NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Supply Of Levonorgestrel Emergency Contraception (LNG-EC) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Lead Author: Consultant in Sexual and Reproductive Health NHSG **Co-ordinator:** Medicines Management Specialist Nurse NHSG	**Consultation Group:** See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian

Signature:		**Signature:**

NoS Identifier: NoS/PGD/LNG_EC/ MGPG1118	**Review Date:** October 2022 **Expiry Date:** October 2023	**Date Approved:** October 2020

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1.3 (Amended March 2022)

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	New PGD Supersedes NHSG/PGD/LNG_EC/MGPG927 v7.1 and NHSG/PGD/CPEHC/MGPG926 v5, NHSH PGD 7_02_V11 and NHST Levonorgestrel Emergency Contraception (LNG-EC 3mg) for women with a BMI >26kg/m2 and weight >70kg out with its licensed use and Levonorgestrel Emergency Contraception (LNG-EC 3mg) for women with a BMI >26kg/m2 and weight >70kg within its licensed use PGDs.

Date of change	**Summary of Changes**	**Section heading**
February 2020	New NoS PGD.	
June 2020	Section on inadequate use of other contraceptive methods removed in-line with FSRH National PGD.	Inclusion criteria
June 2020	Off-label use in certain conditions listed.	Legal status
December 2020	Statement regarding galactose intolerance, total lactase deficiency and glucose-galactose malabsorption removed from medical history section of proforma.	Appendix 4 Proforma
January 2021	Administration removed from PGD along with BLS and anaphylaxis training requirements. PGD to be supply only.	Throughout
January 2022	Reference to the NHSG PGD for domperidone removed.	Advice verbal and proforma
March 2022	Term patient replaced with individual.	Throughout
March 2022	Additional child protection information added.	Inclusion and Exclusion criteria
March 2022	Additional specific child protection questions added.	Appendix 4 Proforma
March 2022	Amendment of IUD to Cu-IUD	Throughout
March 2022	Additional sexual health service referral form for under 18 year old patients and vulnerable adults after supply of EHC added.	Appendix 6

NoS Identifier: NoS/PGD/LNG_EC/MGPG1118

Keyword(s): PGD Patient Group Direction Levonorgestrel EHC proforma emergency contraception

Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	February 2020
	Completed:	August 2020
	Approved:	October 2020 (published – November 2020)
	Amended and Re-authorised:	December 2020, January 2021, March 2022

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Hame Lata **Health Board:** NHSH **Title:** Consultant in Sexual and Reproductive Health **Contact email:** hame.lata@nhs.scot **Signature:** ..... **Date Signed:** 10/03/2022
Senior representative of the professional group who will provide care under the direction	**Name:** Kimberly MacInnes **Health Board:** NHSH **Title:** Service Manager/Lead Nurse Sexual Health Services **Contact email:** kimberley.macinnes@nhs.scot **Signature:** ..... **Date Signed:** 15/03/2022
Lead author	**Name:** Dr Dianna Reed **Health Board:** NHSG **Title :** Consultant in Sexual and Reproductive Health **Contact email:** dianna.reed@nhs.scot **Signature:** ..... **Date Signed:** 08/03/2022
Pharmacist	**Name:** Alison Smith **Health Board:** NHSG **Title :** Medicines Management Pharmacist **Contact email:** AlisonJane.Smith@nhs.scot **Signature:** ..... **Date Signed:** 14/03/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		02/03/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		15/03/2022

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Dr Dianna Reed	**Lead Author:** Consultant in Sexual and Reproductive Health NHSG
Frances Adamson	**Co-ordinator:** Medicines Management Specialist Nurse NHSG
Alison Smith	**Pharmacist:** Medicines Management Pharmacist NHSG
Dr Hame Lata	**Medical Practitioner:** Consultant in Sexual and Reproductive Health NHSH
Kimberly MacInnes	**Senior Representative:** Service Manager/Lead Nurse Sexual Health Services NHSH
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Elaine Maguire	Community Clinical Nurse Team Leader NHSS
Deborah Syme	Team Leader The Corner NHST

Patient Group Direction For The Supply Of Levonorgestrel Emergency Contraception (LNG-EC) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to supply levonorgestrel for emergency contraception (LNG-EC) to individual requesting emergency contraception who report an episode of unprotected sexual intercourse (UPSI), occurring within the previous 72 hours (up to 96 hours off licence) for the prevention of unwanted pregnancy, where the insertion of a copper intrauterine device (Cu-IUD) is declined, unsuitable or or when access to this provision isn't possible. **Note:** Healthcare professionals should advise service users that the available evidence suggests that oral EC administered after ovulation is ineffective. All must be advised that a Cu-IUD is the most effective method of emergency contraception. If they are referred for a Cu-IUD, oral emergency contraception should be issued at the time of referral in case the Cu-IUD cannot be fitted, there is a delay with the procedure or the individual changes their preference. Trial data have shown that the pregnancy rate is lower following treatment with ulipristal acetate (UPA-EC) than with LNG-EC. **LNG-EC should therefore be reserved for when UPA-EC is not an option**. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), the individual Summary of Product Characteristics (SmPC), the Faculty of Sexual and Reproductive Healthcare (FSRH) UKMEC guidance April 2016 (updated September 2019) and the FSRH Clinical Effectiveness Unit guideline Emergency contraception guideline March 2017 (Updated December 2017).
Inclusion criteria	**Follow the Flowchart for Oral Emergency Contraception (EC): LNG-EC Versus UPA-EC (Appendix 3). Ensure the EC Proforma is completed (Appendix 4)** **Note:** The healthcare provider must use their professional judgement to consider, and where appropriate, act on any child protection issues coming to their attention as a result of providing the service. This should be in line with local child

