



## Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit

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### FFPRHC Guidance (April 2006) Emergency contraception

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This Guidance updates and replaces the previous Faculty recommendations on emergency contraception and is applicable to all professionals providing contraceptive services in primary and secondary care in the UK. A key to the grades of recommendations, based on levels of evidence, is given at the end of this document. Details of the methods used by the Clinical Effectiveness Unit in developing this Guidance and evidence tables summarising the research basis of the recommendations are available on the Faculty website ([www.ffprhc.org.uk](http://www.ffprhc.org.uk)). Abbreviations (in alphabetical order) used include: EC, emergency contraception; IUD, copper-bearing intrauterine device; IUS, levonorgestrel-releasing intrauterine system; LH, luteinising hormone; LNG, levonorgestrel; PGD, patient group direction; SPC, Summary of Product Characteristics; STIs, sexually transmitted infections; UPSI, unprotected sexual intercourse.

#### 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.<sup>1-4</sup> Alternative terms such as 'postcoital contraception' or 'the morning-after pill' are often confusing and 'emergency contraception' is the Faculty's preferred term. Currently, women in the UK can be offered an oral hormonal method (levonorgestrel, LNG) or a copper-bearing intrauterine device (IUD)<sup>5</sup> for EC.

#### Mode of action

The mode of action of LNG EC is incompletely understood.<sup>6</sup> However, efficacy is thought to be due primarily to inhibition of ovulation rather than inhibition of implantation. A randomised trial<sup>7</sup> showed that use of LNG in the follicular phase (pre-ovulation) interferes with the ovulatory process. When LNG was given before the luteinising hormone (LH) surge (when follicles were <15 mm in size) follicular rupture was prevented or ovulatory dysfunction (absent LH peak or LH peak after follicular rupture) was apparent in the subsequent 5 days in around 80% of women. Thus, if taken prior to ovulation, LNG can inhibit ovulation for 5-7 days, by which time any sperm in the upper reproductive tract have lost their fertilising ability.

It is widely accepted that IUDs work by inhibiting fertilisation by direct toxicity.<sup>8,9</sup> A systematic review on mechanisms of action of IUDs showed that both pre- and post-fertilisation effects contribute to efficacy.<sup>10</sup> An inflammatory reaction within the endometrium may have an anti-implantation effect should fertilisation occur.<sup>11,12</sup> In addition, alterations in the copper content of cervical mucus occur, which may inhibit sperm penetration.<sup>13,14</sup> In 2002, a Judicial Review ruled that pregnancy begins at implantation, *not* at fertilisation, thus EC is not considered an abortifacient.<sup>15</sup> LNG will not interrupt an existing pregnancy; limited epidemiological data indicate no adverse effects on the fetus.<sup>16-18</sup>

#### When is emergency contraception indicated?

**1 The clinician should summarise evidence of effectiveness and the need for EC in each woman's individual circumstance to allow her to make an informed choice regarding its use (Good Practice Point).**

EC may be required in a range of clinical situations: following consensual sex where no contraception was used; mistake with oral contraception; following rape or sexual assault; when using the withdrawal method;

**Table 1** Recommendations for emergency contraception use in commonly occurring situations

Situation	Indications for emergency contraception
<b>Potential failures of various contraceptive methods</b>	
Combined pills (21 active tablets)	If <i>three or more</i> 30-35 µg EE or <i>two or more</i> 20 µg EE pills have been missed in the first week of pill taking (i.e. Days 1-7) and UPSI occurred in Week 1 or the pill-free week <sup>20</sup>
Progestogen-only pills	If <i>one or more</i> POPs have been missed or taken >3 hours late (>12 hours late for Cerazette®) and UPSI has occurred in the 2 days following this
Intrauterine contraception	If complete or partial expulsion is identified or mid-cycle removal of an IUD/IUS is deemed necessary and UPSI has occurred in the last 7 days
Progestogen-only injectables	If the contraceptive injection is late (>14 weeks from the previous injection for medroxyprogesterone acetate or >10 weeks for norethisterone enantate) and UPSI has occurred
Barrier methods	If there has been failure of a barrier method
<b>Use of liver-enzyme inducers</b>	
Liver enzyme-inducing drugs (including St John's Wort)	An additional barrier method is recommended if oral contraceptives, progestogen implants or contraceptive patch and liver enzyme-inducers are taken concurrently. EC is indicated if there is UPSI or barrier method failure during, or in the 28 days following, use of liver enzyme-inducers

EC, emergency contraception; EE, ethinylestradiol; IUD, intrauterine device; IUS, intrauterine system; POP, progestogen-only pill; UPSI, unprotected sexual intercourse.

