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FFPRHC Guidance Emergency Contraception (April 2003)

This Guidance updates and replaces the previous Faculty recommendations on emergency contraception (EC)¹ and is applicable to all professionals providing contraceptive services in primary and secondary care. Details of the methods used by the Clinical Effectiveness Unit (CEU) in developing this Guidance, and evidence tables summarising the research basis of the recommendations, are available on the Faculty website (www.ffprhc.org.uk). Those providing EC should recognise that women at risk of unintended pregnancy may also be at risk of sexually transmitted infection. A pragmatic approach to clinical management, acknowledging these issues, is required. A key to the grades of recommendations, based on levels of evidence, is given at the end of the document. Abbreviations used: combined oral contraceptive (COC); emergency contraception, both oral and intrauterine (EC); intrauterine contraceptive device (IUD); intrauterine contraceptive system (IUS); last menstrual period (LMP); levonorgestrel (LNG); Patient Group Direction (PGD); progestogen-only emergency contraception (POEC); progestogen-only pill (POP); randomised controlled trial (RCT); sexually transmitted infection (STI); unprotected sexual intercourse (UPSI); World Health Organization (WHO).

What is emergency contraception?

Emergency contraception (EC) provides women with a safe means of preventing pregnancy following unprotected sexual intercourse (UPSI) or potential contraceptive failure.²⁻⁴ Alternative terms such as 'postcoital contraception' or the 'morning-after pill' are often confusing and 'emergency contraception' is the Faculty's preferred term.

What regimens are available?

Combined oestrogen-progestogen EC (Yuzpe regimen) was previously the method of choice in the UK. However, it is no longer recommended since a large randomised controlled trial (RCT) provided evidence for better efficacy and acceptability of progestogen-only emergency contraception (POEC).³ Two methods of EC are currently recommended here. Oral POEC, licensed since 1999, is available on prescription as Levonelle-2 and for pharmacy sale as Levonelle (Schering Health Care Ltd). Both versions comprise two tablets, each containing 750 µg (microgrammes) levonorgestrel (LNG). Copper intrauterine contraceptive devices (IUDs) can also be prescribed for EC use.⁵

The progesterone antagonist, mifepristone, has been shown in RCTs to be an effective EC when taken as a single dose up to 120 hours after UPSI.^{3,6,7} It appears to offer efficacy at least equivalent to that of LNG.^{7,8} However, mifepristone is not licensed nor readily available for this indication in the UK.

Levonorgestrel (LNG)

RCTs confirm the effectiveness of two 750 µg (0.75 mg) LNG tablets, taken 12 hours apart, within 72 hours of UPSI.^{3,7} The pharmacokinetics of LNG are the same when the second dose is taken 12 or 24 hours after the first⁹ and the Summary of Product Characteristics suggests the two doses can be given 12–16 hours apart.¹⁰ To improve efficacy and compliance, women should be encouraged to start POEC as soon as possible, but the second dose can be taken at a convenient time – as long as it is within 16 hours of the first dose.

Serum levels of LNG are similar following a single 1.5 mg dose and following the conventional regimen of

two 0.75 mg doses taken 12 hours apart.⁴ A large, well-conducted multicentre RCT from the World Health Organization (WHO) compared single and divided doses of LNG taken within 120 hours of UPSI.⁷ No differences in pregnancy rates between these regimens were identified. Equivalence cannot be demonstrated with absolute certainty but this study indicated that the single dose of LNG appeared to be equivalent to the divided regimen. Presently, in keeping with the product licence and with the patient information enclosed with the product, we recommend that the divided regimen should continue to be used routinely. In clinical situations where patient compliance is likely to be poor and when appropriate, modified patient information can be given, professionals and women may choose to use a single-dose regimen but this is outside its product licence.

POEC is unlicensed for use more than once in a menstrual cycle. Failure rates of 0.8% per treatment cycle have been identified when POEC has been used more than once.¹¹ Its repeated use is less effective than use of a regular method of contraception and women should be counselled to this effect. Nevertheless, POEC can be used more than once in a cycle if clinically indicated.

Copper IUD

A copper IUD can be inserted up to 5 days (120 hours) after the first episode of UPSI at any time in the menstrual cycle¹² or up to 5 days after the expected date of ovulation in a regular cycle. Ideally, an IUD should be inserted immediately, at first presentation, but women may choose to return for insertion when more convenient. In this circumstance, and if within 72 hours of UPSI, POEC should be given. Should she fail to re-attend, the woman has had the benefit of oral EC. Counselling prior to IUD insertion should cover its continued use and devices with > 300 mm² of copper (Flexi T-300, Multiload Cu-375, Nova-T380, T-Safe 380A) which have the lowest long-term failure rates should be used.^{13,14}

There is no research evidence on the effectiveness of the LNG intrauterine system (IUS) for EC and it is not licensed or recommended for EC use.⁵

Recommendations

- 1 POEC should be started as soon as possible and within 72 hours of UPSI or potential contraceptive failure (Grade B).**
- 2 Currently in routine practice, one tablet containing 0.75 mg LNG should be given and repeated 12 hours later (Grade A).**
- 3 In situations where patient compliance is likely to be poor, POEC may be given as a single dose of 1.5 mg LNG (Grade A).**
- 4 A copper IUD can be inserted up to 5 days after the first episode of UPSI or up to 5 days after the expected date of ovulation in a regular cycle (Grade C).**
- 5 The IUS should not be used as EC (Grade C).**
- 6 An IUD containing > 300 mm² of copper should be used if technically possible (Grade B).**
- ✓ Ideally, the second dose of POEC should be taken 12 hours after the first. However, the interval between doses may be up to 16 hours if this improves compliance.**
- ✓ Ideally, an emergency IUD should be fitted at first presentation, but can be offered at the woman's convenience. In this case POEC should be given if within 72 hours of UPSI or potential contraceptive failure.**
- ✓ If facilities are unavailable for emergency IUD insertion, local referral mechanisms should facilitate access to a specialist who can provide this service.**
- ✓ POEC can be used more than once in a cycle if clinically indicated.**

What drug interactions are relevant to EC use?