	protection procedures and any national or local guidance on under 16s sexual activity. • An individual under 16 years of age may give consent for the supply of LNG-EC, provided they understand fully the benefits and risks involved. The individual should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the individual indicates that they wish to accept the supply, supply should proceed, if the pharmacist deems the individual to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2(4) states that 'a person under the age of 16 years shall have legal capacity to consent on their own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure or treatment. Legal advice from the NHS in Scotland states that if a healthcare professional has been trained and professionally authorised to undertake a clinical procedure which is normally that of a medical practitioner, then that health care professional can be considered to have the necessary power to assess the capacity of a child under the 1991 Act, for that procedure or treatment. If under 13 years of age this PGD cannot be used and the healthcare professional should speak to the local Child Protection lead and follow the local child protection policy. **Licensed use:** Individual's aged 13 years up to and including 54 years of age presenting for EC within 72 hours of UPSI who have been advised that a Cu-IUD is the most effective form of EC and where: • UPSI or failure of another method of contraception has occurred • Criteria for the insertion of a Cu-IUD are not met, the individual declines Cu-IUD or where access to the provision of a Cu-IUD isn't possible. **Use outside of product licence:** The following criteria falls out with the product licence for LNG-EC. As such, the individual must be informed prior to the supply that the use is off-label.

	Individual aged 13 years up to and including 54 years of age presenting for EC who have been advised that a Cu-IUD is the most effective form of EC and where: • They decline or are not suitable for UPA-EC and present within 96 hours of UPSI, in the 5 days before predicted ovulation • They decline or are not suitable for UPA-EC and they weigh >70kg or their BMI is >26 • They decline or are not suitable for UPA-EC and they present between 72 and 96 hours after UPSI at any stage of the cycle. LNG-EC can be given more than once in a cycle. **Note:** UPSI includes the withdrawal method, condom failure and inadequate use of other contraceptive methods. This includes patients with condom failure in the first seven days after 'quick starting' hormonal contraception or within 7 days of an intra-Uterine System (IUS) fitting, if fitted out with day 1 - 7 of their cycle or who are using an oral, patch or implant contraception within 28 days in enzyme inducer use. Best practice advice given by FSRH is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SmPC). This PGD includes off-label use in the following conditions: ○ Use between 72 and 96 hours post UPSI ○ Increased dose for individuals with BMI over 26kg/m^2 or weight over 70kg and in individuals using liver enzyme inducing agent ○ Severe hepatic impairment ○ Individuals with previous salpingitis or ectopic pregnancy ○ Lapp-lactase deficiency ○ Hereditary problems of galactose intolerance ○ Glucose-galactose malabsorption. Where a medicine is recommended off-label consider, as part of the consent process, informing the individual that the medicine is being offered in accordance with national guidance but that this is outside the product licence. Prior to the supply of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.

Exclusion criteria	• Under 13 years (the healthcare professional should speak to the local Child Protection lead and follow the local child protection policy) • 55 years of age and over • Individual under 16 years of age and assessed as not competent to consent to treatment using Fraser guidelines • Allergy or hypersensitivity to LNG-EC or any of the excipients including potato starch, maize starch, colloidal anhydrous silica, magnesium stearate, talc, lactose monohydrate • Pregnancy or suspected pregnancy (if a individual's menstrual period is late or in case of symptoms of pregnancy, pregnancy should be excluded before LNG-EC is supplied) • Given birth in last 3 weeks – (EC not needed). **Note:** EC **is** however needed for UPSI 5 days or more after early pregnancy loss • Most recent UPSI more than 96 hours ago • Taken UPA-EC in the last 5 days • Where there is no valid consent.
Precautions and special warnings	Any gender based violence, child protection and welfare issues should be referred through the appropriate channels. Those who are currently taking ciclosporin as LNG-EC may increase the risk of cyclosporine toxicity due to possible inhibition of ciclosporin metabolism. Those who are currently taking or have taken enzyme-inducing drugs in the past 4 weeks the efficacy of LNG-EC may be reduced. Rifampicin and rifabutin are particularly strong enzyme inducers and individual taking these should be strongly encouraged to have a Cu-IUD. A double dose of LNG-EC (i.e. 3000 micrograms within 72 hours after UPSI) is an option for patients who are unable or unwilling to use a Cu-IUD. Where BMI >26 or weight >70kg LNG-EC effectiveness may be reduced. UPA-EC should be considered. If this is contraindicated a double dose of LNG-EC (i.e. 3000 micrograms within 72 hours after UPSI) is an option. For breastfeeding individuals as LNG-EC is secreted into breast milk. Potential exposure of an infant to LNG-EC can be reduced if the breast-feeding individual takes the tablet immediately after feeding and avoids nursing at least 8 hours following administration. Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as

