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Emergency contraception

**A guideline for service
provision in Europe**

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SECOND EDITION

.....

May 2016

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ECEC

european
consortium
for emergency
contraception

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Emergency contraception **A guideline for service provision in Europe**

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Foreword

It is my pleasure to introduce the second edition of “Emergency contraception. A guideline for service provision in Europe”. The first edition of this guide was published in December 2013, and it was the first publication by the European Consortium for Emergency Contraception (ECEC), a network of individuals and organizations striving to expand knowledge of and access to this contraceptive option in Europe.

The field of emergency contraception (EC) has witnessed many changes in the past few years. New EC products are now available without prescription in most European markets. More data are available on the safety, efficacy and mechanism of action of levonorgestrel (LNG) and ulipristal acetate (UPA) EC pills, and on the interaction of the latter with other hormonal contraceptives. Efforts are underway to reposition the copper IUD as EC, in the context of promoting the use of highly effective and long acting reversible contraceptives. Today we have more EC options, and we know more about each different EC method. Hence, the update of this tool, two years after its first edition.

This guideline can be a useful tool for those countries that have not yet developed guidelines for EC delivery services and/or pharmacies, and for those who want to update their current guides. In this regard, the European Society of Contraception and Reproductive Health (ESC) is pleased that this resource was used by national contraception societies to publish guidelines in at least three countries (Italy, Romania and Spain) during 2014 and 2015.

The ESC works to improve access and to provide information on contraception and reproductive health care in Europe. We also aim at harmonizing the legal framework in the field of contraception in our region. It is the ESC vocation to co-operate with organizations and institutions like the ECEC, that share the Society’s aims to generate and share knowledge and experience on contraception.

Emergency contraception is the only contraceptive method that can be used after intercourse, and it offers women a second chance to prevent pregnancy. Having this method readily available, means expanding the contraceptive choices of women and couples, and creating an enabling environment in which reproductive rights can be fully enjoyed.

Given that since 2015, in many European countries, women can directly access both LNG and UPA EC pills in pharmacies, we, as healthcare providers, need to stay updated and strive to provide each woman with information on her EC choices before her need arises. I encourage national contraception societies and pharmaceutical associations to use this tool in order to be properly equipped to provide the best EC counselling possible to women.



KRISTINA GEMZELL-DANIELSSON

President, European Society of Contraception and Reproductive Health

Introduction

Sexual and reproductive health is a fundamental human right. Scientific advances provide couples with an increasingly wide range of effective and safe contraceptive methods. Emergency contraception (EC) contributes to women's right to reproductive health, and it offers a last chance to prevent pregnancy after unprotected intercourse.

Since 2015 EC pills are more equally available and accessible than ever before in Europe: in all European Union countries, except for Malta and Hungary, both levonorgestrel (LNG) and ulipristal acetate (UPA) EC pills are authorised to be sold directly in pharmacies without prescription. In the rest of Europe EC options are also expanding, with UPA becoming progressively more available. Today women in Europe have more post-coital contraceptive options than ever before, and they need to be informed so they can exercise choice.

This template guide is based on evidence based guidelines developed by the World Health Organization (WHO),^{1,2,3} the International Consortium for Emergency Contraception (ICEC) and the International Federation of Gynecology & Obstetrics (FIGO),⁴ and the Clinical Effectiveness Unit (CEU) of the Faculty of Sexual & Reproductive Healthcare.⁵ The document is intended to facilitate the process of developing or updating national or institutional EC guidelines according to the best evidence available up to February 2016. It can also be used by pharmaceutical associations, given their important role in assisting women who will procure EC directly in a pharmacy without a clinician's counselling.

With this tool, the European Consortium for Emergency Contraception (ECEC) promotes the harmonization of EC provision across Europe. The guide addresses key issues that should be included in clinical guidelines for health professionals providing EC. It covers LNG and UPA EC pills and the use of the copper intrauterine device (Cu-IUD) for EC. The document presents the questions that a provider should ask, and the action that should be taken, when a woman requests EC. It assumes that at least one method of EC is available but provides recommendations based on current evidence to support a decision on which method to use, should more than one be available.

