

Version control		
Version 1	April 2019	
Version 1.1	November 2021	4.2.29 – Change of frequency to required SOP reviews to at least every two years or following an incident 5.2.1 – Changes to enrolment procedure for practitioners 5.2.4 – Removal of CSE training requirement Appendix A – Updated to version 5.0 September 2019 Appendix B 3.3 – Removal of CSE training requirement
Version 1.2	December 2023	4.2.27 – Updated weblink and throughout document 5.1.1 – Updated FSRH guidelines to state updated July 2023 Appendix B. 3.3 – Amend local e-learning to annual community pharmacy emergency contraception refresher training Appendix B. 7 – Changed contact details

SERVICE SPECIFICATIONS

All subheadings are for local determination and agreement.

Service Specification No.	Final version
Service	Emergency Hormonal Contraception Service
Authority Lead	Gina Birkett
Provider Lead	Multiple providers
Period	<i>1 April 2019 to 31st March 2024 (with an option to extend for a period or periods of up to 2 years)</i>
Date of Review	Reviewed December 2023. Next review December 2024.

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. However, the age standardised abortion rate for females aged 15-44 in Hampshire has increased since 2016 and the total number of abortions has increased from 3157 in 2016 to 3506 in 2017.
- 1.1.5 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 and supporting young women to consider the full range of methods of contraception and increase the uptake of Long Acting Reversible Contraception (LARC) methods

will help to reduce unintended conceptions further.

- 1.1.6 There has been a 63% reduction in the Hampshire under-18 conception rate since 1998. In 2016 the under-18 conception rate was 13.3 per 1000 females aged 15-17, approximately 305 conceptions, of which 59% of under 18 conceptions in Hampshire ended in abortion.

1.2 National Policy and Guidance:

- A Framework for Sexual Health Improvement in England (DH 2013)
- Working together to Safeguard Children and Young People (2018)
- 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 Strategy
- Hampshire Children & Young People's Plan (2015-2018)
- Hampshire Sexual Health Strategy (2016-2019)

2. Hampshire County Council Strategic Aims, Priorities and Outcomes

2.1 Strategic Aims & Priorities

2.1.1 The service will focus on reducing unintended conceptions, including under 18 conceptions, and abortions and support the delivery of the sexual health Public Health Outcome Framework indicator:

- Under 18 conceptions

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 2016-19.

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

Hampshire maintains strong and sustainable economic growth and prosperity

We will achieve this by:

- Attracting increased inward investment and promoting Hampshire's global competitiveness

- Improving Hampshire's connectivity
- Supporting businesses to start and grow, helping to create more jobs
- Helping people into work and to develop and maintain skills
- Planning and delivering appropriate development

People in Hampshire live safe, healthy and independent lives

We will achieve this by:

- Enabling children and young people to get a good start in life
- Supporting people to live independently in their own homes
- Meeting people's eligible, statutory needs – ensuring people are cared for in the right place, for the right time and at appropriate cost
- Working to overcome inequalities
- Contributing to keeping you safer

People in Hampshire enjoy a rich and diverse environment

We will achieve this by:

- Enhancing and protecting Hampshire's heritage and culture
- Conserving and using natural resources efficiently
- Protecting and improving Hampshire's environment and quality of life
- Enabling people to live healthy lifestyles, and to access and enjoy Hampshire's countryside
- Maintaining the unique character of the county

People in Hampshire enjoy being part of strong, inclusive communities

We will achieve this by:

- Making it easy for people to find and access support within the community
- Strengthening the role of town and parish councils
- Supporting a thriving and diverse voluntary and community sector and body of volunteers
- Working with the Armed Forces and Veterans communities to enhance relationships with the local

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

2.3.1 A reduction in teenage conception rates

2.3.2 A reduction in the rate of abortions

2.3.3 A reduction in the proportion of repeat abortions

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 signposting young people under the age of 25 to local sexual health services, including the availability of STI home-sampling services and free condoms.
- 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 Eligible trained staff will supply oral Emergency Hormonal Contraception (EHC) when appropriate to clients in line with the requirements of the locally agreed Patient Group Directions (PGDs) (see Appendix A & Ai). PGDs will facilitate supply to young persons under 16 in appropriate circumstances.

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

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

4.2.5 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.

4.2.6 Clients excluded from 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)

4.2.7 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.

4.2.8 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)

4.2.9 Trained staff will provide all young people aged 15-24 accessing the service with information on how to access free online Chlamydia testing.

4.2.10 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.

4.2.11 The provider must maintain appropriate records to ensure effective on-going service delivery and audit. All consultations should also be recorded via the Hampshire EHC service template on the Council's identified Clinical Record and Service Management System.

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

4.2.13 A service will be provided that assesses the need and suitability for a client to receive EHC, in line with the locally developed PGD(s). 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.

