



Patient Group Direction for

**Pharmacist or Nurse Supply for Administration
Of Levonorgestrel for
Emergency Hormonal Contraception (EHC) in
Primary Care in Gloucestershire**

Developed in partnership with the Sexual Health Service (Gloucestershire)

**Practice/Pharmacy
Locality name and address:**

Sanger House
5220 Valiant Court
Gloucester Business Park
Brockworth
Gloucester
GL3 4FE

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

This document has been written and authorised on the understanding that it remains in its entirety with no additions, omissions or alterations.

Prepared By: The Patient Group Directions Working Group

Date Direction Comes Into Force: 1.10.2017

Date Direction Expires: 30.09.2019

Chief executives should ensure that any current or new PGDs comply with new legal requirements and the guidance set out in circular HSC 2000/026

Version number	Change details	Date
2017 - 2019 v1	<ul style="list-style-type: none"> • Revision in light of UKMEC 2016 guidance and FSRH emergency contraception guidance 2017. • Inclusion of Fraser Guidelines Assessment • Addition of Safeguarding training requirement • Updated Summary of Product Characteristics (SPC) and references 	Oct 2017

Continued

Version number	Change details	Date
2016 – 2018	<ul style="list-style-type: none"> • Addition of new NMC Code 2015 • Additional information around competent children declining to provide consent. • Additional exclusion criteria (salpingitis, risk of ectopic pregnancy, severe malabsorption, hepatic impairment) • Interactions list updated • Updated advice around breast feeding • NMC consent reference added • Revision of decision making flow chart – now separate document from Sexual Health Services 	Mar 2016
2014 - 2016	<ul style="list-style-type: none"> • Reviewed/updated 	

Purpose of the Patient Group Directions (PGDs)

- To enable a nurse or pharmacist (or other specified healthcare professional) who has received specific, appropriate training and has been assessed as competent to administer drugs in accordance with the following patient group direction and recommendations issued by NICE: Patient Group Directions (MPG2) Aug 2013, The Medicines and Healthcare Products Regulations Agency 2014 - Patient group directions: who can use them, The Code: Professional standards of practice and behaviour for nurses and midwives (2015) and the NMC Standards for Medicines Management (2008) and the NMC Guidelines for Record Keeping (2007) or the latest GPhC Standards for pharmacy professionals (<http://www.pharmacyregulation.org/standards>)
- The PGDs may be adopted for use by General Practice Surgeries, for practice nurses to use.
- This PGD must be signed off by the Pharmacy Clinical Governance Lead to authorise its use within the pharmacy.
- All information contained within this document was correct at the time of going to press. It is acknowledged that systems and processes change over time and that new drugs may be introduced. As licences vary, if a new brand is introduced it will not necessarily be covered within its corresponding PGD. If there are changes to practice, or the need for more PGDs to be developed, please contact the Head of Medicine Management at NHS Gloucestershire Clinical Commissioning Group (CCG).
- For full product information please refer to the appropriate Summary of Product Characteristics (SPC) or visit the website at: www.emc.medicines.org.uk

Clinic manager/clinical governance lead agreement:

(For all premises other than community pharmacies)

Medical approval for the supply/administration of Levonorgestrel under PGD within the following setting:

I,, (Print name of clinic manager/clinical governance lead for clinic/surgery), give authorisation on behalf of:

.....(Clinic site/location)

Signature Date.....

All departments/surgeries should retain a 'fully signed' copy (completed pages 2, and 3) of the PGD for their files and/or this should be sent on to the head of service for their reference.

Individual Nurse/Pharmacist Agreement:

By signing this Patient Group Direction (PGD) you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligation or accountability

It is the responsibility of each professional to practise only within the bounds of their own competence. You cannot delegate tasks under this PGD to anyone else.

If this is an update or replacement PGD please ensure that all older versions are withdrawn from use with immediate effect.

It is your responsibility to make sure you are using the current version.

- I have read and understood this Emergency Hormonal Contraception PGD, and agree to administer/issue Levonorgestrel 1500mcg as detailed in this PGD within

..... (Location)

- I agree that I fulfil the professional and additional criteria specified in the PGD and am competent to operate under this PGD
- By agreeing to act as an authorised practitioner under this PGD I am extending my role but this extension has not been a compulsory requirement.

NAME OF NURSE OR PHARMACIST AND REGISTRATION NUMBER	SIGNATURE	DATE	LOCATION

Please note: All practitioners using the PGD should retain a ‘fully signed’ copy for their personal use/files.