The first edition of this guide was originally developed by ECEC in December 2013, with financial and scientific support from the European Society of Contraception and Reproductive Health (ESCRH). It was written by Anne Webb, with contributions from ECEC Board members (Emilio Arisi, Teresa Bombas, Christina Fiala, Medard Lech, and Ardian Paravani); ECEC Advisory Committee members (Sharon Cameron, Kristina Gemzell, Anna Glasier and Caroline Moreau); CEU members, Julie Craik and Louise Melvin; and ECEC coordinator, Cristina Puig. Anne Webb, the ECEC Board and Advisory Committee, as well as the ESCRH Internal Scientific Committee, kindly collaborated in the review of this 2nd edition. This includes updates on issues in which recent research points to new recommendations. In particular, on repeated use of UPA and interactions between UPA and progestogen-based contraceptives.

1. Emergency contraceptives in Europe

Emergency contraception (EC) refers to contraceptive methods that women can use to prevent pregnancy after unprotected or inadequately protected sexual intercourse.

Currently in Europe there are three main licenced EC methods:

- Many copper intra uterine devices (Cu-IUD)
- EC pills with ulipristal acetate (UPA) 30mg
- EC pills with levonorgestrel (LNG) 1.5mg

This template guide refers only to these three options, listed in order of effectiveness, as they are the ones most widely available in Europe.

EC can reduce the risk of pregnancy following an act of unprotected or inadequately protected intercourse by between 75% and 99% depending on the method used. Insertion of a Cu-IUD is the most effective EC method, followed by UPA EC pills. LNG EC pills reduce the risk of pregnancy by at least half and possibly by as much as 80% to 90% following an act of unprotected or inadequately protected intercourse.⁴ The effectiveness of oral EC is related to when in the cycle it is taken. Women who use an oral EC method should be advised that pregnancies can still occur despite taking the treatment.

2. How to deal with a request for EC

A few questions (2.1, 2.2 and 2.3) will determine if a woman may already be pregnant or has any medical reasons restricting the use of EC. In most circumstances the woman can complete the assessment herself.

2.1. Could the woman already be pregnant?

The International Federation of Gynecology and Obstetrics (FIGO) defines pregnancy as the part of the human reproduction process *which commences with the implantation of the conceptus in a woman, and ends with either the birth of an infant or an abortion.*⁶

If a woman had unprotected sexual intercourse (UPSI) more than 3 weeks ago and has not had a normal menstrual period since, it is possible she may be pregnant. If a high sensitivity pregnancy test is negative she is definitely not pregnant and can be given any EC.

If she has already ovulated, oral EC (LNG and UPA) will not work. If implantation has occurred, it is too late to use any EC method. Prior to a Cu-IUD fitting the clinician should be reasonably certain that there is not already an implanted pregnancy in the uterus.

WHAT COULD HAPPEN IF A WOMAN WAS ALREADY PREGNANT WHEN SHE USED EC PILLS?

There is no known harm to the woman, the course of her pregnancy, or the fetus if UPA or LNG EC pills are accidentally used during pregnancy.^{3,7} EC pills do not harm either the women or her fetus if she becomes pregnant despite having used EC pills.⁴

Knowing if a woman may be pregnant

Health professionals can be reasonably certain that a woman is not currently pregnant if any one or more of the following criteria are met and there are no symptoms or signs of pregnancy:⁸

-
She has not had intercourse since last normal menses
.....
-
She has been correctly and consistently using a reliable method of contraception
.....
-
She is within the first 7 days of the onset of a normal menstrual period
.....
-
She is within the first 7 days after an abortion or miscarriage
.....
-
She is within 4 weeks of childbirth and is not breastfeeding
.....
-
She is fully or nearly fully breastfeeding and amenorrhoeic, and is less than 6 months from childbirth.
.....

A pregnancy test 3 weeks after last episode of unprotected sexual sexual intercourse can exclude pregnancy. If the pregnancy test is done earlier, it could be falsely negative.

2.2. Is there any risk of pregnancy?

If unprotected, or not fully protected, sexual intercourse has occurred, it is never possible to be absolutely certain that there is no risk of pregnancy. Therefore, EC should always be discussed, regardless of where a woman is in her cycle. It is better to offer EC than to take any risk of unplanned pregnancy.

