Wirral Community NHS
NHS Foundation Trust

Proposal to adopt Patient Group Directions for Wirral Community Pharmacies to provide Emergency Hormonal Contraception

Meeting	Trust Board of Directors		
Date	1 March 2017	**Agenda item**	**12**
Lead Director	Ewen Sim, Medical Director		
Author(s)	Lisa Knight, Medicines Governance Pharmacist		

To Approve	☑	**To Note**	☐	**To Assure**	☐

Link to the Board Assurance Framework:

This paper relates to ensuring continuity of service provision as the new Sexual Health Service launches. This therefore provides assurance in relation to principal risks;

01a. Quality and safety not maintained or improved
08b. Failure to manage contracts (Local Authority)
08d. Sub-contracting arrangements are not effectively managed

Identified risks:

Failure to adopt the PGDs as described would result in a gap in service provision.

Financial implications:

None.

Has an Equality Impact Assessment been completed?	**Yes**	☐	**No**	☑

Does this proposal represent any service improvement or redesign?	**Yes**	☑	**No**	☐

This is a requirement of the new Sexual Health Service model.

Paper history
Has a committee of the board reviewed this paper?

Submitted to	Date	Brief Summary of Outcome
No previous reporting history.		

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Link to strategic objectives - 2014-19 *(please tick those supported by this paper)*			
We will deliver safe and effective patient care	✔	We will further develop and maintain a competent, caring and flexible workforce	✔
We will deliver a positive experience of our services	✔	We will continuously develop the organisation including leadership at every level of the organisation	✔
We will engage effectively with the patients and communities we serve	✔	We will effectively engage with our staff to deliver our strategic objectives	
Reducing health inequalities will be integral to all service developments and delivery	✔	We will optimise the use of our resources	✔
We will effectively manage and develop our relationships with our current and new commissioners and stakeholders	✔	The delivery of sustainable clinical services will be supported by corporate services	✔
We will defend and grow our core business	✔	We will effectively manage our finances and fully deliver our efficiency programme	
We will lead the delivery of out of hospital integrated care	✔	We will deliver transformation supported by innovation and research	✔
We will deliver to the expectations of our commissioners and demonstrate quality and value	✔		

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Proposal to adopt Patient Group Directions for Wirral Community Pharmacies to provide Emergency Hormonal Contraception

Purpose

1. The purpose of this paper is to ask the Board of Directors to adopt two Patient Group Directions (PGDs) currently in use for Wirral Community Pharmacies to provide emergency hormonal contraception to Wirral service users.

Executive Summary

2. The request follows Wirral Community NHS Foundation Trust's successful bid to provide Sexual Health Services across Wirral.

3. The new service now includes an element where the lead provider (WCT) sub-contracts to community pharmacies, the delivery of emergency hormonal contraception.

4. There is provision in law for organisations to adopt PGDs where organisational boundaries change; however for this to occur, the adoption needs to be explicitly noted in Board minutes.

5. The PGDs are required to be in place by 7 February 2017, it is therefore essential that Board approval is obtained electronically to facilitate the tight timescale.

Background and assurances

6. The Board of Directors is asked to approve the adoption of two PGDs, produced by Champs Public Health Collaborative, for the supply and or administration of Levonorgestrel 1500 microgram tablets and a separate PGD for the supply and/or administration of Ulipristal 30mg tablets.

7. Advice on the NHS PGD website, published 15 January 2013, updated on 26 July 2016 states that where organisational boundaries change organisations require an auditable process for managing the adoption of PGDs from any predecessor(s).

8. The Medicines Management Group will ensure that systems and processes are in place for the development, authorisation, implementation and review of these PGDs ensuring compliance with national legal frameworks and associated national guidance.

9. Titles, version numbers and expiry/review dates of the 'inherited' PGDs will be retained within the Datix library in line with best practice.

10. At present the Local Authority directly commissions Wirral Pharmacies to provide emergency hormonal contraception. PGDs produced by Champs Public Health Collaborative are already in use by Wirral Community pharmacies and these documents have already been signed off by the governance lead of each community pharmacy.

11. In the case of large national chains obtaining new authorisation for any new PGDs written by our organisation would not meet the required timescale.

12. Utilisation of the Champs documents is the preferred option for the commissioners as this PGD is used throughout Merseyside and Cheshire.

13. The adoption of these two PGDs will allow for a seamless transfer of Lead Provider for the delivery of emergency hormonal contraception via Wirral pharmacies to service users within Wirral.

14. The risk of not adopting these PGDs would result in a potential gap in service provision.

15. Both PGDs have been professionally produced by subject area specialists from the Merseyside area and provide correct advice on managing the potential situation of unlicensed use of Levonorgestrel 1500 microgram tablets in line with advice within the British National Formulary and supported by the Faculty of Sexual and Reproductive Healthcare.

16. In addition, the PGDs contain comprehensive safeguarding guidance for encounters with patients under the age of 18 years, and this has been strengthened by an addendum from WCT's safeguarding team.

Board action

17. The Board of Directors is asked to formally adopt the following PGDs **(both of which are attached as appendices)** and an addendum for each to strengthen safeguarding advice:

    - PGD for the supply and/or administration of Levonorgestrel 1500 micrograms tablets by Wirral Community Pharmacists
    - PGD for the supply and/or administration of Ulipristal 30mg tablets by Wirral Community Pharmacies
    - Addendum to strengthen safeguarding advice

Ewen Sim
Medical Director

Contributor:
Lisa Knight, Medicines Governance Pharmacist

19 January 2017

Champs Public Health Collaborative

Working together to improve health and wellbeing in Cheshire and Merseyside

WIRRAL

This Patient Group Direction (PGD) must only be used by registered Community Pharmacists who have been named and authorised by their organisation to practice under it. The PGD must only be used in conjunction with a local authority commissioned service specification for Emergency Contraception. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

for the supply and/or administration of

Ulipristal acetate 30mg tablet

by registered Community Pharmacists for

Emergency Hormonal Contraception (EHC)

in Cheshire and Merseyside

Version number: 2.0

Effective From: June 1st 2016
Expires: May 31st 2019

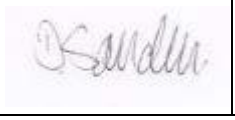
Change history

Version number	Change details	Date
1	Original version developed by Onyia, Mullin, Stubbs, Knight, Carrol, Geoghegan, Cartwright & Major –introduced in April 2014, expires March 31st 2016	April 2014
2	Completely reviewed and updated (February 2016) Takes into account NICE MPG 2 guidance & revised GMC prescribing guidance	March 2016

PGD approval/ development

	Name	Job title and organisation
Members of the PGD approval/development group	John P Hampson	Public Health Specialist, Cheshire West and Chester Council
	Dr Nicola Mullin	Consultant in Sexual and Reproductive Health, Fountains Health, Chester
	David Sanchez	Community Pharmacist, Liverpool
	Jayne Fortune	Health Improvement Practitioner Advanced, Cheshire West and Chester Council
	James Woolgar	Health Improvement Specialist, Warrington Borough Council
	Cheryl Yeardsley	Project Officer, Champs Collaborative Support Team
	Adam Major	Commissioning and Mobilisation Manager, Champs Collaborative Support Team

PGD authorisation

Name		Job title and organisation	Signature	Date
Senior Pharmacist & Lead Author	**John. P Hampson** GPhC No= 2025614	Public Health Specialist, Cheshire West and Chester Council		22/04/2016
Senior doctor	**Dr Nicola Mullin** GMC No = 3547144	Consultant in Sexual and Reproductive Health, Fountains Health, Chester		22/04/2016
Representative of profession using PGD	**David Sanchez** GPhC No= 2045057	Community Pharmacist, Liverpool		26/04/2016
Person signing on behalf of authorising body[1]	Fiona Johnstone	Director of Public Health Wirral Borough Council		9/5/2016

[1] Clinical governance or safety lead of the Local Authority , usually the Director of Public Health or Chief Executive

Community Pharmacist agreement to practise under the Ulipristal Acetate 30mg tablets Patient Group Direction for Community Pharmacists

I have read and understood the Patient Group Direction and agree to supply and/or administer this medicine only in accordance with this PGD

Name	GPhC Number	Signature	Date

Authorised to practice by Superintendent (or person acting on behalf of Superintendent)*

Full Name (print)	
GPhC number	
Signature	
Date	

*** Has responsibility to ensure that only fully competent, qualified and trained professionals implement this PGD.**
Agrees to maintain a current list of the names of individuals who may implement this PGD and to keep this with a pharmacy master copy of the PGD.
"Person acting on behalf of Superintendent" is usually the pharmacist Area or Branch manager.

