Emergency Contraception Protocol

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Action for Boston Community Development/Boston Family Planning

Emergency Contraception–Information for Providers of Family Planning Services

(For more information about this protocol, please contact Deborah Dill at Dill@BostonABCD.org)

Emergency contraception (EC) refers to safe and effective methods of contraception which women can use to prevent pregnancy following unprotected sexual intercourse. Currently in the US one-half of all pregnancies are unintended, and one-half of all unintended pregnancies end in abortion. Use of emergency contraception within 72 hours of unprotected intercourse decreases the likelihood of pregnancy in any one act of unprotected intercourse from 8% to 1.1-2.9% depending on the method used and the timing of use. Programs should increase access to emergency contraception by informing clients at all reproductive health visits of the availability of EC, minimizing barriers to providing EC as needed on request by clients, and by providing emergency contraceptive pills (ECPs) and education in how to use them in advance of need. As of 8/99, three methods of emergency contraception are in use in the US:

1. **Yuzpe method**–combination oral contraceptives containing a total treatment dose of at least 200 mcg. of ethinyl estradiol and 1mg. levonorgestrel or 2mg. norgestrel. In addition to Preven, an FDA approved dedicated emergency contraception product, the FDA has stated that the following combined oral contraceptives are safe and effective for use as ECPs: Ovral, Lo-Ovral, Nordette, Levlen, Levora, Triphasil, Tri-Levlen, Trivora, Alesse, and Levlile. Taken in 2 doses 12 hours apart, and initiated within 72 hours of unprotected coitus, use of the Yuzpe method reduces the chance of pregnancy by 75%, decreasing the rate of pregnancy from 8% to 2% after a single act of unprotected coitus.
2. **Levonorgestrel-only method**—total treatment dose of 150 mcg levonorgestrel (trade name: Plan B) taken in 2 doses 12 hours apart and initiated within 72 hours of unprotected coitus reduces the chance of pregnancy by 89%, decreasing the rate of pregnancy from 8% to 1% after a single act of unprotected coitus.

3. **Copper T IUD** inserted within 5 days of unprotected coitus for those women who would otherwise be appropriate IUD candidates and who desire this method for long term contraception. Most effective method with 0.1% failure rate. (see IUD protocol)

Emergency contraceptive pills have been shown to be more effective the earlier taken after an episode of unprotected coitus. Because of the effectiveness of ECPs in preventing unintended pregnancy and the recommendation to start treatment as soon as possible after unprotected intercourse, advanced provision of ECPs for appropriately screened and educated patients is strongly recommended.

**Safety of emergency contraceptive pills**
The FDA has approved two dedicated emergency contraception products, Preven® and Plan B®, and has stated that ten brands of Norgestrel or Levonorgestrel containing combined oral contraceptives are safe and effective for use as post-coital emergency contraception. **There have been no reports of long or short term health risks associated with EC use.** Because the estrogen in the combined OC method of EC (Yuzpe method) is taken over a short period of time, it has not been shown to cause a change in clotting factors.

Based on the available evidence from studies of fetal development when women are exposed to combined or progesterone-only OCs early in pregnancy, as well as the studies on small numbers of pregnancies after failed emergency contraceptive use, no significant effects on fetal development have been reported. Therefore, pregnancy is a contraindication to ECP use not because of the risk of fetal harm, but because it will not work in the event of an pre-existing pregnancy.
Mechanism of Action of emergency contraceptive pills (ECPs)
ECP prevent pregnancy through the same mechanisms as daily combined or progesterone-only oral contraceptive pills: by inhibiting or delaying ovulation if taken in the follicular stage, preventing fertilization, and/or affecting the endometrial lining and preventing implantation. **ECPs will not disrupt an already existing pregnancy. It is not an "abortion pill."**

**Contraindications**
*For both ECP methods:*

- Pregnancy- because if the client is pregnant the method will not work.
- Hypersensitivity to any component of product

*For Levonorgestrel-only method (per Plan B package insert):*

- Undiagnosed abnormal genital bleeding

*For Yuzpe method (World Health Organization states pregnancy as only contraindication):*

- History of or current migraine with focal neurological symptoms
- Previous history of thromboembolism

