

# Faculty of Family Planning and Reproductive Health Care Royal College of Obstetricians and Gynaecologists

## GUIDANCE APRIL 2000 Emergency contraception: Recommendations for clinical practice

This document is based on previous recommendations for practice issued by the Faculty of Family Planning and Reproductive Health Care.<sup>1,2</sup>

This document has been published to disseminate information about currently licensed emergency contraceptive methods and about research findings that are immediately relevant to professional practice in the UK. Fully revised recommendations for clinical practice will be available from the Faculty later this year.

### Methods currently licensed in the UK: progestogen-only (Levonelle®-2), combined oestrogen-progestogen (Schering® PC4), and the copper IUD.

Emergency contraception (also called postcoital contraception) is a safe and effective way of preventing an accidental pregnancy after unprotected sex. There are three emergency contraceptive methods licensed for use in the UK - two oral hormonal preparations and the postcoital insertion of a copper-containing IUD.

#### Efficacy of emergency contraceptive methods

Because many women treated with emergency contraception would not have become pregnant even without treatment, describing the overall effectiveness of the method is complex.

The overall risk of pregnancy after a single act of unprotected sex on any day in the menstrual cycle is 2-4%. The pregnancy risk from a single act of intercourse is highest (between 20-30%) in the days before and just after ovulation. Counting the first day of menstrual bleeding as Day 1, the pregnancy risk is low before Day 7 and after Day 17 inclusive in a 28-day cycle. Adjusting for shorter and longer cycles displaces these estimated fertile days earlier and later, respectively, within the cycle.

The efficacy of emergency contraceptive methods, as demonstrated in clinical trials, can be described in two ways:

- Expressed as a failure rate, i.e. citing the proportion of women who become pregnant despite using the method. This approach includes as treatment successes all women who had treatment and did not become pregnant in that cycle, many of whom would not have become pregnant even without treatment.
- Expressed as the ratio of observed to expected pregnancies, i.e. estimating the number of pregnancies expected without treatment from the menstrual and coital histories of all women in the trial, and comparing this number with the actual numbers of pregnancies occurring after treatment.

Both of these approaches obviously rely on accurate recollection of date of last menstrual period and coital history.

#### Oral hormonal emergency contraception

There are two different types of emergency contraceptive pill, progestogen-only and combined oestrogen-progestogen. Both are currently Prescription Only Medicines, licensed solely for emergency contraceptive use within 72 hours of exposure to risk of pregnancy.

While emergency contraceptive pills are effective when treatment is started within 72 hours, available evidence from a World Health Organisation (WHO) trial strongly suggests that hormonal emergency contraceptive regimens are most effective in preventing pregnancy when the first dose is taken within 24 hours of unprotected sex. As the coitus-to-treatment interval increases (towards the 72 hour limit), the failure rate increases.<sup>3,4</sup> Calculation of the coitus-to-treatment interval starts from the time of the *first* episode of unprotected sex in the current menstrual cycle.

Emergency contraceptive pills **do not** protect against pregnancy for the remainder of the menstrual cycle. Women who use emergency contraceptive pills must use an effective method of contraception, or abstain from sex, for the remainder of the menstrual cycle after using emergency contraception. For women using regular combined or progestogen-only pills, contraceptive cover is restored when seven pills have been taken on consecutive days after using emergency contraception. Women who have used emergency contraception because of missed pills should continue to take their regular contraceptive pills as usual, and must use an additional (i.e. barrier) method of contraception if they have sex within seven days of the first dose of emergency contraception.

#### Timing of next menses after treatment

Research has demonstrated a range of disturbances in the timing of the next reported menses after both types of oral hormonal emergency contraception. A recent study found that most women (57%) started their next period within three days of their expected date, some (15%) started early, some (15%) were up to seven days late, and the remainder (13%) were more than seven days late.<sup>3</sup> It is important to advise women to return for a pregnancy test if they are more than seven days late with their expected next period. Some intermenstrual bleeding may occur before the next menses after hormonal emergency contraception.<sup>5</sup>

Some bleeding between menses is common after IUD insertion. There is no evidence that the timing of the next menses is altered after postcoital insertion.