Although a 50% increase in the dose of oestrogen-progestogen EC was advised when using liver enzyme inducers,^{1,15} there is little evidence regarding POEC. Advice is that two tablets (1.5 mg) are followed 12 hours later by a single tablet (0.75 mg) – although this is outside the product licence.⁵

An IUD is unaffected by liver enzyme inducers, and may be the preferred option. The effectiveness of POEC is unlikely to be reduced in women using non-enzyme-inducing antibiotics, as progestogens do not undergo significant re-absorption in the bowel.

Caution is advised when prescribing POEC for women using warfarin. It has been observed that the anticoagulant effects of warfarin may be decreased¹⁵ or increased¹⁶ following POEC use.

Recommendations

- 7 Women using liver enzyme inducers should take two tablets (1.5 mg) at first presentation followed by one tablet (0.75 mg) 12 hours later and be advised regarding alternative use of an IUD (Grade C).**
- 8 Women using non-enzyme-inducing antibiotics should follow the normal POEC regimen (Grade C).**

What aftercare and follow-up is required?

Following POEC, the majority (87%) of women menstruate within 7 days after their expected date.³ Women should be advised to return for a pregnancy test if menstruation is delayed by more than 7 days, or is lighter than usual. Clinicians should always consider the possibility of ectopic pregnancy in such women. Failure of POEC is not thought to increase the risk of fetal abnormality. An emergency IUD can be removed without risk of pregnancy after the next menstruation, provided no UPSI has occurred since menses or if hormonal contraception has been started within the first 5 days of the cycle.¹² Failure of a copper IUD should be managed in the same way as failure with a long-term IUD. This is discussed fully in the WHO *Selected Practice Recommendations for Contraceptive Use*.¹²

Advice regarding ongoing contraception

POEC does not protect against pregnancy for the remainder of the cycle.³ Pregnancy rates following POEC are lower (0.8%) if women avoid intercourse until their next menses than if further UPSI, or sex with barrier contraception, continues (1.6%). Counselling should include instruction on abstinence, barrier methods, continuation of any present method, and consideration of future contraceptive methods.

If POEC has been used due to missed pills, then following the second dose of POEC the woman's usual pill should be resumed at her usual time. However, if this would be more than 12 hours after completing POEC, the pill should be restarted early so that no more than 12 hours has elapsed. Seven days of the combined oral contraceptive pill (COC) and 2 days of the progestogen-only pill (POP), respectively, are required to provide contraceptive cover¹² and a barrier method should be used in addition until these consecutive pills are taken¹² (Table 2). Methods such as Persona will be unreliable for up to 3 months following POEC use.¹⁷ If a woman wishes to continue using the IUD, she can be advised to return 3–6 weeks later for a check, as long as she has a normal menstrual bleed following insertion.¹²

Recommendations

- 9 Women should be instructed to return for a pregnancy test if their expected menstruation is more than 7 days late, or lighter than usual (Grade B).**
- 10 POEC does not provide contraceptive cover for the remainder of the cycle and effective contraception or abstinence must be advised (Grade B).**
- 11 An IUD can be removed anytime after the next menstruation if no UPSI has occurred since menses or if hormonal contraception has been started within the first 5 days of the next cycle (Grade C).**
- ✓ Information and counselling should be provided to women on use of their contraceptive method of choice.**
- ✓ Following missed pills, women should be advised to resume hormonal contraception at their usual time as long as this is within 12 hours of the second dose of POEC.**

How effective is EC?

The 'treatment failure rate' is the percentage of women who get pregnant despite using EC. Reported failure rates of POEC range from 1% to 3%. The failure rate for the copper IUD is less than 1%.¹⁸ As the overall risk of

Table 1 Efficacy of EC and time since unprotected sex

Coitus to treatment interval (hours)	Percentage of expected pregnancies prevented (%)
< 24	95
25–48	85
49–72	58

pregnancy following one act of UPSI at any time in the menstrual cycle is only 2–4%,¹⁹ the vast majority of women will not become pregnant following UPSI, even without using EC. For this reason, the efficacy of POEC may be more usefully expressed as the proportion of expected pregnancies prevented. Used within 72 hours of UPSI, oral POEC will prevent up to 86% of expected pregnancies.^{3,12} Copper IUDs will prevent 98% of expected pregnancies.¹⁸ In clinical practice, many factors influence the efficacy of POEC: recall of last menstrual period (LMP); cycle length; whether ovulation has occurred; whether both male and female partners are fertile; and whether intercourse occurred only once in the current cycle.²⁰

