

SERVICE SPECIFICATIONS

All subheadings are for local determination and agreement.

Service Specification No.	
Service	Emergency Hormonal Contraception Service
Authority Lead	<i>This will repeat what is in Part A</i>
Provider Lead	<i>This will repeat what is in Part A</i>
Period	<i>1 April 2016 to 31 March 2019 (plus possible extension for 1 + 1)</i>
Date of Review	

1. Introduction and Context

1.1 National Context & Evidence Base

- 1.1.1 Local authorities are mandated to provide or secure the provision of open access sexual health services which includes access to contraception over and above contraceptive services provided as an “additional Service” under the GP contract.
- 1.1.2 Sexual Health in Hampshire is generally good and is better than national and regional averages but there are significant differences across the county. Sexual health however is not evenly distributed within the population and there are significant differences between population groups.
- 1.1.3 Consistent and correct use of effective contraception is the best way for sexually active women and their male partners to avoid an unplanned pregnancy.
- 1.1.4 The abortion rate in Hampshire is lower than the national rate. The age standardised abortion rate for females aged 15-44 has remained static since 2006. However the number of abortions performed has increased locally from 3040 in 2011 to 3233 in 2012.
- 1.1.5 Rates of repeat abortions in under 25s are lower than national rates. Supporting young women to consider the full range of methods of contraception, including emergency contraception will further help to reduce unintended conceptions.
- 1.1.6 Despite significant reductions in the under 18 conception rate at county level (-41.2% between 1998 and 2012) the Hampshire rate of 21.1 per 1000 females aged 15-17 is worse than in other comparable local authorities.
- 1.1.7 It has been estimated that only 50% of pregnancies are planned, with 16% unplanned and 29% ambivalent. Unplanned and ambivalent pregnancies can have a major impact on individuals, families and wider society
- 1.1.8 Rates of Chlamydia in young people aged 15-24 are much higher than for other age groups and there is a new Public Health Outcome Indicator Framework (2013-2016) for a diagnostic rate of 2300 per 100, 000 young people aged 15-24.

1.2 National Policy and Guidance:

- A Framework for Sexual Health Improvement in England (DH 2013)
- Working together to Safeguard Children and Young People (2013)
- Emergency Contraception Guidance (FSRH 2011) updated (FSRH March 2017)
- Healthy Lives, Healthy People white paper (2010)
- Teenage Pregnancy Strategy Beyond 2010 (2010)
- You're Welcome Quality Criteria (2007)
- Safeguarding Vulnerable Groups Act 2006
- Recommended Standards for sexual health services (MedFASH 2005)
- National Service Framework for children, young people and maternity services (2004)
- Every Child Matters (2004)
- Sexual Offences Act (2003)

1.3 Local Drivers & Guidance:

- Hampshire Comprehensive Sexual Health Needs Assessment 2009 (updated 2013)
- Hampshire Teenage Pregnancy & Parenthood Strategy (2013/14)
- Hampshire Children & Young People's Plan (2013/16)
- Hampshire Sexual Health Strategy & Action Plan (2013-2016)

2. Hampshire County Council Strategic Aims, Priorities and Outcomes

2.1 Strategic Aims & Priorities

2.1.1 The service will focus on reducing under 18 conception and increasing Chlamydia diagnoses towards the delivery of the sexual health Public Health Outcome Framework (2013/16) measures:

- Under 18 conceptions
- Chlamydia diagnoses (15-24 year olds)

2.1.2 Reducing under 18 conception rates is a key priority in the Hampshire Children and Young People's Plan.

2.1.3 Reducing under 18 conception is a priority identified in the Hampshire Sexual Health Strategy and Action plan for 2013-16.

2.1.4 The Hampshire Sexual Health Strategy takes a life course approach to sexual health in line with the Hampshire Health & Wellbeing Strategy and the national framework for sexual health improvement in England (2013). In addition to reducing under 18 conceptions the strategy aims to reduce the rate of abortions among females aged 15-44 and in particular to reduce the proportion of repeat abortions.

2.2 HCC Strategic Aims

Improving Health & Well-being for All:

- Ensure children and young people in Hampshire thrive and achieve full potential
- Promote and support healthy choices for all, reducing the difference between those with the best and worst health
- Help people to manage their health conditions, giving them the choice and maintaining their independence

Promoting Economic Prosperity and Protecting the Environment:

- Provide opportunities for all to develop the skills needed to play a full part in Hampshire's economic success

Working with Communities to Enhance Local Services:

- Ensure that customer and community feedback, together with information about levels of need are used to plan and deliver services
- Improve access to all County Council services
- Work with communities to find the local solutions that work best, giving more control to local communities over services where appropriate
- Help residents to feel safe and be safe by working with partners to reduce crime and anti-social behaviour

The Emergency Contraception Service will support the achievement of HCC strategic aims by:

- Providing women, including vulnerable women, with increased access to sexual health services to prevent unintended pregnancy
- Providing trained and competent staff that can deliver specialist advice on reproductive healthcare within these locations
- Supporting women to manage and make informed choices about their reproductive health and to avoid unintended pregnancy or abortion
- Providing referral onto more specialist sexual health services, for more vulnerable women, if required
- Providing women in Hampshire with more local and equitable access to emergency contraception as well as choice of service providers

2.3 Service Specific Outcomes

2.2.1 A reduction in the rate of abortions

2.2.2 A reduction in the proportion of repeat abortions

2.2.3 A reduction in teenage conception rates

2.2.4 Increase in the diagnostic rate of chlamydia among young people aged 15-24

3. Sustainability, Equalities, Social Value and Other Impacts

3.1 Sustainability

3.1.1 The use of a range of community venues as a point of delivery for this service will build on existing practitioner skills and services and improve access at a local level, thereby reducing requirements to travel.

3.1.2 Provide good local access to this EHC service will facilitate the appropriate use of sexual health services and encourage users to consider more effective methods of on-going contraception.

3.2 Equalities

3.2.1 The service will be available to sexually active women irrespective of race, disability, age, religion or sexual orientation. The service will provide good local access to EHC to people across the county, to those living in dispersed rural populations and those affected by transport poverty.

3.3 Social Value

3.3.1 The service will reduce the negative impact of unintended pregnancies on: the physical and mental health of women and their children; as well as their educational outcomes and economic status and general wellbeing. Through the use of community health services, the EHC service will make a positive contribution to the economy of local communities.

3.4 Other Impacts

3.4.1 The service will reduce demand on GPs and specialist sexual health services for emergency contraception and reduce the costs of unintended conceptions to the local NHS in relation to the commissioning of maternity and termination of pregnancy services.

4. Scope

4.1 Aims and objectives of service

4.1.1 The Emergency Hormonal Contraception Service works to improve sexual health by:

- Providing good local access to emergency contraception and sexual health advice for women who have had unprotected sex in order to reduce unintended pregnancy.
- Increasing knowledge, especially among young people, of the availability and effectiveness of emergency contraception.
- Referring clients, especially those from groups with poorer sexual health outcomes, into mainstream contraceptive services for regular contraception advice and services.
- Increasing the knowledge of risks associated with sexually transmitted infections (STIs) and providing young people under the age of 25 with a Chlamydia testing kit and a supply of free condoms (see separate Chlamydia Testing & Condom Distribution Service Specification)
- Signposting clients who have been at risk of STIs to local sexual health services for STI testing & treatment (e.g. Level 3 integrated sexual health service or GP).
- Strengthening the local network of contraceptive and sexual health services in order to provide improved access to local services.

4.2 Service description and pathway (including referral routes)

4.2.1 The service will be well-advertised through the display of a window-sticker (supplied by the Level 3 integrated sexual health service) or other window display signage.

4.2.2 The service will be available for the majority of the hours the venue is open each week, to include service provision during core hours including when other service providers are closed and on Mondays (day of high demand for the service).

4.2.3 Eligible trained staff will supply Levonorgestrel Emergency Hormonal Contraception (EHC) when appropriate to clients in line with the requirements of the locally agreed Patient Group Direction (PGD) (see Appendix A & Ai). The PGD will facilitate supply to young persons under 16 in appropriate circumstances.

4.2.4 All practitioners will offer a user-friendly, non-judgmental, client-centred and confidential service.

4.2.5 The supply will be made free at the point of delivery to the client.

4.2.6 Those providing the EHC service will link into existing networks for community contraceptive services so that women who need to see a doctor can be referred on rapidly.

4.2.7 Clients excluded from the PGD criteria will be referred to another local service that will be able to assist them, as soon as possible, e.g. GP or Level 3 Integrated Sexual Health service (www.letstalkaboutit.nhs.uk)

4.2.8 Trained practitioners will provide support and advice to clients accessing the service, including advice on the avoidance of pregnancy and sexually transmitted infections (STIs) through safer sex and condom use, advice on the use of regular contraceptive methods and provide onward signposting to services that provide Long Acting Reversible Contraception and diagnosis and management of STIs.

4.2.9 Trained practitioners will provide advice on the alternative methods of emergency contraception including the copper IUD as the most effective method and will provide information on where to access this method (GP or Level 3 integrated sexual health service)

4.2.10 Trained staff will provide all young people aged 15-24 accessing the service with a free Chlamydia testing postal kit as part of the National Chlamydia Screening Programme. Chlamydia testing kits are available to order from Solent Sexual Health Promotion Service Tel: 01256 300436 or solentsexualhealthpromotion@solent.nhs.uk

4.2.11 The contractor has a duty to ensure that practitioners involved in the provision of the service have relevant knowledge and are appropriately trained in the operation of the service, including sensitive, client centred communication skills. The competencies and training framework for this service are detailed in Appendix B. Practitioners are required to be accredited before providing the service.

4.2.12 The provider must maintain appropriate records to ensure effective on-going service delivery and audit. All consultations should be recorded via Hampshire EHC service template on PharmOutcomes www.pharmoutcomes.org.uk/pharmoutcomes

4.2.13 The contractor has a duty to ensure that practitioners involved in the provision of the service are aware of and operate within local protocols.

