CHAPTER 15

Breastfeeding: Lactational Amenorrhea Method (LAM)

www.lalecheleague.org or www.breastfeeding.com or www.ilca.org or www.gotmom.org

DESCRIPTION: The lactational amenorrhea method (LAM) is contingent upon nearly exclusive or exclusive, frequent breastfeeding. LAM is an effective method only under specific conditions:

- Woman breast-feeding exclusively; both day and night feedings (at least 90% of baby's nutrition derived from breast-feeding)
- The woman is amenorrheic (spotting which occurs in the first 56 days postpartum is not regarded as menses)
- The infant is less than 6 months old

In the U.S., the median duration of breast-feeding is about 3 months. It is important to provide a woman with another method to use when she no longer fulfills all the conditions. **The probability that ovulation will precede the first menstrual period in a lactating woman increases from 33-45% during the first 3 months to 64-71% during months 4 to 12 and 87% after 12 months. Among lactating women, 66% are sexually active in the first month postpartum and 88% are sexually active in the second month postpartum** ***[Ford - 1998]***

EFFECTIVENESS: Controlled Studies

Life table pregnancy rate at 6 months: 0.45 and 2.45% in 2 published studies ←
Uncontrolled studies: range from 0 - 7.5% *[Cochran Review-2008]* ←
At any time a woman is concerned, emergency contraception may be used by a nursing mother

MECHANISM: Suckling causes a surge in maternal prolactin, which inhibits ovulation. If ovulation occurs and fertilization occurs, the contraceptive effect of breastfeeding may be partly due to inhibiting implantation of a fertilized egg.

COST: None

ADVANTAGES OF BREASTFEEDING

Menstrual: Involution of the uterus occurs more rapidly; suppresses menses
Sexual/psychological: Breast-feeding pleasurable to many women

- Facilitates bonding between mother and child (if not stressful)

Cancers, tumors, and masses: Reduces risk of ovarian cancer and endometrial cancer
Other:

- Provides the healthiest, most "natural" food for baby
- Protects baby against gastrointestinal and respiratory infecions, otitis media ←
- Facilitates postpartum weight loss
- No cost and less time preparing bottles and feedings

DISADVANTAGES

Menstrual: Return to menses unpredictable
Sexual/psychological:

- Breastfeeding mother may be self-conscious in public or during intercourse
- Hypoestrogenism of breastfeeding may cause temporary atrophic vaginal changes
- Tender breasts may decrease sexual pleasure

Cancers, tumors, and masses: None
Other:

- Working women need support to find time/place/resources to pump
- Effectiveness after 6 months is markedly reduced; return to fertility often precedes menses
- Frequent breastfeeding may be inconvenient or perceived as inconvenient
- No protection against STIs, HIV, AIDS
- If the mother is HIV+, there is a 14%-29% chance that HIV will be passed to infant via breast milk. Antiretroviral therapy decreases risk of transmission. Breastfeeding is not recommended for HIV+ women in the U.S.
- Sore nipples and breasts; risk of mastitis associated with breast-feeding

COMPLICATIONS: Risk of mastitis; return of fertility can precede menses

CANDIDATES FOR USE

- Amenorrheic women less than 6 months postpartum who exclusively breast-feed their babies
- Women free of a blood borne infection which could be passed to the newborn
- Women not on drugs which can adversely affect their babies

MEDICAL ELIGIBILITY CHECKLIST

Ask the patient the questions below. If she answers "NO" to ALL questions, she can use LAM. If she answers Yes to any questions, follow the instructions. Sometimes there is a way to incorporate LAM into her contraceptive plans; in other situations, LAM is contraindicated.

1. Is your baby 6 (3) months old or older?

☐ No ☐ Yes Help her choose another method to supplement the contraceptive effect of LAM. Some experts recommend 3 months since 20% of breastfeeding women ovulate by that time

2. Has your menstrual period returned? (Bleeding in the first 8 weeks after childbirth does not count)

☐ No ☐ Yes After 8 weeks postpartum, if a woman has 2 straight days of menstrual bleeding, or her menstrual period has returned, she can no longer count on LAM as her contraceptive. Help her choose method appropriate for breastfeeding woman