WHAT IS UNPROTECTED SEXUAL INTERCOURSE (UPSI)?

Any situation when a woman has not used contraception or has not used a method correctly and consistently.

What is incorrect and inconsistent use of contraception and when should EC be considered? ⁹

.....
Condoms and other barrier methods: If barriers were not used from first genital contact through to the end of intercourse or if there is any concern about the condom splitting or coming off.

.....
Combined Oral Contraceptives (COC): If three or more consecutive pills are missed.

.....
Combined vaginal ring and patch: Dislodgement, delay in placing, or early removal of a contraceptive hormonal ring or skin patch as stated by manufacturer.

.....
Progestogen-Only Pill (POP) traditional: If pill taken more than 27 hours after the previous pill and had UPSI before the POP has been taken again properly for 48 hours.

.....
POP (desogestrel 75µg): If pill taken more than 36 hours after the previous pill and had UPSI before the desogestrel POP has been taken again properly for 48 hours.

.....
IUD and Intrauterine System containing LNG: If it is expelled or removed and had any UPSI in the seven days up to removal of the device.

.....
DMPA: If she had any UPSI more than 16 weeks after her last injection.

.....
NET-EN: Norethisterone enanthate progestogen-only injection taken more than 2 weeks late.

.....
Combined estrogen-plus-progestogen monthly injection: If given more than seven days late.

.....
Diaphragm or cervical cap: Dislodgment, breakage, tearing, or early removal of a diaphragm or cervical cap.

.....
Withdrawal: Failed withdrawal (e.g. ejaculation in the vagina or on external genitalia).

.....
Spermicides: Failure of a spermicide tablet or film to melt before intercourse.

.....
Abstinence: Miscalculation of the abstinence period, or failure to abstain or use a barrier method on the fertile days of the cycle when using fertility awareness based methods.

Enzyme inducing drugs interact with combined hormonal contraception, POP and implant so may reduce their effectiveness. EC should be considered if no additional contraception was used at the time of UPSI whilst taking the enzyme inducing drugs and for 28 days after finishing them.¹⁰

2.3. Are any cautions necessary when using EC?

2.3.1. IS THE WOMAN ON ANY OTHER MEDICATION?

- **Cu-IUD:** There are no relevant drug interactions.

- **UPA and LNG:** Enzyme inducing drugs (some antiepileptics, antiretrovirals, rifampicin and a herbal remedy, *Hypericum perforatum*) will enhance metabolism of oral EC and reduce effectiveness. Although there is no good evidence to support doubling the dose of LNG, it is often done for women on enzyme inducing drugs.^{5,10}

2.3.2. DOES SHE HAVE ANY MEDICAL CONDITIONS THAT MIGHT RESTRICT USE?

- **LNG:** WHO states that there are no medical restrictions to the use of LNG EC pills.³
- **UPA:** WHO states that there are no medical restrictions to the use of UPA EC pills.³ The manufacturer suggests caution in women who have severe asthma which is not controlled by oral glucocorticoids, those with severe hepatic dysfunction, hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption as well as those who have shown hypersensitivity to UPA.¹¹
- **Cu-IUD:** Use of a Cu-IUD for EC carries the same eligibility criteria as routine Cu-IUD insertion. Women who have heavy menstrual bleeding are eligible for an emergency Cu-IUD. Risk of sexually transmitted infections (STIs), previous ectopic pregnancy, age and nulliparity are not reasons to restrict Cu-IUD use.^{3,5,12}

3. What methods should be offered?

Every woman should be advised, by any health professional talking to her, of all the options that are available on site, and informed of where else she can access any other methods, within the time restrictions for EC. LNG has been available without a medical prescription for some years in most European countries. In January 2015 the European Medicines Agency authorised the sale of UPA EC pills without a prescription and it is currently available in most European Union countries directly from pharmacies.

What method should be offered?

If there was **only one** episode of UPSI...

... less than 72 hours ago, the choices are:

- Cu-IUD most effective
- UPA is slightly more effective than LNG
- LNG.