4.2.14 Inclusion and exclusion criteria, which are detailed in the PGD(s), will be applied during provision of the service.

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

4.2.16 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.

4.2.17 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

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

<https://www.gov.uk/government/publications/rlocal-eference-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:

http://webarchive.nationalarchives.gov.uk/20121202102517/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalasset/@dh/@en/documents/digitalasset/dh_4086914.pdf

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

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.

4.2.18 The service will ensure that young people, under the age of 13 or under 18, 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.

4.2.19 The service will ensure that all sexually active young people under the age of 18, have a risk assessment for sexual exploitation using a standardised proforma at each new presentation at the service in line with guidance from the Hampshire Children's Safeguarding Board

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

4.2.21 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 signposting to free online Chlamydia and other STI home-sampling services.

4.2.22 Condom packs can be provided for young people under 25 including those under 16 years of age in line with Fraser Competence as part of the EHC consultation or when requesting condoms with a C-Card through the Get It On scheme.

4.2.23 Condom distribution through the EHC service will be provided in line with the Get It On scheme. The Get It On scheme was developed to increase access to condoms in community settings for young people in, in order to reduce STIs and teenage pregnancy. The Get It On scheme requires monitoring and appropriate paperwork to be completed (see appendix C).

4.2.24 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. See 4.8.2. (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).

4.2.25 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.

4.2.26 All clients under 18 should be referred to Level 3 integrated sexual health service for follow-up contraception advice with their consent. If the client agrees and gives verbal consent practitioners will complete the consultation form on the Council's Clinical Record & Service Management System and email a referral form 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.

4.2.27 The Authority & 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 [getiton | Health and social care | Hampshire County Council \(hants.gov.uk\)](http://getiton | Health and social care | Hampshire County Council (hants.gov.uk)) and www.letstalkaboutit.nhs.uk

4.2.28 The Authority 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.

4.2.29 In order to provide the EHC service the provider will:

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

- 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 at least every two years, 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 the Authority.
- Co-operate with any locally agreed assessment of service user experience.

4.3 Population covered

4.3.1 This service is available to women of reproductive age who have had unprotected sex within the time limits specified in the PGD(s).

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
- Public Health 0-19 Services (e.g. 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 a private consultation 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 ([getiton | Health and social care | Hampshire County Council \(hants.gov.uk\)](http://getiton.org.uk)) GP or local sexual health clinic (www.letstalkaboutit.nhs.uk). The service must phone the alternative provision to ensure they can provide the service.

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 amended July 2023 <http://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/>

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 EHC as a service via a Patient Group Direction must

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

ensure that all practitioners have the necessary training certificates, have signed the Patient Group Direction for the site at which the service will be delivered, and has the authority of the contracted provider to deliver the service under the PGD. All practitioners will also be required to enrol for the service through the Council's identified Clinical Record & Service Management System. The Authority will regularly review the list of enrolled practitioners to maintain records of named practitioners. Providers may be required to send copies of signed PGDs to the Authority on request.

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

5.2.4 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:

- 100% under 18s offered referral to Level 3 Sexual Health Service for on-going contraceptive advice.
- At least 50% under 18s referred to Level 3 Sexual Health Service for on-going contraceptive advice
- 100% under 18s receive a risk assessment for Child Sexual Exploitation (CSE).

6.2 Monitoring Arrangements

6.2.1 The trained practitioner will complete the online consultation form on the day of the consultation using the Council's identified Clinical Record & Service Management System

6.2.2 All under 18 referrals to the Level 3 integrated sexual health service will be sent via secure email on the same day as the EHC consultation in accordance with 4.2.26.

6.2.3 Data on EHC consultations will be available to the Public Health team and the provider via the Council's identified Clinical Record & Service Management System

7. Price

7. Price

7.1 Providers will be reimbursed:

- £15.50 per EHC consultation
- If supplied, the cost of the oral emergency hormonal contraception drugs as per the PGD at Drug Tariff price plus VAT at the applicable rate,

7.2 Consultations must be recorded on the Council's identified Clinical Record & Service Management System

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

8. Appendices

Appendix A – Patient Group Direction

Appendix B – Competency and Training Framework

Appendix C - Condom Distribution & the Get It On scheme

This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Supply and/or administration of levonorgestrel 1500micrograms tablet(s) for emergency contraception

Within the Hampshire County Council and Isle of Wight Council Locally Commissioned Services for Emergency Hormonal Contraception

Version Number 1.0

Change History	
Version and Date	Change details
Version 1 October 2022	National template used Supply and administration of levonorgestrel 1500micrograms tablet (s) for emergency contraception: PGD template – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice (v1.1 Nov 2020)

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1 st October 2022
Review date	30 th September 2023
Expiry date:	31 st March 2024

Reference Number: HCCIWC_Lev_2022

Valid from: 01.10.2022

Review date: 30.09.2023

Expiry date: 31.03.2024

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in November 2019.

