Emergency Contraception

A guideline for service provision in Europe

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ECEC

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contraception

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FOREWORD

It is my pleasure to introduce “Emergency contraception. A guideline for service provision in Europe”. This is 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 method in Europe.

This template guideline can be a very useful tool for those countries that have not yet developed guidelines for EC delivery services, and for those who are looking to update their current guides, especially given the many changes we have witnessed in this field in the past decade (new EC products in our markets, more data available on the safety and efficacy of levonorgestrel EC pills, and renewed efforts to reposition the Cu-IUD as EC, among others).

The European Society of Contraception and Reproductive Health (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 in all European countries, means expanding the contraceptive choices of women and couples, and creating an enabling environment in which reproductive rights can be fully enjoyed. Evidence-based and up-to-date guidelines are key to the role health providers play in helping women chose their best contraceptive choices, and the best emergency contraceptive therapy for her.

I encourage national contraception societies to use this tool in order to be properly equipped to provide the best EC guidance possible to women.

PROF. JOHANNES BITZER
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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 a woman's right to reproductive health, and it offers her a last chance to prevent pregnancy after unprotected intercourse.

There is a significant diversity in the type of EC products and regimens available in European countries as well as in national service provision regulations, which makes access to EC unequal across the region. This document is a template guide intended to help policy makers and/or programme managers develop or update their own national EC guidelines according to the best evidence available to date, and taking into consideration the local circumstances.

With this tool, the European Consortium for Emergency Contraception (ECEC) hopes to promote the harmonization of EC access and provision across Europe. The guide addresses key issues that should be included in clinical guidelines for health professionals providing EC. It covers EC pills and the use of the copper intrauterine device 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 current evidence to support a decision on which method to use, should more than one be available.

This template guide covers all the issues that a clinical guide should include. These issues are shown as headings in blue. The text following each heading shows the current evidence relating to each issue. Policy makers and/or programme managers wishing to adapt the guideline should use all the headings listed in the template but may wish to adapt the text according to their national situation.

This model guide is based on the World Health Organization (WHO)[1,2,3] and other evidence based guidances.[4,5,6] Once adapted and adjusted in each country, the guide can be of help to professionals providing contraceptive counselling.

The guide has been developed by ECEC with financial and scientific support from the European Society of Contraception and Reproductive Health (ESCRH). It has been written by Anne Webb, with contributions from Teresa Bombas, Anna Glasier, Emilio Arisi, Medard Lech, Ardian Paravani, Christian Fiala and Cristina Puig.

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 more 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 copper IUD is the most effective EC method, followed by UPA EC pills. Levonorgestrel 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 method should be advised that pregnancies can still occur despite taking the treatment.

HOW TO DEAL WITH A REQUEST FOR EC

A few questions (A, B, C) 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.

A) 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.* [7]

If a woman had unprotected 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 TOOK EC PILLS?

There is no evidence to suggest that LNG EC will have teratogenic effects if taken at any stage of pregnancy. Current evidence suggests that UPA in the dose used for EC will do no harm to an on-going pregnancy, but the data available is still scarce. There is no evidence to suggest that Cu-IUDs have teratogenic effects on an established pregnancy.

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 unprotected sexual intercourse helps exclude pregnancy. If the pregnancy test is done earlier, it could be falsely negative.

B) 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 so 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 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 higher dose (desogestrel):
If pill taken more than 36 hours after the previous pill and had UPSI before the desogestel 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.

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.

C) ARE ANY CAUTIONS NECESSARY WHEN USING EC?

IS THE WOMAN ON ANY OTHER MEDICATION?

Cu-IUD: There are no relevant drug interactions.
UPA and LNG: Enzyme inducing drugs (some antiepileptics, antiretrovirals 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.[6,10]

DOES SHE HAVE ANY MEDICAL CONDITIONS THAT MIGHT RESTRICT USE?

LNG: There are no medical restrictions to the use of LNG EC.[3,4]

UPA: The manufacturer suggests caution in women who have severe asthma which is not controlled by oral glucocorticoids, those with 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. Breastfeeding should be avoided for seven days after taking it and UPA should not be repeated in the same cycle.

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.[3,5,6]

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 is currently the easiest method to access, being sold at pharmacies in the majority of European countries.

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 have some effect up to 96 hours

More than 120 hours, the choices are:

- A 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:

- The 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.

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 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 an EC 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 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 IUD offers ongoing contraception for up to 10-12 years with many Cu-IUDs.

She can safely start all hormonal methods (pills, patches, injection, implants) except LNG Intrauterine System (LNG IUS) on the same day as taking EC (quick start) [8], if she wishes. She will need to use extra precautions - condoms or abstention - for between 2 and 16 days depending on the method chosen and on the method of EC used. The quicker she starts 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.

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

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 a risk assessment of their 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. 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 and 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. At this time she could start any other method of contraception as they will be immediately effective.

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 EC, 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 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.

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.[11]

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. EC must be part of any first line service offered to women following sexual assault, and be readily available in emergency care facilities.[12]

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 minimised.

HOW MANY TIMES CAN A WOMAN TAKE EC?

Every time she is at risk of unwanted pregnancy. There is no evidence of any harm from repeated use of LNG EC. Until further surveillance data is available, the manufacturer of UPA recommends not using it more than once per cycle.

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 EC: Can be used with no extra considerations.
- UPA: She should be advised to discard her breast milk for a week. This is on a precautionary principle. UPA has not been shown to cause any harm but it has been found in breast milk and its effects on babies has not been studied.
- Cu-IUD: Can be inserted from four weeks after childbirth[3] 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.

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, LNG 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 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 women may have and to signpost towards any further services required.

Most European countries have EC LNG available in pharmacies. UPA is, as yet, a prescription only drug, but nurses and midwives issue it in some countries.

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 asses if she may be already pregnant, (bullets A,B,C above) 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 site[13] 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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