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following ejaculation onto the external genitalia; when a condom bursts, is dislodged or incorrectly used; or if a diaphragm or cap is incorrectly inserted, damaged, dislodged or removed within 6 hours of sex. Potential contraceptive failures and indications for EC use are summarised in Table 1.

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 last menstrual period. A prospective cohort study<sup>19</sup> showed that only about 30% of women had their fertile period (defined as six fertile days during the menstrual cycle) within the days of the menstrual cycle identified by clinical guidelines. Although this study was small (221 women), the authors concluded that women should be advised that timing of fertility can be highly unpredictable. Nevertheless, the probability of pregnancy in the first 3 days of the cycle appears to be negligible. It is important for the clinician to take an accurate history to assess the 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 last menstrual period and the usual cycle length; when the first episode of UPSI occurred; and details of potential contraceptive failure. Clinical judgement should then allow a decision to be made regarding the need for EC in an individual case – but a pragmatic approach is often required.

### What regimens of oral hormonal emergency contraception are available?

**2 LNG should be given as a single 1.5 mg dose as soon as possible after UPSI, and within 72 hours (Grade A).**

LNG EC has been licensed in the UK since 1999 and is available on prescription and as a purchasable medicine at pharmacies. In pharmacies, the generic name for LNG EC is Levonelle One Step<sup>®</sup> (as a single 1.5 mg dose of LNG). Until recently, on-prescription LNG EC was named Levonelle-2<sup>®</sup> and comprised two 0.75 mg tablets. As of November 2005, Levonelle 1500<sup>®</sup> (the equivalent dose as a single tablet) was introduced. Levonelle 1500 has become the standard formulation issued on prescription. At the present time, both formulations (Levonelle-2 and Levonelle 1500) are available, and this Guidance refers to both.

LNG is currently the only hormonal method of EC available in the UK. Combined oestrogen–progestogen EC (Yuzpe regimen) was previously available in the UK and may still be used in other countries.<sup>1</sup>

### How effective is emergency contraception and how can efficacy be optimised?

**3 Women should be given written and verbal information regarding the failure rates of oral and intrauterine EC to allow them to make informed choices and to increase compliance and efficacy (Grade A).**

**4 LNG EC may be considered between 73 and 120 hours after UPSI, but women should be informed of the limited evidence of efficacy, that such use is outside product licence, and the alternative of an IUD (Good Practice Point).**

**5 Women can be advised that LNG EC can be used more than once in a cycle if clinically indicated (Good Practice Point).**

**6 An IUD (or advice on how to obtain one) should be offered to all women attending for EC even if presenting within 72 hours of UPSI (Good Practice Point).**

**7 IUDs with banded copper on the arms and containing at least 380 mm<sup>2</sup> of copper have the lowest failure rates and should be the first-line choice, particularly if the woman intends to continue the IUD as long-term contraception (Grade A).**

**8 Ideally, an emergency IUD should be fitted at first presentation, but insertion can be offered later, at the woman's convenience. In this case, LNG EC should be given in the interim (Good Practice Point).**

**9 If facilities are unavailable for emergency IUD insertion, local referral mechanisms should facilitate timely access to a specialist who can provide this service (Good Practice Point).**

**10 A copper IUD can be inserted up to 5 days after the first episode of UPSI. If the timing of ovulation can be estimated, insertion can be beyond 5 days of UPSI, as long as it does not occur beyond 5 days after ovulation (Grade C).**

### Levonorgestrel emergency contraception

There are no randomised controlled trials to identify the optimal dose of LNG to prevent pregnancy. In addition, there are limited data on how progestogen-only EC works if ovulation has already occurred. A large multicentre randomised controlled trial<sup>21</sup> confirmed that taking a single 1.5 mg dose of LNG simplified EC use for women (compared with a regimen comprising two 0.75 mg doses 12 hours apart) without reduction in efficacy or increase in side effects. To reflect this evidence, a change in the Summary of Product Characteristics (SPC) occurred in 2003 for Levonelle-2<sup>17</sup> and Levonelle. Levonelle (pharmacy supply) was replaced by a simplified Levonelle One Step (single 1.5 mg tablet)<sup>16</sup> and Levonelle-2 (prescription-only medicine) is being replaced by Levonelle 1500.<sup>18</sup>