The signatures required to comply with a ‘fully signed copy’ are:

1. The signature of the practitioner themselves (above)
2. The signature of the Clinical Governance Pharmacist for the Pharmacy (page 11 or Clinical Governance Lead for the GP surgery premises (page 2). This demonstrates the PGD has been approved for use at each location.

All Departments/Pharmacy Contractors should retain a ‘fully signed’ copy (both signatures as above) of the PGD for their files and/or this should be sent on to the head of service for their reference.

To The Pharmacy Contractor:

NOTE: All Pharmacies should return a fully completed copy of page 11, Appendix 1 (page 13) to:

Claire Procter,
Public Health Outcome Manager
Gloucestershire County Council
Shire Hall
Westgate Street
Gloucester
GL1 2TG

Tel 01452328603 or email: claire.procter@gloucestershire.gov.uk

Patient Group Direction for:

Levonorgestrel for Emergency Hormonal Contraception (EHC)

This PGD was developed in partnership with the Gloucestershire Sexual Health Service
Please note the Emergency Contraception decision making algorithm charts produced by FSRH (Latest at time of PGD development; 29th May 2017 Appendix 2) are at the end of this PGD.

1. Medicine Details

Medicine name	Levonorgestrel
Form (e.g. tabs, inj, etc.)	Tablet
Strength	1500mcg (1.5mg)
Dose including frequency	<p>Single dose 1500mcg (1.5mg)</p> <p>Off-licence dose: Single dose of 3mg (2 x 1.5mg tablets) for:</p> <ul style="list-style-type: none"> • Individuals taking enzyme inducing medications or herbal products or within four weeks of stopping them • Individuals with BMI over 26kg/m² or weight over 70kg <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>
Legal category (POM, GSL or P)	P or POM
Route of administration	Oral - self administration
Duration of treatment	<p>Single dose (see above)</p> <ul style="list-style-type: none"> • Dose can be repeated if vomits within 3 hours • Can be repeated within the same menstrual cycle if required
Storage instructions	<ul style="list-style-type: none"> • Keep in a secure dry place below 25 °C • Protect from direct sunlight • Use only if within expiry date
Administration details	<p>Single dose to be swallowed as soon as possible (preferably immediately) up to 96 hours after unprotected sexual intercourse (UPSI)</p> <p>(Levonorgestrel is licensed for use within 72 hours after UPSI or contraceptive failure. Its use between 72 hours and 96 hours is off-licence but recommended by FSRH.)</p>

<p>Potential adverse reactions.</p> <p>Consult BNF for a more comprehensive list and the Specification Product Characteristics (SPC) available at http://www.emc.medicines.org.uk/</p>	<p>Common undesirable effects include:</p> <ul style="list-style-type: none"> • Nausea • Low abdominal pain • Fatigue • Dizziness • Headache • Diarrhoea/vomiting • Breast tenderness <p>Bleeding patterns may be temporarily disturbed and spotting may occur, but most women will have their next period within seven days of the expected time.</p>
<p>Management of adverse reactions</p>	<p>If vomiting occurs within 3 hours: repeat dose of Levonorgestrel, and consider use of anti-emetic.</p> <p>If an adverse reaction occurs:</p> <ul style="list-style-type: none"> • Stop treatment • Inform patient's GP or emergency services (as applicable) as soon as possible • Document details • Patient advice on how to manage and recognise adverse reactions • If appropriate, report the reaction to the MHRA (Medicines & Healthcare Products Regulatory Agency), using the yellow card system via the following link: http://yellowcard.mhra.gov.uk/

2. Administration/supply criteria

<p>Clinical condition or situation</p>	<p>Emergency contraception within 96 hours of unprotected sexual intercourse (UPSI) or contraception failure</p> <p>For choice of emergency contraceptive method refer to FSRH emergency contraception decision making algorithm https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/</p> <p>(also Appendix 2 at the end of the PGD – ensure using the latest by checking FSRH website)</p>
<p>Inclusion criteria</p>	<ul style="list-style-type: none"> • Female of reproductive age 13 years or over (Where those aged 13 to 15 years are Fraser competent) presenting for emergency contraception within 96 hours of unprotected sexual intercourse (UPSI) or failed contraceptive method • and who has no contraindications to the medicine • and when a copper IUD has been discussed and accepted or declined (see below where IUD not immediately available) • (Patients who have already been treated but who vomited dose within 3 hours and attend for re-treatment) <p>If IUD not immediately available, continue to supply and refer to appropriate health service provider</p> <p>Note: Where clients are believed to be under 16 years of age</p> <p style="text-align: right;">Continued</p>