The risk of pregnancy following one act of UPSI varies throughout the menstrual cycle, increasing around the time of ovulation (Days 10 to 17)¹⁹ to 20–30%.¹ POEC has been shown to be more effective if started within 24 hours of the first episode of UPSI (Table 1).⁷ Effectiveness significantly decreases as time since UPSI increases, and POEC use should not be delayed unnecessarily. Delaying the first dose of oral EC by 12 hours was shown to increase the odds of pregnancy by 50%.^{3,21}

Randomised trials have investigated the use of POEC beyond 72 hours.⁷ Pooled results (1.5 mg LNG and divided doses of 0.75 mg LNG) showed that 60–63% of expected pregnancies were prevented if POEC was taken between 73 and 120 hours of UPSI. However, few women used POEC beyond 72 hours, confidence intervals were wide, and a recommendation for use beyond 72 hours cannot be given.

If the risk of pregnancy (assessed on the basis of the woman's reported menstrual cycle and timing of UPSI) is low (2–4%), POEC used up to 72 hours after UPSI may reduce the risk of pregnancy to less than 1%. If the assessed risk of pregnancy is high (20–30%), the residual pregnancy

risk after POEC may remain unacceptably high for some women. Reported pregnancy rates following emergency copper IUD use are consistently low (0.1–0.2%) throughout the menstrual cycle.^{22,23} The option of an IUD, with its low failure rate and its potential for use as an ongoing method of contraception, should be discussed with all women even if they present within 72 hours of UPSI.

Recommendations

✓ **Women should be fully counselled regarding the failure rates of oral and intrauterine EC to allow them to make an informed choice.**

✓ **An IUD should be offered to all women attending for EC even if presenting within 72 hours of UPSI.**

When is EC indicated?

There is no time in the menstrual cycle when there is no risk of pregnancy following UPSI. This is especially true if the cycle is irregular or if there is uncertainty about the date of the LMP. Nevertheless, the probability of pregnancy in the first 3 days of the cycle appears to be negligible.²⁴ It is important for professionals to take an accurate history to assess risk of pregnancy and the need for EC in each case. Enquiry should cover: the most likely date of ovulation based on the date of the LMP and the usual cycle length; when the first episode of UPSI occurred; details of potential contraceptive failure. Clinical judgement should then allow decisions to be made regarding the need for POEC in individual cases – but a pragmatic approach is often required.

POEC may be indicated in a range of clinical situations: following consensual sex where no contraception was used; following rape or sexual assault; when using withdrawal methods; following ejaculation onto the external genitalia; when a condom bursts; with dislodgement or incorrect condom use; or if a diaphragm or cap is incorrectly inserted, damaged, dislodged or removed within 6 hours of sex. Potential contraceptive method failures and indications for emergency contraceptive use are summarised in Table 2.

Evidence suggests that there is a negligible risk of pregnancy in other situations where women may be

Table 2 Recommendations for EC use with potential failures of various contraceptive methods

Method of contraception	Indications for emergency contraception
Combined pills (21 active tablets)	Indicated if two or more pills have been missed from the first seven pills in a packet and the woman has had UPSI either in the pill-free week or in the first 7 days of the packet. The COC should be continued with additional barrier contraception until pills have been taken on 7 consecutive days. Indicated if four or more pills have been missed from the middle seven pills in the packet and UPSI has occurred in the 7 days since missing the fourth pill. The combined pill should be continued with additional barrier contraception until pills have been taken on 7 consecutive days. Indicated if there has been a failed barrier method or UPSI during short-term antibiotic use or in the 7 days after antibiotic treatment is completed. Indicated if there has been a failed barrier method or UPSI during, or in the 28 days following, the use of liver enzyme-inducing drugs.
Progestogen-only pill (POP)	Indicated if one or more POPs have been missed or taken more than 3 hours late and UPSI has occurred in the 2 days following this. The POP should be continued with additional barrier contraception until pills have been taken correctly on two consecutive days. Indicated if there has been a failed barrier method or UPSI during, or in the 28 days following, the use of liver enzyme inducers.
Intrauterine device	If complete or partial expulsion is identified or mid-cycle removal of the IUD is deemed necessary EC should be considered.
Medroxyprogesterone acetate (Depo-Provera)	Indicated if the contraceptive injection is late (more than 14 weeks from the previous injection) and UPSI and UPSI has occurred.
Progestogen-only implants	Indicated if there has been a failed barrier method or UPSI during, or in the 28 days following, the use of liver enzyme-inducing drugs.

Table 3 Summary of potential contraceptive failures, which do not warrant EC use

Method of contraception	No indication for emergency contraception
Combined pills	No indication if only one COC pill has been missed from the first seven pills in a pack, as long as the last seven pills in the previous pack were taken without omissions. The COC should be continued and additional barrier contraception is required until seven consecutive pills have been taken. No indication if three or fewer pills have been missed from the middle seven pills in the pack and if the first seven pills were taken correctly. The COC should be continued to the end of the pack with additional barrier contraception for 7 days. No indication if three or fewer pills have been missed from the last seven pills in the pack as long as the next pack is started without a pill-free interval. The COC should be continued with additional barrier contraception until seven consecutive pills have been taken.
Medroxyprogesterone acetate (Depo-Provera)	No indication if Depo-Provera is given up to 2 weeks late (up to 14 weeks from the previous injection). The injectable can be given and no additional barrier method is required.

concerned about potential contraceptive failure^{12,25,26} Professionals counselling women in these circumstances may advise that EC is not required – particularly if the woman would have difficulty attending. If a woman is very anxious, however, and wishes to use EC, even in circumstances where the risk of pregnancy is assessed as very low, this may be appropriate after counselling. Table 3 summarises circumstances when EC is seldom indicated. Details regarding missed pills are in line with new WHO *Selected Practice Recommendations for Contraceptive Use* (2002).¹² A UK version of these Recommendations is currently in preparation by the Faculty.