Training and competency of registered Community Pharmacists

	Requirements of registered community pharmacists working under the PGD
Qualifications and professional registration	Community Pharmacists currently registered with the General Pharmaceutical Council (GPhC), who are working in a pharmacy contracted to NHS England (Mersey) or NHS England (Cheshire, Warrington and Wirral).
Initial training	As a minimum requirement, this must be at the same level, covering the same learning objectives and competencies as the Centre for Pharmacy Postgraduate Education (CPPE) e-learning programme for emergency contraception and safeguarding.
Competency assessment	The pharmacist must satisfy the requirements of Self-declaration of Competence for Community Pharmacy for Emergency Contraception. The Pharmacist should be able to demonstrate the competencies specified in NICE's Competency Framework for Health Professionals using Patient Group Directions. http://www.nice.org.uk/mpc/goodpracticeguidance/GPG2.jsp
Ongoing training and competency	The pharmacist must maintain a regular self-assessment declaration of competency every two years or sooner if appropriate. In addition to the statutory requirement for Continuing Professional Development (CPD), each pharmacist is expected to maintain an up to date awareness of developments in emergency contraception.

Clinical condition

Clinical condition or situation to which this PGD applies	Emergency contraception between 72 – 120 hours of unprotected sexual intercourse (UPSI) or suspected failure of a contraceptive method (eg barrier method or missed pills).
Inclusion criteria	• A woman of child bearing age AND presenting within 72 to 120 hours of UPSI. • Can also include women presenting between 72 – 120 hours. o with failure of barrier or normal contraceptive method (see Appendix B). o OR with severe diarrhoea and/or vomiting which may have reduced oral contraceptive efficacy. • Patient has received ulipristal acetate emergency contraception but has vomited within **three** hours of taking it (provided they are still within 120 hours of UPSI). **<u>Special notes on age</u>** **Less than 18 years:** A risk assessment should be undertaken to determine whether the child is at risk of harm. If you have a concern, the matter should be discussed with the local safeguarding lead. **Less than 16 years**: Must be competent as assessed under the Fraser Guidelines on consent to medical treatment. **Less than 13 years**: The matter must be discussed with the local safeguarding lead. The pharmacist must be aware of their local safeguarding contact numbers.
Exclusion criteria	• Woman unable to attend in person. • Hypersensitivity to the active substance or any of the excipients (e.g. lactose, povidone K30, croscarmellose and magnesium stearate) or patient has previously experienced any severe clinical problems with hormonal contraception. • Women with hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose – galactose malabsorption problems. • Up to 72 hours since UPSI. Advise woman that levonorgestrel is available - refer to levonorgestrel PGD. • Confirmed pregnancy. • Previous use of ulipristal acetate within this menstrual cycle. **NB** a second supply for patients who vomit within 3 hours of taking ulipristal acetate (provided the repeat dose is still within 120 hours of UPSI) *<u>is</u>* allowed under this PGD. **Following termination of pregnancy**, consider the date of termination as the last menstrual period. • Previous use of levonorgestrel containing emergency hormonal contraception within this menstrual cycle/ • Any earlier episodes of UPSI which took place more than 120 hours ago and within this menstrual cycle. • No valid consent

	• **Currently taking any medicine which induces hepatic enzymes** Carbamazepine, Eslicarbazepine, Oxcarbazepine Phenobarbital, Phenytoin, Primidone Rufinamide, Topiramate Rifampicin, Rifabutin Ritonavir (long term), Efavirenz, Nevirapine Fosphenytoin St John's Wort (hypericum perforatum) Bosentan Aprepitant For enzyme inducers, this exclusion also covers women who have stopped the medicines listed that induce hepatic enzymes within the last 28 days. • The following drugs have also been reported to interfere with progestogen containing contraceptives:- Aprepitant Bosentan Crizotinib Dabrafenib Efavirenz Fosaprepitant Vemurafenib The manufacturers recommend alternative forms of contraception. Because of the sparsity of information on the nature of these interactions and the potential for teratogenicity in some cases, these patients should be referred for specialist management. • Uncontrolled severe asthma (where asthma is not controlled despite **oral** corticosteroid treatment). • Severe hepatic impairment. • Post partum patients (within 21 days) are not considered at risk of pregnancy and so are excluded from treatment.
Cautions (including any relevant action to be taken)	• **An IUD is the most effective means of post coital contraception and this option must be discussed with the woman. In instances where an IUD is acceptable to the woman, continue to supply ulipristal acetate in case the IUD fitting is not done or proves unsuitable.** • **Severe intestinal malabsorption syndromes e.g. Crohn's disease** The FRSH advise that oral contraception may be less reliable in women with malabsorption due to severe small bowel disease or resection. Women with these conditions should be encouraged to consider an IUD as the preferred method of emergency contraception. • **Breast feeding** For women who are breast feeding inform them that breast feeding is not recommended for 7 days after taking ulipristal acetate. The manufacturers advise that women who are breast feeding should feed their baby immediately before taking the tablet, then pump and discard the milk for 7 days after taking the ulipristal acetate. Breast feeding can be resumed after 7 days. If the woman is unable or unwilling to comply with this advice she is excluded from treatment with ulipristal acetate under this PGD - consider supply under levonorgestrel PGD or

	refer to GP or Community Sexual and Reproductive Health Clinic. • The following drugs should be given 1.5 hours before or 1.5 hours after ulipristal acetate:- Dabigatran, digoxin, fexofenadine.
Arrangements for referral for medical advice	Know the referral pathway into local sexual and reproductive health services or how to contact the local lead doctor for sexual and reproductive health for medical advice.
Action to be taken if patient excluded	• Discuss reasons for exclusions. • Refer immediately to Community Sexual and Reproductive Health Clinic or GP if appropriate. An intrauterine device (IUD) may be fitted up to 5 days after unprotected intercourse or up to 5 days after likely ovulation. • Provide an emergency supply of condoms. • Consider supply and administration of levonorgestrel (refer to levonorgestrel PGD). • Visitors from countries outside the EU are entitled to access this free service on the NHS.
Action to be taken if patient declines treatment	• Discuss reasons patient declines treatment. • Consider the supply and administration of levonorgestrel. Refer immediately to Community Sexual and Reproductive Health Clinic or GP if appropriate.

Details of the medicine

Name, form and strength of medicine	Ulipristal acetate 30mg tablet
Legal category	POM
Indicate any off-label/ unlicensed use	Not applicable
Route/method of Administration	Oral It is recommended that the woman takes the tablet while still in the pharmacy. If the tablet is not taken in the pharmacy, advise the woman to take the tablet as soon as possible.
Dose and frequency	ONE 30mg tablet to be taken as soon as possible after the 72hrs but no later than 120 hours after UPSI. If woman vomits within 3 hours of taking the dose, then a second pack may be issued if the woman is able to take the repeated dose within 120 hours following UPSI. **Administration while the patient is present should be encouraged and supported, although this is voluntary.**
Quantity to be administered and/or supplied	One pack containing one Ulipristal acetate 30mg tablet
Maximum or minimum treatment period	See dose and frequency section above
Adverse effects	Most common side effects may include; ● Headache ● Nausea ● Abdominal pain ● Vomiting ● Dysmenorrhea ● Dizziness (shouldn't drive or operate machinery if affected) Any serious adverse effects must be reported to the MHRA via the yellow card scheme.

