EMERGENCY CONTRACEPTION

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A. General Considerations

- Conception occurs around the time of ovulation but the number of days in a cycle in which a woman is fertile is difficult to quantify. Sperm may remain viable in the female genital tract for up to 5 days but the egg appears to be capable of being fertilized for only about 24 hours.
- Emergency contraception (EC) is any post-coital method of contraception.
- In the US, the most common form of EC is high dose combination oral contraceptives but a new pill, consisting of progesterone only (Plan B) will likely become more popular. The other method of EC involves insertion of the copper-T IUD.
- Half of all pregnancies in the USA are unintended, some 3.2 million per year.
- Worldwide about 50 million pregnancies are terminated each year.
- It is estimated that if widely promoted, EC could annually prevent about 1 million abortions and 2 million unintended pregnancies that end in births
- EC can be used in the following situations:

Indications for Emergency Contraception

Failure to use contraception during intercourse
Slipped or torn condom
Improperly inserted or dislodged diaphragm or cervical cap
IUD expulsion
Oral contraceptives missed more than 2 days consecutively
Failure to withdraw prior to ejaculation
Sexual assault

B. Emergency Contraceptive Pills (ECPs)

1. Mechanism of Action

- ECPs do not interrupt an already established pregnancy
- ECPs can delay or inhibit ovulation.
- Other possible effects include:
  - Interference with corpus luteum function
  - Thickening of the cervical mucus, trapping sperm
  - Alterations in tubal transport
  - Direct inhibition of fertilization

2. Formulations

- ECPs are commonly known as "the morning-after pill" but this is misleading as ECPs should be taken as soon as possible after unprotected intercourse but may be taken up to 72 hours after unprotected intercourse.
- No pelvic examination or other tests are indicated once an already established pregnancy has been excluded by consideration of LMP, etc.
- ECPs may be prescribed over the phone.
- In Washington state (other states have this too), ECPs are available directly from pharmacists through pharmacist prescriptive practice agreements with physicians.
- ECPs are available in several formulations:
  - ordinary birth control pills with estrogen and progestin
    - First described by Yuzpe and Lancee, the combination of 100 micrograms ethinyl estradiol and 0.5 mg of levonorgestrel each, taken within 72 hours of intercourse with the second dose taken 12 hours later is known as the Yuzpe regimen.
    - ECPs are not licensed as a contraceptive as such but the FDA in February, 1997 published a formal notice in the *Federal Register* that 6 brands of commonly used combined oral contraceptives were safe and effective for emergency postcoital use.
  - In 1998, the FCA approved an emergency contraception kit (Preven), which consists of a patient information booklet, a urine pregnancy test, and 4 combination oral contraceptives (levonorgestrel + ethinyl estradiol)
  - progestin-only formulations
    - minipills (Ovrette)
    - levonorgestrel pills (Plan B); approved by the FDA in 1999

Regimens for Oral Emergency Contraception in the USA

Brand	Pills per dose[1]	Ethinyl Estradiol per dose (mcg)	Norgestrel per dose (mg)[2]	Levonorgestrel per dose (mg)
Ovral	2 white pills	100	1.0	
Alesse	5 pink pills	100		0.50
Nordette	4 light-orange pills	120		0.60
Levlen	4 light-orange pills	120		0.60
Lo/Ovral	4 white pills	120	1.2	
Triphasil	4 yellow pills	120		0.50
Tri-Levlen	4 yellow pills	120		0.50
Preven kit	2	100		0.50
Ovrette	20 yellow pills	0	1.5	
Plan B	1	0		0.75

[1] The treatment schedule is one dose within 72 hours after unprotected intercourse, and another dose 12 hours later. Although not FDA approved, recent study[3] suggest both doses of plan B taken at same time within 72º is just as effective as 12º later.

[2] The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive.

[3] Von Hertzen. et al. "Low Dose Mifepristone and two regimens of levonorgestrel for emergency contraception: a who multicentre randomized trial." The Lancet, 2002; 360: 1803-1810.

3. Effectiveness

- It is estimated that use of EC in the form of combination oral contraceptives reduces the risk of pregnancy by 75%. This means that if 100 women have unprotected intercourse once during the 2nd or 3rd week of their cycle, about 8 would become pregnant; following treatment with ECPs, only 2 would become pregnant.
- Progestin-only regimens are estimated to be even more effective, especially if started early after unprotected intercourse.
- The regimen should not be excessively restrictive such that women are denied access to dosing as it is biologically implausible that efficacy abruptly plummets to zero after 72 hours.

