most effective form of EC. • Advise the client to discuss sexual health matters and contraception with a suitable healthcare professional at their GP surgery or YorSexualHealth (leaflets available) • Standard contraceptive methods are the first line in contraception. Emergency contraception should only be used in emergencies. Whilst repeated doses of levonorgestrel can be given in one cycle, there is a risk of interruption of the menstrual cycle, hence repeated courses of EHC are not the best form of contraception.

2. DESCRIPTION OF ORAL EMERGENCY HORMONAL CONTRACEPTION

Name	Levonorgestrel 1500microgram tablet (as Levonelle-1500® Marketing authorisation number PL05276/0019)
Legal status	POM – Prescription Only Medicine
Storage	Do not store above 25°C
Route	For oral administration only
Dose	**1 x 1500micrograms** (highest efficacy is achieved if the tablet is taken as soon as possible (preferably within 12 hours and no later than 72 hours) after UPSI Or

	Where the client is taking enzyme inducing drugs (see drug interactions), the dose 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).
Frequency of administration	Take one tablet as a single dose. The client should usually take the medicine whilst at the pharmacy.
Maximum dose	1500 micrograms
Duration of treatment	Single dose
Contra-indications	See under criteria for exclusion and current SPC
Cautions	**Breast-feeding mothers**: Levonorgestrel is secreted into breast milk. Potential exposure of an infant to levonorgestrel can be reduced if the breast-feeding woman takes the tablet immediately after feeding and avoids feeding for a further four hours
Drug Interactions	• The effectiveness of levonorgestrel, is reduced in women taking enzyme-inducing drugs (and possibly for 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 • If a patient is taking an enzyme-inducing drug and emergency contraception is considered necessary and where a copper intra-uterine device is undesirable or inappropriate, the dose of levonorgestrel could be increased to a total of 3mg taken as a single dose, as referenced in the BNF. Note that this is an unlicensed dose and clients should be advised accordingly. • Rifampicin-like drugs (e.g. rifampicin, rifabutin) are the only antibacterials that are enzyme inducers that have consistently been shown to reduce serum levels of ethinylestradiol. There is no need for the dose of emergency contraception to be increased if the patient is taking antibacterials that are not enzyme inducers. **For a complete list of drug interactions refer to the current BNF.**
Potential adverse reactions	**Nausea** – advise medication to be taken with food. **Vomiting** – provide clients with clear instructions for obtaining an additional tablet if vomiting occurs within 3 hours of the 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. • Refer to product information or BNF for fuller detail • Use the yellow card system to report adverse drug reactions directly to the MHRA **(see BNF)**

Follow up action	• A pregnancy test is recommended if:
	  ◦ 3 weeks after last menstrual period
	  ◦ 3 weeks after UPSI
	  ◦ the patient has abdominal pain
	  ◦ the period is over 7 days late
	  ◦ the period is abnormal in any way e.g. lighter
	• Consider signposting to YorSexualHealth for sexually transmitted infection testing if appropriate
	• Offer free condoms and chlamydia testing kit as defined in the service specification
	• Record keeping – see section below

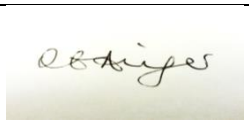
Labelling requirements	The packaging should be labelled in the manner of any prescribed medication and contain a manufacturer's patient information leaflet. Pre-printed labels should allow the client's name and date of dispensing to be added.
Advice to patients	Provide information and advice on levonorgestrel and the Cu-IUD to allow the client to make an informed choice regarding treatment – see decision tree. Also, the client must be given advice on: **Mode of action** - Uncertain but thought to work by preventing ovulation and fertilisation, endometrial changes may also occur which discourage implantation. **Failure rate -** Prevents 84% of expected pregnancies when the tablet is taken within 25-48 hours of UPSI. **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** - if pregnancy does occur, the possibility of an ectopic pregnancy should be considered. Inform the patient to seek prompt medical advice if any abdominal pain occurs. **Dose** - oral EHC is most efficacious the earlier the tablet is taken (after UPSI). The dose should be taken under the supervision of the pharmacist. **Follow-up** – if the next period is delayed by more than seven days, consider pregnancy and seek a pregnancy test. **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. EHC does NOT provide contraceptive cover for the remainder of this menstrual cycle. Clients using oral contraceptives should restart their usual pill within 12 hours 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. **Risk of STI** - EC does not replace necessary precautions against sexually transmitted infections. **Informing the GP** - Request the client's permission to inform their GP that a supply of EHC has/has not been made.
Records to be kept	All details to be recorded on PharmOutcomes as detailed in the on line tool and be retained according to local, legal and professional obligations.
Prescription fees	No fee is payable by the client
• **3.REQUIREMENTS OF REGISTERED PHARMACISTS WORKING UNDER THIS PGD**	
Qualifications/ registration	Registered with the General Pharmaceutical Council (GPhC) of Great Britain
Specialist competencies or qualifications	• Pharmacist with appropriate underpinning knowledge to competently undertake the clinical assessment of patients leading to treatment according to the indications listed in this PGD • The pharmacist must complete the required training as part of the declaration of competence, as defined by the Centre for Pharmacy Postgraduate Education (CPPE) and repeat every 3 years CPPE declaration of competence • Attendance at NYCC training sessions as defined by NYCC. • Accredited pharmacists will retain all training documentation. • Maintenance of accreditation is as defined by CPPE/NYCC. • 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 knowledge of the medicine prior to its supply and to maintain this knowledge and keep up to date with relevant developments
Documents to be retained /	• The pharmacist must sign and retain a copy of the PGD in the pharmacy