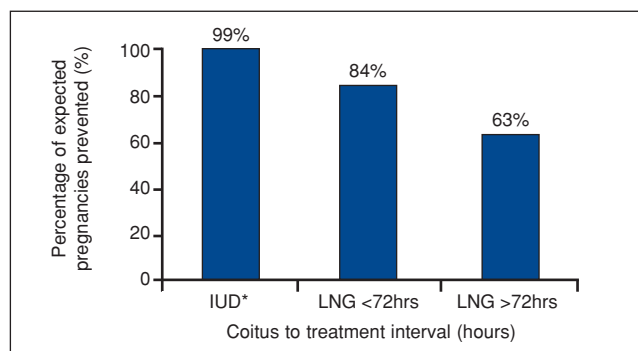
#### Use beyond 72 hours

A large randomised controlled trial by the World Health Organization (WHO) provided evidence that LNG continues to reduce the expected pregnancy rate if taken between 73 and 120 hours after UPSI.<sup>21</sup> Although few women presented at this time (214 women) and results did not reach statistical significance, the data add weight to the theory that LNG does not suddenly stop working beyond 72 hours. No data have been identified relating to use of LNG for EC beyond 120 hours. Use of LNG beyond 72 hours remains outside the product licence.<sup>16–18</sup>

#### Use more than once in a cycle

The CEU continues to support the use of EC more than once in a cycle.<sup>22</sup> The SPC states that repeated administration of LNG is not recommended because of disturbances to the cycle.<sup>16–18</sup> Giving repeat doses of LNG prior to the LH surge may be effective and further UPSI may be an indication for repeat LNG use.<sup>7</sup> Repeated use will not induce abortion if the woman is already pregnant.

No data were identified regarding a minimum time interval between successive EC treatments. The consensus view of the CEU Expert Group was that UPSI within 12 hours of a dose of EC does not require further treatment with EC.



**Figure 1** Efficacy of emergency contraception and time since unprotected sexual intercourse. \*Within 5 days (refer to text for explanation). IUD, intrauterine device; LNG, levonorgestrel.

### Intrauterine devices

Evidence indicates that IUDs act primarily by impairing gamete viability before fertilisation.<sup>23</sup> It is considered that an IUD becomes effective immediately after insertion. If fertilisation has already occurred, it is accepted that there is an anti-implantation effect, although an IUD is not abortifacient.<sup>24</sup> The risk of pregnancy following one act of UPSI varies throughout the menstrual cycle, increasing around the time of ovulation (Days 10–17) to 20–30%.<sup>25</sup> An emergency IUD should be fitted within the first 5 days following UPSI. If the timing of ovulation can be estimated, insertion can be beyond 5 days of sex, as long as insertion does not occur beyond 5 days of ovulation. In this context, it is accepted that there is a very low risk of ovulation up to Day 7 of the menstrual cycle.<sup>26</sup> The ethical problems associated with conducting randomised trials of IUDs for EC purposes mean that efficacy has not been adequately investigated.<sup>24</sup> However, data from non-randomised trials suggest that the failure rate of IUDs for EC is no greater than 1%.<sup>27–30</sup>

For regular (non-emergency) contraceptive use, studies<sup>31</sup> have shown a five-fold decrease in pregnancy rate when the copper content of an IUD increases from 200 to 350 mm<sup>2</sup> (2.2 vs. 0.44 per 100 woman-years). The National Institute for Health and Clinical Excellence (NICE)<sup>23</sup> recommends that health care professionals should be aware that the most effective IUDs contain at least 380 mm<sup>2</sup> of copper and have banded copper on the arms. Women should be informed that the pregnancy rate associated with the use of an IUD as long-acting contraception is very low (<20 in 1000 over 5 years). With a very low pregnancy rate, the risk of ectopic pregnancy is also very low.

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 requesting EC, even if they present within 72 hours of UPSI.

Figure 1 illustrates the number of expected pregnancies prevented for hormonal EC and IUDs.