Inclusion criteria (continued)	<p>(and at least 13 years or over) they must be assessed using Fraser guidelines and the relevant pro-forma completed (Appendix 3)</p> <p>If there are safeguarding concerns regarding the Client, refer to the guidance on G-Care website or contact: adults' safeguarding advice: socialcare.enq@gloucestershire.gov.uk; children's safeguarding advice: childrenshelpdesk@gloucestershire.gov.uk</p>
Exclusion criteria	<ul style="list-style-type: none"> ◆ Under 13 years of age – refer to doctor ◆ More than 96 hours since most recent UPSI ◆ Known or suspected pregnancy (NB 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) ◆ Individual under 16 years of age and assessed as not competent using Fraser guidelines ◆ Individual over 16 years of age and over and assessed as not competent to consent ◆ Less than 21 days following childbirth ◆ Less than 5 days following abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease ◆ Less than 5 days following ingestion of Ulipristal emergency contraception (UPA-EC) ◆ Known hypersensitivity to any of the constituents ◆ Unexplained vaginal bleeding ◆ Inability to swallow tablets ◆ Client's choice not to receive Levonorgestrel
<p>Cautions/need for further advice</p> <p>Drug Interactions See BNF; Appendix 1 for key drug interactions and for a full list, the manufacturers Specification of Product Characteristics (SPC) available at www.emc.medicines.org.uk</p>	<p>General:</p> <ul style="list-style-type: none"> ◆ Any patient requesting EHC who does not fit the inclusion criteria – refer to doctor Consider Ulipristal if the individual presents in the five days leading up to expected day of ovulation ◆ Consider UPA-EC or 3mg LNG-EC if individual has a BMI of $\geq 26\text{kg/m}^2$ or weighs 70kg or more ◆ Discuss with appropriate doctor or independent non-medical prescriber any medical condition or medication of which the clinician is unsure <p><u>Pregnancy and breast-feeding:</u></p> <p>Pregnancy:</p> <ul style="list-style-type: none"> ◆ A pregnancy test is advised three weeks after UPSI <p>Breast-feeding:</p> <ul style="list-style-type: none"> ◆ No available evidence of adverse effect to infant or lactation <p><u>Drug interactions:</u></p> <p>Always check the SPC of both drugs if not sure of risk</p> <ul style="list-style-type: none"> ◆ Interacting medicines (not enzyme inducers) –see current British National Formulary (BNF) ◆ Individuals using enzyme-inducing drugs/herbal products or within four weeks of stopping them, see dosage/frequency section <ul style="list-style-type: none"> ○ Carbamazepine, Eslicarbazepine, Oxcarbazepine, <p style="text-align: right;">Continued</p>

<p>Cautions/need for further advice (continued)</p>	<p>Phenobarbital, Phenytoin, Primidone, Fosphenytoin Griseofulvin, Rufinamide, Topiramate, Rifabutin, Rifampicin, Ritonavir, Efavirenz, Nelfinavir, Nevirapine, St John's Wort, Bosentan, Modafinil, Aprepitant, Sugammadex</p>
<p>Action to be taken for women excluded from, declining or not adhering to the treatment</p>	<ul style="list-style-type: none"> ♦ Patients who decline treatment should have the consequences of this decision explained (a child who is considered to be Fraser Competent can also refuse consent providing it is clear they understand consequences of refusal following an appropriate risk assessment; e.g. Appendix 3) ♦ Document refusal or informed dissent ♦ Refer to GP or sexual health service for further consultation (Tel. 0300 421 6500; www.hopehouse.nhs.uk) <p>NB Adults are classified as 18 years of age or over</p>
<p>Advice to be given to patient or carer.</p> <p>Provide patient information leaflet</p> <p>For the most up to date guidance please refer to sexual & reproductive health website www.fsrh.org</p>	<p>Emergency post coital intrauterine device (Copper Coil /Cu-IUD) should always be considered as a more effective alternative when emergency contraception is required</p> <ul style="list-style-type: none"> ♦ When the Cu-IUD is appropriate and acceptable but not immediately available, continue to supply EHC and refer to appropriate health service provider (GP or Sexual Health Service) ♦ Mode of action of Levonorgestrel and efficacy ♦ Advise that oral EHC may be less effective if patient has a higher weight of greater than 70kg or BMI greater than 26kg/m² despite 3mg Levonorgestrel dose or Ulipristal used. If weight of greater than 85kg or BMI greater than 30kg/m², advise patient that it is not known which is more effective ♦ Advise that oral EHC is ineffective if given after ovulation ♦ Advise about the risks including failure rates and serious side effects and actions taken ♦ Action to take if vomiting occurs within 3 hours of taking ♦ Potential side effects as listed ♦ Advise that oral EHC methods do not provide ongoing contraception ♦ Discuss ongoing contraception and provide written advice on all methods ♦ Direct to Hope House sexual health services website and FPA leaflet on emergency contraception contraception-your-guide.pdf http://www.hopehouse.nhs.uk/ ♦ Ensure the individual has contact details of contraceptive /sexual health services ♦ Advise a pregnancy test three weeks after treatment especially if period is delayed or abnormal, or if using hormonal contraception which may affect bleeding pattern <p>If quick starting contraception refer to FRSB guidance and to use barrier contraception for:</p> <ul style="list-style-type: none"> ♦ 2 days : progestogen only pills (POP) ♦ 7 days: combined hormonal methods including pills (COC),patch, vaginal ring; ♦ 9 days: Qlaira <p>16-24 year olds can order free Chlamydia test kits (and test kits for other sexually transmitted infections) via the Hope House website: www.hopehouse.nhs.uk (posted out discreetly wrapped). If any sexually transmitted infection is suspected direct patient to their GP or the Sexual Health Service (www.hopehouse.nhs.uk; call 0300 421 6500)</p>