Guidance for pharmacy staff	• Medicine counter staff must be trained to refer requests for EC to the pharmacist or a suitable alternative provider if the pharmacist is not present • All requests for EC should be handled in a sensitive, private and non-judgemental manner
4. SAFEGUARDING CHILDREN	
Guidance for all staff in the pharmacy	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 **Designated Nurses for Safeguarding Children** Karen Hedgley 07946 337290 Elaine Wyllie 07917 800793 **Nurse Consultant for Primary Care (Adult and Children's Safeguarding)** Jacqui Hourigan **Designated Doctors for Safeguarding Children** Dr Barbara Stewart 01904 631313 Dr Natalie Lyth 01845 521681 **In an emergency, contact North Yorkshire Police on 999** **OR** **Out of hours – NYY Social Care - Emergency Duty Team 0845 034 9417** **Multi-agency Safeguarding Children Procedures (including referrals forms and details of referral pathway) can be found at: www.safeguardingchildren.co.uk**

5. AUTHORISATION OF PGD

NORTH YORKSHIRE COUNTY COUNCIL AUTHORISATION OF PATIENT GROUP DIRECTION FOR THE SUPPLY OF LEVONORGESTREL 1500 MICROGRAM TABLET AS ORAL EMERGENCY HORMONAL CONTRACEPTION THROUGH ACCREDITED COMMUNITY PHARMACIES

Clinical authorization			
Name	**Job title and organisation**	**Signature**	**Date**
Dr Alison Payne	**Senior doctor GPwSI Sexual Health**		11/09/2015
Rachel Ainger	**Public Health Pharmacist** Prescribing Support Services		11/09/2015
Commissioner authorization			
Dr Lincoln Sargeant	Director of Public Health North Yorkshire County Council		15/09/2015
Version control			
PGD comes into force:	**1 September 2015**		
PGD expires	**31 August 2017**		
Version	2.0		

6. Development team

Georgina Wilkinson	Health Improvement Manager, NYCC
Dr Alison Payne	GPwSI, Sexual Health
Imran Younis	Director, Prescribing Support Services
Rachel Ainger	Public Health Pharmacist
Alison Chorlton	YorSexual Health Lead Nurse

7. References

- Summary of Product Characteristics for Levonelle 1500 microgram tablet, Bayer plc. Last updated 9 October 2014 2012. Accessed July 2015.
- BNF Online. Accessed July 2015
- Guidance from the Clinical Effectiveness Unit of the Faculty of Sexual Health and Reproductive Healthcare (FSRH) of the Royal College of Obstetricians and Gynaecologists:
    - Drug Interactions with Hormonal Contraception. January 2011. Guidance from the Clinical Effectiveness Unit of FSRH (updated 2012)
    - Missed pills: New recommendations. May 2011. Statement from the Clinical Effectiveness Unit of FSRH.
    - Emergency Contraception. August 2011. FSRH Guidance. (Updated January 2012_

Please note Faculty of Sexual Health and Reproductive Healthcare (FSRH) was formerly known as the Faculty of Family Planning and Reproductive Healthcare (FFPRHC)

8. AUTHORISATION OF NAMED PHARMACISTS TO OPERATE UNDER THIS PGD

- **Agreement by Pharmacist**
-

I, ……..., consider that I am competent to supply oral emergency hormonal contraception (levonorgestrel 1500micrograms). I have completed the appropriate training, as recognised by NYCC, which will allow me to provide this professional service. I will maintain this competence to provide this service in line with the requirements outlined by NYCC.

I have read the Patient Group Direction and associated appendices for the supply of oral emergency hormonal contraception levonorgestrel 1500micrograms. I will maintain clinical records as defined by PharmOutcomes and in line with recognised governance standards.

Signature: . . . . . .

G.Ph.C. Registration number . . . . . .

Date: . . . . . .

Full address: . . . . . .

. . . . . .

……

Postcode ……

Email address ……

Telephone number ……..