3. Have you begun to breastfeed less often? Do you regularly give the baby other food or liquid (other than water)?

☐ No ☐ Yes If the baby's feeding pattern has just changed, explain that patient must be fully or nearly fully breastfeeding around the clock to protect against pregnancy. If not, she cannot use LAM effectively. Help her choose method appropriate for breastfeeding woman

4. Has a health-care provider told you not to breastfeed your baby?

☐ No ☐ Yes If a patient is not breastfeeding, she cannot use LAM. Help her choose another method. A woman should not breastfeed if she is taking mood altering recreational drugs, reserpine, ergotamine, antimetabolites, bromocriptine, tetracycline, radioactive drugs, lithium, or certain anticoagulants (heparin and coumadin are safe); if her baby has a specific infant metabolic disorder; or possibly if she carries viral hepatitis or is HIV positive. All others can and should consider breastfeeding for the health benefits to the infant. In 1997, the FDA advised the manufacturer of Prozac (fluoxetine) to revise its labeling; it now states that "nursing while on Prozac is not recommended." Multiple reviews conclude that women using SSRIs should be encouraged to continue breastfeeding *[Nulman Tetralogy, 1996][Briggs, 2002]* and that the overall benefits of SSRIs for depressed breastfeeding women outweigh the risks *[Edwards, 1999]*

5. Are you infected with HIV, the virus that causes AIDS?

☐ No ☐ Yes Where other infectious diseases kill many babies, mothers should be encouraged to breastfeed. HIV, however, may be passed to the baby in breast milk. When infectious diseases are a low risk and there is safe, affordable food for the baby, advise her to feed her baby that other food. Help her choose a birth control method other than LAM. A meta-analysis of published prospective trials estimated the risk of transmission of HIV with breastfeeding is 14% if the mother was infected prenatally but is 29% if the woman has her primary infection in the postpartum period

6. Do you know how long you plan to breastfeed your baby before you start supplementing his/her diet?

☐ No ☐ Yes In the U.S. the median duration of breastfeeding is approximately 3 months. Often breastfeeding women do not know when their menses will return, when they will start supplementing breastfeeding with other foods or exactly when they will stop breastfeeding their infant. It is wise to provide a woman with the contraceptive she will use when the answer to one of the above questions becomes positive and with a backup contraceptive and EC even during the period when breast-feeding is effective

INITIATING METHOD

- Patient should start exclusively breastfeeding immediately or as soon as possible after delivery
- Ensure that woman is breastfeeding fully or almost fully (>90% of baby's feedings); feedings around the clock
- A woman working outside of the home requires a breastfeeding-friendly environment, and preferably on-site childcare so that woman can visit her child every few hours to breastfeed; otherwise, breast pumping is needed
- Encourage use of second method of contraception if any questions about LAM effectiveness

INSTRUCTIONS FOR PATIENT

- Refer to lactation consultant/La Leche League for support/resources (www.lalecheleague.org)
- Breastfeed consistently, exclusively and correctly for maximum effectiveness
- Breast milk should constitute at least 90% of baby's feedings
- Think about methods that can be used once menses return or at 6 months

PROBLEM MANAGEMENT

Deficient milk supply:

- The more a breast is emptied, the more it fills up, therefore, increase feedings or pumpings
- Commonly caused by insufficient nursing, use of artificial nipple (e.g. pacifier), fatigue or maternal stress
- Encourage woman to breastfeed often (8-10 times daily), eat well, get additional rest, drink lots of fluids and take prenatal vitamins and iron supplements
- Immediately postpartum women should breastfeed every 2-3 hours to stimulate milk production
- Seek assistance from a lactation specialist
- Avoid high-dose estrogen-containing contraceptives

Sore nipples:

- Commonly caused by incorrect application of the baby's mouth to the breast. Uncommonly caused by infection
- Check for correct ways of latching and suckling; be sure to break the suction before removing the baby from the breast
- Improve with practice; change the pressure points on the nipple by changing the baby's position for feeding
- Allow nipples to air dry with breast milk on the areola to reduce infection and nipple soreness. Apply lanolin to nipples after each feeding to decrease soreness after nipples have air dried
- Do not cleanse breasts other than with water at any time
- Cool gel packs are available to decrease soreness

Sore breasts:

- Wear a well-fitted, supportive nursing bra; avoid bras that are too tight or have underwire
- Apply heat on sore areas; some women apply teabag as compress on sore nipples
- Nurse frequently or use pump to get excess milk out of affected breast
- Use of an anti-inflammatory agent and a complex of bromelain/trypsin both significantly improved symptoms of engorgement. *[Cochrane Database of systematic reviews. Treatments for breast engorgement during lactation. 2008]*
- Encourage additional rest
- Seek medical evaluation if any erythema, fever or other signs or symptoms of infection develop

Other:

- Stress, fear, lack of confidence, lack of strong motivation to succeed at breastfeeding, lack of partner and/or societal support, and/or poor nutrition can cause problems

FERTILITY AFTER USE: Patient's baseline fertility (ability to become pregnant) is not altered once patient discontinues breastfeeding

TEN STEPS TO SUCCESSFUL BREASTFEEDING

From: Protecting, Promoting and Supporting Breastfeeding: The special role of maternity services. (A joint WHO/UNICEF statement. Geneva, WHO, 1989)

All healthcare facilities where childbirth is undertaken should:

1. **Have a written breastfeeding policy that is routinely communicated to all health care staff.**
2. **Train all health care staff in skills necessary to implement this policy.**
3. **Inform all pregnant women about the benefits and management of breastfeeding.**
4. **Help mothers initiate breastfeeding within the first 30 minutes after birth.**
5. **Show mothers how to breastfeed and how to maintain lactation even if they are separated from their infants because of a medical reason.**
6. **Give newborn infants no milk feeds or water other than breast milk unless indicated for a medical reason.**
7. **Allow mothers and infants to remain together 24 hours a day from birth.**
8. **Encourage natural breastfeeding on demand.**
9. **Do not give or encourage the use of artificial nipples to breastfeed infants.**
10. **Promote the establishment of breastfeeding support groups and refer mothers to these on discharge from the hospital or clinic.**

The importance of breastfeeding has been highlighted by the U.S. Department of Health and Human Services. Year 2010 goals: 75% of women will initiate breastfeeding and 50% will continue for 6 months

CHAPTER 16

Breastfeeding and Contraceptive Decisions

www.lalecheleague.org OR www.breastfeeding.com

All breastfeeding women should be provided contraception because:

- Duration of breastfeeding in the U.S. is brief (median: under 3 months)
- Most couples resume intercourse a few weeks after delivery
- Ovulation may precede first menses
- LAM is an appropriate choice when fully breastfeeding

Table 16.1 ***When to initiate contraception in breastfeeding women:***

METHOD	WHEN TO START IN LACTATING WOMEN	EFFECT ON BREAST MILK
Condoms (Male & Female), Sponge	• Immediately	No effect
Cervical Cap, Diaphragm	• 4-6 weeks postpartum, after cervix and vagina normalized (need to be refitted for postpartum women)	No effect
Progestin-Only Methods • Depo-Provera • Progestin - Only Pills • Implanon	• New CDC Medical Eligibility Criteria 2010 (see appendix) allows for starting progestin-only methods in first month PP. They give this a category 2 which means method can be used because advantages outweigh theoretical or proven risks.	• No significant impact on milk quality or production • Breast-feeding prolonged • Breast fed children of DMPA users grow at normal rate
Combined Pills Patch Vaginal Ring	• American Academy of Pediatrics recommends use of low-dose combined hormonal contraceptives when infant' is not relying solely on breastmilk. No sooner than 3-6 weeks postpartum • New CDC Medical Eligibility Criteria 2010 (see appendix) gives use of CHC in breastfeeding women a category 2 at 1 month PP meaning advantages outweigh disadvantages*	Quality and quantity of breast milk may be diminished if used prior to establishment of lactation. After lactation establishment, low-dose COCs have no significant impact
IUD: • Copper • Levonorgestrel	• Usually await uterine involution to insert (4-6 weeks) • May insert Copper or Levonorgestrel IUD within first 10 minutes after delivery of placenta with special technique	No effect with Paragard. Mirena - same as other progestin-only methods
Tubal Sterilization	Usually done in first 24-48 hours postpartum, or await complete uterine involution for interval tubal sterilization (laparoscopy or Essure) (> 6 weeks postpartum)	No effect

**CDC considering change to category 2 or 3 for the 3-6 week post partum period depending on a woman's risk factors for VTE.*