## Principal indications for emergency contraception

There is no day of the menstrual cycle (LMP) when a clinician can be certain that unprotected sex would not result in pregnancy, particularly if the woman reports having irregular periods or is unsure of her dates.

Where there is anxiety, consider treating rather than waiting to see what happens.

### Unprotected sex

Consensual sex, no contraceptive method used; Rape or sexual assault with risk of pregnancy;  
Coitus interruptus/failed coitus interruptus; Ejaculation on external genitalia

### Potential barrier method failures

Condom rupture, dislodgement or misuse; Diaphragm/cap inserted incorrectly, torn, dislodged during intercourse, removed too early

### Potential pill failure when alternative methods not used/failed

Efficacy of regular (non-emergency) combined or progestogen-only contraceptive pills compromised,  
e.g. unprotected sex/failure of barrier method within seven days after:

- Combined pills
- two or more pills missed from the first seven pills in a packet, or
  - four or more pills missed mid-packet

If two or more combined pills are missed from the last seven pills in a packet, emergency contraception is not necessary provided that the pill-free break is omitted i.e. the woman starts her next packet of pills the day after finishing the current packet.

Progestogen-only pills

- one or more pills taken more than three hours after usual pill-taking time, or missed

### Potential IUD failure

Complete or partial expulsion of an IUD; Mid-cycle IUD removal considered absolutely necessary

### Risk of conception while advised to avoid pregnancy

e.g. following administration of cytotoxic drugs or potentially teratogenic agents

## Progestogen-only emergency contraceptive pills

The Committee on Safety of Medicines approved the progestogen-only emergency contraceptive pill formulation Levonelle™-2 (Schering Health Care Ltd) for use in the UK in 1999. One pack of Levonelle™-2 consists of two tablets, each containing a 750 mcg dose of levonorgestrel. The first dose (one tablet) must be taken within 72 hours of unprotected intercourse, and within 24 hours for best effect. The second dose is taken 12 hours after the first.

### Efficacy<sup>3</sup>

The 1998 WHO trial demonstrated that this progestogen-only emergency contraceptive regimen prevented 86% of expected pregnancies when treatment was initiated within 72 hours of unprotected sex.

### Effect of coitus-to-treatment interval<sup>3,4</sup>

<i>Coitus to treatment interval</i>	<i>Progestogen-only emergency contraception Percentage of expected pregnancies prevented %</i>
24 hours or less	95
25-48 hours	85
49-72 hours	58

The pregnancy rate found for women who reported no further intercourse between treatment and next menses (0.8%, 5/602) was considerably lower than for those who had further unprotected intercourse or used barriers (1.6%, 6/372).

### Commonly reported side effects - nausea and vomiting<sup>3</sup>

The WHO trial found that 23.1% of women who used the progestogen-only regimen experienced nausea, and 5.6% reported vomiting.

### Eligibility criteria for use<sup>6,7</sup>

Established pregnancy contraindicates use. The WHO considers that, on currently available evidence, there are no other medical contraindications to the use of emergency contraceptive pills and that because the dose of hormones is relatively small and the pills are used for a short period of time, the contraindications associated with regular use of progestogen-only pills do not apply to progestogen-only emergency contraceptive pills.

While provision of contraceptive steroids to some women (i.e. those with particular medical conditions or risk factors) requires careful consideration and precautionary measures, the benefits of using progestogen-only emergency contraception will generally outweigh the risks. The Summary of Product Characteristics for Levonelle™-2 includes severe hypertension, diabetes mellitus associated with vascular complications or neuropathy, ischaemic heart disease, stroke or a past history of breast cancer as relative contraindications.

It is highly unlikely that progestogen-only emergency contraceptive pills would have an adverse effect on a continuing pregnancy. However, a normal outcome to any pregnancy cannot be guaranteed.