### Are there any contraindications to emergency contraception?

**11 The WHO Medical Eligibility Criteria for Contraceptive Use advises that there are no medical contraindications to the use of hormonal EC (Grade C).**

The WHO Medical Eligibility Criteria for Contraceptive Use<sup>32</sup> advises that there are no medical contraindications to LNG EC. The SPC<sup>18</sup> advises caution in women with hepatic dysfunction, hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-

galactose malabsorption. Women with severe malabsorption syndromes (such as Crohn's disease) may experience a reduction in efficacy of oral EC. Additionally, any women known to have hypersensitivity to LNG or any of the other components of the tablet should use oral EC with caution.

Use of an IUD for EC carries the same contraindications as does routine IUD insertion. For most women, benefits of IUD use outweigh risks (WHO Category 1, 'unrestricted use') or (WHO Category 2, 'benefits generally outweigh risks').<sup>32</sup> Readers are directed to previous Faculty Guidance, which has covered medical contraindications to IUDs in depth.<sup>33</sup> Risk of sexually transmitted infections (STIs), previous ectopic pregnancy, young age, and nulliparity are not contraindications to IUD use.

### What drug interactions are relevant to emergency contraceptive use?

**12 Women using liver enzyme-inducing drugs should be advised that an IUD is the preferred option for EC (Grade A).**

**13 Women who are using liver enzyme-inducing drugs who are given 0.75 mg tablets of LNG (Levonelle-2) should be advised to take a total of 2.25 mg (three tablets) as a single dose, as soon as possible and within 72 hours of UPSI. This use is outside the product licence (Grade C).**

**14 Women who are using liver enzyme-inducing drugs who are given 1.5 mg tablets of LNG (Levonelle One Step or Levonelle 1500) should be advised to take a total of 3 mg (two tablets) as a single dose, as soon as possible and within the 72 hours of UPSI. This use is outside the product licence (Good Practice Point).**

**15 Women using non-liver enzyme-inducing antibiotics (short- or long-term) should follow the normal LNG regimen (1.5 mg within 72 hours of UPSI) (Grade C).**

**16 There are no drugs that are known to affect emergency IUD use (Grade C).**

### Levonorgestrel emergency contraception

#### Liver enzyme-inducing drugs

Previous Faculty Guidance discussed drug interactions in detail.<sup>34</sup> Liver-enzyme inducing drugs (including the herbal remedy, St John's Wort) may reduce the efficacy of hormonal contraceptives by increasing the metabolism of ethinylestradiol and progestogens. The SPC does not indicate what dose of LNG EC should be administered to women using liver enzyme-inducing drugs.<sup>16–18</sup>

When 0.75 mg tablets are used (Levonelle-2), women are advised to take a total of 2.25 mg (three tablets) as a single dose, within 72 hours of UPSI. This 50% increase in dose is based on established clinical practice but is outside product licence. The most recent *British National Formulary* supports this increase in dose.<sup>35</sup> No studies have been found to confirm that this increase in dose is actually required.

When LNG is used as 1.5 mg tablets (Levonelle One Step or Levonelle 1500), it is advised that women using liver enzyme-inducing drugs should increase the dose by 100%, taking 3 mg at first presentation, within 72 hours of UPSI. This advice is based on clinical judgement, taking into consideration the consequences of an unintended

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pregnancy. There are no published studies on compliance or side effects with this regimen and it is outside product licence. In practice, it is unlikely that women using liver enzyme-inducing drugs will be treated by pharmacists when purchasing EC. In this instance women should be referred to a prescribing clinician.

### Non-liver enzyme-inducing antibiotics

The efficacy of progestogen-only contraceptive methods (including EC) is not reduced by non-liver enzyme-inducing antibiotics as, unlike oestrogens, progestogens do not undergo significant reabsorption in the bowel.<sup>34</sup>

### Other drugs

Caution is advised when prescribing oral EC for women using the anticoagulant drugs, phenindione and warfarin. It has been observed that anticoagulant effects may be altered following LNG use.<sup>35,36</sup> Women should be advised about potential drug interactions and attention should be paid to their anticoagulation monitoring.

### Emergency intrauterine device

IUDs are the preferred option for women using liver enzyme-inducing drugs. No published evidence has been identified suggesting that IUDs are affected by concomitant drug use.