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michael Nevill	Director of Nursing British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant Marie Stopes UK
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSCHG)
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSCHG)
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Pan London PGD working group
Dr Sarah Pillai	Pan London PGD working group
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	Clinical Commissioning Group pharmacist
Tracy Rogers	Associate Director Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Amanda Cooper	Specialist Pharmacy Service
Jo Jenkins (Working Group Co-ordinator)	Specialist Pharmacist PGDs Specialist Pharmacy Service

Reference Number: HCCIWC_Lev_2022

Valid from: 01.10.2022





Review date: 30.09.2023

Expiry date: 31.03.2024

Samrina Bhatti

Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
Dr Emma Harris Senior doctor	Clinical Director – Prescribing, South West Hampshire Place, Hampshire and Isle of Wight Integrated Care Board		26.9.22
Janna Whelan Senior pharmacist	Deputy Head of Medicines Optimisation, Hampshire and Isle of Wight Integrated Care Board		26.9.22
Neil Hardy Senior representative of professional group using the PGD	Associate Director – Medicines Optimisation, Hampshire and Isle of Wight Integrated Care Board		27.9.22
Simon Bryant Person signing on behalf of authorising body	Director of Public Health Hampshire County Council and Isle of Wight Council		28.9.22

Reference Number: HCCIWC_Lev_2022

Valid from: 01.10.2022

Review date: 30.09.2023

Expiry date: 31.03.2024

1. Characteristics of staff

Qualifications and professional registration	<p>Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation.</p> <p>Pharmacists to be registered with the General Pharmaceutical Council.</p>
Initial training	<p>The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy.</p> <p>Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university.</p> <p>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.</p> <p>Training should be successful completion of:</p> <ul style="list-style-type: none"> CPPE open learning Emergency Hormonal Contraception CPPE open learning Contraception CPPE open learning Safeguarding children and vulnerable adults CPPE Emergency Contraception Declaration of Competence Additional local training as detailed in service specification and updates provided by L3 Sexual Health Service
Competency assessment	<ul style="list-style-type: none"> • Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for emergency contraception. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	<ul style="list-style-type: none"> • Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular contraception has been compromised or used incorrectly.
Criteria for inclusion	<ul style="list-style-type: none"> • Any individual presenting for emergency contraception (EC) between 0 and 96 hours following UPSI or when regular contraception has been compromised or used incorrectly. • No contraindications to the medication. • Informed consent given.
Criteria for exclusion	<ul style="list-style-type: none"> • Informed consent not given. • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • This episode of UPSI occurred more than 96 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 96 hours. • Known or suspected pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period since UPSI). • Less than 21 days after childbirth. • Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD). • Known hypersensitivity to the active ingredient or to any component of the product - see Summary of Product Characteristics • Use of ulipristal acetate emergency contraception in the previous 5 days. • Acute porphyria.
Cautions including any relevant action to be taken	<ul style="list-style-type: none"> • All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider. Patient to call Level 3 Sexual Health Service on 0300 300 2016 as soon as possible and request an emergency contraception IUD. • Ulipristal acetate can delay ovulation until closer to the time of ovulation than levonorgestrel. Consider ulipristal if the individual presents in the five days leading up to estimated day of ovulation. • Levonorgestrel is ineffective if taken after ovulation. • If individual vomits within three hours from ingestion, a repeat dose may be given. • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping them - see dose frequency section. • Body Mass Index (BMI) >26kg/m² or weight >70kg – individuals

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	<p>should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. If levonorgestrel is to be given see dosage section.</p> <ul style="list-style-type: none"> • Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of levonorgestrel is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed. • All individuals under 18 years of age should have a child sexual exploitation risk assessment (CSERQ4). • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. See Safeguarding Children Partnership Procedures, contact the professionals line and complete Interagency Referral Form (IARF) where possible. • All immediate safeguarding concerns should be made initially by telephone to the Children's Services Professionals line 01329 225379 or by email to csprofessional@hants.gov.uk Professionals on the Isle of Wight should call 0300 300 0901 or email iowcsprofessional@hants.gov.uk Calls to the Children's Services Professionals' line number will be automatically redirected to the Out of Hours Service outside normal office hours. • If the individual has not yet reached menarche consider onward referral for further assessment or investigation.
Action to be taken if the individual is excluded or declines treatment	<ul style="list-style-type: none"> • Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Offer suitable alternative emergency contraception or refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options, including: <ul style="list-style-type: none"> ○ Level 3 Sexual Health Service (including for Cu-IUD for emergency contraception: 0300 300 2016 or www.letstalkaboutit.nhs.uk)