Recommendations

✓ Professionals should present the evidence of the effectiveness and need for EC in individual situations to allow women to make an informed choice regarding its use.

Are there any contraindications to EC?

The WHO *Medical Eligibility Criteria for Contraceptive Use*²⁷ advise that there are no medical contraindications to POEC. The Summary of Product Characteristics for Levonelle-2 list severe hypertension, diabetes mellitus with associated vascular complications or neuropathy, ischaemic heart disease, stroke, or past history of breast cancer as relative contraindications.¹⁰ A WHO 2 classification is given for severe liver disease (the advantages of the method outweigh the theoretical or proven risks).²⁷ Caution should be used in women with acute active porphyria, severe liver disease and allergy to LNG.

The same medical eligibility criteria should apply to emergency and routine IUD insertion. Risk of sexually transmitted infection (STI), previous ectopic pregnancy, young age and nulliparity are not contraindications for IUD use. An increased incidence of infertility in nulliparous women using IUDs long term was suggested but no corresponding increase was identified following short-term IUD use.²⁸ It is the background risk of STI, and not age or parity *per se*, which influences the risk of pelvic infection.

Table 4 Timing of the next menses following POEC

Timing of the next menses after treatment	Percentage of women (%)
Within 3 days of the expected date of menstruation	57
More than 3 days early	15
Up to 7 days late	15
More than 7 days late	13

Recommendations

- 12 There are no absolute contraindications to the use of POEC but caution should be used in women with porphyria or severe liver disease (Grade C).
- 13 Use of the copper IUD for EC should follow the same relative and absolute contraindications as for routine IUD use (Grade C).

What are the side effects of EC?

Levonorgestrel (LNG)
Disturbances in the timing of the next menses have been described following POEC use (Table 4). The next period will occur within 3 days of the expected date in 57% of women.³
Vomiting is unusual following POEC use, occurring in only 5.6% of women.³ Nausea is reported more frequently (23.1%). If a woman vomits within 2 hours of taking either dose of POEC, she should take a further dose as soon as possible.¹² Absorption of LNG is rapid, with a half-life of less than 1 hour and a time of approximately 2 hours to achieve maximum serum concentrations.²⁹ There are no studies examining the use of anti-emetics with POEC. Domperidone maleate (10 mg), which works by speeding up gastric emptying, does not readily cross the blood–brain barrier and is unlikely to be associated with extra-pyramidal side effects.^{1,5} Domperidone can be given prophylactically to women who have previously vomited with POEC, or to those who have vomited their first or second dose. There is no evidence to support its routine use. An IUD should be considered in women experiencing persistent vomiting with POEC.
Ectopic pregnancy risk does not appear to be increased following POEC use but there are insufficient post-marketing data to allow accurate assessment of risk. However, on theoretical grounds due to its effects on tubal motility, pregnancy following POEC use may be more likely to be ectopic than in the general population. Both clinicians and women should be alert to this possibility.³⁰ Previous ectopic pregnancy is not a contraindication to POEC.²⁷

Copper IUD

Only side effects associated with immediate IUD insertion will be considered here. Other side effects will be discussed in future Guidance on IUD use.
Infective morbidity is related to insertion in the presence of infection rather than to the IUD itself.³¹ The risk of pelvic infection is increased 6.3-fold in the 21 days following IUD insertion.³² There is no continued increased risk with continuing use, unless exposed to new infection. Women should be told how to recognise the symptoms of pelvic infection, which may present in the 4 weeks after insertion.¹² All IUD users should be made aware of the use of barrier contraception to reduce the risk of STI.

Recommendations

14 Women should be advised that menstrual irregularity can occur within the cycle following POEC use (Grade A).

15 If vomiting occurs within 2 hours of taking either dose of POEC, a further dose, anti-emetics, or an IUD should be advised (Grade C).

16 Domperidone maleate is a suitable anti-emetic for women with previous vomiting following POEC or persistent vomiting during current use (Grade C).

17 Women should be counselled regarding a six-fold increase in the risk of pelvic infection in the 21 days following insertion of an IUD. They should be told how to recognise symptoms and when to seek medical advice (Grade B).

✓ Women should be provided with written information on how to access help and advice should any side effects occur.

✓ The possibility of an ectopic pregnancy should be considered if POEC has failed or where an abnormal bleeding pattern follows its use.

What clinical examination and investigation is needed before providing EC?

A sexual history should be obtained from those requesting EC, to allow assessment of STI risk and other sexual health issues. Guidelines have suggested opportunistic testing for *Chlamydia trachomatis* in sexually active women under the age of 25 years, or those over 25 years with a new partner or two or more sexual partners in the previous 12 months.^{33,34} Testing is also advocated prior to uterine instrumentation. A family planning-based study identified prevalence rates of *C. trachomatis* of 5.3% (25–29-year-olds) to 7.6% (under 24 years) in women attending for EC.³⁵ Women requesting EC who fall into these high-risk groups should be offered screening. Appropriate treatment can be given, and, together with counselling regarding safe sex and partner notification, can reduce the risk of re-infection.