... between 72-120 hours ago, the choices are:

- Cu-IUD most effective
- UPA is licenced and effective
- LNG is not licenced, but appears to still have some effect up to 96 hours.

... more than 120 hours, the choices are:

- Cu-IUD can still be used if the woman is thought to be before the first date that a pregnancy would start to implant: at least six days after UPSI and around day 20 of a 28 day cycle.

If there has been **more than one** episode of UPSI the choices are:

- Cu-IUD is the most effective and can be used any time up to the earliest day that implantation could start: at least six days after UPSI and around day 20 of a 28 day cycle.
- UPA can be used if all the episodes of intercourse were within the last 120 hours.
- LNG, as it is considered safe to use outside its licence restrictions.

4. What issues should an EC guide address?

What side effects should a woman expect or be warned about?

Most women who take oral EC (LNG or UPA) have no side effects at all. The next menstrual bleed may come early, on time or late and there can be some unscheduled bleeding. Nausea, vomiting, headache and dizziness can occur but tend to be mild and self-limiting. A pregnancy test should be done if the next menstrual bleed is more than seven days late.

The side effects for a Cu-IUD are the same as for an IUD fitted routinely. These may include discomfort on fitting, increased risk of pelvic inflammatory disease (PID) within the first three weeks, risk of expulsion, displacement or perforation, and heavier or painful bleeds.

What should a woman do if she vomits after oral EC?

In the unlikely event that a woman vomits within 2 hours of taking LNG EC pills or 3 hours of taking UPA EC pills, she may wish to either repeat the dose or access a Cu-IUD.

What follow up is required?

There is no routine follow up required after oral EC. She needs to use contraception for all future episodes of sexual intercourse if she wishes to avoid pregnancy, given that each dose of oral EC will not prevent pregnancy from further intercourse in the same cycle.

Follow up after EC IUD is the same as for a routine Cu-IUD insertion.

If a woman's period is more than 7 days late, or she has not had one within three weeks of using EC, she should carry out a pregnancy test.

What else should the clinician ask about?

HAS SHE GOT ONGOING CONTRACEPTION?

The Cu-IUD offers highly effective ongoing contraception for up to 10-12 years.

The quicker a woman starts ongoing contraception the quicker she is protected, reducing her future pregnancy risk. Many women (30%) have further sexual intercourse whilst awaiting their next period and as oral EC may only delay ovulation the risk of pregnancy may continue later than expected in the cycle.

After LNG EC. A woman can safely start all hormonal methods (pills, patches, injection, implants, ring) except LNG Intrauterine System (LNG IUS) on the same day as taking LNG EC (quick start)⁸, if she

wishes. She will need to use extra precautions – condoms or abstinence - for between 2 and 9 days depending on the ongoing method chosen. See table below.

After UPA EC. New evidence suggests that hormonal contraceptives can disrupt the effect of UPA EC for up to five days. Therefore, any hormonal ongoing contraception should be delayed until the fifth day after taking UPA EC¹³. The woman will need to use extra precautions – condoms or abstinence - during the five-day interval, as well as between 2 and 9 days after starting the ongoing method, depending on the ongoing method chosen. See table below.

If the clinician who sees the women first cannot issue ongoing contraception there should be clear referral pathways to other, locally accessible services.

Duration of additional contraception required when starting hormonal contraception after UPA EC¹⁵

	Methods	Requirement for additional contraception
After taking UPA EC pills, wait at least 5 days before starting or resuming the following hormonal methods:	Combined oral contraceptive pill (except <i>Qlaira</i> ®)	7 days
	Other combined oral contraceptive pills (<i>Qlaira</i> ®)	9 days
	Combined vaginal ring or transdermal patch	7 days
	Progestogen-only pill (traditional or desogestrel)	2 days
	Progestogen-only implant or injectable	7 days

After LNG EC pills, all these methods can be started immediately with requirements for additional contraception as detailed in the right hand column.

Is she at any risk of STI?