### What clinical examinations and investigations are required before providing emergency contraception?

**17 A sexual history should be taken from all women attending for EC to assess risk of STIs (Grade C).**

**18 Prior to emergency IUD insertion, women at higher risk of STIs (age <25 years, change in sexual partner, or more than one partner in the last year) should be offered testing for *Chlamydia trachomatis* (as a minimum) (Grade C).**

**19 For women assessed as being at higher risk of STIs, if results of testing are not available at the time of emergency IUD insertion, the use of prophylactic antibiotics may be considered (Good Practice Point).**

A sexual health history should be obtained from all women requesting EC to allow assessment of risk of STIs and discussion of other sexual health issues. Risk assessment should take into consideration: local prevalence of STIs, the woman's age, and her sexual activity. Guidelines have suggested opportunistic testing for *Chlamydia trachomatis* in sexually active women under the age of 25 years, and in those over 25 years with a new partner, or with more than one partner in the last year.<sup>37</sup>

A systematic review found that the prevalence of *C. trachomatis* in the UK was higher in younger (compared to older) age groups in general practice surgeries (age <20 years, 8.1%, 95% CI 6.5–9.9; age 20–24 years, 5.2%, 95% CI 4.3–6.3; age 25–29 years, 2.6%, 95% CI 2.0–3.3; age >30 years, 1.4%, 95% CI 1.0–1.9).<sup>38</sup> A cross-sectional study at genitourinary medicine (GUM) clinics found higher rates of *C. trachomatis* in adolescents who had previously used EC (odds ratio 2.5, 95% CI 1.1–5.9,  $p = 0.029$ ).<sup>39</sup>

A National Chlamydia Screening Programme (NCSP) has been established in England. The programme offers opportunistic testing for chlamydia to men and women under the age of 25 years in non-clinical and clinical screening venues. Results from the first year of screening

among young people attending non-GUM clinics found positive tests in 10.1% (1538/15 241) of women and 13.3% (156/1172) of men.<sup>40</sup>

Women requesting EC who fall into these higher-risk groups should be offered testing. Appropriate treatment can be given, and safer sex and partner notification should be discussed to help reduce the risk of re-infection.

The WHO *Selected Practice Recommendations for Contraceptive Use*<sup>26</sup> recommends that testing for STIs prior to routine (non-emergency) IUD insertion should cover *C. trachomatis* as a minimum. Testing for other infections will depend on age, individual risk, and local prevalence. There is no indication to test for other lower genital tract organisms in asymptomatic women attending for IUD insertion, since the results would not affect management.<sup>33</sup>

Prior to emergency IUD insertion, 'higher-risk' women should be offered testing for *C. trachomatis* as a minimum. The use of routine prophylactic antibiotics for IUD insertion is not recommended.<sup>26,41</sup> However, for women assessed as at higher risk of STIs, if results of testing are not available immediately, the use of prophylactic antibiotics may be considered. Choice of antibiotic regimen should be based on local prevalence of STIs. Emergency IUD insertion should not be delayed unnecessarily.

### What are the side effects of emergency contraception?

**20 Women who experience vomiting within 2 hours of administration of LNG EC should be advised to return as soon as possible for a repeat dose (Good Practice Point).**

**21 Women should be advised that a small increase in pelvic infection occurs in the 20 days following IUD insertion, but the risk is the same as for the non-IUD-using population thereafter (Grade A).**

### Levonorgestrel emergency contraception

*Vomiting* following LNG administration is unusual, occurring in only 1% of women.<sup>21</sup> Nausea is reported more frequently (14%). If a woman vomits within 2 hours of taking LNG EC she should take a further dose as soon as possible.<sup>26</sup> Anti-emetics are not routinely recommended. An IUD should be considered for a woman experiencing persistent vomiting with oral EC.

*Disturbances to the cycle* are common after LNG EC. In the WHO trial,<sup>21</sup> 16% of women experienced bleeding (unrelated to expected menstruation) in the 7 days following treatment. Around 50% of women menstruated a few days earlier or a few days later than their expected time. These bleeding disturbances are important in clinical practice as women and clinicians generally rely on the reassurance of menstruation as confirmation that EC has been effective and pregnancy has not ensued. It may be difficult to differentiate between non-menstrual bleeding in the early days after EC and actual menstruation. Clinicians and women should always err on the side of caution, and undertake pregnancy testing if there is any doubt that menstruation has followed EC use.