A medical history and clinical examination are felt to be essential and mandatory in all circumstances by the WHO to allow the safe and effective use of routine intrauterine contraception.¹² Testing for STIs is felt to contribute substantially to the safe and effective use of IUDs.²⁷ A Cochrane Review on prophylactic antibiotic use prior to routine IUD insertion did not show that oral doxycycline or azithromycin conferred any benefit over placebo.³¹ Evidence is lacking on the use of prophylactic antibiotics at the time of emergency insertion.

Recommendations

18 A sexual history should be taken from all those attending for EC to assess risk of STI and other sexual health issues (Grade C).

19 Prior to emergency IUD insertion those at high risk should be tested for STIs, particularly *Chlamydia trachomatis* (Grade C).

20 The use of prophylactic antibiotics routinely at the time of emergency IUD insertion cannot be recommended but in high-risk groups their use may be considered (Grade C).

✓ For high-risk women undergoing emergency IUD insertion, antibiotics and abstinence may be advised after testing and pending results. Azithromycin 1 g stat or doxycycline 200 mg twice daily for 7 days are suitable regimens.

✓ Service providers should offer STI screening to all those attending for EC.

Who can supply EC?

Currently, EC can be obtained from a variety of services: family planning, general practice, some accident/emergency departments, departments of genitourinary medicine, gynaecology, National Health Service (NHS) 'walk-in' centres or pharmacies. These services have different facilities, approaches and knowledge of EC provision.³⁶ Differences in specific knowledge relating to EC are evident between these specialities.^{36,37}

The roles of doctors and of nurses in providing EC differ between different services. Nurse supply and prescription of POEC is the norm in some settings and should be encouraged in order to improve availability and access. IUD insertion requires specific skills and should only be undertaken by a competent and trained practitioner. Appropriate local referral mechanisms should be in place so that women can readily access this method. Training should be provided for all clinical and support staff involved in EC supply to improve knowledge and access and remove barriers.

Patient Group Directions

Extending the role of nurses in various clinical and community settings can improve access and quality of EC supply, and reflects the changing needs of modern clinical practice. Patient Group Directions (PGDs), formerly known as group protocols, can be developed for POEC in various settings.^{38,39} PGDs comprise specific, written instructions for the supply and administration of drugs in an identified clinical situation. PGDs should be drawn up locally and signed by doctors, pharmacists and nurses and approved by the employer and relevant professional advisory committees. Group Directions apply to groups of patients or service users who need not be individually identified before presentation for treatment. Guidance on PGD development has been published.⁴⁰ A PGD should include: the time period during which the PGD has effect; the class of medicine which may be supplied; any restrictions to its supply and administration; the clinical situations in which the medicine may be supplied; the clinical criteria under which a person is eligible for treatment; persons excluded from treatment; circumstances under which further advice should be sought from a doctor; the dose and administration regimens of the medicine; any specific warnings such as side effects; any necessary follow-up arrangements; arrangements for referral for medical advice; and details of the record of supply and administration.⁴⁰

Pharmacists, health visitors, midwives, nurses and paramedics can supply and administer medicines under PGDs. All professionals prescribing, supplying or administering medicines should take personal responsibility for maintaining and updating their knowledge and practice – including taking part in clinical audit. Professionals should never prescribe in situations beyond their individual competence.^{39,41}

Pharmacy supply of POEC

Following a change in the legal status of POEC, Levonelle was made available to women aged over 16 years, off

prescription and over the counter from pharmacists in January 2001. This deregulation extends the way that women in the UK can access POEC and has been welcomed by the public generally.^{42,43} The price of Levonelle may represent a barrier to use. Pharmacists can supply POEC free of charge under the NHS, following PGDs. Comprehensive guidance has been provided to all pharmacists regarding best practice for the supply of POEC.⁴⁴

Recommendations

21 PGDs should be developed locally to facilitate nurse and pharmacist supply and administration of POEC in different clinical and community settings (Grade B).

22 Adequate training for clinical and support staff involved in services providing EC should be provided (Grade B).

✓ Managed clinical care pathways should be developed locally to promote integrated working between different service providers to ensure good access, counselling, and quality of care.

Should EC be provided in advance of need?

Advance provision of POEC allows for appropriate counselling on other issues relating to reproductive and sexual health. RCTs have shown that, for selected women, advance supply is safe, may reduce the rate of unintended pregnancies, is used correctly by the majority of women, does not decrease the use of other contraceptive methods,⁴⁵ and is not associated with an increase in unprotected sex.⁴⁶ Women are more likely to use POEC when required if they have advance supplies than if they have to attend to receive supplies.⁴⁵ Repeat POEC use is given a WHO 1 classification (no restrictions for use).²⁷ The annual pregnancy risk for women who use POEC as their only method of contraception is lower if the first dose of POEC can be taken within 1 hour of UPSI.⁴⁷

Recommendation

23 Advanced provision of POEC and instructions on use can be offered to those attending family planning and sexual health services (Grade A).

What information about EC do women need?