3. Description of treatment

Name, strength & formulation of drug	Levonorgestrel 1500 micrograms tablet (N.B. this is equivalent to 1.5mg levonorgestrel)
Legal category	P/POM
Route of administration	Oral
Off label use	<p>Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).</p> <p>This PGD includes off-label use in the following conditions</p> <ul style="list-style-type: none"> ○ Use between 72 and 96 hours post UPSI ○ Increased dose for individuals with BMI over 26kg/m² or weight over 70kg and in individuals using liver enzyme inducing agent ○ Severe hepatic impairment ○ Individuals with previous salpingitis or ectopic pregnancy ○ Lapp-lactase deficiency ○ Hereditary problems of galactose intolerance ○ Glucose-galactose malabsorption <p>Drugs should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Optimisation team must be consulted. Where drugs have been assessed by pharmacy/Medicines Optimisation team in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with the pharmacy and Medicines Optimisation team.</p> <p>Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence</p>
Dose and frequency of administration	<ul style="list-style-type: none"> ● Levonorgestrel 1500mcg (1 tablet) to be taken as soon as possible up to 96 hours of UPSI. ● Dose for those individuals taking enzyme inducing medicines or herbal products: An individual who requests levonorgestrel whilst using enzyme-inducing drugs, or within 4 weeks of stopping them, can be advised to take a total of 3mg levonorgestrel (two 1500mcg tablets) as a single dose and within 96 hours of UPSI. ● Dose for those individuals with a body mass index of more than 26kg/m² or who weigh more than 70kg: An individual who requests levonorgestrel with a body mass index of more than 26kg/m² or who weighs more than 70kg can be offered a total of 3mg levonorgestrel (two 1500mcg tablets) as a single dose and within 96 hours of UPSI.

Duration of treatment	<ul style="list-style-type: none"> • A single dose is permitted under this PGD. • If vomiting occurs within 3 hours of levonorgestrel being taken a repeat dose can be supplied under this PGD. • Repeated doses can be given within the same cycle. Please note: <ul style="list-style-type: none"> ○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal) ○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel)
Quantity to be supplied	<ul style="list-style-type: none"> • Appropriately labelled pack of one tablet. • Two tablets can be supplied for individuals taking enzyme inducing drugs and/or individuals with a BMI of more than 26kg/m² or who weigh more than 70kg.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org
Identification & management of adverse reactions	<p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org</p> <p>The following side effects are common with levonorgestrel (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> • Nausea and vomiting are the most common side effects. • Headache, dizziness, fatigue, low abdominal pain and breast tenderness, diarrhoea. • The FSRH advises that bleeding patterns may be temporarily disturbed and spotting may occur, but most individuals will have their next menstrual period within seven days of the expected time
Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> • Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the individual's medical record. • Report any adverse reactions via organisation incident policy.
Written information and further advice to be provided	<ul style="list-style-type: none"> • All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception. The individual requesting emergency contraception should be provided with EHC if clinically appropriate and advised to call the Level 3 Sexual Health Service on 0300 300 2016 and ask for emergency contraception IUD (www.letstalkaboutit.nhs.uk) • Ensure that a patient information leaflet (PIL) is provided within the original pack. • If vomiting occurs within three hours of taking the dose, the individual should return for another dose. If this could be outside of opening

	<p>hours, ensure woman knows of other local pharmacy that will be open and provides service such as 100hr pharmacy.</p> <ul style="list-style-type: none"> • Explain that menstrual disturbances can occur after the use of emergency hormonal contraception. • Provide advice on ongoing contraceptive methods, including how these can be accessed. Further information available at www.letstalkaboutit.nhs.uk. • Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur. • Individuals using hormonal contraception should restart their regular hormonal contraception immediately. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. • Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern. • Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs. More information at www.letstalkaboutit.nhs.uk, including: <ul style="list-style-type: none"> ○ Free condom by post service ○ Free STI tests, including testing by post. • Free condom pack to be provided to all under 25-year-old individuals if pharmacy participates in scheme. If not signpost to website for supply. • Signpost all under 25-year-old individuals to free Chlamydia online test kit • There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.
Advice/follow up treatment	<ul style="list-style-type: none"> • The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. • Pregnancy test as required (see advice to individual above). • Individuals advised how to access on-going contraception and STI screening as required: <ul style="list-style-type: none"> ○ Ongoing contraception via GP or Level 3 Sexual Health Service www.letstalkaboutit.nhs.uk or call 0300 300 2016 ○ STI screening visit www.letstalkaboutit.nhs.uk or call 0300 300 2016
Records	<p>Record:</p> <ul style="list-style-type: none"> • The consent of the individual and <ul style="list-style-type: none"> ○ If individual is under 13 years of age record action taken ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. ○ If individual over 16 years of age and not competent, record