Records to be kept	• Where possible*, a consultation proforma for the "Supply and Administration of EHC" should be fully completed and signed for all consultations, irrespective of whether a supply is made. The following details should be recorded: o Valid informed consent has been given o Patient's name, address (optional) and date of birth o Name of GP o Dose given o Date of supply o A record of the counselling about encouragement to consider an IUD o Advice given o Advice given if patient excluded or declines treatment o Details of any adverse reactions and actions taken o Signature, GPhC number and name of pharmacist who administered or supplied the medication o Document if the dose is administered on the premises o The supply must be entered in the Patient Medication Record (PMR) o All records should be clear, legible and contemporaneous. This can be recorded via a paper or electronic version (or both) • A "Fraser Ruling Assessment of Competency" form must be completed for all women under 16 years of age. ** The Human Medicines Regulations 2012[2] confirms that in the case of supply of oral contraception, the requirements for recording information are relaxed. It is therefore reasonable for pharmacists to exert their professional judgement when supplying a woman with EHC who does not wish to provide any information.*

[2] http://www.legislation.gov.uk/uksi/2012/1916/regulation/253/made, paras 1,2,3 & 4

Patient information

Written information to be given to patient or carer	Give copy of the patient information leaflet and discuss as required e.g. failure rate (approx. 2 women out of 100 will become pregnant despite taking EHC. An IUD has negligible failure rate). Supply woman with appropriate leaflets and information about local Sexual and Reproductive Health services.
Follow-up advice to be given to patient or carer	• Woman should be advised to have a pregnancy test after 3 weeks to check for failure of EHC. • Ulipristal acetate is not intended for use during pregnancy and should not be taken by any woman suspected or known to be pregnant. Limited human data regarding pregnancy exposure to ulipristal acetate do not suggest any safety concern. However, if a woman does become pregnant, she must inform her doctor. • Advise patient that she could still become pregnant. If next period is delayed by more than 7 days or is abnormal in any way (light, heavy or painful), woman should seek medical advice. • Emphasise that the tablet is for emergency use only and is not as effective as a regular method of contraception. She must continue to use another method for the remainder of the cycle. • Also suggest that the woman makes a medical appointment to obtain regular contraception where appropriate. • Seek medical advice if there is any lower abdominal pain because this could signify an ectopic pregnancy. • Advise that the patient may be at risk of sharing sexually transmitted infections (STIs) and the need for condom use. Patients may be asymptomatic. Further advice, screening and treatment can be accessed from Community Sexual and Reproductive Health Services or their GP. • **If the patient wishes to resume hormonal contraception, they should do so AFTER 5 days.** Patient should be advised to abstain from sex or use a condom during these 5 days because **no other hormonal contraception can be used** during this period. When restarting oral contraception after this "gap" (i.e. on day 6), additional barrier method must be used for the requisite number of days as outlined in appendix B. • Breastfeeding is not recommended for 7 days after taking ulipristal acetate. During this time it is recommended to express and discard the breast milk in order to stimulate lactation. • Advise that if vomiting occurs within 3 hours of taking ulipristal acetate to immediately return to the pharmacy or seek advice from a Community Sexual and Reproductive Health clinic or GP. Second dose can be given within THREE hours of first dose. • Advise not to drive or operate machinery if affected by dizziness.

APPENDICES

Appendix A: Key References

Faculty of Sexual & Reproductive Healthcare. *Clinical guidance: Emergency contraception.* London, Clinical Effectiveness Unit, 2012
http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf

Faculty of Sexual & Reproductive Healthcare. *EMA Review of emergency contraception and weight Update.* London, Clinical Effectiveness Unit, 2014
http://www.fsrh.org/pdfs/FSRH_ECDecisionGuide.pdf

Electronic Medicines Compendium. *Summary of Product Characteristics: ellaOne 30mg tablet .* Paris, eMC (Laboratoire HRA Pharma), January 2015
https://www.medicines.org.uk/emc/medicine/22280 accessed 12th January 2016.

British National Formulary. *BNF: 70*. London, Pharmaceutical Press, 2015
Also electronic version www.bnf.org accessed 9th March 2016

General Medical Council. Good practice in prescribing and managing medicines and devices. London: GMC, 2013 (updated 2014)
http://www.gmc-uk.org/Prescribing_guidance.pdf_59055247.pdf

Dickson N. The GMC's stance on Avastin. *BMJ* 2015; 350:h204

National Institute for Health and Care Excellence. *Medicines Practice Guideline 2: Patient Group Directions*. London: NICE , 2013
https://www.nice.org.uk/guidance/mpg2/resources/patient-group-directions-1779401941189

National Institute for Health and Care Excellence. *Public health guideline 51: Contraceptive services for under 25s*. London: NICE , 2014
https://www.nice.org.uk/guidance/ph51/resources/contraceptive-services-for-under-25s-1996413367237

National Institute for Health and Care Excellence. *NICE local government briefing 17: Contraceptive services*. London: NICE , 2014
https://www.nice.org.uk/guidance/lgb17/resources/contraceptive-services-60521151465925

Cheng L, Che Y, Gulmezoglu AM. Interventions for emergency contraception (Review). *Cochrane Database of Systematic Reviews* 2012

Levonorgestrel and ulipristal remain suitable emergency contraceptives for all women regardless of bodyweight. *Letter, Medicines and Healthcare Products Regulatory Agency.* London: MHRA, 2014

Faculty of Sexual & Reproductive Healthcare. *Clinical Effectiveness Unit Statement: Missed pill recommendations.* London, Clinical Effectiveness Unit, 2011
http://www.fsrh.org/pdfs/CEUStatementMissedPills.pdf

Appendix B: Common reasons for usual method failure

- Misplaced / dislodged diaphragm / incorrect insertion / torn / removed too early.
- Condom breakage /leakage /ejaculation on/near external genitalia.
- IUD: If complete or partial expulsion is identified or mid cycle, removal of the IUD is deemed necessary and EHC should be considered. Also indicated if the device has expired i.e. more than 3 (Jaydess), 5 or 10 years since insertion, depending on type.
- Miscalculation of fertility awareness method.
- Reduced contraceptive protection because of e.g. severe diarrhoea and vomiting which may have reduced oral contraceptive efficacy.
- Missed or late contraceptive pill COC or Progestogen only contraceptive (POP) (further notes available in BNF chapter 7.3.1).
- Combined vaginal ring (CVR) (NuvaRing ®)
  - Left in for more than 4 weeks
  - New ring hasn't been inserted following the 7 day break
  - Ring has been expelled from the vagina either spontaneously or during intercourse and not replaced within 3 hours
  - Expelled more than once per cycle
- Allowed more than 14 weeks (98 days) to elapse since the last medroxyprogesterone acetate (Depo Provera or Sayana Press) contraceptive injection.
- Using contraceptive patch which becomes partially or fully dislodged or missed the change day (refer to current SPC for further advice).
- Barrier method failure in women on the COC/POP/Progestogen implants or CVR who are also taking liver enzyme inducing drugs (and for 28 days after stopping the liver enzyme inducing drugs).
- Progestogen implant: Indicated if the implant has expired (more than 3 years since insertion). Also if there has been a failed barrier method or UPSI during, or in the 28 days following, the use of liver enzyme inducing drugs.

N.B. For "missed pill" failures – please see tables overleaf

Appendix B continued - Common reasons for usual method failure

"Missed pill" failures which DO warrant EHC ULIPRISTAL ACETATE ADMINISTRATION

Combined pills 21 active tablets	**Week 1 –** If 2 or more pills are missed in the **first week** of pill taking and client has had UPSI either in the pill free week or in the first 7 days of the packet give EHC. Following this the COC should be continued with additional barrier contraception until pills have been taken on 7 consecutive days. Week 2 and 3 – If 2 or more pills are missed in the **middle or last week** of pill taking the woman should be advised to continue taking her pills and use condoms for 7 days in case of further missed pills. If there are not 7 pills left in the pack following the missed pills she should continue with the next pack without her usual 7 day break. If the pill free interval is avoided in this way she does not need emergency contraception. If there is uncertainty over which pills have been missed, EC should be given, along with advice to continue taking the pill and use a barrier method until a further 7 consecutive pills have been taken. EHC is indicated if there has been a failed barrier method or UPSI during or within the 7 days after a vomiting or severe diarrhoeal illness. EHC is indicated if there has been a failed barrier method or UPSI during, or in the 28 days following, the use of liver enzyme inducing drugs.
Progestogen-only pill (POP)	Indicated if one or more POPs have been missed or taken more than 3 hours late and UPSI has occurred in the 2 days following this. The POP should be continued with additional barrier contraception until pills have been taken correctly on two consecutive days. Exception is a desogestrel POP which can be taken up to 12 hours late without loss of contraceptive cover. EHC is indicated if there has been a failed barrier method or UPSI during or within the 2 days after a vomiting or severe diarrhoeal illness. Indicated if there has been a failed barrier method or UPSI during, or in the 28 days following, the use of liver enzyme inducing drugs.