4.2.14 A service will be provided that assesses the need and suitability for a client to receive EHC, in line with the PGD. Where appropriate a supply will be made; where a supply of EHC is not appropriate, advice and referral to another source of assistance, if appropriate, will be provided.

4.2.15 Inclusion and exclusion criteria, which are detailed in the PGD, will be applied during provision of the service.

4.2.16 The service will follow a process for obtaining informed client consent is in line with the Department of Health guidance.¹

4.2.17 The service will be provided in compliance with Fraser guidance² and Department of Health guidance on confidential sexual health advice and treatment for young people aged under 16³ and will also be provided inline with guidance from Hampshire Safeguarding Children Board.⁴ It is the responsibility of the practitioner to ensure that any young person under 16 years of age is competent to make an informed decision in line with Fraser competence.

4.2.18 The service will ensure that any young person under 16 years of age is competent to make an informed decision in line with Fraser Competence. Note that issues of child protection overrule the right to confidentiality; however any person under the age of 16 will be informed if other agencies are to be involved. Practitioners will refer to the appropriate guidance for working with the sexually active under 18's as agreed by their local safeguarding board.

4.2.19 The service will ensure that young people, under the age of 13 or under 16, where abuse is suspected (including child sexual exploitation), will be managed in accordance with Local Safeguarding procedures and complies with the requirements of relevant national guidelines, including the Children's Act.

¹ Reference Guide to consent for examination and treatment, DH July 2009:

<https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition>

² Fraser Guidelines – based on a House of Lords Ruling; A health professional can give advice or treatment to a person under 16 without parental consent providing they are satisfied that;

- The young person will understand the advice;
- The young person cannot be persuaded to tell his or her parents or allow the doctor to tell them that they are seeking contraceptive advice;
- The young person is likely to begin or continue having unprotected sex with or without contraceptive treatment; and
- The young person's physical or mental health is likely to suffer unless he or she receives contraceptive advice or treatment.

³ Guidance available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4110056

⁴ <http://www.hampshiresafeguardingchildrenboard.org.uk/index.html>

4.2.20 The service will ensure that all sexually active young people under the age of 18, should have a risk assessment for sexual exploitation using a standardised proforma at each new presentation at the service.

4.2.21 DBS checks - Carry out an assessment of both its staff and the services to ensure compliance with the Safeguarding Vulnerable Groups Act 2006.⁵

4.2.22 Verbal and written advice on the avoidance of STIs and the use of regular contraceptive methods, including advice on the use of condoms, will be provided to the client. This includes provision of a condom pack to **all** clients under 25 and provision of a free Chlamydia testing postal kit to all young people aged 15-24. (NB. Condom and testing kits to be used are the same as for the Community Service for the supply of free Chlamydia testing Kits and Condom Distribution). All advice should include a referral to a service that can provide treatment and further advice and care.

4.2.23 Clients presenting at a venue that is temporarily unable to provide the service (e.g. due to annual leave or sickness) **must** be signposted promptly to another participating service (please contact the service beforehand to ensure that a trained practitioner is available) or referred to another service provider (e.g. GP or level 3 sexual health service).

4.2.24 Professionals may need to share relevant information with other health care professionals and agencies, in line with locally determined confidentiality arrangements, including, where appropriate, the need for express consent of the client to share the information.

4.2.25 All clients under 18 will be referred to Level 3 integrated sexual health service with their consent. If the client agrees and gives verbal consent practitioners will complete the consultation form on PharmOutcomes and email a referral form via PharmOutcomes to the Level 3 integrated sexual health service on the same day as the consultation, explaining to the client that the Level 3 service will contact them by telephone within 5 working days.

4.2.26 HCC & Solent NHS Trust will provide up to date details of other services which staff can use to refer service users to who require further assistance onto the 'Get It On' website at www3.hants.gov.uk/getiton and www.letstalkaboutit.nhs.uk

4.2.27 HCC will be:

- Responsible for the promotion of the service locally, including the development of publicity materials, which EHC services will use to promote the service to the public.
- Responsible for the provision of health promotion material, including leaflets on EHC, long-term contraception and STIs to pharmacies.

4.2.28 In order to provide the EHC service the contractor will:

- Be expected to ensure that all practitioners carrying out the emergency contraception service have satisfied the requirements as set out in Appendix B staff training and competency.
- Have appropriate health promotion material available for the client group, actively promote its uptake, and be able to discuss the contents of the material with the client, where appropriate.
- Review its standard operating procedures (SOPs) for the service on an annual basis, and following any significant untoward incidents related to the service.
- Demonstrate that practitioners involved in the provision of the service have undertaken CPD relevant to this service.
- Provide data that meets the requirements of HCC.
- Co-operate with any locally agreed assessment of service user experience.

