Advice on emergency contraception

This third article discusses issues to consider when providing emergency contraception

SARAH PILLAI DIPGUM, MFFP, IS A LEAD CLINICIAN AT NHS BARNET

EMERGENCY contraception is defined as the measures taken after an act of unprotected (or inadequately protected) sexual intercourse (UPSI) to avoid pregnancy. In the UK, three methods are licensed for use: two types of emergency hormonal contraception (EHC) as well as the insertion of a copper-bearing intrauterine contraceptive device (IUCD).

EHC

The products licensed in the UK for EHC are Levonelle One Step (over-the-counter), Levonelle 1500 (prescription-only) and EllaOne (ulipristal 30mg; POM). Both the Levonelle products contain 1,500µg of levonorgestrel. If taken before ovulation, this appears to delay ovulation by five to seven days and arrests the development of the ovarian follicle. It is not known whether levonorgestrel has any effect at or just after ovulation — if it does, its mechanism of action is unknown. The summary of product characteristics for Levonelle goes so far as to state: “Levonelle is not effective once the process of implantation has begun.”

EllaOne is a progestogen receptor modulator and appears to work later in the cycle than Levonelle, interrupting the luteinising hormone surge just before ovulation. It is licensed for use within 120 hours of UPSI and studies indicate that the rate of pregnancy prevention continues at the same level for the five days.

EllaOne is still a “black triangle” product. Although there are few data, at present there have been no adverse outcomes following administration with a subsequent pregnancy. However because of a lack of knowledge and partly because of cost, EllaOne is not yet prescribed widely.

There is no evidence to suggest that EHC will interrupt an existing pregnancy — although it will not work, it will not cause

Case studies

Case 1 A 35-year-old woman asks for emergency contraception. She is married with two young children. She and her husband normally practise withdrawal for contraception and she has not used emergency contraception before. She is taking carbamazepine for epilepsy but is otherwise well. Her last period was last week. She looks embarrassed.

On questioning in your consultation area, she tells you that she went to an office party the night before without her husband and “one thing led to another”. She did not have full penetrative intercourse but there was genital contact and potential for semen to enter the vagina. She is terrified that her husband will find out and worried that she might have caught an infection.

Case 2 A woman in her 20s comes into the pharmacy requesting emergency contraception. She is taking Microgynon but went away for the weekend and forgot to take her packet. This means she missed taking two of her pills from the last week in her packet. When she finds out how much the product costs, she asks: “do I really need it?”

Case 3 A young girl comes into the pharmacy. She says she is 16 but looks younger. She is with two friends, who push her forward and tell you that she wants “the morning after pill”. She looks embarrassed. She does not take any medicines. Her last period was “about two weeks ago”. She had unprotected intercourse yesterday and about a week ago. She took Levonelle within 24 hours of the previous unprotected sex.

The author will be available to answer questions on this topic until 24 September 2012

Ask the expert

www.pjonline.com/expert

Suggested actions on p4.
harm to the woman or the fetus if inadvertently used.

**IUCD**

The latter is less well known and not so commonly requested or offered. However, it is more effective than EHC and has the advantage of providing ongoing contraception. It is also licensed for use beyond the 72 or 120 hour window that applies to EHC, and can work for multiple risks.

**“How long do I have?”**

Both Levonelle products are licensed for use in the 72 hours after UPSI. A World Health Organization study1 showed use in the first 24 hours to be most effective but this has not been demonstrated in subsequent studies. It is also interesting that further studies taken together4 demonstrate that efficacy does not drop to zero at 72 hours after unprotected sex and that, in fact, Levonelle appears to be effective up to at least 96 hours post UPSI. Use in such circumstances is not licensed in the UK but, in practice, is widely prescribed on an individual patient basis as a result of this research. According to Bayer, there are no plans to extend the licensed use to include this extended time interval. EllaOne is licensed for use up to 120 hours after UPSI. An emergency IUCD can be fitted later depending on the time of the cycle (see Panel 1).

**“Do I need to take it?”**

A common trigger for EHC requests in pharmacies is the possibility of failure of a regular contraceptive, for example, if the woman has had an episode of diarrhoea or vomiting that could have resulted in the contraceptive not being absorbed effectively or if she has forgotten to take her pill.

If emergency contraception is requested but not really needed, I usually explain the rules (see Panel 2 for a summary) but allow the client to take EHC if she wishes — after all, no contraception is 100 per cent effective and harm caused by EHC is minimal.

**“Can I use it again?”**

When I am asked how often Levonelle can be used, I normally reply “as often as it is required”. It is not a huge dose of hormone and it has few side effects. The SPC mentions disruption to the cycle but this is not a valid argument against the risks of possible pregnancy. Moreover, if EHC has been used previously in a cycle, ovulation may have been delayed so a further dose of EHC is indicated. Of course, every woman should be using a more effective form of contraception but some people cannot manage anything else. Ulipristal, however, can only be used once per cycle.