	<p>action taken</p> <ul style="list-style-type: none"> ○ If individual is under 18 years of age, document CSE risk assessment questionnaire ● Name of individual, address, date of birth ● GP contact details where appropriate ● Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight ● Any known drug allergies ● Name of registered health professional operating under the PGD ● Name of medication supplied ● Date of supply ● Dose supplied ● Quantity supplied ● Advice given, including advice given if excluded or declines treatment ● Details of any adverse drug reactions and actions taken ● Advice given about the medication including side effects, benefits, and when and what to do if any concerns ● Any referral arrangements made ● Any supply outside the terms of the product marketing authorisation ● Recorded that supplied via Patient Group Direction (PGD) <p>Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
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4. Key references

Key references (accessed December 2019)	<ul style="list-style-type: none"> ● Electronic Medicines Compendium http://www.medicines.org.uk/ ● Electronic BNF https://bnf.nice.org.uk/ ● NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 ● Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017 Updated December 2018 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ ● Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception - November 2017 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/ ● Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines
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Appendix A - Registered health professional authorisation sheet

Patient Group Direction (PGD) for the supply and/or administration of levonorgestrel 1500micrograms tablet(s) for emergency contraception

Within the Hampshire and Isle of Wight Locally Commissioned Services for Emergency Hormonal Contraception

PGD Name/Version: HCCIWC_Lev_2022v1 Valid from: 1.10.2022 Expiry: 31.03.2024

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

Pharmacy Name and Address where PGD to be used:			
Pharmacy Name:			
Address:		Post Code:	
F Code:			
I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of (insert name of organisation) for the above-named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

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Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation. This authorisation sheet should be retained by the Pharmacy to serve as a record of those registered health professionals authorised to work under this PGD.

Authorisation to work under the Locally Commissioned Service PGD is provided electronically by the Authorising Organisation via the Declaration of Competence via the E-Recording System used to monitor emergency contraception provision.

The PGD document and authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

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This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception

Within the Hampshire County Council and Isle of Wight Council Locally Commissioned Services for Emergency Hormonal Contraception

Version Number 1.0

Change History	
Version and Date	Change details
Version 1 October 2022	National templated use Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception: PGD template – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice (v1.1 Nov 2020)

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	1 st October 2022
Review date	30 th September 2023
Expiry date:	31 st March 2024

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in November 2019.

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This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michael Nevill	Director of Nursing British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant Marie Stopes UK
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSHCG)
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSHCG)
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Pan London PGD working group
Dr Sarah Pillai	Pan London PGD working group
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	Clinical Commissioning Group pharmacist
Tracy Rogers	Associate Director Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Amanda Cooper	Specialist Pharmacy Service
Jo Jenkins (Woking Group Co-ordinator)	Specialist Pharmacist PGDs Specialist Pharmacy Service
Samrina Bhatti	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service





ORGANISATIONAL AUTHORISATIONS

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Name	Job title and organisation	Signature	Date
Dr Emma Harris Senior doctor	Clinical Director – Prescribing, South West Hampshire Place, Hampshire and Isle of Wight Integrated Care Board		26.9.22
Janna Whelan Senior pharmacist	Deputy Head of Medicines Optimisation, Hampshire and Isle of Wight Integrated Care Board		26.9.22
Neil Hardy Senior representative of professional group using the PGD	Associate Director – Medicines Optimisation, Hampshire and Isle of Wight Integrated Care Board		27.9.22
Simon Bryant Person signing on behalf of authorising body	Director of Public Health Hampshire County Council and Isle of Wight Council		28.9.22

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1. Characteristics of staff

Qualifications and professional registration	<p>Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation.</p> <p>Pharmacists to be registered with the General Pharmaceutical Council.</p>
Initial training	<p>The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy.</p> <p>Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university.</p> <p>The healthcare professional has completed locally required training (including updates) in safeguarding children and vulnerable adults or level 2 safeguarding or the equivalent.</p> <p>Training should be successful completion of: CPPE open learning Emergency Hormonal Contraception CPPE open learning Contraception CPPE open learning Safeguarding children and vulnerable adults CPPE Emergency Contraception Declaration of Competence Additional local training as detailed in service specification and updates provided by L3 Sexual Health Service</p>
Competency assessment	<ul style="list-style-type: none"> Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for emergency contraception. Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	<ul style="list-style-type: none"> Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. Organisational PGD and/or medication training as required by employing Trust/organisation.
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

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2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular non-hormonal contraception has been compromised or used incorrectly.
Criteria for inclusion	<ul style="list-style-type: none"> • Any individual presenting for emergency contraception (EC) between 0 and 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly. • No contraindications to the medication. • Informed consent given.
Criteria for exclusion	<ul style="list-style-type: none"> • Informed consent not given. • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • This episode of UPSI occurred more than 120 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 120 hours. • Known or suspected pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period). • Less than 21 days after childbirth. • Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD). • Known hypersensitivity to the active ingredient or to any component of the product - see Summary of Product Characteristics • Use of levonorgestrel or any other progestogen in the previous 7 days (i.e. hormonal contraception, hormone replacement therapy or use for other gynaecological indications). • Regular use of antacids, proton-pump inhibitors or H₂-receptor antagonists in the last 6 days. • Severe asthma controlled by oral glucocorticoids. • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping. • Acute porphyria
Cautions including any relevant action to be taken	<ul style="list-style-type: none"> • All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception.