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)

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. Amongst other factors, the success of levonorgestrel 1500micrograms in preventing pregnancy depends upon how soon the dose is taken after unprotected sexual intercourse (UPSI). Levonelle-1500® prevents about 84% of expected pregnancies when the tablet is taken within 72 hours (3 days) of UPSI.

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
- Patient advice leaflet **(see Appendix 3)** for oral emergency hormonal contraception - essential
- Leaflet on methods of contraception and websites www.brook.org.uk and www.fpa.org.uk - advisable
- Leaflet on local Family Planning Services (YorSexualHealth) - advisable
- Leaflet on Family Planning Clinics, Out of Hours and Genito-Urinary Services (GUM) - 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 – 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 oEHC 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.

Practising Safer Sex
Neither oEHC nor oral contraceptive pills are appropriate for practising safer sex.

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

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 and unprotected intercourse has occurred since finishing the last packet.
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.

Note: The Faculty of Sexual and Reproductive Healthcare offers 2 different types of missed pill advice depending on the ethinylestradiol content of the contraceptive pill, in its guidance issued in May 2011. The missed pill information above offers the same advice regardless of the ethinylestradiol content of the contraceptive pill; it is a simplified, more cautious version of advice issued by the Faculty of Sexual and Reproductive Healthcare (see link for FSRH EC guidance which also contains useful summary on when EC may be indicated -
http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf

b) Oral progestogen only contraceptive pills
The following advice is now recommended by family planning organisations:
'If you forget a pill, take it as soon as you remember and carry on with the next pill at the right time. 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 another method, such as the condom, for the next 2 days.'

The Faculty of Sexual and Reproductive Healthcare recommends emergency contraception if one or more progestogen-only contraceptive tablets are missed or taken more than 3 hours (12 hours for *Cerazette*®) late and unprotected intercourse has occurred before 2 further tablets have been correctly taken – see link http://www.fsrh.org/pdfs/CEUGuidanceProgestogenOnlyPills.pdf .

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.

APPENDIX 3

Patient Advice Leaflet for Oral Emergency Hormonal Contraception (Levonorgestrel 1500mcg)

Please read this information carefully and speak to a health professional if you have any questions. You should also read the manufacturer's 'patient information leaflet' supplied with your medication. If you have any serious medical problems you should discuss them with a health professional to ensure this medicine is safe for you.

For the purpose of this leaflet, unprotected sexual intercourse (UPSI) is when sexual intercourse has taken place and the woman is at risk of becoming pregnant.

How does this medicine work? – Levonorgestrel is very similar to the natural female sex hormone progesterone. It is thought to work by making the lining of the womb unsuitable for pregnancy to develop and by delaying the release of an egg from the ovaries.

Taking the tablet – Take one tablet as soon as possible. It must be taken no later than 72 hours (3 days) after UPSI. The tablet works better the sooner you take it after UPSI.

Success rate - Levonorgestrel 1500micrograms is an effective emergency contraceptive method, preventing around 85% of pregnancies. However, it is not as effective as established methods of contraception especially long acting methods, such as the implant, injection and IUD/IUS ("coil"). There are alternative emergency contraceptive measures should this option not be suitable.

Effects on the baby - Should this method of contraception fail and conception takes place, there is no evidence that this medication will have any effect on the baby.

Nausea and vomiting – Occasionally patients may feel nauseous or be sick after taking this medication. Taking the tablet with or after food can reduce the chance of this. Should you be sick within three hours of taking the tablet you should contact a health professional immediately for advice to obtain a further tablet or make alternative arrangements.

Additional Patient Information – The following advice leaflets are available:

- Manufacturer's patient information (with tablet) - supplied
- This patient advice leaflet for oral emergency hormonal contraception - supplied
- Methods of contraception
  www.brook.org.uk www.fpa.org.uk
- Local Family Planning Services (YorSexualHealth) - supplied /on request
- Family Planning, Out of Hours and Genito-Urinary Medicine (GUM) - supplied /on request

Follow-up Advice

Menstrual periods – Your next period may arrive early, on time or late and may be lighter or heavier than normal.

Suspected Pregnancy – If you suspect you may be pregnant or your next period is short, light or more than seven days late, then do a home pregnancy test or see YorSexualHealth website for further advice on pregnancy and getting tested https://www.yorsexualhealth.org.uk/contraception-and-pregnancy/pregnancy-and-getting-tested/ .

Abnormal abdominal pain or heavy bleeding – Seek medical advice

Informing your GP – To help improve your quality of healthcare it is recommended that you inform your GP that you have taken this medication, or allow us to do so on your behalf.

Future Contraception – You should visit your GP surgery or YorSexualHealth about three weeks after taking this medication. As well as checking you are not pregnant, you may be advised about future contraception and practising safer sex. Emergency contraception should not be used as an alternative to regular contraception.