⁵ http://www.legislation.gov.uk/ukpga/2006/47/pdfs/ukpga_20060047_en.pdf

4.3 Population covered

4.3.1 This service is available to women of reproductive age who have had unprotected sex and the episode of unprotected sex has occurred within the last 72 hours.

4.4 Any acceptance and exclusion criteria and thresholds

4.4.1 All exclusion criteria are detailed in the Patient Group Direction for Emergency Hormonal Contraception (see appendix A).

4.5 Interdependencies with other services

4.5.1 Community EHC providers providing this service will need to work in close co-operation with the Level 3 Integrated Sexual Health Service provided by Solent NHS Trust (www.letstalkaboutit.nhs.uk).

4.5.2 Community EHC Service providers will also be aware of the benefits of working in partnership with other providers to ensure a networked approach to improving sexual health of local population. Partners include:

- Community Pharmacy
- General Practice
- Local Authority Children & Family Services, including Safeguarding
- Local Authority Adult Services
- Maternity services
- Gynaecology
- Rape and sexual abuse services.
- Hampshire SARC
- Educational establishments
- Community Health Services
- Voluntary Sector provides of SRE or Sexual Health interventions to young people and adults
- Health visiting
- School nursing
- Substance Misuse Services
- CAMHS
- Young people and adults with additional needs e.g. learning disability services

4.6 Any activity planning assumptions

4.6.1 This is an open access service and in order to maintain staff competency, it is expected that practitioners will at all times maintain current training & competency requirements (appendix B).

4.7 Provider Premises

4.7.1 The service will be provided from the premises when the trained practitioner is present.

4.7.2 The consultation must take place in an area or room that is:

- a. clean and not be used for storage of any stock (other than stock that is stored in closed storage units or stock that may be used, sold or supplied during a consultation – for example, hand wipes, emergency hormonal contraception, needle and syringe exchange stock etc.);
- b. so laid out and organised that any materials or equipment which are on display are healthcare related; and
- c. so laid out and organised that once a consultation begins, the patient's confidentiality is respected, and no member of staff who is not involved in the consultation is able to enter the area unless authorised by the trained practitioner, such authority being

given only if the confidentiality of the discussions during the consultation is preserved. Interruptions to the consultation must be kept to a minimum.

4.8 Days/Hours of Operation

4.8.1 The service will be available for the majority of the hours the venue is open each week, to include (where opening hours allow) service provision on Saturdays and Sundays (when other service providers are closed) and Mondays (day of high demand for the service).

4.8.2 The service is only accessible when the trained health professional is available. If the trained professional is not available (annual/sick leave) staff must be able to signpost onto another participating EHC service (www3.hants.gov.uk/getiton) GP or local sexual health clinic (www.letstalkaboutit.nhs.uk).

4.9 Public Health Planning

4.9.1 The Authority may review elements of the Service Specification in accordance with changes to Public Health delivery plans.

5. Applicable Service Standards

5.1.1 The service is underpinned by the following standards:

- NICE Emergency Contraception Summary: <http://cks.nice.org.uk/contraception-emergency#!topicsummary>
- Faculty of Sexual & Reproductive Healthcare Guidance on Emergency Contraception: <http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf>
- Faculty of Sexual and Reproductive Healthcare (FSRH) <http://www.fsrh.org/> FSRH Guideline Emergency Contraception March 2017 <http://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/>
- National Chlamydia Screening Programme Standards: www.chlamydia-screening.nhs.uk

5.1.2 The service will be provided in accordance with the guidance as set down in the Patient Group Direction for Emergency Hormonal Contraception.

5.1.3 The Service should aim to use the Department of Health's You're Welcome quality criteria and local resources where available, as guiding principles, when planning and implementing changes and improvements, in order for the service to become young people friendly where appropriate⁶.

5.2 Applicable local standards

5.2.1 Providers wishing to provide the EHC as a service via a Patient Group Direction must be trained and have their names on a service provider list kept by Hampshire County Council.

5.2.2 Completion of the CPPE modules is a pre-requisite to providing the EHC service in Hampshire:

- CPPE in emergency contraception
- CPPE in Safeguarding Children and Vulnerable Adults
- CPPE in Contraception

5.2.3 If the health practitioner providing this service is not a pharmacist (e.g. a nurse) then

⁶ You're Welcome Guidance available from <https://www.gov.uk/government/publications/quality-criteria-for-young-people-friendly-health-services>

evidence of relevant reproductive, sexual health and safeguarding training will need to be agreed with HCC before providing this EHC service.

5.2.4 All practitioners will also need to complete and pass local e-learning training that can be accessed www.training.hampshire.nhs.uk and complete the HCC e-learning on Child Sexual Exploitation accessed via www.kwango.com.

5.2.5 Local training and competency framework for the provision of the emergency contraception service is detailed in appendix B

6. Quality Standards, Performance Measures

6.1.1 Quality Outcomes Indicators: Other than those set out above in section 5 there are no additional quality outcomes.

6.1.2 Performance Indicators: The following will be used to measure the success of service delivery:

- At least 50% under 18s referred to Level 3 Sexual Health Service for on-going contraceptive advice
- 70% of young people aged 15-24 accessing this EHC service to be provided with a free Chlamydia testing kit
- Service advertised to residents via EHC window sticker or alternative window signage

6.2 Monitoring Arrangements

6.2.1 The trained practitioner will complete the online consultation form on the day of the consultation using PharmOutcomes.