Mode of action

The mode of action of POEC is incompletely understood.⁴⁸ Ovulation is inhibited in up to 80% of women if POEC is taken before the luteinising hormone (LH) surge.⁴⁹ Other effects on the length of the luteal phase, or a reduction in luteal phase LH levels, may be important.⁵⁰ An anti-implantation effect has been postulated, but there is little evidence to support this.^{49,51}

An IUD works primarily by inhibition of fertilisation. A secondary mode of action is to inhibit implantation of a fertilised ovum – and this may be relevant when an IUD is used as EC. A pregnancy is not recognised to exist legally until implantation is completed.⁵² EC methods are not abortifacient – and this should be emphasised when counselling prior to use.

Confidentiality

Young people, in particular, have concerns regarding confidentiality in sexual health services and specific information and reassurance regarding confidentiality should be readily available. EC can be prescribed safely and legally to women under the age of 16 years.

Is EC a cost-effective intervention?

EC appears to be cost-effective, whether it is provided on request or as an advance supply to be used when needed.⁵³ A greater use of EC could reduce the medical and social costs of unintended pregnancy. Strategies to increase knowledge, access and uptake of EC should be investigated, such as provision by school nurses. EC can now be obtained through a variety of agencies, but the impact of this on unintended pregnancy rates and the development of the service will be difficult to measure until accurate data are collected on its supply and outcomes.

✓ Providers of family planning and sexual health services should work together with other providers and local health authorities to collect data on use of EC and pregnancy rates.

References

- 1 Faculty of Family Planning and Reproductive Health Care. Emergency contraception: recommendations for clinical practice, April 2000.
- 2 Turner AN, Ellertson C. How safe is emergency contraception? *Drug Saf* 2002; **25**: 695–706.
- 3 Task Force on Postovulatory Methods of Fertility Regulation. Randomized controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 1998; **352**(9126): 428–433.
- 4 Ho PC, Kwan MSW. A prospective randomized comparison of levonorgestrel with the Yuzpe regimen in post-coital contraception. *Hum Reprod* 1993; **8**: 389–392.
- 5 PRODIGY Guidance: contraception – emergency. London: Department of Health, 2001. www.prodigy.nhs.uk
- 6 Ashok PW, Stalder C, Wagaarachchi PT, et al. A randomised study comparing a low dose of mifepristone and the Yuzpe regimen for emergency contraception. *Br J Obstet Gynaecol* 2002; **109**: 553–560.
- 7 von Hertzen H, Piaggio G, Ding J, et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. *Lancet* 2002; **360**: 1803–1810.
- 8 Cheng L, Gulmezoglu AM, Ezcurra E, et al. Interventions for emergency contraception (Cochrane Review). *The Cochrane Library* 2002; **4**.
- 9 Tremblay D, Gainer E, Ulmann A. The pharmacokinetics of 750 µg levonorgestrel following administration of one single dose or two doses at 12- or 24-h interval. *Contraception* 2001; **64**: 327–331.
- 10 Levonelle: summary of product characteristics. www.levonelle.co.uk
- 11 Bhattacharjee SK, Romeo J, Kononova ES, et al. Postcoital contraception with levonorgestrel during the peri-ovulatory phase of the menstrual cycle. *Contraception* 1987; **36**: 275–286.
- 12 World Health Organization (WHO). *Selected practice recommendations for contraceptive use*. Geneva: WHO, 2002.
- 13 Wilson JV. A New Zealand randomised comparative study of the IUDs (Nova T, MLCu375, MLAGCu375): 1, 2 and 3 year results. *Adv Contracept* 1992; **82**: 153–159.
- 14 Task Force on the Safety and Efficacy of Fertility Regulating Methods. WHO Special Programme of Research, Development and Research Training in Human Reproduction. The Cu380A, TCu220C, Multiload 250 and Nova T IUD at 3, 5 and 7 years of use – results from three randomised multi-centre trials. *Contraception* 2002; **42**: 141–158.
- 15 British Medical Association and the Royal Pharmaceutical Society of Great Britain. *British National Formulary* 43. Wallingford: Pharmaceutical Press, 2002.
- 16 Ellison J, Thomson AJ, Greer IA. Apparent interaction between warfarin and levonorgestrel used for emergency contraception. *BMJ* 2000; **321**(7273): 1382–1383.
- 17 Persona: product description. 2003. www.persona.org.uk
- 18 World Health Organization (WHO). *Emergency contraception: a guide to the provision of services*. Geneva: WHO, 1998.
- 19 Wilcox AJ, Weinberg CR, Baird DD. Timing of sexual intercourse in relation to ovulation – effects on the probability of conception, survival of the pregnancy and sex of the baby. *N Engl J Med* 1995; **333**(23): 1517–1521.
- 20 Stirling A, Glasier A. Estimating the efficacy of emergency contraception – how reliable are the data? *Contraception* 2002; **66**: 19–22.
- 21 Piaggio G, von Hertzen H, Grimes DA, et al. Timing of emergency contraception with levonorgestrel or the Yuzpe regimen. *Lancet* 1999; **353**: 721.
- 22 Liying Z, Bilian X. Emergency contraception with Multiload Cu-375 SL IUD: a multicentre clinical trial. *Contraception* 2001; **64**: 107–112.