Advice for the Oral Contraceptive Pill – If you missed one or more doses of your regular oral contraceptive pills you may require advice about continuing the pill and the possible need for barrier contraception (condoms) for the next seven days. If you are starting the pill you may start it on the first day of your next period or withdrawal bleed after taking levonorgestrel, however you will need to either not have sex, or use a condom for the next seven days.

APPENDIX 4

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……..

G.Ph.C. Registration number…….. …….

Appendix 2

PATIENT GROUP DIRECTION
for the supply of
ORAL EMERGENCY HORMONAL CONTRACEPTION (EHC)
by community pharmacists

(Ulipristal 30mg x 1 tablet)

PATIENT GROUP DIRECTION
for the supply of
Ulipristal 30mg x 1 tablet as
ORAL EMERGENCY HORMONAL CONTRACEPTION (EHC)
by accredited community pharmacists

INDEX	PAGE

Signed document for employees of primary care contractors retained by each contractor's Clinical Governance Lead

IMPORTANT NOTES:

- ***UPSI*** *- For the purpose of this document (and appendices) unprotected sexual intercourse (UPSI) means sexual intercourse where the female is at risk of becoming pregnant. It may include situations where there has been a missed dose of the oral contraceptive pill or a failure in any barrier method of contraception.*
- **The Faculty of Sexual and Reproductive Healthcare (FSRH) state that the most effective form of EC is the copper intrauterine device (Cu-IUD). If the woman accepts Cu-IUD, refer to YorSexualHealth for emergency fitting and supply EHC in the meantime if conditions in the PGD are met.**

1. CLINICAL CONDITIONS FOR ORAL EMERGENCY HORMONAL CONTRACEPTION	
Title of Patient Group Direction:	Ulipristal 30mg tablet (ellaOne®) Emergency Hormonal Contraception by community pharmacists
PGD valid from:	1 September 2015
Expiry Date:	31 August 2017
Clinical area where PGD applies	Accredited community pharmacists employed within an NHS community pharmacy within boundaries of North Yorkshire County Council (NYCC) in pharmacies that are commissioned to provide this EHC service.
Clinical condition to which PGD applies	Emergency contraception, within 120 hours of the first episode of UPSI or failed contraceptive (missed pills/patches, failed condom/barrier method)
ADVANCE SUPPLY IS NOT INCLUDED IN THIS PGD	
Inclusion criteria	• The female has decided to avoid risk of pregnancy in this instance • Female has encountered initial UPSI within the last 120 hours and is either ◦ aged 16 - 24 ◦ aged 13, 14 or 15 and satisfies the operators assessment for the Fraser Guidance (see Appendix 1) • Female has encountered initial UPSI within the last 120 hours due to possible failure of contraceptive method e.g. ◦ Potential barrier method failure ◦ Missed/failed combined contraceptive pill/patch ◦ Missed/failed progesterone only pill ◦ Medroxyprogesterone depot (Depo-Provera) > 89 days (twelve weeks and 5 days) lapsed since the last injection ◦ Norethisterone enantate injection (Noristerat) 200mg > 70 days lapsed since the last injection ◦ Severe gastrointestinal upset that may have affected contraceptive efficacy **(see current BNF)**, or vomiting within 3 hours of taking ulipristal EHC or ◦ Risk of conception whilst advised to avoid pregnancy, such as following administration of cytotoxic agents or potentially

	teratogenic drugs • The female's medical history indicates prophylaxis is appropriate • The female has agreed to complete the prophylactic course For further guidance on inclusion criteria (see Appendix 2)
Exclusion criteria (any one excludes)	• More than 120 hours since any episode of UPSI • No third party supplies are permissible • Female aged under 13 years of age or over 24 years of age • Female aged 13, 14 or 15 who did not satisfy the pharmacist's assessment for the Fraser Ruling (see Appendix 1) • Relevant medical history is not provided by the client • A menstrual bleed is overdue (i.e. the female may already be pregnant) **NOTE** *for post-natal clients before their first post-natal menstruation, UPSI more than 21 days after delivery can lead to pregnancy (EHC is not necessary in the first 21 days post-natal)* • No menstrual period within the last 24 months (12 months if over 50 years old) • Last menstrual period was abnormal in any way (timing or character) • Female has not consented to taking ulipristal 30mg • Unexplained vaginal bleeding • Severe hepatic impairment • Acute active porphyria • Uncontrolled severe asthma (insufficiently controlled by oral steroids) • Previous supply of levonorgestrel or ulipristal within this cycle. • Taking interacting medicines either currently or within 28 days of completing treatment. ◦ Drugs that increase gastric pH (e.g. antacids, histamine H2 antagonists and PPI's) ◦ Liver enzyme-inducing drugs (e.g. rifampicin, long term ritonavir, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoin, nevirapine, oxcarbazepine, primidone, rifabutine, St John's wort) **See current BNF Appendix 1 for full list of interacting drugs.** • Any condition causing severe malabsorption e.g. Crohn's disease • Galactose intolerance, Lapp lactase deficiency or glucose galactose malabsorption • History of adverse event with hormonal contraception • Hypersensitivity to any component of the product • Any contraindication to ulipristal see manufacturer's **ellaOne SPC**
If patient is excluded or declines (the service provider should offer to assist the patient in this process)	• If consumption of the dose would be beyond 120 hours since UPSI, refer to YorSexualHealth https://yorsexualhealth.org.uk/ , GP or A&E immediately for consideration of possible alternative prophylaxis (e.g. Cu-IUD) • If excluded for any other reason, seek suitable healthcare provision immediately if emergency contraception considered necessary • If treatment is refused, this must be recorded on PharmOutcomes
Advice to all	• Advise the patient to discuss 'Sexual Health' and contraception with a suitable healthcare professional at their GP surgery or YorSexual