	acute/active inflammatory bowel disease or Crohn's disease. Although the use of levonorgestrel is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed.
Action if excluded from treatment	Refer to GP or Sexual Health Service (SHS) for further consultation. If more than 72 hours have elapsed, Cu-IUD or UPA-EC (if within 120 hours) will need to be considered. If an IUD is considered the most appropriate intervention, individual should be referred to the SHS as soon as possible. Oral EC should be given (if suitable under PGD) at the time of the referral in case the IUD cannot be fitted or the individual changes their mind. A Cu-IUD can be fitted up to 5 days after a single episode of UPSI in a cycle or up to 5 days after the earliest ovulation date expected within a regular cycle. It can also be fitted up to day 13 of a patch, COC, ring free interval, assuming previous correct use. If an individual presents within 72 hours of UPSI, and the UPSI is likely to have taken place during the 5 days prior to the estimated day of ovulation (usually days 11- 15 of cycle) and Cu-IUD is not acceptable, then a supply of UPA-EC via PGD is recommended unless UPA-EC is contraindicated (refer to UPA-EC PGD). For anyone presenting for treatment under this PGD aged under 13 years, the local child protection team must be contacted. Consultation with sexual health services or their GP should be prioritised. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	The individual should be advised of the risks of not receiving the supply of LNG-EC. Refer to sexual health service or GP. Document that the supply was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the PGD

Name form and strength of medicine	Levonorgestrel (LNG-EC) 1500 microgram tablet.

Legal status	Levonorgestrel (LNG-EC) 1500 microgram tablet is a Prescription-only Medicine (PoM). In accordance with the MHRA all medicines **supplied** under a PGD **must** either be from over-labelled stock, or be labelled appropriately in accordance with the regulatory body guidelines for the labelling of medicines for the professional providing the supply. **Note:** There are some indications for LNG-EC described in this PGD which are outside the terms of the marketing authorisation, and constitutes an off-label use of the medicine. These are clearly identified in the PGD, and individual must be informed prior to the supply that the use is off-label.
Dosage/Maximum total dose	**In individuals whose BMI <26 and weighing 70kg or less and on no interacting medication:** • One LNG-EC 1500 microgram tablet to be taken orally • Where possible the tablet should be taken at the end of consultation • If there are concerns that the individual may be pregnant, carry out a pregnancy test (PT) and if negative supply the tablet. If unable to carry out a PT immediately, advise test and supply tablet and inform the individual to take tablet if PT is negative • If vomiting occurs within 3 hours of LNG-EC intake, another 1500 microgram tablet should be taken. **In individuals whose BMI >26 OR weighing >70 kg, individual who decline or are unsuitable for UPA-EC OR individual on interacting medication (the following constitute use outside of product licence):** • Patients who request oral EHC while using enzyme-inducing drugs or within 28 days of stopping them should be advised to take a total of 3000 micrograms LNG-EC (two 1500 microgram tablets) as a single dose as soon as possible and within 72 hours of unprotected sexual intercourse (UPSI). • Patients should be informed that a weight >70kg or BMI >26kg/m2 could reduce the effectiveness of oral emergency contraception, particularly LNG-EC. They should be advised to take a total of 3000 micrograms LNG-EC (two 1500 microgram tablets) as a single dose • Individual who decline or are not suitable for UPA-EC who present within 96 hours of UPSI in the 5 days before predicted ovulation should take 1500 micrograms (one tablet) as a single dose, for patients who's weight >70kg see above for dosing.

	• Individual who decline or are not suitable for UPA-EC who present between 72 and 96 hours after UPSI at any stage of the cycle should take 1500 micrograms (one tablet) as a single dose. For patients who's weight >70kg see above for dosing.
Frequency of dose/Duration of treatment	See Dosage/Maximum total dose section above.
Maximum or minimum treatment period	Once only dose for that episode of UPSI or potential contraceptive failure. Dose can be repeated if individual vomits within 3 hours of ingestion.
Route/Method of administration	Oral. Nausea is less likely if taken with or after food.
Quantity to be supplied	See Dosage/Maximum total dose section above.
Storage requirements	This medicinal product does not require any special storage conditions.
Follow-up (if applicable)	Ensure the individual is advised to return if vomiting occurs within 3 hours after taking LNG-EC. Additionally, ensure information regarding where to access LNG-EC should vomiting occur out with the hours the service is available. EC does not prevent a pregnancy in every instance. Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern. If abdominal pain is experienced which is not typical of the individual's usual dysmenorrhoea or pregnancy is suspected for any other reason, pregnancy should be excluded. Individuals should also be advised to seek medical advice if they have signs and symptoms suggestive of an ectopic pregnancy. The individual may wish to make an appointment to discuss any aspect of their LNG-EC use, it is therefore important to ensure the individual has the contact number for appropriate follow up services (this may be her GP).