- 23 Van Look P, Stewart F. Emergency contraception. In: Hatcher R, et al. (eds), *Contraceptive technology* (17th edn). New York, NY: Ardent Media, 1998.
- 24 Wilcox AJ, Dunson DB, Weinberg CR, et al. Likelihood of conception with a single act of intercourse: providing benchmark rates for assessment of post-coital contraceptives. *Contraception* 2001; **63**: 211–215.
- 25 Elomaa K, Rolland R, Brosens I, et al. Omitting the first oral contraceptive pills of the cycle does not automatically lead to ovulation. *Am J Obstet Gynecol* 2002; **179**: 41–46.
- 26 Landgren BM, Csemiczky G. The effect on follicular growth and luteal function of “missing the pill”. A comparison between a monophasic and a triphasic combined oral contraceptive. *Contraception* 1991; **43**: 149–159.
- 27 World Health Organization (WHO). *Improving access to quality care in family planning. medical eligibility criteria for contraceptive use*. Geneva: WHO, 2000.
- 28 Doll H, Vessey M, Painter R. Return of fertility in nulliparous women after discontinuation of the intrauterine device: comparison with women discontinuing other methods of contraception *Br J Obstet Gynaecol* 2001; **108**: 304–314.
- 29 Fotherby K. Levonorgestrel: clinical pharmacokinetics. *Clin Pharmacokinet* 1995; **28**: 203–215.
- 30 Chief Medical Officer. *Levonelle/Levonelle 2 emergency contraception: new advice*. 35, 2003.
- 31 Grimes D. Intrauterine device and upper-genital tract infection. *Lancet* 2000; **356**: 1013–1019.
- 32 Farley TNM, Rosenberg MJ, Rose PJ, et al. Intrauterine contraceptive devices and pelvic inflammatory disease: an international perspective. *Lancet* 1992; **339**: 785–788.
- 33 Scottish Intercollegiate Guidelines Network (SIGN) Guideline. Management of genital *Chlamydia trachomatis* infection. 42, 2002.
- 34 Expert Advisory Group Report on *Chlamydia trachomatis*. Chief Medical Officer. 1998.
- 35 Kettle H, Cay S, Brown A, et al. Screening for *Chlamydia trachomatis* infection is indicated for women under 30 using emergency contraction. *Contraception* 2002; **66**: 251–253.
- 36 Sherman CA, Harvey SM, Beckman LJ, et al. Emergency contraception: knowledge and attitudes of health care providers in a health maintenance organization. *Womens Health Issues* 2001; **11**: 448–457.
- 37 Beckman LJ, Harvey SM, Sherman CA, et al. Changes in providers’ views and practices about emergency contraception with education. *Obstet Gynecol* 2001; **97**: 942–946.
- 38 Marshall J, Edwards C, Lambert M. Administration of medicines by emergency nurse practitioners according to protocols in an accident and emergency department. *J Accid Emerg Med* 1997; **14**: 233–237.
- 39 Brittain D. Establishing an educational programme for nurses to supply emergency hormonal contraception (combined method) to protocol. *Br J Fam Plann* 1999; **25**: 118–121.
- 40 The Prescription Only Medicines (Human Use) Amendment Order 2000. Statutory Instrument 2000 No. 1917.
- 41 Department of Health. Review of prescribing, supply and administration of medicines: a report on the supply and administration of medicines under group protocols. London: Department of Health, 1998.
- 42 Folkes L, Graham A, Weiss M. A qualitative study of the views of women aged 18–29 on over-the-counter availability of hormonal emergency contraception. *J Fam Plann Reprod Health Care* 2001; **27**: 189–192.
- 43 Iversen L, Mollison J, MacLeod TNN. Attitudes of the general public to the expanding role of community pharmacists: a pilot study. *Fam Pract* 2001; **18**: 534–536.
- 44 Royal Pharmaceutical Society of Great Britain. Practice guidance on the supply of emergency hormonal contraception as a pharmacy medicine. *Pharm J* 2000; **265**(7127): 890–892.
- 45 Glasier A, Baird D. The effects of self-administering emergency contraception. *N Engl J Med* 1998; **339**: 1–4.
- 46 Ellertson C, Ambardekar S, Hedley A, et al. Emergency contraception: randomized comparison of advance provision and information only. *Obstet Gynecol* 2001; **98**: 570–575.
- 47 Shelton JD. Repeat emergency contraception: facing our fears. *Contraception* 2002; **66**: 15–17.
- 48 Croxatto HB. Emergency contraception pills: how do they work? *IPPF Medical Bulletin*, 2002; **36**: 1–2.
- 49 Durand M, del Carmen Cravioto M, Raymond EG, et al. On the mechanisms of short-term levonorgestrel administration in emergency contraception. *Contraception* 2001; **64**: 227–234.
- 50 Hapangama D, Glasier AF, Baird DT. The effects of peri-ovulatory administration of levonorgestrel on the menstrual cycle. *Contraception* 2001; **63**: 123–129.
- 51 Marions L, Hultenby K, Lindell I, et al. Emergency contraception with mifepristone and levonorgestrel: mechanism of action. *Obstet Gynecol* 2002; **100**: 65–71.
- 52 Department of Health. Judicial review of emergency contraception. London: Department of Health, 2002.
- 53 Trussell J, Koenig J, Ellertson C, et al. Preventing unintended pregnancy: the cost-effectiveness of three methods of emergency contraception. *Am J Public Health* 1997; **87**: 932–937.