When to refuse

An anecdotally is appropriate here: when I was fairly new to contraceptive and reproductive health services, I counselled a woman who had missed a single combined oral contraceptive pill (COCP) mid-packet and had presented for emergency contraception. Following the rules to the letter, I confidently explained that her risk was minimal and, therefore, there was no need for emergency contraception. She returned two weeks later with a positive pregnancy test result, and said: “It’s just the same as what happened to me last year, doc.” It is not clear that she would not have fallen pregnant had I given her the EHC but, since then, I have been cautious of refusing it even if there is no apparent risk. After all, the woman has made the effort to seek treatment and the harm caused by unnecessary treatment is minor.

There are, of course, situations in which emergency contraception is not required. Some women have extreme anxiety around the possibility of pregnancy and women making a number of repeat requests should be referred appropriately.

Contraindications to Levonelle are few and include allergy to levonorgestrel or any of the excipients, and acute porphyria. Although the SPC states that Levonelle is not recommended in severe hepatic impairment, the UK Medical Eligibility Criteria for Contraceptive Use1 lists only active trophoblastic disease (eg, choriocarcinoma) as evidenced by an abnormal human chorionic gonadotrophin level as a “category 3” contraindication (defined by WHO as when risks outweigh benefits and when EHC can be given only after discussion with a specialist). In such a case, an IUCD would also be contraindicated.

**Panel 1: Emergency IUCD**

An IUCD can be inserted up to five days after a single act of UPSI, or up to five days after the earliest expected day of ovulation. An emergency IUCD is more effective than EHC, so should be suggested at any consultation for emergency contraception. An IUCD is particularly appropriate for women who have had multiple acts of unprotected sex during one menstrual cycle, who are taking medicines that interact with EHC (eg, potent enzyme inducers) and in whom it could be an ongoing contraceptive method of choice. Contraindications include existing pregnancy, uterine abnormalities and allergy to copper. Neither nulliparity, or young age are contraindications, nor is an existing or possible sexually transmitted infection — this can be treated at the time of insertion. However, an IUCD should not be fitted less than four weeks after giving birth (unless within the first 48 hours) or in women with active trophoblastic disease. The woman may need to take antibiotic prophylaxis at the time of insertion if there is a high likelihood of chlamydia or other cervical infection but a diagnosis cannot be confirmed in time. It should be noted that there is a higher incidence of STIs in young nulliparous women than in the general population.

The timing is easy to work out. We assume that ovulation occurs about 14 days before the start of menstruation so to find the earliest predicted day of ovulation, the shortest length of cycle is elicited, and 14 days is taken from this. Assuming a 28-day cycle, ovulation should occur around day 14. The ovum lasts for approximately 24 hours so we can assume that the ovulation date is the same as the day of fertilisation. The time taken for a fertilised ovum to travel and be implanted is seven days. So to fulfil the law and not procure an abortion (fitting an IUCD into a uterus containing an implanted blastocyst would be an example of procuring an abortion) we confine fitting the IUCD to up to five days after the date of fertilisation. This will then prevent implantation.

The IUCD rules following missed pills can be worked out in the same way. The earliest possible day for ovulation to occur in a woman taking the COCP is nine days after the last correct pill taking day so an emergency IUCD can be fitted up to five days after this.

If EHC is not contraindicated, it is best to offer it in addition to referring the client for an emergency IUCD — she may not get to the clinic or revise her memory of the date of her last period and, occasionally, IUCD insertion is not successful.

The SPC points out that severe malabsorption syndromes might impair the efficacy of EHC. EllaOne is contraindicated in those who have had previous unprotected sex during the current cycle, for those who have taken Levonelle in the current cycle and for those using enzyme inducers.

Because it is a progesteron receptor modulator, it may interact with other hormonal contraception so current advice is to use barrier methods of contraception for seven days after use plus the time it takes for the contraceptive to become effective once more (ie, seven days for combined hormonal contraception, the IUS, injectable progesteron and implant, nine days for Qiara, 48 hours for progesteron-only pills).

It is also contraindicated in severe asthma insufficiently controlled by oral glucocorticoïds. Caution should be taken in women with hepatic impairment,
It is important for trust to be established, and community pharmacists are in an ideal position to foster ongoing relationships. Some male pharmacists might worry about situations in which they are in a private area with a woman, but if the rapport is appropriate, and respect is met on both sides, misunderstandings should not prevail.

Health promotion
If a woman has had unprotected sex she is at risk of sexually transmitted infections (STIs). The commonest age group for STIs is 16–24 years, and chlamydia has now overtaken genital warts as the most common infection. Most areas in the UK now have chlamydia screening programmes and pharmacists should either be participating in such schemes or be aware of where to refer the person for screening.

If the sexual partner is at high risk of HIV or is known to be HIV positive, the woman should be referred immediately, either to the local genitourinary medicine clinic or to the nearest accident and emergency department, for consideration for post exposure prophylaxis. This would also be a consideration for women who have been raped. If there has been sexual abuse or rape, the woman may be encouraged to inform the police, and could be helped in her decision by local rape advisory services.

It is common for unprotected sex to occur as a response to excessive use of alcohol or recreational drugs; this may need to be explored particularly for those who request EHC on a regular basis.