*Ectopic pregnancies* have been identified following administration of LNG EC in case series,<sup>42–45</sup> however the overall risk does not appear to be increased following LNG EC. There are insufficient post-marketing data to allow accurate assessment of risk. Clinicians and women should be alert to the possibility of an ectopic pregnancy, but the risk is likely to be small.<sup>46</sup>

**Emergency intrauterine device**

A review of 12 randomised trials and one non-randomised WHO trial,<sup>47,48</sup> covering 22 908 IUD insertions and more than 51 399 woman-years, identified a low overall rate of pelvic inflammatory disease of 1.6 per 1000 woman-years. After adjusting for confounding factors, although a six-fold increase was identified in the 20 days following IUD insertion, the overall risk was low.

**What aftercare and follow-up is required?**

**22 Women should be given information and counselling on use of their future contraceptive method of choice (Good Practice Point).**

**23 LNG EC does not provide contraceptive cover for the remainder of the cycle and effective contraception or abstinence must be advised (Grade B).**

**24 Women should be advised to have a pregnancy test if their expected menstruation is more than 7 days late, or lighter than usual (Grade B).**

**25 An emergency IUD can be removed at any time after the next menstruation if no UPSI has occurred since menses or if hormonal contraception was started within the first 5 days of that cycle (Grade C).**

Following LNG EC, more than 80% of women menstruate before, or within 2 days after, their expected date; and 95% menstruate within 7 days after their expected date.<sup>21</sup> Women should be advised to have 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.

An emergency IUD can be removed after the next menstruation without risk of pregnancy, provided no UPSI has occurred since menses or if hormonal contraception was started within the first 5 days of that cycle.<sup>26</sup> In the case of a woman who has not menstruated following emergency IUD insertion, the device can be removed after 3 weeks as long as it is reasonably certain that she is not pregnant.

Failure of an emergency IUD should be managed in the same way as a long-term IUD. This is discussed fully in the WHO *Selected Practice Recommendations for Contraceptive Use*.<sup>26</sup>

**Advice concerning future contraception**

The SPC for LNG EC state that its use does not contraindicate the continuation of a regular method of contraception.<sup>16-18</sup> The CEU has recommended in previous Guidance<sup>22</sup> that LNG EC does not provide effective contraceptive cover for the remainder of the cycle, and effective contraception or abstinence must be advised.

After EC use because of 'missed pills', women should be advised to resume hormonal contraception within 12 hours of taking LNG EC.<sup>20</sup>

After EC use because of UPSI, clinicians and women should discuss initiating a regular method of contraception. This can be started at any time in the cycle if it is *reasonably certain* that the woman is not pregnant.<sup>22,32</sup> It would be appropriate to initiate a regular method of contraception immediately if abstinence, or condom use, is unlikely.

A woman having an emergency IUD inserted may choose to keep it in place as a regular method of

contraception. She should be advised to return 3-6 weeks after insertion for a check to exclude infection, perforation or expulsion. IUD users should be counselled about when to seek medical advice if they develop symptoms of pelvic infection, pain, persistent menstrual abnormalities, missed period or non-palpable threads.<sup>23,26,33</sup>

**Who can supply emergency contraception?**

**26 Patient group directions (PGDs) can be developed to allow nurses and other health care professionals to supply and administer contraceptives. PGDs may include use outside the terms of the product licence provided such use is justified by current best practice; the PGD clearly describes the status of use outside the licence; and the documentation includes the reason why such use is necessary (Grade C).**

Currently, EC can be obtained from a variety of services including family planning, general practice, GUM departments, pharmacies, gynaecology departments, National Health Service (NHS) 'walk-in centres' and some accident and emergency departments. These services have different facilities, approaches and knowledge of EC provision.<sup>49</sup>

**Patient group directions**

Extending the roles of nurses can improve patient care. Patient group directions (PGDs) can be developed to allow nurses and other health care professionals to supply and administer medicines. PGDs are written instructions for the supply and administration of a medicine (or medicines) where the patient need not be individually identified before presenting for treatment.<sup>50</sup>