**Side effects**

<table>
<thead>
<tr>
<th></th>
<th>estrogen/progestin (Yuzpe)</th>
<th>levonorgestrel only (Plan B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>50%</td>
<td>23%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>20%</td>
<td>6%</td>
</tr>
<tr>
<td>Menstrual irregularities-spotting, menses earlier or later than normal, heavier or lighter than</td>
<td>25%</td>
<td>25%</td>
</tr>
<tr>
<td>Normal Flow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Fatigue</td>
<td>29%</td>
<td>17%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>17%</td>
<td>11%</td>
</tr>
<tr>
<td>Breast tenderness</td>
<td>10-20%</td>
<td>11%</td>
</tr>
</tbody>
</table>

*Other side effects for both methods include headache, abdominal pain/cramps*

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**Boston Family Planning Medical Protocol**

**EMERGENCY CONTRACEPTIVE PILLS (ECPs)**

**I. Definition**

A form of safe and effective contraception appropriate for a woman who has experienced unprotected coitus within 72 hours and does not desire pregnancy. Because of its efficacy at preventing unintended pregnancy and the need for prompt start of treatment following unprotected coitus, barriers to access for emergency contraception should be minimized.

**II. Indications**

Unprotected intercourse within the past 72 hours at any point in the menstrual cycle as a result of lack or failure of contraceptive method

- no method used
- male condom slipped, broke, leaked
- female condom inserted or removed incorrectly leading to ejaculation in vagina or on external genitalia
- diaphragm or cervical cap inserted incorrectly, dislodged, removed too early, or found to be torn when removed
- withdrawal or periodic abstinence (natural family planning) used unsuccessfully
- missed OCPs with no back-up method: more than 2 pills missed midpack or 1 or more missed before or
after pill free interval so that the interval is prolonged more than 7 days

- missed one or more progestin-only pills with intercourse occurring before 48 hours on a correct schedule
- an IUD has been expelled or partially expelled
- sexual assault

### III. Contraindications

- **Pregnancy:** Use of ECPs will not disrupt or harm an already existing pregnancy. Although a pregnancy test is not required prior to use of ECPs, a highly sensitive urine pregnancy test should be performed before starting ECPs if there is any question as to
  1. the timing or quality of the LMP
  2. symptoms of pregnancy
  3. more than one incident of unprotected coitus since LMP
- Hypersensitivity to any component of the product
- For levonorgestrel only method (Plan B):
  - undiagnosed abnormal genital bleeding per package insert
- For combined OC method (Yuzpe):
  - current or history of migraine with focal neurological symptoms
  - history of thromboembolic disease
  - history of severe nausea/vomiting with estrogen containing OC
  - use levonorgestrel only method if history of above

### IV. Evaluation

By family planning counselor, LPN, RN, NP, CNM, PA, or MD, on the telephone or in person:
- History of unprotected coitus: the precise efficacy of ECPs in preventing pregnancy is unknown if more than 72 hours has elapsed since last unprotected coitus
- History of LMP: earlier or later than normal? normal in length and amount?
- Medical history
- Current use of contraception and what method desired in future

V. Physical exam/ labs- NONE REQUIRED PRIOR TO ECP RX UNLESS:

- suspicion of pregnancy - perform sensitive urine hcg prior to treatment
- symptoms of STD or ectopic pregnancy- pelvic exam with STD screening

VI. Management

First dose to be taken within 72 hours of unprotected coitus. Second dose to be taken 12 hours later. The earlier treatment begins after un-protected coitus the more effective the method. Recommend that clients take the first dose ASAP after unprotected intercourse. The following is a table of FDA approved emergency contraceptive pills and dosing:

<table>
<thead>
<tr>
<th>Brand name and hormonal content in each tablet ()</th>
<th># of tablets to take as soon as possible and within 72 hours of unprotected coitus</th>
<th># of tablets to take 12 hours after the first dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan B 0.75 mg levonorgestrel</td>
<td>1 white</td>
<td>1 white</td>
</tr>
<tr>
<td>Preven levonorgestrel 0.25 mg/</td>
<td>2 blue</td>
<td>2 blue</td>
</tr>
<tr>
<td>ethinyl estradiol 50 mcg</td>
<td></td>
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</table>