	Health (leaflets available) • Standard contraceptive methods are the first line in contraception. Emergency contraception should only be used in emergencies.
2. DESCRIPTION OF ORAL EMERGENCY HORMONAL CONTRACEPTION	
Name	**Ulipristal 30mg tablet (ellaOne® ▼)**
Legal status	POM – prescription only medicine
Storage	Do not store above 25^{O}C
Route	For oral administration only
Dose	Highest efficacy is achieved if the tablet is taken as soon as possible (no later than 120 hours) after UPSI
Frequency of administration	Take one tablet as a single dose under supervision in the pharmacy.
Maximum dose	30 mg
Duration of treatment	Single dose
Contra-indications	See criteria for exclusion
Cautions	**Breast-feeding mothers**: breastfeeding should be avoided for **7 days** after use of ellaOne®. In order to maintain and stimulate lactation during this time it is advised that women express and discard the breast milk.
Drug Interactions	• The effectiveness of ulipristal, is reduced in women taking ○ Drugs that increase gastric pH (e.g. antacids, histamine H2 antagonists and PPI's ○ Liver enzyme-inducing drugs (e.g. rifampicin, long term ritonavir, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoine, nevirapine, oxcarbazepine, primidone, rifabutine, St John's wort) and possibly for 4 weeks after stopping. **but please refer to the current BNF Appendix 1for a full list of drug interactions** • If a patient is taking an interacting drug and emergency contraception is considered necessary then they should seek suitable healthcare provision immediately, e.g. YorSexualHealth, GP or A&E, where a Cu-IUD can be offered instead.
Potential adverse reactions	**Nausea** – advise medication to be taken with food. **Vomiting** – provide patients with clear instructions for obtaining an additional tablet if vomiting occurs within 3 hours of the dose. **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. • Refer to product information (SPC) or BNF for fuller detail • Use the yellow card system to report adverse drug reactions

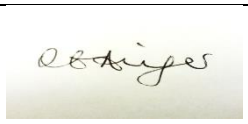
	directly to the MHRA (see BNF)
Follow up action	• A pregnancy test is recommended if: ◦ 3 weeks after last menstrual period ◦ 3 weeks after UPSI ◦ the patient has abdominal pain ◦ the period is over 7 days late ◦ the period is abnormal in any way e.g. lighter • Consider referral for sexually transmitted infection testing if appropriate
Labelling requirements	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 dispensing date to be added.
Advice to patients	Provide information and advice on ulipristal and the IUD to allow the patient to make an informed choice regarding treatment. Also, the patient must be advised regarding: **Mode of action** - inhibition or delay of ovulation **Failure rate –** at least as effective as levonorgestrel when taken within 120 hours of UPSI. **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** - if pregnancy does occur, the possibility of an ectopic pregnancy should be considered. Inform the patient to seek prompt medical advice if any abdominal pain occurs. **Dose** - oral emergency contraception is most efficacious the earlier the tablet is taken (after UPSI). **Follow-up** – if the next period is delayed by more than seven days, consider pregnancy and seek a pregnancy test. **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. Emergency hormonal contraception does NOT provide contraceptive cover for the remainder of this menstrual cycle. Clients using oral contraceptives should restart their usual pill within 12 hours of talking ellaOne® For women requiring emergency contraception because of missed pills, please refer to advice in Appendix 2. **Future contraception** - barrier contraception (condoms) recommended until the start of the next menstrual cycle. 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. **Risk of STIs** - emergency contraception does not replace necessary precautions against sexually transmitted infections. **Informing the GP** - Request the client's permission to inform their GP that a supply of contraception has/has not been made.
Records to be kept	All details to be recorded on PharmOutcomes as detailed in the on line tool and be retained according to local, legal and professional obligations.
Prescription fees	No fee is payable by the client
3. REQUIREMENTS OF REGISTERED PHARMACISTS WORKING UNDER THIS PGD	
Qualifications/ registration	Registered with the General Pharmaceutical Council (GPhC) of Great Britain
Specialist competencies or qualifications	• Pharmacist with appropriate underpinning knowledge to competently undertake the clinical assessment of patients leading to treatment according to the indications listed in this PGD • The pharmacist must complete the required training as part of the declaration of competence, as defined by the Centre for Pharmacy Postgraduate Education (CPPE) and repeat every 3 years CPPE declaration of competence • Attendance at NYCC training sessions as defined by NYCC. • Accredited pharmacists will retain all training documentation. • Maintenance of accreditation is as defined by CPPE/NYCC. • 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 knowledge of the medicine prior to its supply and to maintain this knowledge and keep up to date with relevant developments
Documents to be retained /	• The pharmacist must sign and retain a copy of the PGD in the pharmacy
Guidance for pharmacy staff	• Medicine counter staff must be trained to refer requests for EC to the pharmacist or a suitable alternative provider if the pharmacist is not present • All requests for EC should be handled in a sensitive, private and non-judgemental manner
4. SAFEGUARDING CHILDREN	
Guidance for all staff in the	All staff should discuss any concerns that may undermine the safety of a vulnerable young person, including sexually active young people.