Advice (Verbal)	The option of a Cu–IUD should be discussed with **all** individuals requesting emergency contraception, even if presenting within 72 hours. Efficacy of the Cu-IUD is superior to that of LNG-EC, the failure rate is estimated at no greater than 1% and allows ongoing contraceptive benefit. The Cu-IUD can be inserted up to 5 days after UPSI or, if time of ovulation can be reliably estimated, up to 5 days following ovulation (i.e. up to day 19 of menstrual cycle in regular 28 day cycle). A careful menstrual history is necessary to establish likely date of ovulation and amenorrhoea does not exclude risk of pregnancy. Patients should be informed that LNG-EC is unlikely to be effective if taken post-ovulation. Advise the individual (as per proforma): • How the LNG-EC works, benefits of treatment and how it should be taken • Possible adverse effects • About failure rate, and that EC does not prevent a pregnancy in every instance. Patients should be advised that oral EC administered after ovulation is unlikely to be effective • Presenting after UPSI within 5 days of predicted ovulation that UPA-EC is more effective than LNG-EC • On what to do if they vomit within three hours of taking the pill(s). The individual should be advised where to obtain more supplies if this occurs • Provide information regarding all methods of ongoing contraception and how to access these • If taking the oral contraceptive pill, using a patch or ring and LNG-EC is needed individual should continue their usual method and use barrier contraception or abstain until they have taken the pill, or used the patch or ring correctly for 7 days • Provide advice about ongoing contraception/abstinence if LNG-EC has been needed because of inadequate use of Depo-Provera®, Nexplanon®, Cu-IUD or IUS • It is important to return for a pregnancy test if the next menses is missed/lighter or more than 7 days late • Light bleeding 2-3 days after taking LNG-EC is common and should not be assumed to be a period or a guarantee that the LNG-EC has been effective • After using EC treatment only provides protection for that episode of UPSI. It is recommended that subsequent acts of intercourse be protected by a reliable barrier method until the next menstrual period starts • If currently taking or has taken enzyme inducing medication within the last 4 weeks (if rifampicin/rifabutin within the last

	3 months) provide the MHRA leaflet 'Levonorgestrel emergency contraception: important information for patients taking other medicines' (Appendix 5) • Discuss safer sex and sexually transmitted infections. Where possible provide information about how to access testing if needed • If serious adverse or persistent effects occur, the individual should be advised to contact their GP/Accident and Emergency department/NHS24.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Details of local Sexual Health Service and how to contact them. Additional individual information leaflets such as those below should be provided where available: • Family Planning Association: Your Guide to Emergency Contraception and Your Guide to Contraception. Available at www.sexwise.fpa.org.uk.
Identifying and managing possible adverse reactions	**Reduced Efficacy of Levonorgestrel** The metabolism of LNG-EC is enhanced by concomitant use of liver enzyme inducers. Medicines suspected of having the capacity to reduce the efficacy of LNG-EC include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing hypericum perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin. **Effect of Levonorgestrel on other Medication** There is possibility that LNG-EC may increase oral hypoglycaemic and insulin requirements - therefore, it is a recommendation that blood sugar levels should be monitored closely for 24 hours, after taking LNG-EC. LNG-EC may enhance or reduce the anticoagulant effects of warfarin and phenindione. Additional monitoring may be needed for 72 hours post administration. If currently taking ciclosporin, inform the individual that LNG-EC may alter the ciclosporin level and they may need a review of ciclosporin dose with their GP.

	The most commonly reported undesirable effects are; Headache Nausea Abdominal pain Fatigue Delay of menses more than 7 days** Dizziness Diarrhoea Vomiting Breast tenderness Irregular menstruation **Bleeding patterns may be temporarily disturbed, but most patients will have their next menstrual period within 5-7 days of the expected time. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF:** BNF British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Report any severe reactions using the Yellow Card System. https://yellowcard.mhra.gov.uk/
Facilities and supplies required	The following are to be available at sites where the medicine is to be supplied: • Appropriate storage facilities • An acceptable level of privacy to respect individual's right to confidentiality and safety • Access to a working telephone • Access to medical support (this may be via the telephone) • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to supply medicine(s) under PGD

Professional qualifications	Registered nurses and midwives as recognised by the Nursing and Midwifery Council (NMC), and pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).

Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's capacity to understand the nature and purpose of the medicine supply in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD • Competent to undertake supply of the medicine • Competent to work under this PGD. **Additionally:** **Pharmacists** Community pharmacists must have completed the following TURAS e-learning and assessment packages and be able to provide evidence of this if requested to do so: • Emergency Contraception • Contraception • Safeguarding Children and Vulnerable Adults. **Nurses and Midwives** Must hold a recognised qualification in contraception/sexual health (an introduction to contraception is not sufficient) **Or** Have undertaken significant training and have evidenced experience in contraception and sexual health.