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	<p>If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider. Patient to call Level 3 Sexual Health Service on 0300 300 2016 as soon as possible and request an emergency contraception IUD.</p> <ul style="list-style-type: none"> • Ulipristal is ineffective if taken after ovulation. • If individual vomits within three hours from ingestion, a repeat dose may be given. • Body Mass Index (BMI) >26kg/m² or weight >70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. • Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of ulipristal is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed. • Breast feeding – advise to express and discard breast milk for 7 days after ulipristal dose. • The effectiveness of ulipristal can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs for 5 days after ulipristal. See section 'Written information and further advice to be given to individual'. • All individuals under 18 years of age should have a child sexual exploitation risk assessment (CSERQ4). • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding policy. See Safeguarding Children Partnership Procedures, contact the professionals line and complete Interagency Referral Form (IARF) where possible. • All immediate safeguarding concerns should be made initially by telephone to the Children's Services Professionals line 01329 225379 or by email to csprofessional@hants.gov.uk Professionals on the Isle of Wight should call 0300 300 0901 or email iowcsprofessional@hants.gov.uk Calls to the Children's Services Professionals' line number will be automatically redirected to the Out of Hours Service
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	<p>outside normal office hours.</p> <ul style="list-style-type: none"> • If the individual has not yet reached menarche consider onward referral for further assessment or investigation.
<p>Action to be taken if the individual is excluded or declines treatment</p>	<ul style="list-style-type: none"> • Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Offer suitable alternative emergency contraception or refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options, including: <ul style="list-style-type: none"> ○ Level 3 Sexual Health Service (including for Cu-IUD for emergency contraception: 0300 300 2016 or www.letstalkaboutit.nhs.uk)

3. Description of treatment

Name, strength & formulation of drug	Ulipristal acetate 30mg tablet
Legal category	P
Route of administration	Oral
Off label use	<p>Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).</p> <p>This PGD includes off-label use in the following conditions:</p> <ul style="list-style-type: none"> • Lapp-lactase deficiency • Hereditary problems of galactose intolerance • Glucose-galactose malabsorption • Severe hepatic impairment <p>Drugs should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Optimisation team must be consulted. Where drugs have been assessed by pharmacy/Medicines Optimisation team in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with the pharmacy and the Medicines Optimisation team.</p> <p>Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.</p>
Dose and frequency of administration	<ul style="list-style-type: none"> • One tablet (30mg) as a single dose taken as soon as possible up to 120 hours after UPSI.
Duration of treatment	<ul style="list-style-type: none"> • A single dose is permitted under this PGD. • If vomiting occurs within 3 hours of ulipristal being taken a repeat dose can be supplied under this PGD. • Repeated doses can be given within the same cycle. <p>Please note:</p> <ul style="list-style-type: none"> ○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal) ○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel)
Quantity to be supplied	Appropriately labelled pack of one tablet.

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Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org
Identification & management of adverse reactions	<p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org</p> <p>The following side effects are common with ulipristal acetate (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> • Nausea or vomiting • Abdominal pain or discomfort • Headache • Dizziness • Muscle pain (myalgia) • Dysmenorrhea • Pelvic pain • Breast tenderness • Mood changes • Fatigue • The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception.
Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report any adverse reactions via organisation incident policy.
Written information and further advice to be given to individual	<ul style="list-style-type: none"> • All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception. The individual requesting emergency contraception should be provided with EHC if clinically appropriate and advised to call the Level 3 Sexual Health Service on 0300 300 2016 and ask for emergency contraception IUD (www.letstalkaboutit.nhs.uk) • Ensure that a patient information leaflet (PIL) is provided within the original pack. • If vomiting occurs within three hours of taking the dose, the individual should return for another dose. If this could be outside of opening hours, ensure woman knows of