<p>Referral arrangements</p>	<ul style="list-style-type: none"> • Contact the Sexual Health service doctor on call if more information or advice is required (Sexual Health Services Booking Line:0300 421 6500) • Contact the Sexual Health service doctor on call when further sexual health follow up or contact tracing is required <p>Sexual health services are provided from Hope House at GRH and from The Milsom Centre in Cheltenham (which replaces services previously provided from CGH, Benhall and the family planning clinic in St Pauls). For up to date information on local sexual health services, patients should be directed to www.hopehouse.nhs.uk</p>
<p>Consent</p>	<p>All women for whom treatment is proposed should give their valid consent to treatment at the time of administration. Written consent or documented verbal consent must be obtained before the supply of Levonorgestrel. A record of consent must be maintained for all patients</p> <p>For consent to be valid, the patient or person with parental responsibility must:</p> <ul style="list-style-type: none"> • be competent to take the particular decision • have received sufficient information to take it • not be acting under duress <p>Anybody aged 18 years or over (adult) is assumed to be capable of making decisions unless there is reasonable doubt.</p> <p>Anybody aged 16 years or 17 years (young person) is also assumed to be capable of making decisions unless there is reasonable doubt.</p> <p>If the requirements for valid consent are met, it is not legally necessary to obtain consent from the person with parental responsibility for the young person. It is however good practice to involve the young person's family in the decision making process, unless the young person specifically wishes to exclude them. If a person aged 16 or 17 years gives valid consent to treatment the person with parental responsibility cannot override that consent.</p> <p>Anybody less than 16 years of age (child) is not automatically assumed to be capable of making decisions. That capacity to make decisions is related to their maturity and level of understanding in relation to each decision, rather than their age.</p> <p>For inclusion in PGDs for contraception only- 'Children under 16 years of age who are considered competent in accordance with the Fraser Guidelines and understands fully what is involved in their proposed procedure can give valid consent and additional consent by a person with parental responsibility is not required. The decision of a competent child to accept treatment can then not be over-ridden by the person with parental responsibility for the child. It is however good practice to involve the child's parents in the decision making process, but take into account the wishes of a competent child about that involvement.</p> <p style="text-align: right;">Continued</p>

<p>Consent (continued)</p>	<p>The refusal of treatment by a patient less than 18 years of age might be overruled even if he/she is competent, if the treatment is deemed in his/her best interest.</p> <p>Anyone who lacks capacity is treated in his or her best interests.</p> <p>Only people with 'parental responsibility' are entitled to give consent on behalf of their children until they achieve Fraser competence.</p> <p>For young people and children aged 16 and below it is recommended when possible to involve the person with parental authority in the decision regarding consent</p> <p>Healthcare professionals need to carefully document the consent that is obtained (Appendix 3). Any queries need to be discussed with an experienced colleague or sexual health services.</p> <p>For further guidance please refer to the Department of Health document consent for examination or treatment (second edition) DH 2009. Gateway reference 11911 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653_1_.pdf</p> <p>GPhC guidance on consent (latest) https://www.pharmacyregulation.org/search/site/consent Or the Nursing Midwifery Council (NMC) guidelines for professional practice</p> <p>Reference guide to consent for examination or treatment, second edition 2009 : Department of Health - Publications</p>
<p>Records for Pharmacists (to also allow audit trail)</p>	<p>The EHC proforma must be completed (whether EHC is supplied or not) via PharmOutcomes. Claims are triggered (or generated) via PharmOutcomes proforma.</p> <p><i>Patient medical records must be kept for 8 years, or if under 16 years until aged 25.</i></p> <p>Complete a Fraser Guidelines assessment form for all individuals under 16 years (Appendix 3)</p>
<p>Records for Dispensing Practice Nurses or other Nurses where Levonorgestrel is provided.</p>	<p>A record of administration / supply should be made on patient medication record. This should include:</p> <ul style="list-style-type: none"> • Name or clinic number and date of birth • Consent – if individual is under 16 years document that they meet Fraser Guidelines • Date of last menstrual period and hours since UPSI • Date and time of administration/supply • Name and form of drug • Dose • Frequency • Route of administration • Batch number and expiry date • Side effects (if any) • Advice given – oral and written <p style="text-align: right;">Continued</p>