A PGD can be developed locally by doctors, pharmacists and other health care professionals and must meet certain legal criteria. Each PGD must be signed by a doctor (or dentist) and a pharmacist, and approved by an appropriate body, usually a primary care NHS trust.<sup>50</sup> A PGD should include: the time period during which the PGD has effect; the class of supply and administration; the clinical situations in which the medicine may be supplied; the clinical criteria under which a person is eligible for treatment; circumstances under which further advice should be sought from a doctor; the dose and administration of the regimens of the medicine; any specific warnings such as side effects; necessary follow-up arrangements; arrangements for referral for medical advice; and details of the record of supply and administration.<sup>51</sup> A PGD can include a flexible dose range so that the health care professional can select the most appropriate dose for the patient.<sup>50</sup> Medicines used outside the product licence can be included in PGDs provided such use is exceptional, justified by current best practice, and that such a direction clearly describes the status of the product. Each PGD should state when the product is being used outside the terms of the product licence and the documentation should include the reasons why this is necessary.<sup>52</sup>

**Emergency contraception and young people**

**27 If a young person is assessed for competency, this should be documented in case notes as being 'Fraser ruling competent' (advice understood, will have or continue to have sex, advised to inform parents, in best interest) (Grade C).**

There is no medical reason why a young person need be restricted in her contraceptive choices on the basis of age

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alone.<sup>32</sup> Health care professionals should promote safe and responsible sexual health, while being sensitive and aware of the issues surrounding child protection.<sup>53</sup>

Research shows that many young people are sexually active before the legal age of consent.<sup>54</sup> Health care professionals working with young people are able to provide confidential advice and treatment to ensure that each young person is able to make an informed choice about his or her sexual activity.<sup>55</sup> Guidance indicates that the duty of confidentiality to persons aged under 16 years, in any setting, is the same as that owed to any other person.<sup>56</sup>

If a young person (aged <16 years) requests EC, it is in the interests of the clinician, and the young person herself, that she is assessed for 'competency'. Following the case of *Gillick vs. West Norfolk and Wisbech Area Health Authority* (1986),<sup>57</sup> the Department of Health provided guidance<sup>57</sup> for clinicians specifically relating to contraceptive provision for those aged under 16 years. The Law Lords' ruling (the Fraser ruling) stated that a clinician may provide contraceptive advice and treatment to a young person under the age of 16 years, without parental consent, provided that he/she has confirmed that the young person is competent and that the Fraser criteria (advice understood, will have or continue to have sex, advised to inform parents, in their best interest) are met.

### Should emergency contraception be supplied in advance of need?

**28 Advance provision of LNG can be offered to women to increase early use when required (Grade A).**

'Advance provision' of EC refers to provision in advance of need. Previous CEU Guidance supported the advance provision of hormonal EC for women attending family planning and sexual health services.<sup>22</sup> Additionally, WHO recognises that in certain circumstances an advance supply of EC is appropriate and acceptable.<sup>26</sup>

Clinicians may consider advance provision for any women who may be at risk (e.g. for women relying on barrier methods or travelling abroad). Randomised trials have shown that advance supply of LNG to selected women is safe and effective. Increasing the uptake of EC may reduce the rate of unintended pregnancies without increasing the number of women having UPSI.<sup>58,59</sup> In a trial, women who had advance supplies at home were more likely to use EC when required, without compromising regular contraceptive use or sexual behaviour.<sup>60</sup> Interviews with women who had received EC in advance highlighted that while advance supplies were seen as useful, they were not considered an alternative to other forms of contraception.<sup>61</sup> A population-based study did not show that providing sexually active women with EC in advance of need had any impact on abortion rates.<sup>62</sup>

### Emergency contraception in the future

The progestogen antagonist, mifepristone, has been shown in trials to be an effective emergency contraceptive when taken as a single dose up to 120 hours after UPSI.<sup>2,3,63</sup> It appears to offer efficacy at least equivalent to that of LNG.<sup>21,64</sup> A systematic review suggests that low- to mid-doses (25–50 mg) of mifepristone offer high efficacy with an acceptable side-effect profile.<sup>65</sup> At present, mifepristone is neither licensed nor readily available for this indication in the UK.