CHAPTER 17

Fertility Awareness Methods (FAM)

www.usc.edu/hsc/info/newman/resource/nfp.html
www.cyclebeads.com OR www.irh.org

DESCRIPTION: FAMs should only be used by women with regular menstrual cycles. They involve monitoring the cycle and having intercourse only during infertile phases or using another method, e.g. condoms, during fertile phases. A woman cannot identify the exact day of ovulation using FAM methods; rather she estimates when the fertile phase of her cycle begins and ends. A woman's fertile phase may begin 3-6 days before ovulation (because sperm can live in cervical mucus for 3-6 days) and ends 24 hours after ovulation

For purposes of FAM, a woman's menstrual cycle has 3 phases:

1. *Infertile phase:* before ovulation
2. *Fertile phase:* Approximately 5-7 days in the mid-portion of the cycle, including several days before and the day after ovulation;
3. *Infertile phase:* after the fertile phase

During the fertile phase, a couple should be abstinent or use a barrier method to avoid pregnancy. Of the FAM methods discussed, the Calendar Method, Standard Days Method, and the Cervical Mucus Method can be used to identify the beginning and the end of the fertile period; the BBT Method can only be used to identify the end of the fertile period. Thus, couples using the BBT Method could only safely have unprotected intercourse during the post-ovulatory period, as the method cannot be used to define the pre-ovulatory infertile phase. As couples using either the Calendar or the Cervical Mucus Methods can theoretically identify the beginning and the end of the fertile period, they may have unprotected intercourse during the pre-ovulatory infertile phase and the post-ovulatory infertile phase. However, in order to minimize the chance of an unintended pregnancy, some advocate that couples only have unprotected intercourse during the post-ovulatory infertile phase regardless of the method of FAM they are using.

Comparative efficacy of FAM methods is unknown due to poor subject retention in efficacy trials *[Grimes-2005]*

Techniques used to determine high-risk fertile days include:

1. Calendar Method: To calculate the fertile days:

- Record days of menses prospectively for 6-12 cycles
- Most estimates assume that sperm can survive 2-3 days and ovulation occurs 14 days before menses (motile sperm have been found as long as 7 days after intercourse and the extreme interval following a single act of coitus leading to an achieved pregnancy is 6 days *[Speroff-1999]*)
- Earliest day of fertile period = day # in a cycle corresponding to **shortest cycle length minus 18**
- Latest day of fertile period = day # in a cycle corresponding to **longest cycle length minus 11**

2. Standard Days Method Utilizing Color-Coded Beads; cyclebeads™

- For women with MOST cycles 26-32 days long, avoid UNPROTECTED intercourse on days 8-19 (white beads on CycleBead necklace). No need for 3-6 months of extensive cycle calculations
- 4.75% failure over 1 year with perfect use; 11.96% with typical use *[Arevalo-2002]*
- Resources available from the Institute for Reproductive Health, www.irh.org (CD, training manual, patient brochure, sample beads). Beads can also be ordered from www.cyclebeads.com

3. Cervical Mucus Ovulation Detection Method

- Women check quantity and character of mucus on the vulva or introitus with fingers or tissue paper each day for several months to learn cycle:
  - Post-menstrual mucus: scant or undetectable
  - Pre-ovulation mucus: cloudy, yellow or white, sticky
  - Ovulation mucus: clear, wet, stretches, sticky (but slippery)
  - Post-ovulation fertile mucus: thick, cloudy; sticky
  - Post-ovulation post-fertile mucus: scant or undetectable

- When using method during preovulatory period, must abstain 24 hours after intercourse to make test interpretable as semen and vaginal fluids can obscure character of cervical mucus
  - Abstinence or barrier method through fertile period (ie abstinence for a given cycle begins as soon as the woman notices any cervical secretions)
  - Intercourse without restriction beginning 4th day after the last day of wet, clear, slippery mucus (post ovulation)

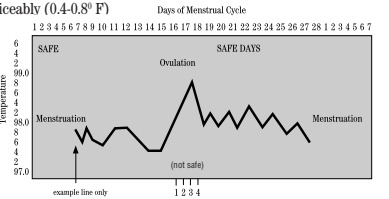
4. TwoDay Method

- Uses cervical secretions, but is much simpler
- Each day woman asks herself 1.) "Did I notice secretions today?" and 2.) Did I notice secretions yesterday?
- If no secretions two consecutive days, OK to have intercourse