N.B the above recommendations regarding additional barrier methods are in addition to the 5 day "gap" mentioned in the "follow-up advice to be given to patient or carer"

Potential contraceptive failures which do NOT warrant EHC use

Combined pills 21 active tablets	**No** indication if only one COC pill has been missed from the first 7 pills in a pack, as long as the last 7 pills in the previous pack were taken without omissions**.** Additional barrier contraception for 7 days is recommended, in case of further omissions. No indication if pills have been missed from the middle 7 pills in the pack as long as the first 7 pills were taken correctly. The COC should be continued to the end of the pack. Additional barrier contraception for 7 days is recommended, in case of further omissions. No indication if pills have been missed from the last 7 pills in the pack as long as the next pack is started without a pill-free interval. Additional barrier contraception for 7 days is recommended, in case of further omissions
Depo-provera	No indication if Depo Provera is given up to 2 weeks late (up to 14 weeks from the previous injection). The injectable can be given and no additional barrier method is required.

Appendix C: Advice to Young People Under 16

In considering the provision of advice or treatment on contraception, doctors and other professional staff need to take special care not to undermine parental responsibility and family stability. The doctor or other professional should therefore always seek to persuade the young person to tell the parents or guardian (or other person in loco parentis), or to let her inform them, that contraceptive advice is being sought and the nature of any advice or treatment that is given. It should be most unusual for a doctor or other professional to provide advice or treatment in relation to contraception to a young person under 16 without parental knowledge or consent.

Exceptionally, there will be cases where it is not possible to persuade the young person either to inform the parents or to allow the doctor or other professional to do so. This may be, for example, where family relationships have broken down. In such cases, a doctor or other professional would be justified in giving advice and treatment without parental knowledge or consent, provided they followed the Fraser Guidelines.

FRASER GUIDELINES

In law young people under 16 years are entitled to confidentiality in the same way as over 16 year olds. In 1985 Lord Fraser established the current legal position that a doctor or other professional can give contraceptive advice or treatment to a person under 16 without parental consent providing they are satisfied that:

- The young person will understand the risks and benefits of the treatment offered and the advice given.
- The young person cannot be persuaded to tell his or her parents or allow a health professional to inform them that he or she is seeking contraception advice.
- The young person is likely to begin or continue having intercourse with or without contraceptive treatment.
- Unless he or she receives contraceptive advice the young person's physical or mental health is likely to suffer.
- It is in the young person's best interests to give them contraceptive advice or treatment.

Reference Gillick v West Norfolk & Wisbech Area Health Authority (1984) AC 1121 ALL ER

- Where there are concerns about children and young people's welfare appropriate actions should be taken to address those concerns, working to agreed local policies and procedures. Refer to Safeguarding Children Flow Chart for Referral.

MEDICOLEGAL ASPECTS

Medical legal aspects regarding supply to under 16 year olds

1. **It's illegal for them to be having sex**
   Answer: It is illegal for a man to have sexual intercourse with a girl under age 16 years. The girl is not committing any offence. The historical background to this Act was the need to have some structure to prevent child prostitution.

2. **You are aiding and abetting an illegal act**
   Answer: Taking action after an event to minimise its ill consequences cannot be interpreted as aiding and abetting-any more than the investigation and treatment of sexually transmitted infection would be.

   The medical Defence Union opinion is that aiding and abetting would only be involved if a person actually were present at the time of the sexual intercourse and was encouraging it.

3. **The Age of Consent is 16 years**
   Answer: In English Law the validity of consent depends upon the capacity of the person to understand. The House of Lords considered the specific case of consent to contraceptive treatment in a ruling (Gillick v West Norfolk and Wisbech Area Health Authority and the Department of Health and Social Security, delivered October 1989). Attached is the advice which was issued after this by the Department of Health in the Handbook of Contraceptive Practice 1990 edition, pages 92 and 93.

   Note that the exceptional nature of providing emergency contraception under protocol to young persons under 16 is confirmed by the actual numbers seen and considered under the protocol, compared to the numbers of older women.
   Note also the young person is fully entitled to confidentiality. The guidance in paragraph 2 is that a doctor or other professional should always seek to persuade the young person to tell, or to permit to inform. No information should be given without the young person's consent and consent to disclosure given under pressure or undue persuasion would not be valid.
   The pharmacists training package includes a role play of the type of discussion which is valid and appropriate.

4. **It shouldn't be allowed for the very young, it will just encourage them**
   Answer: Note that there is a lower age limit for sale of alcohol and for sale of cigarettes, but no lower age limit for the sale of condoms. Any deterrent effect in differential use is not immediately obvious!!

   Rosemary Kirkman
   Senior Lecturer in Family Planning, University of Manchester
   Hon Consultant, Mancunian Community Family Planning Services

Contraceptive advice and treatment for young people under 16
(HN(81)5/LASS(81)2 has now been replaced by the following text which forms the Appendix to HC(86)1/HC(FP)(86)1/LAC(86)3 "Family Planning Services for Young People" issued in March 1986 – this also applies to England and Wales only).

1. The following guidance draws the attention of health authorities and others concerned to the considerations doctors and other professionals need to have in mind when providing contraceptive advice and treatment to young people under 16, and to the circumstances in which such advice and treatment can be given without parental knowledge or consent. The guidance results from a review of that in Section G of the Memorandum of Guidance on the Family Planning Service, as specified in the Appendix to HN(81)5 and LASSL(81)2, in the light of the House of Lords, decision in the case of Gillick v West Norfolk and Wisbech Area Health Authority and the Department of Health and Social Security delivered last October.

2. In considering the provision of advice or treatment on contraception doctors and other professional staff need to take special care not to undermine parental responsibility and family stability. The doctor or other professional should therefore always seek to persuade the young person to tell the parents or guardian (or other person in loco parentis)*, or to let them inform them, that contraceptive advice is being sought and the nature of any advice or treatment that is given. It should be most unusual for a doctor or other professional to provide advice or treatment in relation to contraception to a young person under 16 without parental knowledge or consent.

3. Exceptionally, there will be cases where it is not possible to persuade the young person either to inform the parents or to allow the doctor or other professional to do so. This may be, for example, where family relationships have broken down. In such cases, a doctor or other professional would be justified in giving advice and treatment without parental knowledge or consent, provided they were satisfied:

- that the young person could understand their advice and had sufficient maturity to understand what was involved in terms of the moral, social and emotional implications;

- that they could neither persuade the young person to inform the parents, nor to allow them to inform them, that contraceptive advice was being sought;

- that the young person would be very likely to begin, or continue having, sexual intercourse with or without contraceptive treatment;

- that without contraceptive advice or treatment, the young person's physical or mental health, or both would be likely to suffer;

- that the young person's best interests require them to give contraceptive advice, treatment or both without parental consent.

4. Decisions about whether to prescribe contraception in such cases are for a doctors clinical judgement, if a doctor who is not the young person's general practitioner has formed the view, after due consideration of the points made above, that it is in the best interest of the young person to prescribe contraception without parental knowledge or consent, it may be advisable and helpful for them, with the young person's agreement, to discuss the matter in confidence with her own general practitioner before making his decision.

5. In organising contraceptive services for young people, health authorities may find it helpful to make separate, less formal arrangements that those for older age groups. The staff should be experienced in dealing with young people and their problems.

*Where the parental rights and duties in respect of a young person are vested in the local authority (by virtue of a care order or a parental rights resolution under Section 3 of the Child Care Act 1980) the authority must be treated as the young person's parents for the purposes of giving consent to medical treatment in respect of a young person under 16. Where the authority does not have parental rights, the natural parent's rights are not affected. Where a young person has been committed to the care of a local authority under wardship proceedings, the consent of the High Court must be obtained by the local authority. Where a local authority shares the parental rights and duties with another person, the consent of the local authority is sufficient unless the other person indicates an objection.

EMERGENCY CONTRACEPTION For Pharmacy Use with PGD Only

Appendix D

Client requesting emergency contraception (EC)

- Take full contraceptive, sexual and menstrual history, including risk of sexually transmitted infection (STI)
- Exclude existing pregnancy and medical contra-indications to various EC methods
- Check current/recent use of enzyme-inducing drugs
- Check whether client has used emergency hormonal contraception (EHC) in this cycle already
- Establish:
  - Number of episodes of unprotected sexual intercourse (UPSI) in this cycle.
  - Timing of earliest and most recent UPSI in relation to last menstrual period (LMP).
  - Timing of intercourse in relation to incorrect contraception use, including in pill/patch/ring free week.
  - Earliest possible date of ovulation (=14 days before period, based on shortest possible cycle).
  - Timing of earliest and most recent UPSI in relation to earliest possible date of ovulation.