<p>Records for Dispensing Practice Nurses or other Nurses where Levonorgestrel is provided. (continued)</p>	<ul style="list-style-type: none"> • Contra-indications and medical advice • Referral arrangements • Address <p>Signature or computerised entry recorded by the nurse (using an individual protected password)</p> <p>Complete a Young Persons' Fraser Guidelines assessment form for all individuals under 16 years (Appendix 3)</p>
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3. Professionals

<p>Professional group</p>	<p>Registered Professional E.g. RN with current NMC registration, or pharmacist registered as a practising pharmacist with GPhC GB.</p>
<p>Additional personal criteria</p>	<p>All practitioners must be:</p> <ul style="list-style-type: none"> • Contracted through a current signed Service Specification with Gloucestershire County Council for the provision of advanced sexual health services and act in accordance with the requirements of this specification. • Practice Nurses within Gloucestershire (where PGD has been adopted by the surgery) <p>All practitioners must have read and understood, and act in accordance with appropriate professional guidance:</p> <ul style="list-style-type: none"> • The Medicines and Healthcare Products Regulations Agency 2014 - Patient group directions: who can use them • The Code: Professional standards of practice and behaviour for nurses and midwives (2015) • The Department of Health 1998, the NMC Code of Professional Conduct: standards for conduct, performance and ethics (2007) • The NMC Standards for Medicines Management (2008). • the NMC Standards for the Administration of Medicines for all nursing staff (or equivalent from GPhC) • Current GPhC Standards of Conduct, Ethics and Performance relevant to this direction, for all pharmacists <p>In addition all practitioners must:</p> <ul style="list-style-type: none"> • Sign the signature sheet for the PGD • Have completed the Gloucestershire or equivalent and approved EHC training programme (as detailed in the Service Specification for Community Pharmacy Sexual Health Advanced Services); and have been assessed as competent by an instructing Family Planning Doctor or Assessor and be prepared to accept this delegated role. • Have completed and submitted a declaration of competence (DOC) (uploaded to PharmOutcomes). • Keep up-to-date with changes to recommendations for medicines covered by this PGD • Be able to demonstrate competencies and be up to date with current contraceptive methods and research (may be self-directed) • Have completed self-directed training on safeguarding (e.g. CPPE module on safeguarding children and vulnerable adults). <p style="text-align: right;">Continued</p>

Additional personal criteria (continued)	<p>Follow link below for the NICE competency framework for people working under PGDs</p> <p>GPG2 Patient group directions: competency framework for health professionals using patient group directions (23 January 2014)</p> <p>For the most up to date guidance please refer to sexual & reproductive health website www.fsrh.org</p>
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4. Signatures

<p>Signatures:</p> 	<p>NHS Gloucestershire CCG Clinical Chair Dr Andrew Seymour</p> <p>Date 9/10/17</p>
	<p>NHS Gloucestershire CCG Deputy Director of Quality Teresa Middleton</p> <p>Date 3/10/17</p>
	<p>NHS Gloucestershire CCG Executive Nurse and Quality Lead Dr Marian Andrews-Evans</p> <p>Date 3/10/17</p>
<p>Name (print) <u>SARAH SCOTT</u> Signature  Date <u>4/10/17</u></p>	<p>Director of Public Health Gloucestershire County Council Sarah Scott</p> <p>Date 4/10/17</p>
<p>To Pharmacy Contractor: Please ensure this is signed by appropriate pharmacist and send a copy of this page and a completed copy of Appendix 1 to Claire Procter at Shire Hall (page 14)</p>	<p>Clinical Governance Pharmacist (for the Pharmacy)</p> <p>Name (print).....</p> <p>Signature.....</p> <p>Date.....</p>