Ongoing training and competency	**All professionals working under this PGD must:**
	• Have undertaken PGD training as required/set out by each individual Health Board
	• Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct
	• Have knowledge and familiarity of the following;
	  ○ SmPC for the medicine(s) to be supplied in accordance with this PGD.
	
	Additionally:
	• Nurses and midwives must ensure they update their training regularly in relation to safeguarding children and vulnerable adults. Additionally, they must also ensure they update their contraception/sexual health knowledge annually. This could be achieved by attending either:
	  ○ In-house training

	○ Session with a contraception trained doctor/nurse ○ Attends relevant study day ○ On-line learning, e.g. FSRH eLearning modules.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to supply the medicine(s) specified in this direction.

Documentation

Authorisation of supply	Nurses and midwives working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to supply the medicine(s) specified in this PGD by their Professional Line Manager/Consultant/Practice GPs. Community pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to supply the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
Record of supply	An electronic or paper record for recording the screening of individuals and the subsequent supply, or not of the medicine(s) specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum: • Date and time of supply • Individuals name and CHI • Exclusion criteria, record why the medicine was not supplied (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route of the medicine supplied

	• Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who supplied the medicine • Record of any adverse effects (advise individuals GP/relevant medical practitioner). Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • NaSH – Sexual Health Electronic Patient Record • BadgerNet – Digital Maternity Notes • Individual's GP records if appropriate • Individual service specific systems • Electronic Patient Medication Records (use of Appendix 4 EC-Proforma is recommended).
Audit	All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines supplied under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Levonorgestrel 1500 microgram Tablet (Bayer) – Date of revision of text 02/07/2021 accessed 08/03/2022. British National Formulary and British National Formulary for Children https://www.bnf.org/products/bnf-online/ accessed 12/02/20. Faculty of Sexual and Reproductive Healthcare Emergency Contraception March 2017 (updated Dec 17) Faculty of Sexual and Reproductive Healthcare Drug interactions with hormonal contraception January 2017 (updated Jan 2019) MHRA 2016 Levonorgestrel-containing emergency hormonal contraception: advice on interactions with hepatic enzyme inducers and contraceptive efficacy Faculty of Sexual & Reproductive Healthcare Clinical Standards Committee: Statement on the prescription, administration or supply of Contraceptive Medicines for use outside the terms of their reference December 2009

	Faculty of Sexual & Reproductive Healthcare UK Medical Eligibility Criteria for Contraceptive Use April 2016 (Updated September 2019) The family planning association: Under 16s consent and confidentiality (Fraser) FSRH CEU Statement: Contraceptive Choices and Sexual Health for Transgender and Non-Binary People (October 2017) - Faculty of Sexual and Reproductive Healthcare

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1

Healthcare Professional Agreement to Supply Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to supply the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Supply Of Levonorgestrel Emergency Contraception (LNG-EC) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

I have completed the appropriate training to my professional standards enabling me to supply the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2