PT = Pregnancy test

SPC = Summary of Product Characteristics

STI = sexually transmitted infection

SRH = Sexual Reproductive Health Clinic

EC not required → Reassurance

EC required

EC not suitable → PT in 3 weeks via GP/SRH

Up to 5 days since earliest UPSI

More than 5 days since earliest UPSI

Discuss hormonal EC and copper-intrauterine device (copper-IUD) → **Copper-IUD preferred/more suitable**

- May be inserted up to 5 days after 1st UPSI.
- If timing of ovulation can be estimated copper-IUD may be inserted beyond 5 days of UPSI, as long as it does not occur beyond 5 days of earliest possible date of ovulation.
- Most effective EC method and provision of ongoing contraception.
- Most suitable method if on enzyme-inducers.
- If separate appointment for insertion (or referral to clinic /GP) needed, give interim hormonal EC.
- Consider prophylactic azithromycin if STI risk .
- If requested remove copper-IUD with next period or when no pregnancy risk and start alternative contraception.

Hormonal EC preferred option

Ulipristal acetate (see ǂ below)

- Greater than 72 hours since earliest UPSI
- Consider referral to GP/Sexual Health Clinic if patient choice prior to 72hr
- No hormonal EC taken this cycle
- Not on liver enzyme-inducing drugs
- Consider IUD/levonorgestrel if ulipristal acetate is excluded

Should only be used once per cycle (see SPC)

Levonorgestrel

Up to 72 hours since earliest UPSI or 72-120hrs if ulipristal acetate is contraindicated

May use more than once in cycle

If EC given because of UPSI:

- Advise condom use for remainder of cycle.
- Discuss ongoing contraception and provide method for future use.

After levonorgestrel use:
Consider 'quick-starting'* ongoing hormonal contraception (=starting method at time of giving levonorgestrel). Additional condom use for 1 week after levonorgestrel. PT in 3 weeks advisable.

After ulipristal acetate use:

- Hormonal contraception may be quick started **after a gap of 5 days **** during which abstinence or a barrier method are strongly advised. Barrier method should then be continued until the hormonal method is effective ie an additional 2 days for POP, 7 days for COC and 9 days for Qlaira. PT in 3 weeks advisable.

If current enzyme inducing drug use:

- Give double dose of levonorgestrel*. Don't use ulipristal acetate (SPC advice). Consider copper-IUD.

If breast feeding:

- Can use levonorgestrel. Avoid breastfeeding for 7 days after ulipristal acetate use.

Avoid concomitant use of levonorgestrel and ulipristal acetate

All EC methods

- Full counselling, including side-effects, action to be taken if vomiting within 2 to 3 hours (hormonal EC only), etc.
- Provide written information.
- Accurate documentation.
- Consider STI testing.
- Follow-up as appropriate.

ǂ This choice only applies where the pharmacy is commissioned to use the ulipristal acetate PGD for Community Pharmacy. When the woman prefers to receive ulipristal acetate, she must be referred to the local Sexual & Reproductive Health Service.

**Unlicensed dose.*

*** Recommendations from the Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Healthcare (September 2015 statement)*

(Ulipristal PGD, Champs 2016)

Champs Public Health Collaborative

Working together to improve health and wellbeing in Cheshire and Merseyside

WIRRAL

This Patient Group Direction (PGD) must or
pharmacists who have been named and authorised by their organisation to practice under it. The PGD must only be used in conjunction with a local authority commissioned service specification for Emergency Contraception. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

for the supply and/or administration of

Levonorgestrel 1500 microgram tablets

by registered community pharmacists for

Emergency Hormonal Contraception

in Cheshire and Merseyside

Version number: 2.0

Effective From: June 1st 2016

Expires: May 31st 2019

Change History

Version number	Change details	Date
1	Original version developed by Onyia, Mullin, Stubbs, Knight, Carrol, Geoghegan, Cartwright & Major – introduced in April 2014, expires March 31st 2016	April 2014
2	Completely reviewed and updated (February 2016) Takes into account NICE MPG 2 guidance & revised GMC prescribing guidance	March 2016

PGD approval/ development

	Name	Job title and organisation
Members of the PGD approval/development group	John P Hampson	Public Health Specialist, Cheshire West and Chester Council
	Dr Nicola Mullin	Consultant in Sexual and Reproductive Health, Fountains Health, Chester
	David Sanchez	Community Pharmacist, Liverpool
	Jayne Fortune	Health Improvement Practitioner Advanced, Cheshire West and Chester Council
	James Woolgar	Health Improvement Specialist, Warrington Borough Council
	Cheryl Yeardsley	Project Officer, Champs Collaborative Support Team
	Adam Major	Commissioning and Mobilisation Manager, Champs Collaborative Support Team

PGD authorisation

Name		Job title and organisation	Signature	Date
Senior Pharmacist & Lead Author	**John. P Hampson** GPhC No = 2025614	Public Health Specialist, Cheshire West and Chester Council		22/04/2016
Senior doctor	**Dr Nicola Mullin** GMC No = 3547144	Consultant in Sexual and Reproductive Health, Fountains Health, Chester		22/04/2016
Representative of profession using PGD	**David Sanchez** GPhC No = 2045057	Community Pharmacist, Liverpool		26/04/2016
Person signing on behalf of authorising body[1]	Fiona Johnstone	Director of Public Health Wirral Borough Council		9 May 2016

[1] Clinical governance or safety lead of the Local Authority , usually the Director of Public Health or Chief Executive

Community Pharmacist agreement to practise under the Levonorgestrel 1500 microgram tablets Patient Group Direction for Community Pharmacists

I have read and understood the Patient Group Direction and agree to supply and/or administer this medicine in accordance with this PGD

Name	GPhC Number	Signature	Date

Authorised to practice by Superintendent (or person acting on behalf of Superintendent)*

Full Name (print)	
GPhC number	
Signature	
Date	

*** Has responsibility to ensure that only fully competent, qualified and trained professionals implement this PGD.**
Agrees to maintain a current list of the names of individuals who may implement this PGD and to keep this with a pharmacy master copy of the PGD.
"Person acting on behalf of Superintendent" is usually the pharmacist Area or Branch manager.

Training and competency of registered community pharmacists

	Requirements of registered community pharmacists working under the PGD
Qualifications and professional registration	Community Pharmacists currently registered with the General Pharmaceutical Council (GPhC), who are working in a pharmacy contracted to NHS England (Mersey) or NHS England (Cheshire, Warrington and Wirral).
Initial training	As a minimum requirement, this must be at the same level, covering the same learning objectives and competencies as the Centre for Pharmacy Postgraduate Education (CPPE) e-learning programme for emergency contraception and safeguarding.
Competency assessment	The pharmacist must satisfy the requirements of Self-declaration of Competence (DOC) for Community Pharmacy for Emergency Contraception. The Pharmacist should be able to demonstrate the competencies specified in NICE's Competency Framework for Health Professionals using Patient Group Directions http://www.nice.org.uk/mpc/goodpracticeguidance/GPG2.jsp
Ongoing training and competency	The pharmacist must maintain a regular self-assessment declaration of competency every two years or sooner if appropriate. In addition to the statutory requirement for Continuing Professional Development (CPD), each pharmacist is expected to maintain an up to date awareness of developments in emergency contraception.