Bibliography

BNF latest on line version
 CBNF- latest on line version
 FSRH clinical guidance: www.fsrh.org
 The Medicines and Healthcare Products Regulations Agency 2014
<https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them>
 Nursing and Midwifery Council: Standards for Medicines Management 2008
<http://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-standards-for-medicines-management.pdf>
http://www.ukmi.nhs.uk/filestore/ukmiamt/Guide_to_NeLM_20_pages.pdf
 Summary of Product Characteristics (SPC) <http://emc.medicines.org.uk>
<http://www.doh.gov.uk>

The Code Professional standards of practice and behaviour for nurses and midwives (2015)

<http://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/revised-new-nmc-code.pdf>

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

CBNF- latest on line version

FSRH clinical guidance: www.fsrh.org

GPhC Standards of conduct, ethics and performance-

<https://www.pharmacyregulation.org/standards/conduct-ethics-and-performance>

<http://www.fsrh.org/pdfs/CEUStatementQuickStartingAfterUPA.pdf>

NHS Gloucestershire Clinical Commissioning Group Policies

Membership of the PGD Working Group

Teresa Middleton	NHS Gloucestershire CCG Deputy Director of Quality
Andrew Seymour	NHS Gloucestershire CCG Clinical Chair
Marion Andrews-Evans	NHS Gloucestershire CCG Executive Nurse and Quality Lead
Karyn Probert	NHS Gloucestershire CCG Clinical Learning and Development Manager
Liz Ponting	NHS Gloucestershire CCG Senior Medicines Optimisation Pharmacist

Additional advice from:

Louise Plumridge	Specialist Pharmacist HIV & Sexual Health Gloucestershire Care Services NHS Trust
Dr Rachel Westwick	Consultant Sexual and Reproductive Healthcare Gloucestershire Care Services NHS Trust
Evelyne Beech	IP Pharmacist with Special Interest, St Catherine's Surgery, Cheltenham
Maggie Pugh	NHS Gloucestershire CCG Practice Nurse Facilitator Forest of Dean and Tewkesbury Localities

Appendix 1

Template form for completion by Pharmacy Contractor with regard to the PGD for Levonorgestrel and Ulipristal

(Note: Just one of form of Appendix 1 may be used to cover all EHC PGDs, providing the additional pages which have been signed by the Clinical Governance Lead for each PGD as stated below is also submitted)

To The Pharmacy Contractor:

Please ensure the following are sent to Claire Procter at Shire Hall (see below):

- ♦ Copy of completed relevant section of the PGD for Ulipristal tablets (section 4)
- ♦ Copy of completed relevant section of the PGD for Levonorgestrel tablets (section 4)
- ♦ Copy of completed relevant section of the PGD for Domperidone tablets (section 4)
- ♦ Copy of this page

Name of Pharmacist (print)	GPhC registration number	Date of EHC training	Signature

This page -

requires the name, registration number, date of training and signature of pharmacist(s) employed by you who and will be providing sexual health services under the Service Agreement.

Name and Address of Premises:

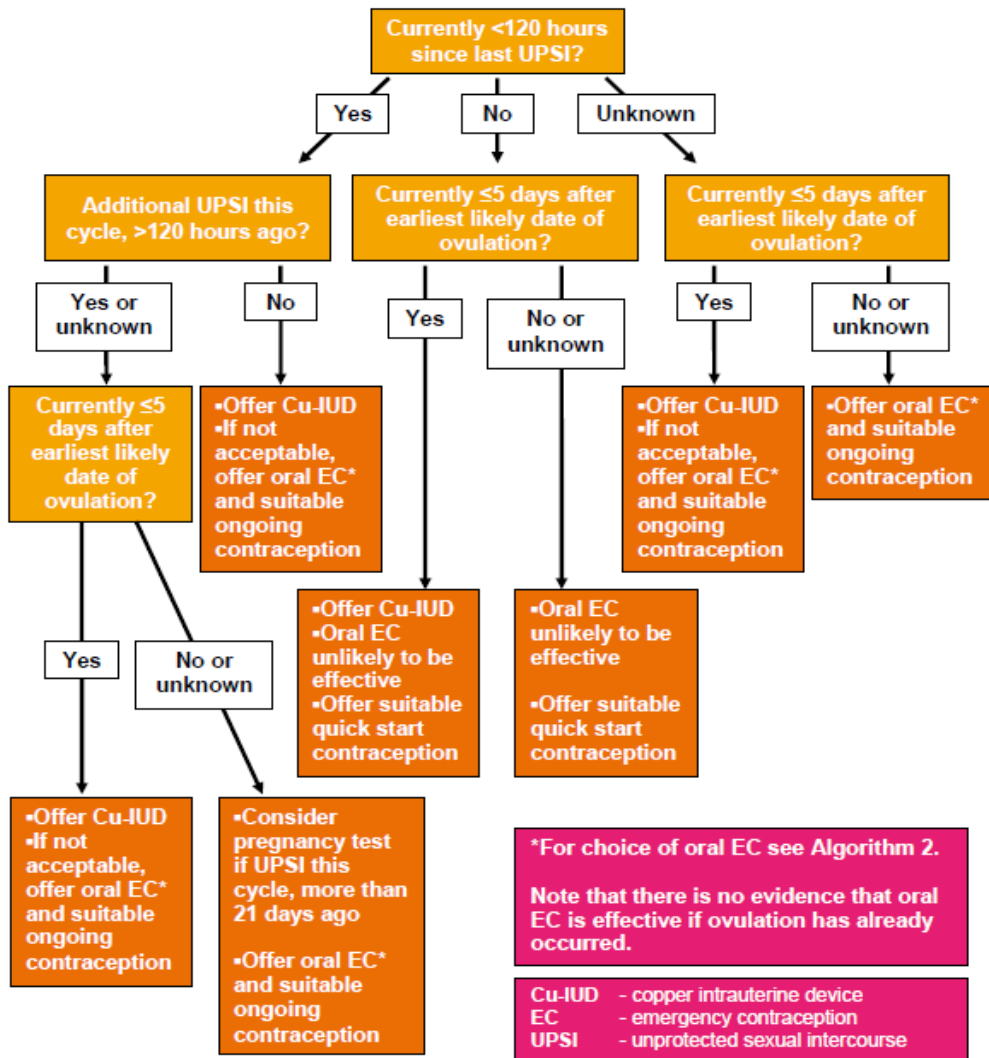
*Claire Procter,
Public Health Outcome Manager
Gloucestershire County Council
Shire Hall
Westgate Street
Gloucester
GL1 2TG
Tel 01452328603 or email: Claire.procter@gloucestershire.gov.uk*

Appendix 2 - FSRH Decision making algorithms



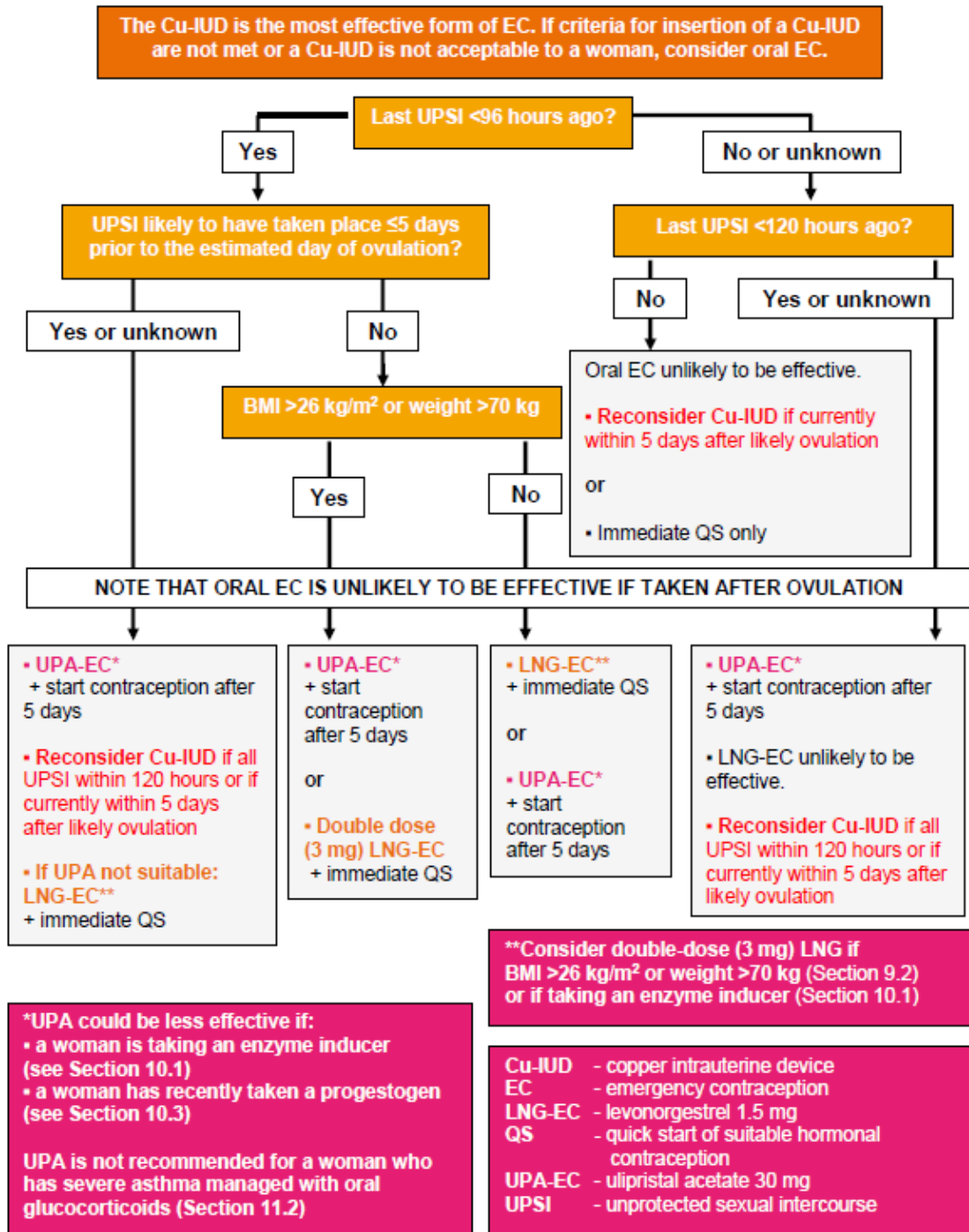
Decision-making Algorithms for Emergency Contraception