6.2.2 All under 18 referrals to the Level 3 integrated sexual health service will be sent via PharmOutcomes on the same day as the EHC consultation.

6.2.3 Data on EHC consultations will be available for commissioners and pharmacy contractors via PharmOutcomes.

7. Price

7. Price

7.1 Providers will be reimbursed:

- £15.50 per EHC consultation
- The cost of Levonorgestrel at Drug Tariff price plus VAT at the applicable rate, if supplied.

7.2 A 'valid' consultation must be completed on PharmOutcomes <https://pharmoutcomes.org/pharmoutcomes>

7.3 There are no agreed increases during the duration of the contract (and clause B8.3 shall have no affect).

7.4 Information to be provided to support activity and to authorise payments shall be done via PharmOutcomes which will generate a notice of payment based on the information recorded on that software. No further information will be required from the pharmacy.

7.5 Payment will be made in arrears (Details included in the Contract)

8. Appendices

Appendix A – Patient Group Direction

Appendix B – Competency and Training Framework

Patient Group Directions for the Supply of Medicines for Contraception and Sexual Health for Community Pharmacies within Hampshire Local Authority Area

Review Date
30th September 2019

The medicines to which this PGD suite relates are:

Medicine	Number	Issue Date & Latest Version
Levonorgestrel for Emergency Hormonal Contraception (EHC) (licensed and unlicensed indications)	PGD 03	Version 3.0 September 2017

Major amendments for individual medicines will result in the issue of a new suite with a new issue and review date.

If a practitioner is asked to supply any medicine not included within this PGD suite or supply is not covered in the inclusion criteria, a patient specific direction (PSD), i.e. a prescription, is first required from a prescriber.

Authorised Staff Characteristics

Professional qualifications of staff supplying and/or administering medicines under these PGDs.	Pharmacists registered with the General Pharmaceutical Council Completion of locally required CPPE training
Competence	<p>All registered practitioners are personally accountable for their practice and in the exercise of professional accountability. There is a requirement to demonstrate and maintain competence in the following before undertaking administration or supply under this PGD suite:</p> <ul style="list-style-type: none"> • An understanding of professional standards for the administration and supply of medicines • Familiarity with the local policies and procedures relating to medicines • Appropriate training to carry out the clinical assessment of a patient • Basic training in the legal framework and use of PGDs for the supply and administration of medicines • Understanding of pharmacology of medicines supplied and/or to be administered to patients and relevant medical condition • Annual child protection updates (as applicable to young people) including a working knowledge of the Sexual Offences Act • Ensure relevant CPPE courses are up to date

Clinical Situation

Client Assessment	<p>Health details are to be recorded on the relevant patient consultation record form and will include:</p> <ol style="list-style-type: none"> 1. Reason for requesting treatment 2. If emergency contraception (EC) requested, details of last menstrual period (LMP) and details of normal menstrual cycle, details of unprotected sexual intercourse i.e. time and date, day of menstrual cycle and previous unprotected sexual intercourse (UPSI) and any use of EC in current cycle 3. Details of current and previous contraception use (where relevant) 4. Personal medical history (including previous use of EC, ectopic pregnancy, Liver disease, Malabsorption syndromes, severe diarrhoea, suspected pregnancy, lower abdominal pain, unexpected bleeding, acute porphyria or allergic reactions to the treatment) 5. Other Medication - current and in the previous 8 weeks (including herbal products such as St John's Wort) 6. Age 7. Allergies 8. All clients under 16 years old will be assessed for Fraser competence and all clients under 18 years old should have a risk assessment for sexual exploitation 9. If Weight > 70kg or BMI >26kg/m²
Consent	<ul style="list-style-type: none"> • All clients should be informed about the most common possible side effects and contraindications before verbal consent is obtained. • Manufacturers' information leaflets must be available in an appropriate language and given with all oral medication. • Young people attending for contraception deemed to be Fraser competent can give their own consent

Patients excluded from these PGDs and actions to be taken	<p>See individual product PGD</p> <ul style="list-style-type: none"> • No consent or consent declined • Previous severe local or generalised reaction to the specific or class of Medicine • Treatment contraindicated in patient or patient excluded from PGD <p>The practitioner will arrange for the client to be referred to an appropriate clinic or GP. If no doctor is available in the clinic, the client will be referred to the next appropriate sexual health clinic for Contraceptive Services, their GP, primary care out of hours service or hospital emergency department.</p>
Action if client declines care under PGD	<ul style="list-style-type: none"> • Counsel client fully as to the risks and benefits of the treatment. Offer referral to a doctor • Document advice given