Clinical condition

Clinical condition or situation to which this PGD applies	Emergency contraception up to 72 hours of unprotected sexual intercourse (UPSI) or suspected failure of a contraceptive method.
Inclusion criteria	• A woman of child bearing age AND presenting up to 72 hours of UPSI. • Can also include women presenting up to 72 hrs of UPSI o with failure of barrier or normal contraceptive method (see Appendix B) o OR severe diarrhoea and/or vomiting which may have reduced oral contraceptive efficacy. o OR treated previously with levonorgestrel in the same cycle (N.B. see Cautions) • Can be given in women presenting between 72-120 hours in whom ulipristal acetate is inappropriate AND although an IUD has been recommended is either refused or thought unlikely to be complied with.(N.B. unlicensed indication). **<u>Special notes on age</u>** **Less than 18 years:** A risk assessment should be undertaken to determine whether the child is at risk of harm. If you have a concern, the matter should be discussed with the local safeguarding lead. **Less than 16 years**: Must be competent as assessed under the Fraser Guidelines on consent to medical treatment **Less than 13 years**: The matter must be discussed with the local safeguarding lead. The pharmacist must be aware of their local safeguarding contact numbers.
Exclusion criteria	• Woman unable to attend in person. • Hypersensitivity to the active substance or any of the excipients (e.g. lactose, potato starch, maize starch, anhydrous colloidal silica, magnesium stearate and talc). • Women with hereditary problems of galactose intolerance, lactase deficiency or glucose – galactose malabsorption problems. • A woman presenting following most recent UPSI more than 72hrs (NB – IUD or ulipristal acetate may still be an option). • No valid consent. • Confirmed pregnancy. • Acute active porphyria. • Acute trophoblastic disease – seek specialist advice. • Severe hepatic dysfunction. • Less than 21 days postpartum. • The following drugs have been reported to interfere with Progestogens containing contraceptives:- Aprepitant Bosentan Crizotinib Dabrafenib Efavirenz Fosaprepitant Vemurafenib *-please see commentary on next page-*

	The manufacturers recommend alternative forms of contraception. Because of the sparsity of information on the nature of these interactions and the potential for teratogenicity in some cases, these patients should be referred for specialist management.
Cautions (including any relevant action to be taken)	• **An IUD is the most effective means of post coital contraception and this option must be discussed with the woman. In instances where an IUD is acceptable to the woman, continue to supply levonorgestrel in case the IUD fitting is not done or proves unsuitable.** • If the last period was more than 4 weeks ago then a pregnancy test should be performed. • If levonorgestrel is used more than once in a cycle, advise the woman that she may have a delayed period or irregular bleeding. • Severe malabsorption syndromes such as Crohn's disease might impair the efficacy of levonorgestrel. Women with these conditions should be encouraged to consider an IUD as the preferred method of emergency contraception. • Currently taking any medicines which induce hepatic enzymes:_ Carbamazepine Eslicarbazepine Fosphenytoin Griseofulvin Herbal medicines containing Hypericum perforatum (St John's Wort) Nevirapine Oxcarbazepine Perampanel Phenobarbital Phenytoin Primidone Rifabutin Rifampicin Ritonavir Rufinamide Topiramate These enzyme inducers can potentially reduce the effectiveness of levonorgestrel i.e. cause pill failure. Such enzyme induction can persist up to 4 weeks after stopping the medication. In this case, the woman should be offered a copper intrauterine device (IUD) which is considered to be more effective in this context. However, if the pharmacist feels that the suggestion of an IUD is unlikely to be acted upon, a higher dose (3 mg) can be offered instead. The pharmacist must explain that this dose is "off label" i.e. outside the marketing authorisation of the product. • Women currently taking anticoagulant drugs: the anticoagulant effects may be altered following treatment with levonorgestrel. Women must be advised to give extra attention to anticoagulant monitoring. • Unexplained vaginal bleeding.
Arrangements for referral for medical advice	Know the referral pathway into local sexual and reproductive health services or how to contact the local lead doctor for sexual and reproductive health for medical advice.

Action to be taken if patient excluded	Document exclusion criteria, discuss alternative measures and refer to a Community Sexual and Reproductive Health doctor or GP as appropriate. For those presenting more than 72 hours after UPSI, ulipristal acetate or an IUD may be an option. This remains true for an IUD even if beyond 120 hours. Warn the woman that a delay in starting treatment may compromise its efficacy.
Action to be taken if patient declines treatment	Record decision in the patient clinical record. Discuss alternative and refer to a Community Sexual and Reproductive Health clinic or GP.

Details of the medicine

Name, form and strength of medicine	Levonorgestrel 1500 microgram tablet
Legal category	POM
Legal status	The higher dose (3mg) for women taken enzyme inducing drugs is outside the product licence (but consistent with the BNF) and the woman should be informed accordingly. When given between 72-120 hrs where ulipristal acetate is inappropriate, is outside the product licence and the woman should also be informed accordingly.
Route/method of administration	Oral The earlier in the 72hr period when taken, the greater the efficacy. It is recommended that the woman takes the tablet while still in the pharmacy. If the tablet is not taken in the pharmacy, the woman should be advised to take it as soon as possible.
Dose and frequency	• One tablet, no later than 72 hours after UPSI. Ideally, the tablet should be taken within 12 hours of UPSI. • If vomiting occurs within THREE hours of taking the tablet, a second tablet should be taken immediately. • If the woman is taking concomitant enzyme inducing drugs (see Cautions) then 3 mg (two tablets) should be taken. The woman should be warned that this is outside the product licence but in line with advice in the BNF.
Quantity to be administered and/or supplied	Either • One tablet to be taken as a single dose as soon as possible after UPSI or • Two tablets to be taken as a single dose as soon as possible after UPSI for a patient taking enzyme-inducing drugs (or within 28 days of stopping).
Maximum or minimum treatment period	As often as required, although women returning for repeat dosage should be advised to seek a reliable ongoing method of contraception from their GP or Community Sexual and Reproductive Health clinic.
Adverse effects	Common side effects include:- headache, nausea, lower abdominal pain, bleeding not related to menses and fatigue. Less common side effects are:- dizziness, diarrhoea, vomiting, irregular menstruation, breast tenderness, and an alteration in the timing of the next period by more than seven days. However, if the next menstrual period is more than seven days overdue, pregnancy should be excluded. Much less common side effects are abdominal pain, rash, urticaria, pruritus, pelvic pain, dysmenorrhoea and facial oedema. Any serious adverse effects must be reported to the MHRA via the yellow card scheme.
Records to be kept	• Where possible*, a consultation proforma for the “Supply and Administration of EHC” should be fully completed and signed for all consultations, irrespective of whether a supply is made. The

Records to be kept (continued)	following details should be recorded: o Valid informed consent has been given o Patient's name, address (optional) and date of birth o Name of GP o Dose given o Date of supply o A record of the counselling about encouragement to consider an IUD o Advice given o Advice given if patient excluded or declines treatment o Details of any adverse reactions and actions taken o Signature, GPhC number and name of pharmacist who administered or supplied the medication o Document if the dose is administered on the premises o The supply must be entered in the Patient Medication Record (PMR) o All records should be clear, legible and contemporaneous. This can be recorded via a paper or electronic version (or both) • A "Fraser Ruling Assessment of Competency" form must be completed for all women under 16 years of age ** The Human Medicines Regulations 2012[2] confirms that in the case of supply of oral contraception, the requirements for recording information are relaxed. It is therefore reasonable for pharmacists to exert their professional judgement when supplying a woman with EHC who does not wish to provide any information.*

[2] http://www.legislation.gov.uk/uksi/2012/1916/regulation/253/made, paras 1,2,3 & 4

Patient information

Written information to be given to patient or carer	Give copy of the patient information leaflet and discuss as required e.g. failure rate (1-3 women out of 100 will become pregnant despite taking EHC. An IUD has negligible failure rate). Supply woman with appropriate leaflets and information about local Sexual and Reproductive Health Services
Follow-up advice to be given to patient or carer	• Stress the need to use a reliable ongoing method of contraception. • Explain other available treatment option including an IUD. • Advise the patient that the drug given at this consultation for this episode of UPSI, will have no effect for previous risks (UPSI) i.e. more than 72 hours ago. • Advise that if vomiting occurs within 3 hours of taking levonorgestrel to immediately return to the pharmacy or seek advice from a Community Sexual and Reproductive Health clinic or GP. • Advise patient that she could still become pregnant. If next period is delayed by more than 7 days or is abnormal in any way (light, heavy or painful), woman should seek medical advice. • In women using bridging (follow on) contraception, stress the need to use additional barrier methods for the requisite number of days (dependent on method). • If a pregnancy has occurred, following failure of levonorgestrel treatment, the patient should contact a Community Sexual and Reproductive Health clinic or GP for further advice. • Seek medical advice if there is any lower abdominal pain because this could signify an ectopic pregnancy. • Advise that the patient may be at risk of sharing sexually transmitted infections (STIs) and the need for condom use. Patients may be asymptomatic. Further advice, screening and treatment can be accessed from Community Sexual and Reproductive Health Services or their GP. • If further dose(s) are given in the same cycle, the woman should be advised that levonorgestrel may cause disturbance of subsequent cycles. Repeated administration is not advisable because of this possibility. • For breast feeding mothers: a very small amount of levonorgestrel is excreted in breast milk, although there is no evidence that this is harmful. If breast feeding, the woman should be advised to take the tablet immediately after feeding and warned that the Product Information Leaflet(PIL) suggests discarding milk for 8 hours after taking the dose. After reviewing the most recent literature, however, the PGD group felt there is little information to support this suggestion. On balance, it is probably better for breast feeding women to feed just before taking LNG and avoid feeding for a few hours after (if possible) although no harm is likely. For individuals who are reluctant to comply with this, the option of having an IUD should be discussed as an alternative. • Emergency contraception is an occasional method. It should in no instance replace a regular method of contraception. • There is no evidence to date that the hormones used postcoitally carry any risk of teratogenicity should the method fail and a pregnancy occur.