Algorithm 1: Decision-making Algorithm for Emergency Contraception (EC):
Copper Intrauterine Device (Cu-IUD) vs Oral EC





Algorithm 2: Decision-making Algorithm for Oral Emergency Contraception (EC): Levonorgestrel EC (LNG-EC) vs Ulipristal Acetate EC (UPA-EC)



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*UPA could be less effective if:

- a woman is taking an enzyme inducer (see Section 10.1)
- a woman has recently taken a progestogen (see Section 10.3)

UPA is not recommended for a woman who has severe asthma managed with oral glucocorticoids (Section 11.2)

**Consider double-dose (3 mg) LNG if BMI >26 kg/m² or weight >70 kg (Section 9.2) or if taking an enzyme inducer (Section 10.1)

Cu-IUD - copper intrauterine device
 EC - emergency contraception
 LNG-EC - levonorgestrel 1.5 mg
 QS - quick start of suitable hormonal contraception
 UPA-EC - ulipristal acetate 30 mg
 UPSI - unprotected sexual intercourse

Appendix 3: Fraser Guidelines Questionnaire (relating to contraception)

1. The young person understands the advice being given.
2. The young person cannot be convinced to involve parents/carers or allow the medical practitioner to do so on their behalf.
3. It is likely that the young person will begin or continue having intercourse with or without treatment/contraception.
4. Unless he or she receives treatment/contraception their physical or mental health (or both) is likely to suffer.
5. The young person's best interests require contraceptive advice, treatment or supplies to be given without parental consent.

COMMUNITY PHARMACY LOCALLY ENHANCED SERVICES FOR CLIENTS WHO ARE BELIEVED TO BE UNDER 16 YEARS OF AGE

Any Pharmacy Staff having a discussion with the young person should gently explore the following issues at each consultation. This should be fully documented and should include an assessment of the young person's maturity, and whether they are acting voluntarily.

YOUR ASSESSMENT OF FRASER	YES	NO
Understanding of advice given		
<i>e.g. understands the service they are accessing, understands what actions they need to take during or following access to the service.</i>		
Notes: (please record discussion)		
Encouraged to involve parent / carer		
<i>e.g. client not prepared to talk to parent/carer at this time but will try to do so in due course. May be able to discuss with another responsible adult. Any coercion?</i>		
Notes:		
The effect of physical or mental health of young person if advice / treatment withheld		
<i>e.g. advice/ treatment/ service is needed now, to ensure their wellbeing.</i>		
Notes:		
Action in the best interest of the young person		
<i>e.g. providing the professional service/ advice at this time is in the best interest of the client, regardless of parental consent.</i>		
Notes:		

If the answer to each of these questions is 'YES' then the service may be supplied.

If a child is not competent to give consent i.e. a 'NO' to the questions, you should seek consent from a person with "parental responsibility" (this will often, but not always, be the child's parent/ carer).

Pharmacist's/ Staff member's Signature:
 ...

Date:

Client's Name

Service Provided

Please retain this completed document for your record /service file – electronically or as hard copy