Clinical Standards

Counselling	<ul style="list-style-type: none"> • Each client should be given advice and information such that they can exercise their right to informed choice when receiving this treatment • Clients will be seen by an accredited pharmacist with appropriate qualifications • All clients should be given verbal and written information on use, associated risk factors, side effects and potentially significant symptoms of their medication • All clients must have details on how to contact level 3 sexual health services, relevant opening times and the alternative sources of contraception when the clinics are not open • Clients must be assured of complete confidentiality • Clients will be supplied with their medication by the pharmacy, who will make appropriate records • Clients will be advised when/if they should be seen again for follow up or further supplies
Referral arrangements for medical advice	The pharmacist must be able to identify and contact a clinician at a level 3 sexual health service who can take responsibility for the patient's care.
Facilities to be available for use at site	A suitable private consultation room that complies with all current NHS Pharmaceutical Services regulations.
Safe administration, supply and record keeping	<p>A record of all patients supplied and/or administered with medicines will be available for audit purposes</p> <ul style="list-style-type: none"> • Ensure the recommended storage conditions have been observed. • Complete the standard contraceptive services record for each client. <p>Document the following inside the patient notes according to local procedures:</p> <ul style="list-style-type: none"> • Name of Drug • Quantity and date supplied • Dose • Document any refusal and reasons why <p>For medication supplied:</p> <ul style="list-style-type: none"> • Ensure all medication supplied is labelled with the client's name, date of supply, suitable dose and pharmacy address. The words 'Keep out of the reach

	<p>of children' and any other recommended advisory or warning labels.</p> <ul style="list-style-type: none"> • Ensure a manufacturers' product information leaflet is given to the client with each supply of contraceptive <p>Severe local and general reactions: record in clients' PMR computer record where available. Consider reporting to Medicines and Healthcare products Regulatory Agency (MHRA), especially medicines under intense surveillance (▼), on a Yellow card at the back of current BNF, telephone 0800 731 6789, or online at: www.yellowcard.gov.uk</p> <p>Consider informing clients GP with their consent.</p>
Additional Information	<p>The following information sources should be readily available on site:</p> <ul style="list-style-type: none"> • Current British National Formulary (see website link below) • Summary of Product Characteristics and Patient Information Leaflets for the relevant products. (see website link below) • A current, signed copy of this PGD
References	<p>Faculty of Sexual and Reproductive Healthcare (FSRH) http://www.fsrh.org/ FSRH Guideline Emergency Contraception March 2017 http://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/</p> <p>Drug interactions with hormonal contraception January 2017 http://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/</p> <p>British National Formulary No 73 March 2017 http://www.bnf.org Drug interactions with hormonal contraception (Appendix 1) and missed pill guidance (section 7.3)</p> <p>Electronic Medicines Compendium http://www.medicines.org.uk/ (for Summary of Product Characteristics of specific products).</p> <p>Centre for Pharmacy Postgraduate Education (CPPE) http://www.cppe.ac.uk/.</p> <p>Pharmaceutical company medicinal information teams – see BNF Index of Proprietary Manufacturers for up to date contacts details.</p>

PGD 03CP: Levonorgestrel 1500 microgram for EHC (licensed & unlicensed use)

Issue Date: September 2017

1. Clinical Condition

1.1	Situation/condition	Women requiring Emergency Hormonal Contraception (EHC)
1.2	Criteria for inclusion	<p>Women of childbearing age having had unprotected sexual intercourse or failure of usual contraception method within 72 hours of unprotected sexual intercourse</p> <p>Women presenting within 72 hours of unprotected sexual intercourse who have vomited within 3 hours of taking EHC</p> <p>Women who have received EHC once already in this cycle and subsequently had unprotected sexual intercourse or failure of usual contraception method within 72 hours</p> <p>Unlicensed indications: <i>Women taking enzyme-inducing drugs within the last 4 weeks (two tablets per dose)</i></p> <p><i>Women suffering from severe diarrhoea or severe malabsorption syndromes (two tablets per dose)</i></p> <p><i>Women weighing > 70kg or with a BMI >26kg/m² (two tablets per dose)</i></p>
1.3	Criteria for exclusion	<p>3rd party presentation</p> <p>Last unprotected sexual intercourse (UPSI) more than 72 hours prior to presentation</p> <p>Suspected pregnancy, at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy), lower abdominal pain or unexplained bleeding</p> <p>Known allergy to Levonorgestrel or excipients in the tablet.</p> <p>Contains lactose (galactose intolerance, Lapp lactase deficiency, or glucose – galactose malabsorption)</p> <p>Current severe liver disease including jaundice</p> <p>Acute porphyria (with or without symptoms)</p> <p>Women under 16 & not Fraser competent</p> <p>Use of ulipristal (Ellaone) in current cycle</p> <p>Women who have already received 2 supplies of EHC in current cycle</p> <p>Clients taking ciclosporin (may cause ciclosporin toxicity)</p>
1.4	Action if patient excluded	<p>Discuss with client the reason for exclusion and document on the consultation record form</p> <p>Discuss with client alternative methods of emergency contraception.</p> <p>Refer to clients own GP or local sexual health service</p>