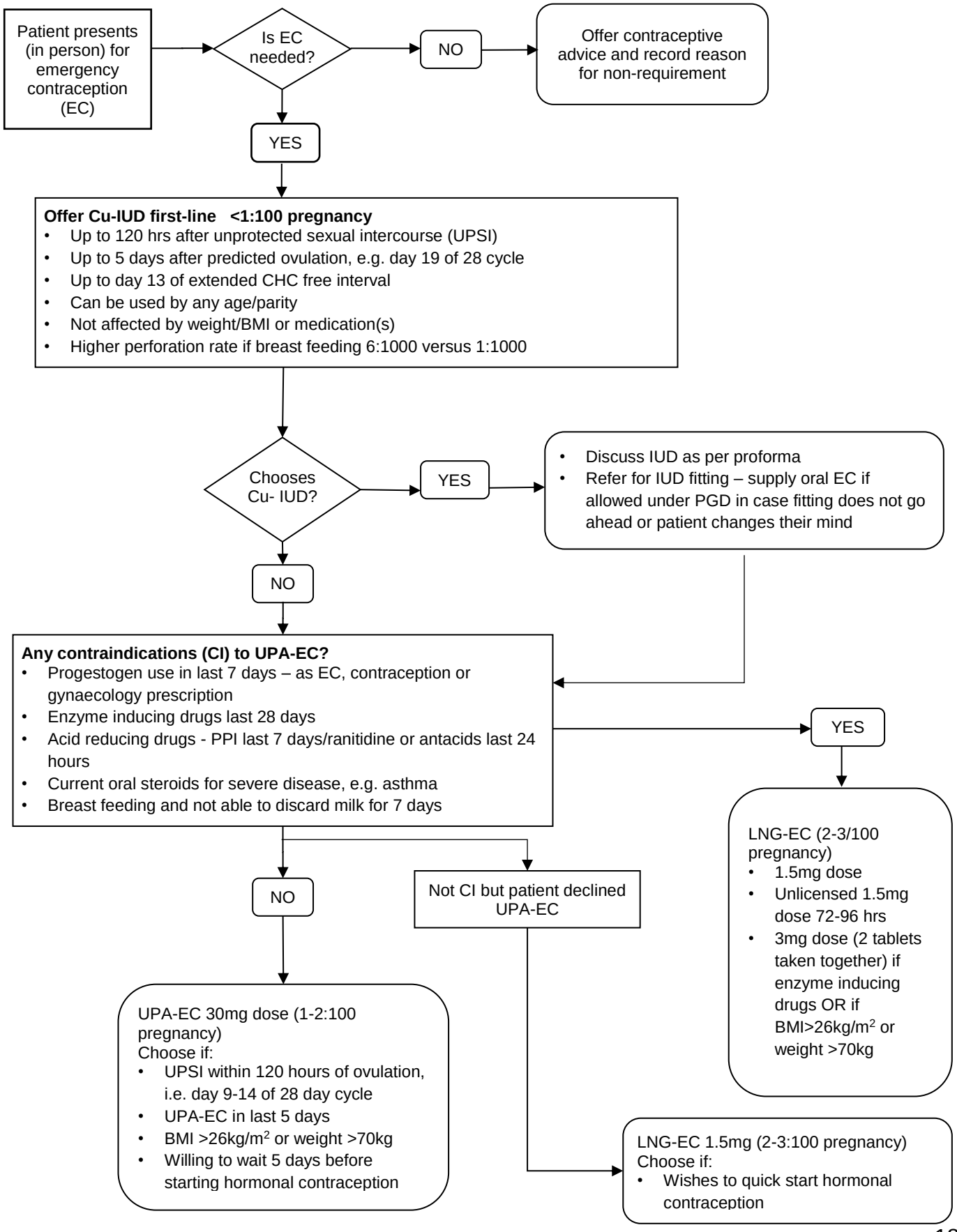
Healthcare Professionals Authorisation to Supply Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to supply the medicine(s) under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to supply the medicine(s) under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
Patient Group Direction For The Supply Of Levonorgestrel Emergency Contraception (LNG-EC) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Supply Of Levonorgestrel Emergency Contraception (LNG-EC) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**

Appendix 3 - Flowchart for Oral Emergency Contraception (EC): LNG-EC versus UPA-EC



Emergency Contraception Proforma Appendix 4

This form is for use within Sexual Health Services (SHS) and in community pharmacies commissioned to provide EHC.

Consultation Details

Healthcare Professional Name (PRINT):	Date of Consultation:
Client Name:	Date of Birth: Age:
Client under 16 years of age and assessed as competent under the Fraser Guidelines? Yes ☐ No ☐	
Client not competent or is under 13 years of age referral made to child protection as per local guidance Yes ☐ No ☐	

Circumstances Leading to EHC Request

UPSI
Time since UPSI? ☐ 12 hrs or less ☐ 12-24 hrs ☐ 24-48 hrs ☐ 49-72 hrs ☐ 72-120 hrs ☐ >120 hrs

Reason for UPSI (tick relevant)	
☐	No contraception used
☐	Oral contraceptive failure (indicate reason as below)
	☐ Severe diarrhoea
	☐ Severe vomiting
	☐ Missed pill(s)
☐	Barrier method failure
☐	Late contraceptive injection
☐	Other (please state below)
Was alcohol a contributing factor? Yes ☐ No ☐	

History	
Day 1 of last menstrual period (LMP)	/ /
LMP regular?	Yes ☐ No ☐
Any other episodes of UPSI since last menstrual period?	Yes ☐ No ☐
If there has been other episode of UPSI was LNG-EC or UPA-EC taken since LMP?	LNG-EC ☐ UPA-EC ☐
Pregnancy test undertaken? (Test should be done if period is late, LMP unsure or LMP unusual) Refer to GP if positive.	Yes ☐ No ☐ Test: Positive ☐ Negative ☐
Are there any concerns in regard to abuse? (If yes refer to the appropriate service as per local guidelines)	Yes ☐ No ☐

Medical History	**Yes**	**No**	**Action/Information**
Allergy to UPA-EC or LNG-EC?			If yes advise Cu-IUD and refer for fitting. If declined refer to GP or Sexual Health Service (SHS).
Current unexplained vaginal bleeding?			If yes refer to GP or Sexual Health Service (SHS)
Previous vomiting with EC?			Advise to return for a repeat dose if vomiting occurs within 3 hours of LNG-EC/UPA-EC.
Progesterone or levonorgestrel in the last 7 days?			If yes UPA-EC less effective – advise Cu-IUD or use LNG-EC.
BMI >26kg/m^2 or >70kg in weight			If yes advise Cu-IUD (first line), UPA-EC if suitable or LNG-EC 3000 microgram dose (unlicensed).
Currently breastfeeding?			Not affected by IUD or LNG-EC. Advise to discard breast milk for 7 days after UPA-EC use.
Given birth within the last 3 weeks?			If yes EC is not required. **Note:** Early pregnancy loss **does** require EC.
Severe asthma treated with oral glucocorticoids?			If yes UPA-EC not suitable, consider LNG-EC if UPSI is <96 hours or refer to GP or SHS if greater.
Severe malabsorption syndrome e.g. Crohn's disease or severe diarrhoea?			If yes suggest Cu-IUD as LNG-EC and UPA-EC may be less effective.