4. Side-Effects

- 50% of women taking combination ECPs experience nausea and 20% vomit.
- If vomiting occurs within 2 hours of a dose, some clinicians recommend repeating the dose. Others feel that vomiting indicates systemic absorption of the pills and that additional doses are therefore not required. The women may also insert pills into her vagina which will reduce nausea and vomiting.
- Combined ECPs containing levonorgestrel have substantially fewer side-effects of nausea and vomiting than those containing norgestrel[1]
- Users of ECPs containing levonorgestrel may experience spotting, heavier or lighter menses than normal, or delay in onset of menses.

5. Safety

- Almost all women can safely take ECPs.
- The World Health Organization and the International Planned Parenthood Organization have stated that the only absolute contraindication is pregnancy because ECPs will not work (ECPs do not affect an ovum which has already implanted)
- Combined ECPs may not be appropriate in the woman with active migraine with neurologic symptoms or with crescendo migraine.[2]
- ECPs were not associated with a substantially increased risk of venous thromboembolism in a study in the United Kingdom.[3]
- Although no changes in clotting factors have been detected following ECPs, use of progestin-only pills or insertion of a copper-T IUD may be more appropriate for the woman with a history of CVA or thromboembolism.
- ECPs may be used in patients with a prior history of ectopic pregnancy but must be followed closely for sign/sx of ectopic pregnancy and for failure to have a withdrawal bleed.

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[1] Sanchez-Borrego R, Balasch J. Ethinyl estradiol plus dl-norgestrel or levonorgestrel in the Yuzpe method for post-coital contraception: results of an observational study. *Hum Reprod.* 1996; 11:2449-2453.
[2] Webb A. How safe is the Yuzpe method of contraception? *Fert Control Rev.* 1995; 4:16-18.
[3] Vasilakis C, Jick S, and Jick H. The risk of thromboembolism in users of postcoital contraceptive pills. Contraception, 1999;59:79-83.

- Safety of the fetus:
  - No conclusive studies have been done of women who were already pregnant when they took ECPs or who became pregnant following ECPs. However:
    - ✓ ECPs are taken long before organogenesis occurs.
    - ✓ Babies born to women who continue to take combined oral contraceptives do not have an increased risk of birth defects.

6. Counseling

- Make sure that women understand that ECPs do not provide protection against conception in the days or weeks following treatment. Discuss long-term birth control options with them at the time of the visit.
- Advise women that their menses will not start immediately but may rather be a few days early or late; spotting may occur.
- The patient should return to clinic for a pregnancy test if her period is > 1 week late.
- Patients with a history of ectopic pregnancy should be counseled to seek care if they develop abdominal pain or experience no menses.
- ECPs are NOT to be used routinely as birth control as the failure rate and side effects are greater than with traditional contraception.
- Providers should consider giving patients a prescription for EC to fill as needed as patient access may become an issue given the narrow time frame of effectiveness.
- Studies have thus far not supported concerns that EC self-administration promotes contraceptive carelessness.[4]

C. Use of Mifepristone as Emergency Contraception

- Mifepristone has been studied as a postcoital contraceptive in doses as low as 10 mg.[5]
- It is considered to be at least as effective as the Yuzpe method with fewer side effects.
- An additional benefit is that mifepristone can be used up to 5 days after unprotected intercourse.
- The only significant side-effect is delay of menses which is consistent with one of the drug's mechanisms of action, interference with ovulation.
- As EC, mifepristone is used at much lower doses than those that would induce abortion.
- Mifepristone's use as an abortifacient may prevent its acceptance in the US.

D. The Copper-T IUD

- This device can be inserted up to the time of implantation, about 5 days after ovulation, to prevent pregnancy.

[4] Glasier A, Baird D. The effects of self-administering emergency contraception. NEJM 1998;339:1-4.
[5] Task force on Postovulatory Methods of Fertility Regulation. Lancet, 1999; 353:697-702.

- Many protocols allow insertion only up to 5 days following unprotected intercourse as it is difficult to determine the time of ovulation.
- This method is more efficient at preventing pregnancy than Rx with ECPs or minipills, preventing 99% of pregnancies.
- This method is particularly ideal for those women who wish to continue to use the copper-T IUD for contraception. It may be left in place to prevent pregnancy for 10 years after insertion.
- IUDs are not ideal for women at risk for STDs as this may result in PID.

E. Other information

- **Emergency Contraception Web site:** http://opr.princeton.edu/ec/
- **Emergency Contraception Hotline: 1-888-NOT-2-LATE**
- **Planned Parenthood Clinic Hotline: 1-800-230-PLAN**

References

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