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	<p>other local pharmacy that will be open and provides service such as 100hr pharmacy.</p> <ul style="list-style-type: none"> • Explain that menstrual disturbances can occur after the use of emergency hormonal contraception. • Provide advice on ongoing contraceptive methods, including how these can be accessed. Further information available at www.letstalkaboutit.nhs.uk. • Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur. • In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following ulipristal acetate use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective. • Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern. • Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs. More information at www.letstalkaboutit.nhs.uk, including: <ul style="list-style-type: none"> ○ Free condom by post service ○ Free STI tests, including testing by post. • Free condom pack to be provided to all under 25-year-old individuals if pharmacy participates in scheme. If not signpost to website for supply. • Signpost all under 25-year-old individuals to free Chlamydia online test kit • There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.
<p>Advice / follow up treatment</p>	<ul style="list-style-type: none"> • The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. • Pregnancy test as required (see advice to individual above). • Individuals advised how to access on-going contraception and STI screening as required: <ul style="list-style-type: none"> ○ Ongoing contraception via GP or Level 3 Sexual Health Service www.letstalkaboutit.nhs.uk or call 0300 300 2016

	<ul style="list-style-type: none"> ○ STI screening visit www.letstalkaboutit.nhs.uk or call 0300 300 2016
Records	<p>Record:</p> <ul style="list-style-type: none"> ● The consent of the individual and <ul style="list-style-type: none"> ○ If individual is under 13 years of age record action taken ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. ○ If individual over 16 years of age and not competent, record action taken ○ If individual is under 18 years of age, document CSE risk assessment questionnaire ● Name of individual, address, date of birth ● GP contact details where appropriate ● Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight ● Any known medication allergies ● Name of registered health professional operating under the PGD ● Name of medication supplied ● Date of supply ● Dose supplied ● Quantity supplied ● Advice given, including advice given if excluded or declines treatment ● Details of any adverse drug reactions and actions taken ● Advice given about the medication including side effects, benefits, and when and what to do if any concerns ● Any referral arrangements made ● Any supply outside the terms of the product marketing authorisation ● Recorded that administered/supplied via Patient Group Direction (PGD) <p>Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>

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4. Key references

Key references (accessed December 2019)	<ul style="list-style-type: none">• Electronic Medicines Compendium http://www.medicines.org.uk/• Electronic BNF https://bnf.nice.org.uk/• NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2• Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/• Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception - November 2017 https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/• Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines
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Appendix A - Registered health professional authorisation sheet

Patient Group Direction (PGD) for the supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception

Within the Hampshire and Isle of Wight Locally Commissioned Services for Emergency Hormonal Contraception

PGD Name/Version: HCCIWC_Upa_2022v1 Valid from:1.10.2022 Expiry:31.03.2024

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

Pharmacy Name and Address where PGD to be used:			
Name:			
Address:			Post Code:
Pharmacy F Code:			
I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf (insert name of organisation) for the above-named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

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Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation. This authorisation sheet should be retained by the Pharmacy to serve as a record of those registered health professionals authorised to work under this PGD.

Authorisation to work under the Locally Commissioned Service PGD is provided electronically by the Authorising Organisation via the Declaration of Competence via the E-Recording System used to monitor emergency contraception provision.

The PGD document and authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

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Appendix B: Emergency Hormonal Contraception Service Competencies and Training Framework

1.	Introduction Practitioners wishing to provide the EHC service as a locally commissioned 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, the Authority <i>or other Commissioning Bodies</i> ”.
2.	Core Competencies The core competencies have been mapped from the Emergency Contraception Declaration of Competence (available at www.cppe.ac.uk) <ol style="list-style-type: none">1) Able to communicate with clients appropriately and sensitively.2) Able to counsel and advise on emergency contraception and regular methods of contraception using an evidence based approach.3) Understands how and when to refer clients and when to ask for support and advice.4) Understands confidentiality issues and is aware of their role in the process of safeguarding.5) Understands the different types and methods of hormonal contraception and non-hormonal contraception; their use, advantages, failure rates and complications.6) Understands the pharmacotherapy for the full range of available medication and appropriate clinical guidance (e.g. NICE).7) Understands and is able to apply the medico-legal aspects of EHC provision in accordance with a Patient Group Direction.8) Able to demonstrate knowledge of the clinical content of the relevant Patient Group Direction(s).9) Able to satisfy the NICE competency framework for health professionals using Patient Group Direction(s).10) Able to support the pharmacy team in the delivery of a safe and effective service.
3.	Framework of Training 3.1 Underpinning Knowledge The Centre for Pharmacy Postgraduate Education (CPPE) open learning / e-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 (awareness and knowledge of local processes) 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.

Appendix B: Emergency Hormonal Contraception Service Competencies and Training Framework

3.3 Local training

All practitioners delivering the EHC service need to attend or view the annual community pharmacy emergency contraception training provided by Solent NHS Trust. Links to the training are available upon request, enrolment or via the CPSC webpages.

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 training 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 training

- Sexual Health Clinician(s) must be involved in the presentation and content of the training.
- The training must include consultation scenarios.