A request for EC is a good opportunity for promoting the prevention of STI and the use of condoms, where there is a risk. All women should be encouraged to make an assessment of their own risk of STIs bearing in mind the local prevalence of infection and the testing facilities. If she is at risk the test should, ideally, be offered at the same visit or she should be signposted to a service that can provide the service after any necessary wait (e.g. it can take up to 3 months for an HIV test to become positive from the time of risk).

Can the clinician quantify the level of risk of pregnancy and advise different methods depending on the level of risk?

No. The date of ovulation in a cycle is very variable even in women who have ‘regular’ cycles and who know the date of the first day of their last period. Therefore, it is not possible, with any degree of certainty, to say where a woman is in her cycle relative to ovulation. Only she can determine what degree of risk she is willing to accept and, based on this, which method she prefers to use, if she has a choice of EC method. The risk of pregnancy in the first three days of a normal cycle is very low so a woman may choose not to use EC at this time. In this instance she could start any other method of contraception as they will be immediately effective.

Women should be provided with clear, up-to-date and evidence based information so they can decide what EC method they prefer to use. ECEC has developed a user-friendly tool to assist women when choosing their EC method. See www.ec-ec.org.

Is EC advised even if the man did not ejaculate?

There can be sperm in the pre-ejaculate so there is always a risk of pregnancy if there was any close contact between the penis and vagina. If a woman wishes to avoid pregnancy she should use EC after any risk.

Can EC pills affect an implanted pregnancy or cause an abortion?

No. There is no evidence that, at the doses of LNG or UPA used for EC, these methods would prevent implantation or cause an abortion. EC pills should not be confused with drug regimes used for legal termination of pregnancy.

Regarding the use of Cu-IUD for EC, whether it should be avoided if there is any risk of implantation but before a pregnancy test is definite, will depend on national regulations.

Are there any lower or upper age limits?

No. If a woman is at risk of pregnancy she should have access to all EC methods, regardless of her age. A woman can get pregnant from before her first ever period (menarche) and until the menopause, which can only be diagnosed in retrospect.

There are no medical reasons ever for denying LNG EC to anyone who has had a risk of pregnancy but does not wish to be pregnant as the alternative may be an unplanned and possibly unwanted pregnancy. The restrictions to use of UPA and Cu-IUD are very few (as indicated in section 2.3.2), but are not related to the age of the user.

Nulligravida and nulliparity (not having had a pregnancy or a baby) are not contraindications to Cu-IUD insertion. Younger women are also eligible to use a Cu-IUD.³

However, issues of safeguarding children or vulnerable adults should not be ignored. Each country should clearly define the legal framework around consent to sex and treatment as well as any professional body recommendations with regards to caring for children who cannot or have not consented to sex.

Should EC be issued to women with higher body weights?

Yes. No woman should be refused or discouraged from using EC based on her weight.¹⁴

EC pills may be less effective among women with BMI of 30 kg/m² or higher, than among women with BMI of 25 kg/m² or lower.³ For all women, the copper IUD is the most effective EC method, followed by UPA and then LNG. For women at higher bodyweights, special emphasis should be placed on the benefits of the copper IUD or UPA.¹⁴

Should EC be issued to women after sexual assault/rape?

Yes. EC should be discussed with all women who have been sexually assaulted and who are at any risk of pregnancy. A full choice of EC must be part of any first line service offered to women following sexual assault, and be readily available in emergency care facilities.¹⁵

Is timing important?

Yes. A woman can only get pregnant for about a week out of every month. Her highest risk is on the day just before and of, ovulation. Because oral methods only work up to just before ovulation the sooner the treatment is given the more likely it is to be used whilst it still works. Delays to access to all methods need to be minimized.

How many times can a woman take EC?

Every time she is at risk of unwanted pregnancy. WHO states that there are no restrictions on repeated use of LNG or UPA EC pills.³ There is no evidence of any harm from repeated use of LNG EC. Repeated use of UPA has not been so widely studied but the evidence is reassuring and no woman should be denied further doses if she requires them.

However, as there appears to be an interaction between progestogen and UPA in the first five days after taking UPA, if repeat EC is required within 5 days of taking either oral method (UPA or LNG), repeating the same method is recommended. It is thus fine to take a repeat dose of UPA after previous UPA in the same cycle, and to take a repeat dose of LNG after previous LNG, but mixing both in the same cycle is not recommended as it may compromise efficacy.¹³ A Cu-IUD should also be considered as it has a longer window of action.