Medical History	Yes	No	Action/Information
Porphyria?			If yes UPA-EC is not suitable – advise Cu-IUD or use LNG-EC.
Currently taking medicines that increase gastric pH?			UPA-EC will have a reduced effect if PPI taken in the last 7 days or H2 antagonist or antacid taken within the last 24 hours.
Currently taking enzyme inducing medication?			If yes UPA-EC is not suitable. The only licensed option is an IUD or consider LNG-EC 3000 microgram dose (unlicensed).
Currently taking any interacting medicines? (See BNF Appendix1)			If yes refer to GP or SHS.

Counselling Checklist to be Discussed Prior to Treatment

Pregnancy Risk:

Days 9-16 of /28 cycle	20-30% risk of pregnancy with x 1 UPSI
Days 1-8 and >16 of /28 cycle	2-3% risk of pregnancy with x 1 UPSI
LNG-EC within 96 hours	2-3 in 100 patients will become pregnant
UPA-EC within 120 hours	1-2 in 100 patients will become pregnant
Copper IUD up to 120 hours after UPSI / or ovulation	< 1 in 100 patients will become pregnant

☐	Cu-IUD discusses as most effective 1st line option.	☐	Mode of action, efficacy and failure rates (see above)
☐	Action if vomiting occurs within 3 hours.	☐	Explain any common side effects
☐	If EC fails there is no increased risk of fetal abnormality	☐	Next period may be late/early and light bleeding may occur over the next few days (not to be counted as a period)
☐	Return if there is a further episode of UPSI	☐	Read the PIL for the EC
☐	When to seek medical advice i.e. should severe abdominal pain occur	☐	If no normal menstrual period within 3 weeks take pregnancy test

For 13- 18 year olds or vulnerable adults (poor mental health, drugs or alcohol issues, GBV etc): individual consents to local SEXUAL HEALTH SERVICE being informed to arrange follow up (pregnancy test, STI screen or testing, further contraception discussion and supply)	Yes ☐ No ☐

Planned Treatment **Note:** Tick to confirm that Cu-IUD has been offered to client ☐

☐	Referred for Cu-IUD	☐	Too late for any EC (Refer to GP or SHS)
☐	LNG-EC 1500 microgram single dose under PGD Batch No: Expiry Date: / /	☐	UPA-EC 30mg single dose under PDG Batch No: Expiry Date: / /
☐	LNG-EC 3000microgram single dose under PGD (unlicensed) Batch No: Expiry Date: / /	☐	Too late for either UPA-EC or LNG-EC, but declines Cu-IUD (Refer to GP or SHS)
☐	No EC required		

Referral	Referred to Sexual Health Service ☐	Referred to Out of Hours Service ☐	Referred to GP ☐

STI Advice (when appropriate)

STI risk discussed	Yes ☐ No ☐
How/Where to access STI testing or treatment discussed	Yes ☐ No ☐
14 day window period for chlamydia, gonococcal and trichomoniasis swabs	Yes ☐ No ☐
3 month window period for syphilis, hepatitis B,C and HIV	Yes ☐ No ☐

Contraception Advice (when appropriate)		
Intended Contraception Discussed Yes ☐ No ☐ (Indicate as below if discussed)		
☐ Client declined/undecided	☐ POP	☐ RING
☐ Condoms only	☐ Patch	☐ Injection
☐ IUD/IUS	☐ COC	☐ Implant

Additional questions for 13- 15 year olds, or under 18 year olds in care to exclude child sexual abuse and exploitation. *A child protection concern is not an exclusion criteria for the PGD as the pregnancy risk might continue.*		
How old is the person or are the persons you are having sex with? If there is an age gap over 2 years (24 months) between the individual and the person(s) they have sexual contact with- **Follow local Health Board Child Protection Policies**		
Have you ever been made to do something sexual that you didn't want to do?	Yes ☐ No ☐	If the individual says yes – **Follow local Health Board Child Protection Policies**
Have you ever been made to feel scared or uncomfortable by the person/s you have been having sexual contact with?	Yes ☐ No ☐	If the individual says yes – **Follow local Health Board Child Protection Policies**
Has anyone ever given you something like gifts, money, drugs, alcohol or protection for sex?	Yes ☐ No ☐	If the individual says yes – **Follow local Health Board Child Protection Policies**

Consent			
Emergency hormonal contraception treatment risks have been fully explained to me and I agree to treatment. I have been informed of how my data will be stored and who will be able to access that information, as well as how it may be used.			
Client Signature		Date	
Healthcare Professional Supplying Signature		Date	

Appendix 5

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Levonorgestrel emergency contraception: important information for women taking other medicines

Some medicines, or herbal remedies that contain the ingredient St John's wort, might reduce how well levonorgestrel emergency contraception works.