Condition and product specific - MUST be used with the signed PGD Suite

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1.5	Cautions	<p>The effectiveness of levonorgestrel is reduced by the concomitant use of enzyme inducing drugs within the last 4 weeks e.g. carbamazepine, efavirenz, eslicarbazepine, griseofulvin, nelfinavir, nevirapine, oxcarbazepine, phenytoin, phenobarbital, primidone, ritonavir, rifabutin, rifampicin, St John's Wort and topiramate. Please refer to current SPC and BNF for full details</p> <p>Severe intestinal malabsorption syndromes e.g. Crohn's Disease (may impair efficacy)</p> <p>Women weighing >70kg or with a BMI >26kg/m²</p>
1.6	Action if patient declines	Document consultation and reason/s client declined, discuss alternative method to be used and/or referral

2. Description of Treatment

2.1	Name of Medicine	Levonorgestrel 1500 micrograms
2.2	Legal status	POM
2.3	Licensed or unlicensed	Licensed (Faculty of Sexual and Reproductive Healthcare (FSRH) best practice guidance supports use in under 16 years and unlicensed indication doses)
2.4	Dose	<p>Licensed indication</p> <p>One tablet to be taken as soon as possible, preferably within 12 hours and no later than 72 hours following unprotected sexual intercourse</p> <p>If vomiting occurs within 3 hours of taking the tablet, another 1500mcg tablet can be supplied and should be taken immediately</p> <p>Unlicensed Indications: enzyme inducing drugs within the last 4 weeks, malabsorption syndrome, or women weighing > 70kg or with a BMI >26kg/m²</p> <p>Women suffering from severe diarrhoea or severe malabsorption syndromes or who are taking enzyme-inducing drugs within the last 4 weeks should take two tablets as soon as possible. This should be documented as such and there should be appropriate discussion with the patient</p> <p>Women should be informed that it is possible that higher weight or BMI could reduce the effectiveness of Levonorgestrel and that two tablets should be taken as soon as possible. This should be documented as such and there should be appropriate discussion with the patient</p>
2.5	Route of Administration	Oral

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2.6	Supply	Licensed indication: One tablet Unlicensed indications: enzyme inducing drugs within the last 4 weeks <u>or</u> malabsorption syndrome <u>or</u> women weighing >70kg or with BMI >26kg/m ² : Two tablets
2.7	Side Effects	Generally well tolerated, but side effects may include nausea and vomiting, low abdominal pain, breast tenderness, headache, dizziness, fatigue and temporary disturbance of bleeding patterns Please refer to current SPC or BNF for full details

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2.8	Written/verbal advice	<p>Having established inclusion criteria and excluded contraindications, provide the patient with comprehensive information concerning:</p> <p>How to take the treatment including:-</p> <ol style="list-style-type: none">1. Take immediately or as soon as practical.2. If vomiting occurs within 3 hours advise obtain a further supply by returning to the clinic or visiting a local pharmacy3. Advise that the treatment is most effective the sooner it is taken after UPSI or failure of routine method of contraception - a glass of water may be offered to the client so that they may take the medicine on the premises <p>Failure rate of treatment</p> <p>Advise client that an intra-uterine contraceptive device (IUCD) is the most effective form of emergency contraception. If a client wishes to have an IUCD fitted please issue levonorgestrel if not excluded, and refer to GP or Sexual Health Team.</p> <p>Advise to seek medical advice if lower abdominal pain occurs.</p> <p>Advise to perform pregnancy test if menstrual bleeding is delayed by more than 5 days or menstrual bleed is lighter than normal or abnormal bleeding occurs.</p> <p>A 99% accurate pregnancy test can be done 3 weeks after last unprotected sexual intercourse.</p> <p>If an unlicensed indication, inform the client that this is current best practice.</p> <p>A manufacturer's patient information leaflet must be provided to patients who have a medicine supplied under a PGD.</p> <p>Advice must be given regarding on-going contraception including the importance of using a barrier method (e.g. condom, diaphragm or cap) or abstinence for the remainder of the current cycle.</p> <p>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 nursing at least 8 hours following levonorgestrel administration.</p> <p>The possible risk of exposure to a sexually transmitted infection and details of the Level 3 Sexual Health Service should screening be indicated.</p> <p>If not taken on the premises label the pack as per dispensed medicine and provide a patient information leaflet.</p> <p>Counselling will be undertaken verbally and in conjunction with manufacturer's product information leaflets.</p>	Condition and product specific - MUST be used with the signed PGD Suite
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2.9	Records	A copy of the consultation record must be completed at the time of supply All records must be stored securely for 8 years or until the patient's 25 th birthday (whichever is longer). Undertake a Fraser competence assessment for those under 16. Undertake a risk assessment for sexual exploitation for those under 18.	
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References

- Faculty of Sexual and Reproductive Healthcare (FSRH) Guidance; Emergency Contraception, last updated March 2017
- BNF Vol 73 March 2017

Summary Product Characteristics Levonorgestrel, www.medicines.org.uk

Appendix B: Emergency Hormonal Contraception Service Competencies and Training Framework

1. Introduction

Practitioners wishing to provide the EHC service via a Patient Group Direction must be trained and have their names on a service provider list kept by Hampshire County Council on whose behalf they are providing the service. Throughout this document the abbreviation HCC is used in place of "Hampshire County Council *or other Commissioning Bodies*".