As LNG and UPA remain in the body for some time after ingestion, ECPs do not need to be taken more than once every 24 hours even if multiple acts of unprotected sex occurred within this timeframe.¹⁶

Every occasion is an opportunity to discuss ongoing contraception and STI prevention/testing. Repeated use of oral EC may lead to temporary variation in the bleeding pattern.

Can EC be used by a breastfeeding woman?

Yes.

- LNG: Can be used with no restrictions, as stated by WHO.³
- UPA: WHO states that it can be generally used by a breastfeeding woman, but that as a precautionary measure, she should not to breastfeed for a week, and instead express and discard her breast-milk.³ UPA has not been shown to cause any harm but its effects on babies have not been studied.
- Cu-IUD: Can be inserted from four weeks after childbirth³ even in breast feeding women.

Can EC cause infertility?

No. EC, oral or Cu-IUD, has no effect on long term fertility.

Is there an increased risk of ectopic pregnancy?

No, not even with a Cu-IUD. Past history of ectopic pregnancy, is not a contraindication for the use of any type of EC. Furthermore, EC, like all contraceptives, contributes to reducing the absolute risk of ectopic pregnancy by preventing pregnancy overall.

Is there any increased risk of stroke or cerebrovascular accident?

No.

Are any tests necessary before issuing EC?

No. No tests are required before using EC. If the history suggests that the woman may already be pregnant, a pregnancy test, if available, should be done. If it is not available, oral EC can be issued.

Does increased access to EC increase the rate of STIs?

No.

Does increased access to EC reduce the use of ongoing contraception?

No.

Where should EC be available?

EC pills should be available in as many outlets as possible (pharmacies, supermarkets, vending machines, etc.) It is not necessary to see the woman for oral EC, so clear guidance should be available, in each country, about arrangements for 'phone' prescriptions, where needed, and referrals for timely Cu-IUD fitting.

Who can issue EC?

Anyone who has the appropriate training. The woman herself can make most of the assessments. Any health professional, doctor, nurse, midwife and pharmacist, following simple guidelines, should be able to have a confidential, sensitive conversation to assist with any issues the woman may have and to signpost her towards any further services required.

Most European countries have LNG and, since 2015, UPA EC pills available in pharmacies without a prescription (see www.ec-ec.org)

IUDs are fitted by appropriately trained nurses, midwives, family doctors/general practitioners, specialists in Sexual Health and gynaecologists.

Can a health professional refuse to issue EC for personal reasons?

Every country needs clear legally based advice on this. As oral EC only works before ovulation and EC does not disrupt pregnancy, advice on EC should be different to advice on abortion. Any personal views of the clinician should be balanced against their professional duty of care, and the imbalance of power between the clinician and the woman should be taken into account. If a health professional refuses to issue EC, he or she must refer the patient to someone who will provide EC.

Can oral EC be issued in advance?

There is no medical reason why oral EC cannot be issued in advance, especially in countries or regions where accessibility is a problem. A woman may wish to have EC pills as back up to her usual method and the sooner she takes oral EC after UPSI, the more likely she is to take it at a time of the cycle when it will be effective.

Can oral EC be issued to anyone other than the woman who is going to use it?

As long as the woman taking it has the necessary information to address the few, simple issues that will help her assess if she has any condition that may prevent her from using EC pills (see sections 2.1 to 2.3) there is no medical reason not to issue EC pills to a third party. Each country should clearly define the legal position, if there are any restrictions.

What to do if no licenced EC is available?

It is possible to make up the relevant dose of levonorgestrel by using progestogen only pills or to use the combined estrogen/progestagen (Yuzpe) method, though this is less effective and has more side effects. Women and clinicians can consult the www.not-2-late.com web site¹⁷ to find out the pills and dosage that can be used for EC in any given country.

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The European Consortium for Emergency Contraception is a network of individuals and organizations that aims to increase **knowledge** and **access** to emergency contraception in Europe.

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