What you need to do

Tell the doctor, pharmacist, or nurse if you are currently taking a medicine to treat any of the following, or you have used one in the past 4 weeks:

- epilepsy (eg, medicines called barbiturates, primidone, phenytoin, or carbamazepine)
- tuberculosis (eg, rifampicin, rifabutin)
- HIV (eg, ritonavir, efavirenz)
- a fungal infection (eg, griseofulvin)
- or if you have taken any herbal remedies that contain the ingredient St John's wort (scientific name *Hypericum perforatum*)

If you are taking any medicines or herbal remedies and are not sure if they might affect levonorgestrel emergency contraception check with your doctor, pharmacist, or nurse.

What happens now?

Your doctor, pharmacist or nurse will talk to you about whether this applies to medicines you have recently taken. If it does, you should either:

- see a doctor or nurse to have another type of emergency contraception called a copper intrauterine device or 'coil' inserted into the womb (this does not interfere with the action of other medicines);

or:

- take a double dose of levonorgestrel emergency contraception. The pharmacist will give you 2 packs, which should be taken together at the same time

Further information about levonorgestrel emergency contraception

Levonorgestrel is a hormonal type of emergency contraception. It can be used within 3 days (72 hours) after unprotected sex or failure of a usual contraceptive method.

Levonorgestrel emergency contraception may not prevent pregnancy every time. It works best the sooner it is taken—preferably within 12 hours.

Advice for women taking levonorgestrel emergency contraception:

- see your doctor or nurse for advice on effective ongoing contraception
- do a pregnancy test to ensure that you are not pregnant if your period does not come at the right time or if you suspect you could be pregnant
- if the test is positive and you are pregnant (even after taking levonorgestrel), see a doctor or nurse as soon as possible to ensure that you receive the best care
- read the leaflet that comes with levonorgestrel, which provides further information about this emergency contraception including any potential side effects
- if you think that you may have had a side effect after taking levonorgestrel, remember you can report it on a Yellow Card (https://yellowcard.mhra.gov.uk/)

Appendix 6

Notification to local Sexual Health Service to arrange follow up for under 18 year old patients and vulnerable adults after supply of EHC

This form is not suitable for urgent referrals of patients for the insertion of an EC IUD), oral EC but unsuitable for treatment via PGD or for the treatment of patients with symptomatic STIs. Please call your local Sexual Health Service to arrange any urgent appointment instead.

CONFIDENTIAL WHEN COMPLETED
Data protection confidentiality note: this message is intended only for the use of the patient or entity to whom it is addressed and may contain information that is privileged, confidential and exempt from disclosure under law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited.

Sexual Health Service (name):	
Address	
The following patient has been supplied with oral EC today:	
Patient name	
Date of birth/CHI	
Patient address	
Postcode	
Mobile number	
Landline number	
Any additional requirements (Interpreter etc.):	
GP name	
GP practice address	

☐ The client is consenting to be contacted by the Sexual Health Service phone call/text (mobile)/ phone call (landline)/ by letter.

Please delete any mode of communication the patient is NOT consenting to.

Please arrange a follow up appointment for this patient at your clinic for:

- ☐ pregnancy testing
- ☐ contraceptive counselling
- ☐ contraception supply
- ☐ STI screening or testing
- ☐ other (please specify):

Additional relevant information (please tick which applicable and give details):

- ☐ Repeat unplanned pregnancies:
- ☐ Child(ren) in care:
- ☐ Learning disability:
- ☐ Gender-based violence:
- ☐ Drug misuse:
- ☐ Alcohol misuse:
- ☐ Mental health problems:
- ☐ Homelessness:
- ☐ Complex medical history, drug interactions or contraindications to contraception:
- ☐ Other:

Any other comment:

Other agencies involved:

Patient consent:

I give my permission to allow my healthcare provider to pass, to my local Sexual Health Service, details of this consultation and to arrange follow up within their service.

Patient signature	Date

This form should be sent (in paper form or electronically) to your local Sexual Health Service and a copy retained. Please discuss with your local Sexual Health Service about the quickest and safest way to do this.

Referring health care professional (name):

Referring health care professional (signature):

Job title:

Referring organisation/agency/ service:

Contact number:

E-mail:

Additional Information about confidentiality to patients requesting EC between 13 and 15:

“If you're between 13 to 15, you have the same rights to confidentiality as an adult and your health care provider won't tell your parents, or anyone else, as long as they believe that you fully understand the information and decisions involved. They'll encourage you to consider telling your parents or carers, but they won't make you.

Even if the health care provider feels that you're not able of making a decision yourself, the consultation will still be confidential. They won't tell anyone that you saw them, or anything about what you said.

The only time a health care provider might want to tell someone else is if they believe there is a risk to your safety or welfare, such as abuse, or to the safety of someone else. The risk would need to be serious, and they would usually discuss this with you first”.