pharmacy	Advice for Healthcare Professionals can be obtained by following the professional and training links through: www.safeguardingchildren.co.uk **Designated Nurses for Safeguarding Children** Karen Hedgley 07946 337290 Elaine Wyllie 07917 800793 **Nurse Consultant for Primary Care (Adult and Children's Safeguarding)** Jacqui Hourigan **Designated Doctors for Safeguarding Children** Dr Barbara Stewart 01904 631313 Dr Natalie Lyth 01845 521681 **In an emergency, contact North Yorkshire Police on 999** **OR** **Out of hours – NYY Social Care - Emergency Duty Team 0845 034 9417** **Multi-agency Safeguarding Children Procedures (including referrals forms and details of referral pathway) can be found at: www.safeguardingchildren.co.uk**

5. Authorisation of PGD

NORTH YORKSHIRE COUNTY COUNCIL AUTHORISATION OF PATIENT GROUP DIRECTION FOR THE SUPPLY OF ULIPRISTAL 30mg supply as emergency hormonal contraception by community pharmacies

Clinical authorization			
Name	**Job title and organisation**	**Signature**	**Date**
Dr Alison Payne	**Senior doctor GPwSI Sexual Health**		11/09/2015
Rachel Ainger	**Public Health Pharmacist** Prescribing Support Services		11/09/2015
Commissioner authorization			
Dr Lincoln Sargeant	Director of Public Health North Yorkshire County Council		15/09/2015
Version control			
PGD comes into force:	**1 September 2015**		
PGD expires	**31 August 2017**		
Version	2.0		

8. Development team

Georgina Wilkinson	Health Improvement Manager, NYCC
Dr Alison Payne	GPwSI, Sexual Health
Imran Younis	Director, Prescribing Support Services
Rachel Ainger	Public Health Pharmacist
Alison Chorlton	YorSexualHealth Lead Nurse

9. References

- Summary of Product Characteristics for ellaOne 30mg tablet, HRA Pharma. Last updated 28th January 2015. Accessed July 2015.
- BNF Online. Accessed July 2015

Guidance from the Clinical Effectiveness Unit of the Faculty of Sexual Health and Reproductive Healthcare (FSRH) of the Royal College of Obstetricians and Gynaecologists

- Drug Interactions with Hormonal Contraception. January 2011. Guidance from the Clinical Effectiveness Unit of FSRH (updated 2012)
- Missed pills: New recommendations. May 2011. Statement from the Clinical Effectiveness Unit of FSRH.
- Emergency Contraception. August 2011. FSRH Guidance. (Updated January 2012)

Please note Faculty of Sexual Health and Reproductive Healthcare (FSRH) was formerly known as the Faculty of Family Planning and Reproductive Healthcare (FFPRHC)

8. AUTHORISATION of NAMED PHARMACISTS to operate under this PGD

Agreement by Pharmacist

I, ……..., consider that I am competent to supply oral emergency hormonal contraception (ulipristal 30mg). I have completed the appropriate training, as recognised by NYCC, which will allow me to provide this professional service for up to **three years** from the date of the last NYY PCT/ NYCC accredited training session I attended.

I have read the Patient Group Direction and associated appendices for the supply of oral emergency hormonal contraception ulipristal 30mg. I will maintain clinical records as defined by PharmOutcomes and in line with recognised governance standards.