## Combined oestrogen-progestogen emergency contraceptive pills

The Committee on Safety of Medicines approved the combined oestrogen-progestogen emergency contraceptive pill formulation Schering® PC4 (Schering Health Care Ltd) in 1984. One pack of Schering® PC4 consists of four tablets, each containing 50 mcg ethinylestradiol plus 500 mcg norgestrel (equivalent to 250 mcg levonorgestrel). The first dose (two tablets taken together) must be taken within 72 hours of unprotected intercourse, and within 24 hours for best effect. The second dose of two tablets is taken 12 hours after the first.

### Efficacy<sup>3,8</sup>

A 1999 review of efficacy studies estimated that the combined oestrogen-progestogen regimen prevents at least 74% of expected pregnancies when treatment is initiated within 72 hours,<sup>8</sup> whereas the 1998 WHO trial found that the combined oestrogen-progestogen regimen prevented 57% of expected pregnancies when treatment was initiated within 72 hours.<sup>3</sup> This difference is probably due to slightly different methodologies being used in the calculation of conception probabilities, and is being investigated.

### Effect of coitus-to-treatment interval<sup>3,4</sup>

The 1998 WHO trial found that the combined oestrogen-progestogen regimen was more effective when treatment was initiated within 24 hours of unprotected sex.

<i>Combined oestrogen-progestogen emergency contraception</i>	
<i>Coitus to treatment interval</i>	<i>Percentage of expected pregnancies prevented %</i>
24 hours or less	77
25-48 hours	36
49-72 hours	31

The pregnancy rate found for women who reported no further intercourse between treatment and next menses (1.9%, 12/619) was considerably lower than for those who had further unprotected intercourse or used barriers (5.3%, 19/360).

### Commonly reported side effects - nausea and vomiting<sup>3</sup>

The WHO trial found that 50.5% of women who used the combined oestrogen-progestogen regimen experienced nausea, and 18.8% reported vomiting.

### Eligibility criteria for use<sup>6,7</sup>

Established pregnancy contraindicates use. The WHO considers that, on currently available evidence, there are no other medical contraindications to the use of emergency contraceptive pills and that, because the dose of hormones is relatively small and the pills are used for a short period of time, the contraindications associated with regular use of combined oral contraceptives do not apply to combined emergency contraceptive pills. No evidence was found that this method increases the risk of ectopic pregnancy above the woman's pre-existing risk.

The current Summary of Product Characteristics for Schering PC4 includes a history of severe cardiovascular complications, acute focal migraine, severe liver disease and a possible relative increase in ectopic pregnancy amongst other conditions as contraindications or precautions for use.

It is highly unlikely that a combined oestrogen-progestogen emergency contraceptive pills would have an adverse effect on a continuing pregnancy. However, a normal outcome to any pregnancy cannot be guaranteed.

## Intra-uterine emergency contraception

A copper-containing IUD is inserted in the usual way within five days (120 hours) of unprotected sex, at any time in the menstrual cycle. Where the earliest episode of unprotected sex was more than five days previously, an IUD can be fitted, in good faith, up to five days after the calculated earliest day of ovulation (i.e. up to Day 19 of a 28 day shortest cycle by history, counting the first day of menstrual bleeding as Day 1).

Providers should be aware of the risk of post insertion pelvic infection, and must consider testing women for sexually transmitted infection, particularly *Chlamydia trachomatis*. If positive, appropriate follow-up and contact tracing should be arranged. Antibiotic cover is advisable where an STI risk is identified and where testing is unavailable or not practical.

The levonorgestrel releasing intra-uterine system, Mirena®, is not recommended for postcoital use.

### Efficacy

The copper IUD has the highest efficacy of any currently available emergency contraceptive, and is the method of choice where efficacy is the priority. From the number of reported pregnancies following postcoital copper IUD insertion, the failure rate has been estimated to be no higher than 0.1%.<sup>9</sup>

### Side effects

As associated with IUDs fitted for ongoing contraception. An IUD fitted postcoitally can be removed at the beginning of menstruation if the woman does not wish to continue to use it.