This Guidance was developed by the Clinical Effectiveness Unit (CEU) of the Faculty of Family Planning and Reproductive Health Care (FFPRHC): Gillian Penney (Director), Susan Brechin (Senior Lecturer/ Unit Co-ordinator) and Alison de Souza (Research Assistant) in consultation with the Clinical Effectiveness Committee (which includes service user representation) and an Expert Group of Health Care Professionals involved in Family Planning and Reproductive Health Care. The Expert Group comprised: Susan Carr (Consultant in Family Planning and Sexual Health, The Sandyford Initiative, Glasgow); Alyson Elliman (Lead SCMO, Croydon PCT, Surrey); Gillian Flett (Consultant in Sexual and Reproductive Health Care, Aberdeen); Kate Guthrie (Consultant in Sexual and Reproductive Health Care, Hull and East Yorkshire Community NHS Trust); Myra Lamont (Associate Director Nursing, The Sandyford Initiative, Glasgow); Noreen Khan (Head of Community Gynaecology and Reproductive Health Care, Manchester); Karen Fairhurst (Senior Lecturer in General Practice, University of Edinburgh). We also acknowledge the statistical advice of Jill Mollison (Medical Statistician, Department of Public Health, University of Aberdeen). This Guidance is also available online at www.ffprhc.uk. Evidence tables are available on the FFPRHC website. These summarise relevant published evidence on emergency contraception, which was identified and appraised in the development of this Guidance. The clinical recommendations within this Guidance are based on evidence whenever possible.

Grades of Recommendations	
A	Evidence based on randomised-controlled trials (RCTs)
B	Evidence based on other robust experimental or observational studies
C	Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities
✓	Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the Expert Group

Electronic searches were performed for: MEDLINE (1996–2002); EMBASE (1996–2002); the Cochrane Library (to 2002) and the US National Guideline Clearing House. The searches were performed using relevant medical subject headings (MeSH), terms and text words. The Cochrane Library was searched for systematic reviews, meta-analyses and controlled trials relevant to EC. Previously existing guidelines from the FFPRHC, the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and reference lists of identified publications were also searched. Similar search strategies have been used in the development of other national guidelines. Selected key publications were appraised according to standard methodological checklists before conclusions were considered as evidence. Evidence was graded as above, using a scheme similar to that adopted by the RCOG and other guideline development organisations.

Discussion Points

- 1 Advance prescribing of emergency hormonal contraception (EHC) does not increase repeat use nor encourage risk-taking behaviour. If money was not an issue, how would you go about providing this (e.g. on demand, for every client who chooses condoms or fertility awareness as their only method of contraception, outreach environments, at time of termination of pregnancy)? Would there be any disadvantages to advance prescribing?
- 2 Women seeking EC may have also risked STIs. Should screening be available to all women seeking EC, regardless of whether they opt for an emergency IUD? Should all having emergency IUD have prophylactic antibiotics?
- 3 How will you ensure that women get the correct advice on starting regimes for hormonal contraception and the need for additional barrier protection at a time when the Summary of Product Characteristics may not yet reflect the 2002 WHO *Selective Practice Recommendations for Contraceptive Use* data?
- 4 Patient Group Directions may be developed to include indications outside the licence for EHC if agreed with the Trust. There seems to be such local variation that it may be difficult to give national guidance on what can be included. Discuss how you would approach these issues and in which off-license situations would patients benefit from having their needs met at the first point of contact with a nurse or pharmacist.

Questions for Recommendations for Clinical Practice Emergency Contraception

Indicate your answer by ticking the appropriate box for each question

	True	False
1 Pharmacists can sell Levonelle to women younger than 16 years.	<input type="checkbox"/>	<input type="checkbox"/>
2 Repeat doses of Levonelle-2 may be issued outside the licence in any one cycle.	<input type="checkbox"/>	<input type="checkbox"/>
3 Liver enzyme inducers taken concurrently or within the previous 28 days would require an increase in dosage of Levonelle-2 by 50%.	<input type="checkbox"/>	<input type="checkbox"/>
4 Efficacy of POEC between 73 and 120 hours after intercourse has been found in a WHO study (2002) to be greater than previous WHO data between 49 and 72 hours.	<input type="checkbox"/>	<input type="checkbox"/>
5 EC is not required unless injection of Depo-Provera is delayed until more than 14 weeks and UPSI has occurred.	<input type="checkbox"/>	<input type="checkbox"/>
6 Severe hypertension is an absolute contraindication to emergency hormonal contraception (EHC).	<input type="checkbox"/>	<input type="checkbox"/>
7 The copper IUD can be inserted any time up to 5 days beyond predicted ovulation, regardless of how many acts of UPSI have occurred that cycle.	<input type="checkbox"/>	<input type="checkbox"/>
8 There is evidence that IUDs with 380 cm ² copper are more effective than those with less copper in the emergency situation.	<input type="checkbox"/>	<input type="checkbox"/>
9 The use of EHC protects against pregnancy for the rest of the current cycle.	<input type="checkbox"/>	<input type="checkbox"/>
10 There is good quality evidence to support one dose of 1.5 mg levonorgestrel in place of two doses of 0.75 mg (current regimen) in everyday practice.	<input type="checkbox"/>	<input type="checkbox"/>

Answers

- | | | |
|---------|---------|----------|
| 1 False | 5 True | 8 False |
| 2 True | 6 False | 9 False |
| 3 True | 7 True | 10 False |
| 4 True | | |

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