	• Advise that when given between 72-120hrs when ulipristal acetate is inappropriate (and an IUD has been refused) is outside the product licence. Although the Faculty of Sexual and Reproductive Healthcare support this indication, warn that an IUD is much more effective.

APPENDICES

Appendix A: Key References

Faculty of Sexual & Reproductive Healthcare. *Clinical guidance: Emergency contraception.* London, Clinical Effectiveness Unit, 2012
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Levonorgestrel and ulipristal acetate remain suitable emergency contraceptives for all women regardless of bodyweight. *Letter, Medicines and Healthcare Products Regulatory Agency.* London: MHRA, 2014

Faculty of Sexual & Reproductive Healthcare. *Clinical Effectiveness Unit Statement: Missed pill recommendations.* London, Clinical Effectiveness Unit, 2011
http://www.fsrh.org/pdfs/CEUStatementMissedPills.pdf

Appendix B: Common reasons for usual method failure

- Misplaced / dislodged diaphragm / incorrect insertion / torn / removed too early.
- Condom breakage /leakage /ejaculation on external genitalia.
- IUD: If complete or partial expulsion is identified or mid cycle, removal of the IUD is deemed necessary and EHC should be considered. Also indicated if the device has expired i.e. more than 3 (Jaydess), 5 or 10 years since insertion, depending on type.
- Miscalculation of fertility awareness method.
- Reduced contraceptive protection because of e.g. severe diarrhoea and vomiting which may have reduced oral contraceptive efficacy.
- Missed or late contraceptive pill COC or Progestogen only contraceptive (POP) (further notes available in BNF chapter 7.3.1).
- Combined vaginal ring (CVR) (NuvaRing ®)
  - Left in for more than 4 weeks
  - New ring hasn't been inserted following the 7 day break
  - Ring has been expelled from the vagina either spontaneously or during intercourse and not replaced within 3 hours
  - Expelled more than once per cycle
- Allowed more than 14 weeks (98 days) to elapse since the last medroxyprogesterone acetate (Depo Provera or Sayana Press) contraceptive injection.
- Using contraceptive patch which becomes partially or fully dislodged or missed the change day (refer to current SPC for further advice).
- Barrier method failure in women on the COC/POP/Progestogen implants or CVR who are also taking liver enzyme inducing drugs (and for 28 days after stopping the liver enzyme inducing drugs).
- Progestogen implant: Indicated if the implant has expired (more than 3 years since insertion). Also if there has been a failed barrier method or UPSI during, or in the 28 days following, the use of liver enzyme inducing drugs.

N.B. For "missed pill" failures – please see tables overleaf

Appendix B continued - Common reasons for usual method failure

"Missed pill" failures which DO warrant EHC LEVONORGESTREL ADMINISTRATION

Combined pills 21 active tablets	**Week 1 –** If 2 or more pills are missed in the **first week** of pill taking and client has had UPSI either in the pill free week or in the first 7 days of the packet give EHC. Following this the COC should be continued with additional barrier contraception until pills have been taken on 7 consecutive days. Week 2 and 3 – If 2 or more pills are missed in the **middle or last week** of pill taking the woman should be advised to continue taking her pills and use condoms for 7 days in case of further missed pills. If there are not 7 pills left in the pack following the missed pills she should continue with the next pack without her usual 7 day break. If the pill free interval is avoided in this way she does not need emergency contraception. If there is uncertainty over which pills have been missed, EC should be given, along with advice to continue taking the pill and use a barrier method until a further 7 consecutive pills have been taken. EHC is indicated if there has been a failed barrier method or UPSI during or within the 7 days after a vomiting or severe diarrhoeal illness. EHC is indicated if there has been a failed barrier method or UPSI during, or in the 28 days following, the use of liver enzyme inducing drugs.
Progestogen-only pill (POP)	Indicated if one or more POPs have been missed or taken more than 3 hours late and UPSI has occurred in the 2 days following this. The POP should be continued with additional barrier contraception until pills have been taken correctly on two consecutive days. Exception is a desogestrel POP which can be taken up to 12 hours late without loss of contraceptive cover. EHC is indicated if there has been a failed barrier method or UPSI during or within the 2 days after a vomiting or severe diarrhoeal illness. Indicated if there has been a failed barrier method or UPSI during, or in the 28 days following, the use of liver enzyme inducing drugs.

Potential contraceptive failures which do NOT warrant EHC use

Combined pills 21 active tablets	**No** indication if only one COC pill has been missed from the first 7 pills in a pack, as long as the last 7 pills in the previous pack were taken without omissions**.** Additional barrier contraception for 7 days is recommended, in case of further omissions. No indication if pills have been missed from the middle 7 pills in the pack as long as the first 7 pills were taken correctly. The COC should be continued to the end of the pack. Additional barrier contraception for 7 days is recommended, in case of further omissions. No indication if pills have been missed from the last 7 pills in the pack as long as the next pack is started without a pill-free interval. Additional barrier contraception for 7 days is recommended, in case of further omissions
Depo-provera	No indication if Depo Provera is given up to 2 weeks late (up to 14 weeks from the previous injection). The injectable can be given and no additional barrier method is required.

Appendix C: Advice to Young People Under 16

In considering the provision of advice or treatment on contraception, doctors and other professional staff need to take special care not to undermine parental responsibility and family stability. The doctor or other professional should therefore always seek to persuade the young person to tell the parents or guardian (or other person in loco parentis), or to let her inform them, that contraceptive advice is being sought and the nature of any advice or treatment that is given. It should be most unusual for a doctor or other professional to provide advice or treatment in relation to contraception to a young person under 16 without parental knowledge or consent.

Exceptionally, there will be cases where it is not possible to persuade the young person either to inform the parents or to allow the doctor or other professional to do so. This may be, for example, where family relationships have broken down. In such cases, a doctor or other professional would be justified in giving advice and treatment without parental knowledge or consent, provided they followed the Fraser Guidelines.

FRASER GUIDELINES

In law young people under 16 years are entitled to confidentiality in the same way as over 16 year olds. In 1985 Lord Fraser established the current legal position that a doctor or other professional can give contraceptive advice or treatment to a person under 16 without parental consent providing they are satisfied that:

- The young person will understand the risks and benefits of the treatment offered and the advice given.
- The young person cannot be persuaded to tell his or her parents or allow a health professional to inform them that he or she is seeking contraception advice.
- The young person is likely to begin or continue having intercourse with or without contraceptive treatment.
- Unless he or she receives contraceptive advice the young person's physical or mental health is likely to suffer.
- It is in the young person's best interests to give them contraceptive advice or treatment.

Reference Gillick v West Norfolk & Wisbech Area Health Authority (1984) AC 1121 ALL ER

- Where there are concerns about children and young people's welfare appropriate actions should be taken to address those concerns, working to agreed local policies and procedures. Refer to Safeguarding Children Flow Chart for Referral.

MEDICOLEGAL ASPECTS

Medical legal aspects regarding supply to under 16 year olds

1. **It's illegal for them to be having sex**
   Answer: It is illegal for a man to have sexual intercourse with a girl under age 16 years. The girl is not committing any offence. The historical background to this Act was the need to have some structure to prevent child prostitution.

2. **You are aiding and abetting an illegal act**
   Answer: Taking action after an event to minimise its ill consequences cannot be interpreted as aiding and abetting-any more than the investigation and treatment of sexually transmitted infection would be.