**Combined OC used as ECPs**

<table>
<thead>
<tr>
<th>Brand name and hormonal content in each tablet</th>
<th># and COLOR of tablets to take as soon as possible and within 72 hours of unprotected coitus</th>
<th># and COLOR of tablets to take 12 hours after the first dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ovral norgestrel 0.5 mg/EE 50 mcg</td>
<td>2 white</td>
<td>2 white</td>
</tr>
<tr>
<td>Lo-Ovral norgestrel 0.3 mg/EE 30 mcg</td>
<td>4 white</td>
<td>4 white</td>
</tr>
<tr>
<td>Nordette, Levlen levonorgestrel 0.15mg/EE 30 mcg</td>
<td>4 light orange</td>
<td>4 light orange</td>
</tr>
<tr>
<td>Levora levonorgestrel 0.15mg/EE 30 mcg</td>
<td>4 white</td>
<td>4 white</td>
</tr>
<tr>
<td>Triphasil, Tri-Levlen levonorgestrel 0.125 mg/EE 30 mcg</td>
<td>4 yellow</td>
<td>4 yellow</td>
</tr>
<tr>
<td>Trivora levonorgestrel 0.125mg/EE 30 mcg</td>
<td>4 pink</td>
<td>4 pink</td>
</tr>
<tr>
<td>Alesse, Levlite levonorgestrel 0.1 mg/EE 20 mcg</td>
<td>5 pink</td>
<td>5 pink</td>
</tr>
</tbody>
</table>

**VII. Side effect management**

- Nausea occurs in 1/2 of women using the Yuzpe method. Nausea may be decreased if doses are taken with food. Long acting anti-emetics are helpful if given one hour prior to the first dose with the Yuzpe method, for example, RX: Meclizine hydrochloride (OTC-
Dramamine II or Bonine) 1or2- 25 mg tablets taken one hour before the first dose. Meclizine may cause drowsiness.

- If vomiting occurs after a Yuzpe ECP dose, it is most likely related to the absorption of the estrogen component. Replacement doses in the event of vomiting may increase the nausea/vomiting. There is no research evidence on which to base a recommendation that replacing the dose will increase ECP effectiveness in this situation (ACOG 1996). Dr. Yuzpe recommends replacing a dose only if emesis occurs within one hour of an ECP dose. Or, a dose may be replaced if client can see the pills in the emesis. Be sure to use an anti-emetic one hour before replacement or 12 hour repeat dose.

VIII. Follow-up

- Inform client that she is not protected from pregnancy if repeated acts of unprotected intercourse occur after ECP treatment, and counsel to use barrier method or continue OC after ECP treatment.
- In 75-85% of cases, menses onset after ECP treatment is within seven days of when normally expected. If still no menses three weeks after completing ECPs, need sensitive HCG to rule out pregnancy.
- Immediate follow-up if abdominal pain or abnormal bleeding to rule out ectopic pregnancy.
- Follow-up for pelvic exam, labs, STD evaluation, reliable contraceptive method as indicated.
- If sexual assault/rape, refer as indicated.
- IX. Full cycle OC regimen- For women who wish to continue on OC as their method of contraception:
  - screen for OC initiation (see oral contraceptive protocol).
  - if client meets criteria for daily OC use, use Lo-ovral, Nordette, Levlen, Levora, Alesse or Levlité as ECP (follow ECP dosing), then begin taking one pill each day until the end of the pack. May also use any ECP including Plan B, then begin a new pack of the chosen
OC the next day. Use back-up contraception or abstain for 7 days.

- for OC users, if late by one or more days to begin new cycle of OC, or missed 2 or more OCPs, can use ECPs then continue with normal OC pack, use back-up contraception or abstain for seven days.

X. Repeating ECPs

No studies have shown that the availability of ECPs decreases the likelihood that women will use a more reliable method of contraception. Women must be counseled that repeated use of ECPs is not as effective in preventing pregnancies as many other contraceptive methods, and should be offered the choice of a more reliable contraceptive method. However, there is no contraindication to repeated ECP use, and women should not be denied repeat access to ECPs if needed.

XI. Advanced prescription of ECP for future use is strongly recommended

Use ECP consent form and give verbal and written instructions for use, including a number to call with questions, and instructions to either come in for a pregnancy test or use a home pregnancy test before use if any suspicion or symptoms of pregnancy. Counsel about follow-up as with any ECP user.

XII. Counseling

For immediate use: method use, failure rate, mechanism of action, 72 hour window of use, side-effects, follow-up, range of contraceptive options, STD/HIV prevention. EC should be discussed and offered as a contraception option at every family planning visit.

References


www.path.org (very good source of provider and client information).


Plan B website prescribing information, patient information, manual for healthcare providers. Women's Capital Corporation.
www.go2planb.com


Other websites for EC

- www.not-2-late.com
- www.en3dias.org.mx (information about EC in Spanish)