### Eligibility criteria for use<sup>6,7</sup>

Established pregnancy contraindicates use. The WHO considers that the same eligibility criteria that apply to insertion of a copper IUD in routine circumstances should be applied for insertion as an emergency contraceptive. Providers should be aware of the contraindications and precautions listed by the manufacturer in the data-sheet/Summary of Product Characteristics, including known hypersensitivity to product components.

Failure of a postcoital IUD is highly unlikely.<sup>9</sup> The risks and benefits of gently removing the device (if easily accessible) should be discussed if a woman who is pregnant despite postcoital IUD fitting chooses to continue her pregnancy.<sup>10</sup>

## The management of a request for emergency contraception

### 1. Estimate likely date of ovulation and risk of pregnancy by recording:

- usual length of menstrual cycle
- did the last period start at the expected time and was it shorter or lighter than usual?
- timing of all inadequately protected intercourse (including any missed pill history and intercourse during a lengthened pill-free interval) - which day(s) of the current cycle?

### 2. Calculate number of hours since first episode of unprotected intercourse

### 3. Identify any contraindications to emergency contraceptive methods and conditions which require consideration and/or precautionary measures

Note: pelvic examination cannot be justified routinely to exclude pregnancy. If the date or character of LMP and recent coital history give cause for concern, urine hCG estimation will give a more sensitive and specific diagnosis.

### 4. Explain method options:

#### If less than 72 hours since unprotected sex, offer emergency contraceptive pills or copper IUD

Explain:

- mode of action
- efficacy
- risks and side effects
- possible effect on menstrual cycle
- if emergency contraceptive pills used, need to abstain from sex or use barrier method correctly and consistently for remainder of current menstrual cycle
- the importance of follow-up if next period does not start within seven days of the expected date
- that, while there is no evidence that emergency contraceptive methods carry any risk of teratogenicity, a normal outcome to any pregnancy cannot be guaranteed.

#### If oral hormonal emergency contraception chosen

Advise:

- when pills should be taken
- what to do if either dose of pills is vomited within two hours.

Domperidone maleate 10 mg may be prescribed to counter acute nausea and vomiting. This preparation does not readily cross the blood-brain barrier and is less likely to cause extra-pyramidal side effects than metoclopramide or the phenothiazines.

#### If more than 72 hours since unprotected sex, explain and offer copper IUD

### 5. Document, sign and date an accurate record

Document the consultation and the woman's decision regarding emergency contraception after full discussion backed by written information such as the Family Planning Association leaflet.

### 6. Discuss on-going contraception and offer follow-up

Future contraception must be discussed sympathetically, and preferably arranged, for the time until next menses if an IUD has not been used, and for the next cycles as appropriate. Women who have taken emergency hormonal contraception because of missed pills should discard any missed tablets and the tablet for the day of postcoital treatment. They should then continue to take their pills as usual, and be warned that they will not be contraceptively covered until they have taken seven tablets on consecutive days at the correct time. If women wish to start using the combined or progestogen-only pill, these may be started on the first day of the subsequent period without additional precautions. Depot medroxyprogesterone acetate can be started up to Day 5 of the next menstrual cycle without additional precautions.

- Advise when she can expect her next period - advise her to seek immediate help if the bleeding is significantly different from her usual period, especially if the period is exceptionally short or light (i.e. possible failed treatment) and how to contact such help.
- Offer appointment/explain arrangements for seeking advice if she experiences any other problems or concerns about treatment.
- Offer appointment/explain arrangements for on-going contraceptive information/supply as necessary.
- Offer appointment/make arrangements for communication of infection screen results and IUD removal if not required for ongoing contraception.

- References
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  - 10 *Mechanism of action, safety and efficacy of intrauterine devices*. Report of a WHO Scientific Group. Geneva: WHO, 1987.