Signature: . . . . . .

G.Ph.C. Registration number . . . . . .

Date: . . . . . .

Full address: . . . . . .

. . . . . .

……

Postcode ……

Email address ……

Telephone number ……

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 (ulipristal 30mg)

Failure rate

ellaOne® 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. Amongst other factors, the success of ulipristal 30mg in preventing pregnancy depends upon how soon the dose is taken after unprotected sexual intercourse (UPSI). EllaOne0® prevents about 85% of expected pregnancies when the tablet is taken within 120 hours of UPSI.

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 120 hours of the first unprotected intercourse of that cycle. Anti-emetics may be advised. If the new dose would be later than 120 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
- Patient advice leaflet **(see Appendix 3)** for oral emergency hormonal contraception - essential
- Leaflet on methods of contraception and websites www.brook.org.uk and www.fpa.org.uk - advisable
- Leaflet on local Family Planning Services (YorSexualHealth) - advisable
- Leaflet on Family Planning Clinics, Out of Hours and Genito-Urinary Services (GUM) - 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 – 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 oEHC 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.

Practising Safer Sex

Neither oEHC nor oral contraceptive pills are appropriate for practising safer sex.

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 patients 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

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 and unprotected intercourse has occurred since finishing the last packet.
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.

Note: The Faculty of Sexual and Reproductive Healthcare offers 2 different types of missed pill advice depending on the ethinylestradiol content of the contraceptive pill, in its guidance issued in May 2011. The missed pill information above offers the same advice regardless of the ethinylestradiol content of the contraceptive pill; it is a simplified, more cautious version of advice issued by the Faculty of Sexual and Reproductive Healthcare (see link for FSRH EC guidance which also contains useful summary on when EC may be indicated -
http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf

b) Oral progestogen only contraceptive pills
The following advice is now recommended by family planning organisations:
'If you forget a pill, take it as soon as you remember and carry on with the next pill at the right time. 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 another method, such as the condom, for the next 2 days.'

The Faculty of Sexual and Reproductive Healthcare recommends emergency contraception if one or more progestogen-only contraceptive tablets are missed or taken more than 3 hours (12 hours for *Cerazette*®) late and unprotected intercourse has occurred before 2 further tablets have been correctly taken.

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.

APPENDIX 3

Patient Advice Leaflet for Oral Emergency Hormonal Contraception (Ulipristal 30mg)

Please read this information carefully and speak to a health professional if you have any questions. You should also read the manufacturer's 'patient information leaflet' supplied with your medication. If you have any serious medical problems you should discuss them with a health professional to ensure this medicine is safe for you.

For the purpose of this leaflet, unprotected sexual intercourse (UPSI) is when sexual intercourse has taken place and the woman is at risk of becoming pregnant.

How does this medicine work? – Ulipristal is similar to the natural female sex hormone progesterone. It is thought to work by making the lining of the womb unsuitable for pregnancy to grow and by delaying the release of an egg from the ovaries.

Taking the tablet – Take one tablet as soon as possible. It must be taken no later than 120 hours after UPSI. The tablet works better the sooner you take it after UPSI.

Success rate - Ulipristal 30mg is an effective emergency contraceptive but not as effective as the copper coil. Emergency contraception is not as effective as regular contraception such as the pill, the implant, the injection or the coil. It does not prevent sexually transmitted infections.

Effects on the foetus – if ulipristal fails and you get pregnant, there is no evidence that it will cause damage to your baby.

Nausea and vomiting – some women feel sick or vomit after taking ulipristal. To reduce the chance of this, take the tablet with or after food and if you vomit within 3 hours of taking it, contact a health professional to obtain another tablet.

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

- Manufacturer's patient information (with tablet) - supplied
- This patient advice leaflet for oral emergency hormonal contraception - supplied
- Methods of contraception www.brook.org.uk or www.fpa.org.uk - supplied /on request
- Local Family Planning Services (YorSexualHealth) - supplied /on request
- Family Planning, Out of Hours and Genito-Urinary Medicine (GUM) - supplied /on request

Follow-up Advice

Menstrual periods – Your next period may arrive early, on time or late and may be lighter or heavier than normal.

Suspected Pregnancy – If you suspect you may be pregnant or your next period is short, light or more than seven days late, then do a home pregnancy test or see YorSexualHealth website for further advice on pregnancy and getting tested https://www.yorsexualhealth.org.uk/contraception-and-pregnancy/pregnancy-and-getting-tested/ .

Abnormal abdominal pain or heavy bleeding – Seek medical advice

Informing your GP – To help improve your quality of healthcare it is recommended that you inform your GP that you have taken this medication, or allow us to do so on your behalf.