   The medical Defence Union opinion is that aiding and abetting would only be involved if a person actually were present at the time of the sexual intercourse and was encouraging it.

3. **The Age of Consent is 16 years**
   Answer: In English Law the validity of consent depends upon the capacity of the person to understand. The House of Lords considered the specific case of consent to contraceptive treatment in a ruling (Gillick v West Norfolk and Wisbech Area Health Authority and the Department of Health and Social Security, delivered October 1989). Attached is the advice which was issued after this by the Department of Health in the Handbook of Contraceptive Practice 1990 edition, pages 92 and 93.

   Note that the exceptional nature of providing emergency contraception under protocol to young persons under 16 is confirmed by the actual numbers seen and considered under the protocol, compared to the numbers of older women.

   Note also the young person is fully entitled to confidentiality. The guidance in paragraph 2 is that a doctor or other professional should always seek to persuade the young person to tell, or to permit to inform. No information should be given without the young person's consent and consent to disclosure given under pressure or undue persuasion would not be valid.

   The pharmacists training package includes a role play of the type of discussion which is valid and appropriate.

4. **It shouldn't be allowed for the very young, it will just encourage them**
   Answer: Note that there is a lower age limit for sale of alcohol and for sale of cigarettes, but no lower age limit for the sale of condoms. Any deterrent effect in differential use is not immediately obvious!!

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Contraceptive advice and treatment for young people under 16
(HN(81)5/LASS(81)2 has now been replaced by the following text which forms the Appendix to HC(86)1/HC(FP)(86)1/LAC(86)3 "Family Planning Services for Young People" issued in March 1986 – this also applies to England and Wales only).

1. The following guidance draws the attention of health authorities and others concerned to the considerations doctors and other professionals need to have in mind when providing contraceptive advice and treatment to young people under 16, and to the circumstances in which such advice and treatment can be given without parental knowledge or consent. The guidance results from a review of that in Section G of the Memorandum of Guidance on the Family Planning Service, as specified in the Appendix to HN(81)5 and LASSL(81)2, in the light of the House of Lords, decision in the case of Gillick v West Norfolk and Wisbech Area Health Authority and the Department of Health and Social Security delivered last October.

2. In considering the provision of advice or treatment on contraception doctors and other professional staff need to take special care not to undermine parental responsibility and family stability. The doctor or other professional should therefore always seek to persuade the young person to tell the parents or guardian (or other person in loco parentis)*, or to let him inform them, that contraceptive advice is being sought and the nature of any advice or treatment that is given. It should be most unusual for a doctor or other professional to provide advice or treatment in relation to contraception to a young person under 16 without parental knowledge or consent.

3. Exceptionally, there will be cases where it is not possible to persuade the young person either to inform the parents or to allow the doctor or other professional to do so. This may be, for example, where family relationships have broken down. In such cases, a doctor or other professional would be justified in giving advice and treatment without parental knowledge or consent, provided they were satisfied:

    - that the young person could understand their advice and had sufficient maturity to understand what was involved in terms of the moral, social and emotional implications;
    - that they could neither persuade the young person to inform the parents, nor to allow them to inform them, that contraceptive advice was being sought;
    - that the young person would be very likely to begin, or continue having, sexual intercourse with or without contraceptive treatment;
    - that without contraceptive advice or treatment, the young person's physical or mental health, or both would be likely to suffer;
    - that the young person's best interests require them to give contraceptive advice, treatment or both without parental consent.

4. Decisions about whether to prescribe contraception in such cases are for a doctors clinical judgement, if a doctor who is not the young person's general practitioner has formed the view, after due consideration of the points made above, that it is in the best interest of the young person to prescribe contraception without parental knowledge or consent, it may be advisable and helpful for them, with the young person's agreement, to discuss the matter in confidence with her own general practitioner before making his decision.

5. In organising contraceptive services for young people, health authorities may find it helpful to make separate, less formal arrangements that those for older age groups. The staff should be experienced in dealing with young people and their problems.

*Where the parental rights and duties in respect of a young person are vested in the local authority (by virtue of a care order or a parental rights resolution under Section 3 of the Child Care Act 1980) the authority must be treated as the young person's parents for the purposes of giving consent to medical treatment in respect of a young person under 16. Where the authority does not have parental rights, the natural parent's rights are not affected. Where a young person has been committed to the care of a local authority under wardship proceedings, the consent of the High Court must be obtained by the local authority. Where a local authority shares the parental rights and duties with another person, the consent of the local authority is sufficient unless the other person indicates an objection.

Appendix D

Client requesting emergency contraception (EC)

- Take full contraceptive, sexual and menstrual history, including risk of sexually transmitted infection (STI)
- Exclude existing pregnancy and medical contra-indications to various EC methods
- Check current/recent use of enzyme-inducing drugs
- Check whether client has used emergency hormonal contraception (EHC) in this cycle already
- Establish:
  - Number of episodes of unprotected sexual intercourse (UPSI) in this cycle.
  - Timing of earliest and most recent UPSI in relation to last menstrual period (LMP).
  - Timing of intercourse in relation to incorrect contraception use, including in pill/patch/ring free week.
  - Earliest possible date of ovulation (=14 days before period, based on shortest possible cycle).
  - Timing of earliest and most recent UPSI in relation to earliest possible date of ovulation.

PT = Pregnancy test

SPC = Summary of Product Characteristics

STI = sexually transmitted infection

SRH = Sexual Reproductive Health Clinic

EC not required → Reassurance

EC required

EC not suitable → PT in 3 weeks via GP/SRH

Up to 5 days since earliest UPSI

More than 5 days since earliest UPSI

Discuss hormonal EC and copper-intrauterine device (copper-IUD) → **Copper-IUD preferred/more suitable**

- May be inserted up to 5 days after 1st UPSI.
- If timing of ovulation can be estimated copper-IUD may be inserted beyond 5 days of UPSI, as long as it does not occur beyond 5 days of earliest possible date of ovulation.
- Most effective EC method and provision of ongoing contraception.
- Most suitable method if on enzyme-inducers.
- If separate appointment for insertion (or referral to clinic/GP) needed, give interim hormonal EC.
- Consider prophylactic azithromycin if STI risk.
- If requested remove copper-IUD with next period or when no pregnancy risk and start alternative contraception.

Hormonal EC preferred option

Ulipristal acetate (see ǂ below)

- Greater than 72 hrs since earliest UPSI
- Consider referral to GP/Sexual Health Clinic if patient choice prior to 72hr
- No hormonal EC taken this cycle
- Not on liver enzyme-inducing drug
- Consider IUD/levonorgestrel if ulipristal acetate is excluded

Should only be used once per cycle

Levonorgestrel

Up to 72 hours since earliest UPSI or 72-120hrs if ulipristal acetate is contraindicated

May use more than once in cycle

If EC given because of UPSI:

- Advise condom use for remainder of cycle
- Discuss ongoing contraception and provide method for future use

After levonorgestrel use:
Consider 'quick-starting'* ongoing hormonal contraception (=starting method at time of giving levonorgestrel). Additional condom use for 1 week after levonorgestrel. PT in 3 weeks advisable.

After ulipristal acetate use:

- Hormonal contraception may be quick started **after a gap of 5 days **** during which abstinence or a barrier method are strongly advised. Barrier method should then be continued until the hormonal method is effective ie an additional 2 days for POP, 7 days for COC and 9 days for Qlaira. PT in 3 weeks advisable

If current enzyme inducing drug use:

- Give double dose of levonorgestrel*. Don't use ulipristal acetate (SPC advice). Consider copper-IUD

If breast feeding:

- Can use levonorgestrel. Avoid breastfeeding for 7 days after ulipristal acetate use

Avoid concomitant use of levonorgestrel and ulipristal acetate

ǂ *This choice only applies where the pharmacy is commissioned to use the ulipristal acetate PGD for Community Pharmacy. When the woman prefers to receive ulipristal acetate, she must be referred to the local Sexual & Reproductive Health Service.*

**Unlicensed dose.*

*** Recommendations from the Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Healthcare (September 2015 statement)*

All EC methods

- Full counselling, including side-effects, action to be taken if vomiting within 3 hours (hormonal EC only), etc.
- Provide written information.
- Accurate documentation.
- Consider STI testing.
- Follow-up as appropriate.

(Levonorgestrel PGD, Champs 2016)