Ongoing contraception
The pharmacist giving out EHC is in a unique position to advise and direct the woman to contraceptive services, either in a community clinic or to her GP. Some areas also have condom distribution schemes for young people so that the pharmacist can give the young person a free pack of condoms and advise about correct usage.

Advance supply
The FPA and the Faculty of Sexual and Reproductive Healthcare have endorsed the advance supply of EHC for some years but frequently, for a variety of reasons, health professionals are reluctant to supply it on this basis. There is a fear that it encourages unprotected sexual intercourse but there is no evidence supporting this view.

Advance provision neither alters abortion rates nor affects women’s uptake of other forms of contraception.5,6

---

**Panel 3: Enzyme Inducers**

- Carbamazepine
- Ciclosporin
- Phenobarbital
- Phenylbutazone
- Primidone
- Rifabutin
- Rifampicin
- Ritonavir
- St John’s Wort
Suggested actions for case studies on p79

Case 1 At no time in the cycle is it possible to say that there is no risk of pregnancy, particularly as menses differ, memories are sometimes unreliable and ovulation is not always predictable. A study reported in the BMJ showed differing ovulation times in women with regular 28-day cycles.1 Sperm survival is also a significant factor in the equation and, in some cases, can be as long as seven days. The issues here are that the woman is taking an enzyme inducer and so EHC may not be as effective as an emergency IUCD. Ideally, she should be screened for sexually transmitted infections, and the options for emergency contraception need discussing carefully. It is clear that she does not want a pregnancy from this encounter so the most effective option is an IUCD. However, this may cause vaginal bleeding and her husband may detect the strings of the IUCD when they have intercourse. Two tablets of Levonelle would be another option. The woman should make an individual informed choice.

She should also be advised to refrain from intercourse until she has had an STI screen. Ideally, this should occur after a week from the incident to allow micro-organisms such as chlamydia and gonorrhoea to become detectable. HIV is not usually detectable until eight to 10 weeks after transmission. The woman may need ongoing counselling, and referral to a genitourinary medicine (GUM) clinic and specialist contraception clinic would be appropriate.

Case 2 There is little risk of contraceptive failure from missing two Microgynon pills in the last week of the cycle. She should be advised to continue her pills and do not take a pill free interval. If she refuses, she can still take Levonelle or have an emergency IUCD; EllaOne would not be appropriate in this case because she could lose her continuing contraceptive cover from the Microgynon.

Case 3 It is ideal to talk to the girl away from her friends to take a more accurate history. If she refuses, one friend would be appropriate but encourage her to speak for herself. Guidance from the Royal Pharmaceutical Society is pharmacists should “make every reasonable effort to satisfy themselves that women are aged 16 years or over”. However, where they believe the woman to be under 16, the request should be dealt with sympathetically and the client should be offered support to obtain EHC by another route.

Having taken Levonelle already is not a contraindication to taking it again, but a discussion should take place about an emergency IUCD at this point because this is the most effective method and will protect from pregnancy from both acts of unprotected intercourse.

Use of the phrase “morning after pill” should be discouraged because it gives the wrong message about the timing of the treatment. You should discuss STIs and offer chlamydia screening. Offer her condoms and discuss other methods of ongoing contraception, pointing her in the direction of services that offer this and giving Family Planning Association leaflets if appropriate.

The aim is to provide a holistic consultation. The girl should leave the consultation with confidence and respect intact.

Clients under 16 years of age

Over-the-counter provision of EHC to a girl under 16 years of age would be outside the product licence of Levonelle. However, contraception (regular or emergency) can legally be prescribed or provided under a patient group direction to a girl under 16 if she fulfils the following criteria:

- She is at risk of pregnancy
- She is sufficiently mature to understand what you are telling her
- You have discussed parental consent with her

This follows the Lord Justice Fraser ruling in the House of Lords in Gillick vs Wischec Area Health Authority and these criteria are commonly known as the “Fraser guidelines”.

Several primary care organisations are now inviting pharmacists to provide EHC to girls under 16 under a patient group direction and providing pharmacists with the necessary training.

It is incumbent on all health professionals dealing with children, including pharmacy staff, to be aware of child protection issues and to follow local guidance if the child appears to be at risk of abuse.

Further reading

- Guidance is available from the Faculty of Family Planning and Reproductive Healthcare Clinical Effectiveness Unit ("The use of contraception outside the terms of the product licence") on the pragmatic use of emergency contraception in exceptional circumstances (Journal of Family Planning and Reproductive Health Care 2005; 31: 225–42).

References

1 Croxatto HB, Brache V, Pavez M, Cochlon L, Forcelledo ML, Alvarez F et al. Pfluitary-ovarian function following the standard levonorgestrel emergency contraceptive dose or a single 0.75mg dose given on the days preceding ovulation. Contraception 2004;70:442–50.
4 Faculty of Family Planning and Reproductive Healthcare. UK medical eligibility criteria for contraceptive use. Available at www.fsrh.org (accessed on 29 August 2012).