4. Summary of Assessment & Accreditation

To become accredited, each practitioner must complete the local training and successfully complete the required assessments:

- a) CPPE EHC online assessment
- b) CPPE Contraception online assessment
- c) CPPE Safeguarding online assessment

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

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 to be 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

Appendix B: Emergency Hormonal Contraception Service Competencies and Training Framework

	<p>CPD and there must be at least one per annual cycle.</p> <p>CPPE updates must be identified and completed within 3 months of being issued.</p>
6.	<p>Cross Accreditation</p> <p>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.</p> <p>Practitioners accredited outside Hampshire but wishing to provide the EHC PGD service within the HCC Local Authority area are advised to contact HCC.</p>
7.	<p>Enquiries on training & competency for EHC service:</p> <p>Gina Birkett Public Health Practitioner Adults' Health and Care Public Health Elizabeth II Court West (3rd) The Castle, Winchester SO23 8UQ</p> <p>Tel: 07590 774314 Email : gina.birkett@hants.gov.uk and public.health.contracts@hants.gov.uk</p>

Appendix C - Condom Distribution & the Get It On scheme

Condom Distribution during the EHC consultation and using a C-Card under the Get It On scheme

Condoms are a popular choice for young people and are the only method of contraception that can provide protection against both STIs and pregnancy.

Condom distribution during EHC consultation

Please provide a free condom pack to young people aged 13-24 years old who attend your service for an EHC consultation with or without a C-card. Condom distribution must be recorded when distributed as part of the EHC consultation on the Solent Sexual Health monitoring form (example below).

Condom distribution under the Get It On scheme

Providers of the EHC service can also provide condoms to young people who have a C-Card through the Get It On scheme. Only practitioners who have completed the GET IT ON training can issue C-Cards.

When a young person comes in **with** a C-card this means that they have already been seen by a trained practitioner and have been deemed to be Fraser competent to be given condoms.

When a young person asks for free condoms **without** a C-card you will need to tell them that they need to have a C-card to access condoms from you in future. Let them know where they can get a C-card from (all sexual health clinics & some youth projects). All venues offering young people C-cards are listed on www.hants.gov.uk/getiton

If the young person **without** a C-card is **16 or older** you can on this occasion give a free pack of condoms but you need to encourage them to get a C-card in order to access condoms from your service in the future. If young person is under 16 then they will have to see a trained practitioner who will make an assessment (using the Fraser Guidelines) to see if they are competent to receive condoms.

The C Card

The card has 12 boxes on the card. Every time a user comes for condoms a box should be dated and codes as shown on the card should be used. The codes are D for Demo and C for Condoms. Boxes should be completed with the code and the date i.e. D / C / 12.12.15 would show that a demonstration and condoms were delivered on the 12.12.15

Organisation					
Name of Practitioner					
Date of Issue (Use QR)					

Young people who have been issued a C-Card and consequently forget it when going for free condoms would need to go through the Fraser Guidelines / condom demonstration again to be re-issued a C-Card.

When condoms are distributed, the practitioner needs to complete the appropriate box on the C-Card.

Practitioners who distribute condoms to young people who present a C-Card should record it as such on the monitoring form. This will allow monitoring of the use of the C-Cards.

All condom distribution must be recorded when distributed as part of the EHC consultation or to a young person presenting with a C-Card.

Appendix C - Condom Distribution & the Get It On scheme

Whilst the C-Card aims to increase access to condoms for young people it is not intended to stop conversations between practitioners and young people about sex and relationships. If a young person has not used the C-Card for a number of weeks, practitioners are encouraged to have a discussion with the young person and/or signpost them to a young person's clinic.

For further information on the Get It On Scheme please see <https://www.letstalkaboutit.nhs.uk/get-it-on-condom-distribution/>

Where do I order condoms for the GIO scheme?

Condoms and GIO C-Cards are provided by the Solent NHS Trust Sexual Health Service. You must complete an order and monitoring form in order to receive free condoms.

Email your request to: solentsexualhealthpromotion@solent.nhs.uk

Monitoring

A monitoring form must be completed every time condoms are distributed and returned to Solent Sexual Health Promotion Campaigns and resources either monthly or when you re-order supplies. The form must be returned to enable your condom supply to be replenished.

Example of monitoring form:

Date Issued	Age 13-15	Age 16-18	Age 19-24	Client Gender (M/F)	No. Packs Issued	Issued with C-Card (✓)	Issued with EHC (No C-Card) (✓)	Signed (Pharmacy Staff)	Comments e.g. referred back to registration point
	(✓)	(✓)	(✓)						

Monitoring forms can be returned to: Campaigns & Resources Office, Sexual Health Promotion, Crown Heights, Basingstoke, RG21 7TY. Call 0300 123 6604 or Email solentsexualhealthpromotion@solent.nhs.uk