Future Contraception – emergency contraception should not be used as an alternative to regular contraception. You should visit your GP surgery or a Family Planning Clinic (YorSexualHealth) about three weeks after taking this medication. As well as checking you are not pregnant, you may be advised about future contraception and practising safe sex.

Advice for the Oral Contraceptive Pill – If you missed one or more doses of your regular oral contraceptive pills you may require advice about continuing the pill and the need for barrier contraception for the next seven days. If you are starting the pill you may start it on the first day of your next period or withdrawal bleed after taking ulipristal, however you will need extra contraceptive protection for the next 14 days.

APPENDIX 4

PRIVATE AND CONFIDENTIAL

Date: *Pharmacy stamp:*

Dear Dr . . . . . .

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

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

Client's address . . . . . .

. . . . . .

. . . . . .

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

D. I am writing to inform you that the above patient requested a course of ulipristal 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……..

G.Ph.C. Registration number…….. …….

Appendix 3

Emergency Contraception Decision Tree

NYCC Emergency Contraception Aide Memoir

NB These documents are intended to support, not replace, the PGD documentation

Confidentiality

Be open and honest about confidentiality with the client. Give reassurance that information will only be shared with other agencies if there is any risk to the client or anyone else and the client will be informed of this, or otherwise will be shared for information purposes with consent.

Safeguarding

Consider any safeguarding issues
Consider Fraser competency
Refer to PGDs for full details

Determine that EC is indicated

- take full contraceptive, sexual and menstrual history, including STIs
- exclude existing pregnancy and medical contra-indications to various EC methods
- check current/recent use of enzyme-inducing drugs
- check whether woman has used EHC in this cycle already
- establish:
    - number of episodes of unprotected sexual intercourse (UPSI) in this cycle
    - timing of earliest and most recent UPSI in relation to last menstrual period (LMP)
    - timing of intercourse in relation to incorrect contraception use, including in pill/patch/ring free week
    - earliest possible date of ovulation (=14 days before period, based on shortest possible cycle)
    - timing of earliest and most recent UPSI in relation to earliest possible date of ovulation

Three options for emergency contraception – discuss all three

Copper IUD | Levonorgestrel | Ulipristal acetate

Assess client suitability

Assess suitability for the three EC options.
Use the decision tree and then refer to the PGD to make a final decision on eligibility.
Signpost / refer on to other services if required.

Supply of emergency hormonal contraception

Supply in line with the PGD if clinically appropriate.
Signpost / refer on to other services if required.

Give advice

If EHC supplied, give advice on what to do if vomiting occurs within 3 hours of taking. Provide advice on contraception for the remainder of this cycle and beyond. Give advice on sexually transmitted infections – advice on screening if indicated - and condom use. Supply condoms as appropriate.

Documentation

Ensure that all relevant documentation is completed. Refer to other healthcare professionals and document accordingly as set out in the PGD documentation.

NYCC - Emergency contraception decision tree

Check concomitant medication and breast feeding status:

- If using PPIs or antacids within previous 24 hours use LNG 1500 instead of ulipristal 30mg at all times
- If using enzyme inducing medication including St John's Wort use double dose LNG (1500mcg x2) instead of ulipristal 30mg at all times (NB off license)
- If ulipristal first line choice and taking oral contraception, discuss effect on regular contraception and need to use barrier method - may wish to use LNG
- If ulipristal first line choice and breastfeeding, discuss effect and consider LNG

Abbreviations
Cu-IUD copper intrauterine device
E(H)C = emergency (hormonal) contraception
LMP = last menstrual period
LNG = levonorgestrel
PPI = proton pump inhibitors
UPSI = unprotected sexual intercourse

Female presents for EC. Take history.

Offer Cu-IUD as most effective form of EC to all where no contraindication and ≤120hours since UPSI (including multiple episodes) or within 5 days of expected date of ovulation

Accepts Cu-IUD – refer for **emergency** fitting at YorSexualHealth or GP. **Continue to supply EHC also**

Declines Cu-IUD

Any previous UPSI (>120hours) in cycle where LNG was not taken as EC (ensure aware of pregnancy risk)

Yes → Refer to YorSexual Health or GP

No

Less than 72 hours since UPSI

Between 72 and 120 hours since UPSI

Taking enzyme inducing medication

Yes → Offer Cu-IUD as most effective form of EC

No

Is ulipristal contra-indicated / not suitable (including taking enzyme inducers)?

Yes → Refer to YorSexualHealth

No

Refuses Cu-IUD

Within 3 days before and 2 days after expected ovulation (i.e. days 10-15 of 28 cycle) or unsure of date of LMP

No

Yes

Is ulipristal contra-indicated/not suitable?

Yes

No

Levonorgestrel 1500micrograms x 2

(off license – ensure patient aware)

Levonorgestrel 1500 micrograms x 1

Ulipristal 30mg x 1