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This Guidance was developed by the Clinical Effectiveness Unit (CEU) of the Faculty of Family Planning and Reproductive Health Care (FFPRHC): Ms Lisa Allerton (Research Assistant), Dr Gillian Penney (Director), Dr Susan Brechin (Co-ordinator) and Ms Gillian Stephen (Research Assistant) in consultation with the Clinical Effectiveness Committee, which includes service user representation and a multidisciplinary expert group of health care professionals involved in family planning and reproductive health care. The multidisciplinary group comprised: Dr Kirsten Black (Associate Specialist, Lambeth Primary Care Trust), Dr Karen Fairhurst (Senior Lecturer, Division of Community Health Science – GP section, University of Edinburgh), Dr Gillian Flett (Consultant in Sexual and Reproductive Health, Square 13, Centre for Sexual and Reproductive Health, NHS Grampian, Aberdeen), Ms Lorraine Forster (Clinical Governance Co-ordinator, Sandyford Initiative, Glasgow), Dr Noreen Khan (Consultant in Community Gynaecology and Sexual Health, Charlestown Sexual Health Clinics, North Manchester PCT) and Dr Anne Webb (Consultant in Family Planning and Reproductive Health Care, Abacus Clinics for Contraception and Sexual Health, Liverpool). Written feedback was obtained from expert group member Ms Toni Belfield (Director of Information, fpa, London).

This Guidance is also available online at [www.ffprhc.uk](http://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	
<b>A</b>	Evidence based on randomised controlled trials
<b>B</b>	Evidence based on other robust experimental or observational studies
<b>C</b>	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 (CD Ovid version) (1996–2006); EMBASE (1996–2006); PubMed (1996–2006); The Cochrane Library (to December 2005) and the US National Guideline Clearing House. The searches were performed using relevant medical and subject headings (MeSH), term and text words. The Cochrane Library was searched for systematic reviews, meta-analyses and controlled trials relevant to emergency contraception. Previously existing guidelines from the Faculty of Family Planning and Reproductive Health Care, the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization, 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/Q+As

### Discussion Points for Emergency Contraception

The following discussion points have been developed by the FFPRHC Education Committee.

#### Discussion Points

- 1 Women seeking emergency contraception (EC) may also be at risk of sexually transmitted infections (STIs). Should screening for STIs be available to all women seeking EC? If women choose an emergency IUD, should they receive prophylactic antibiotics?
- 2 Discuss how you would develop a patient group direction (PGD) for levonorgestrel emergency contraception (LNG EC) in your area. For what situations would you extend the PGD outside the product licence (if agreed by the Trust)?
- 3 Discuss the possible advantages and disadvantages of supplying LNG EC in advance of need. How would you organise this in a clinical service (assume unlimited funding)?
- 4 What do you consider are the key aspects of counselling for women presenting for EC? How might you ensure that these are undertaken in a consistent manner in your service?

### Questions for Emergency Contraception

The following questions and answers have been developed by the FFPRHC Education Committee.

Indicate your answer by ticking the appropriate box for each question

	<i>True</i>	<i>False</i>
1 Levonorgestrel (LNG)-containing emergency contraception (EC) is licensed for use up to 120 hours after unprotected sexual intercourse (UPSI).	<input type="checkbox"/>	<input type="checkbox"/>
2 Repeat doses of LNG EC may be issued in a cycle.	<input type="checkbox"/>	<input type="checkbox"/>
3 Vomiting occurs in 10% of women who take LNG EC.	<input type="checkbox"/>	<input type="checkbox"/>
4 Severe hypertension (BP >160/120) is an absolute contraindication to LNG EC.	<input type="checkbox"/>	<input type="checkbox"/>
5 The copper intrauterine device (IUD) can be inserted any time up to 5 days beyond the earliest estimated day of ovulation, regardless of how many acts of UPSI have occurred in that cycle.	<input type="checkbox"/>	<input type="checkbox"/>
6 Current Faculty Guidance recommends EC when Depo-Provera <sup>®</sup> is more than 13 weeks late and UPSI has occurred.	<input type="checkbox"/>	<input type="checkbox"/>
7 The evidence for increasing the dose of LNG EC by 100% in women using liver enzyme-inducing drugs is based on clinical trials.	<input type="checkbox"/>	<input type="checkbox"/>
8 The risk of pelvic infection is increased six-fold in the first 20 days after IUD insertion.	<input type="checkbox"/>	<input type="checkbox"/>
9 After taking LNG EC women should resume hormonal contraception within 12 hours.	<input type="checkbox"/>	<input type="checkbox"/>
10 There are no drugs known to affect emergency IUD use and efficacy.	<input type="checkbox"/>	<input type="checkbox"/>

Answers

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