2. Core Competencies

These core competencies have been mapped to the General Level Framework (available at www.codeg.org).

- a) Able to communicate with clients appropriately and sensitively.
- b) Able to counsel and advise on emergency contraception and regular methods of contraception.
- c) Understands how and when to refer clients and when to ask for support and advice.
- d) Understands confidentiality issues and is aware of their role in the process of safeguarding.
- e) Understands the different types and methods of hormonal contraception and non-hormonal contraception; their use, advantages, failure rates and complications.
- f) Understands the pharmacotherapy for the full range of available medication and appropriate clinical guidance (e.g. NICE).
- g) Understands and is able to apply the medico-legal aspects of EHC provision in accordance with a Patient Group Direction.
- h) Able to demonstrate knowledge of the clinical content of the relevant Patient Group Direction(s).
- i) Able to support the Team in the delivery of a safe and effective service.

3. Framework of Training

3.1 Underpinning Knowledge

Three Centre for Pharmacy Postgraduate Education (CPPE) open learning programmes provide pharmacists with the necessary knowledge to underpin the provision of EHC as an enhanced service:

Emergency Hormonal Contraception

Safeguarding Children & Vulnerable Adults

Contraception

Completion of the CPPE modules is a pre-requisite to providing the EHC service in Hampshire.

3.2 Other relevant training:

If the health practitioner providing this service is not a pharmacist (e.g. a nurse) then evidence of relevant reproductive, sexual health and safeguarding training will need be shared and agreed with HCC before providing this EHC service.

3.3 Local HCC e-learning package

All practitioners delivering the HCC EHC service need to undertake the Hampshire e-learning EHC training and the Child Sexual Exploitation (CSE) e-learning.

This training can be accessed at www.training.hampshire.nhs.uk

The CSE e-learning can be accessed at www.kwango.com Please login on the right-hand side of the screen using the following: Username: Hants Health and Password: HAH.

a) Aims

To enable practitioners to become competent to provide an EHC service in accordance with a Patient Group Direction, understanding the clinical, ethical, cultural and legal aspects of this work.

b) Objectives

The e-learning package should review the underpinning clinical knowledge required to provide an EHC service and should ensure that the practitioner:

- I. Understands the aims of an EHC service and its place in Sexual Health Services overall.
- II. Understands confidentiality issues and has an awareness of child protection issues.
- III. Understands and is able to apply the medico-legal aspects of EHC provision - especially as applied to under-age females i.e. under 16yrs (Fraser Ruling).
- IV. Understands and is able to use the Patient Group Direction and associated paperwork.
- V. Is aware of the details of when to carry out a pregnancy test, and the actions to be taken following the result.
- VI. Understands how and when to refer clients and when to ask for support and advice from the local Sexual Health Services.
- VII. Is able to counsel and advise clients appropriately and sensitively, and refer for further contraceptive care.
- VIII. Experiences problematic situations through role play, and gains confidence in dealing with them.
- IX. Knows what sources of support are available to the pharmacists involved in the provision of this service.

c) Features of the e-learning package

- Sexual Health Clinician(s) must be involved in the presentation and content of the e-learning package.
- The e-learning package must include a consultation role play scenario.

4. Summary of Assessment & Accreditation

To become accredited, each practitioner must complete the local e-learning package and successfully complete the required assessments:

- a) CPPE EHC online assessment (completed prior to undertaking the e-learning).
- b) CPPE Contraception online assessment (completed prior to the e-learning).
- c) CPPE Child Protection online assessment (completed prior to the e-learning).

Accreditation is proved by possession of dated certificates. Practitioners will not be able to sign up to the EHC PGD to provide the service without obtaining accreditation.

If the health practitioner providing this service is not a pharmacist (e.g. a nurse) then evidence of relevant reproductive, sexual health and Safeguarding training will need be shared and agreed with HCC before providing this EHC service.

5. Re-accreditation

Self-identified learning can be used to update CPD. These updates must be logged as CPD and there must be at least one per annual cycle.

CPPE updates must be identified and completed within 3 months of being issued.

6. Cross Accreditation

Trained practitioners must be advised that if they wish to provide an EHC service to another commissioner, they should contact that commissioner for further information.

Practitioners accredited outside Hampshire but wishing to provide the EHC PGD service within the HCC area are advised to contact HCC.

7. Enquiries on training & competency for EHC service:

Gina Birkett
Public Health Practitioner
Adults' Health and Care
Public Health
Elizabeth II Court West (3rd)
The Castle, Winchester
SO23 8UQ

Tel: 01962 845142

Email : gina.birkett@hants.gov.uk