5. Basal Body Temperature Method (BBT)

- Assumes early morning temperature measured before arising will increase noticeably (0.4-0.8^0 F) with ovulation; fertile period is defined as the day of first temperature drop or first elevation through 3 consecutive days of elevated temperature. Temperature drop does NOT always occur
- Abstinence begins first day of menstrual bleeding and lasts through 3 consecutive days of sustained temperature rise (at least 0.2^0 C or 0.4^0 F)

Figure 17.1 Basal body temperature variations during a menstrual cycle



6. Post-ovulation Method

- Permits unprotected intercourse only after signs of ovulation (BBT, cervical mucus, etc) have subsided

7. Symptothermal Method

- Combines at least two methods — usually cervical mucus changes with BBT
- May also include mittelschmerz, change in libido, and changes in cervical texture, position and dilation to detect ovulation:
  - During preovulatory and ovulatory periods, cervix softens, opens and is moister
  - During postovulatory period, cervix drops, becomes firm and closes

EFFECTIVENESS (see Table 13.2, page 38)

NFP/FAM First-year failure rate (100 women-years of use)

Method	***Typical use****	***Perfect use***
Calendar	25	9
Standard Days Method	12	5
Ovulation Method	25	3
Symptothermal	25	2
Post-ovulation	25	1
TwoDay Method	13.7	3.5 *[Arevalo-2004] [Dunson-2001]*

*FAM usually more effective than NFP *[Trussell IN Contraceptive Technology, 2004]*

HOW FAM WORK: Abstinence or barriers used during fertile period

COST: Training, supplies (special digital basal body thermometer, Cycle Beads, charts)

ADVANTAGES

Menstrual: No change. Helps woman learn more about her menstrual physiology

Sexual/psychological: Men and women can work together in using this method. Men must be aware that abstinence or use of second method is essential during the fertile period

Other:

- May be only method acceptable to couples for cultural or religious reasons
- Helps couples achieve pregnancy when practiced in reverse

DISADVANTAGES

Menstrual: No effect on menses ←

Sexual/psychological:

- Requires rigorous discipline, good communication and full commitment of both partners
- Requires abstinence, barrier method, or another contraceptive that does not change pattern of ovulation during 6-12 month learning/data-gathering period (unless CycleBead method is used)
- Complete abstinence in an anovulatory cycle, if using post-ovulation techniques. This method demands great self-control: either abstinence or use of another method must be used during long periods of time when woman is or may become fertile
- Requires abstinence at time of ovulation, which typically is the time of peak libido

Cancers, tumors, and masses: None

Other:

- Difficult to use in early adolescence, when approaching menopause, and in postpartum women when cycles are irregular (or absent)
- Even women with "regular" periods can vary as much as ± 7 days in any given cycle
- Cervical mucus techniques may be complicated by vaginal infections
- May not be helpful during time of stress
- Method very unforgiving of improper use
- Does not protect against STIs
- Relatively high failure rate with typical use
- Less reliable in settings of fever, vaginal infections, douching, and use of certain medications

COMPLICATIONS: None

CANDIDATES FOR USE

- Women with regular menstrual cycles at minimal risk for STIs
- Women wanting to avoid hormones and devices
- Those with religious/cultural proscriptions against using other methods
- Highly motivated couples willing to commit to extensive abstinence or to use barriers during vulnerable periods

Adolescents: Not appropriate until regular menstrual cycles established

MEDICAL ELIGIBILITY CHECKLIST: Ask the woman the questions below. If she answers NO to ALL questions, she CAN use any fertility awareness-based method if she wants. If she answers YES to any question, follow the instructions. No conditions restrict use of these methods, but some conditions can make them harder to use effectively

1. Do you have a medical condition that would make pregnancy especially dangerous?

☐ No ☐ Yes She may want to choose a more effective method. If not, stress careful use of fertility awareness-based methods to avoid pregnancy and availability of EC

2. Do you have irregular or prolonged menstrual cycles? Vaginal bleeding between periods? For younger women: Are your periods just starting? For older women: Have your periods become irregular?

☐ No ☐ Yes Predicting her fertile time with only the calendar method may be hard or impossible. She can use basal body temperature (BBT) and/or cervical mucus, or she may prefer different method

3. Did you recently give birth or have an abortion? Are you breastfeeding? Do you have any other condition that affects menstrual bleeding?

☐ No ☐ Yes These conditions may affect fertility signs, making fertility awareness-based methods hard to use. For this reason, a woman or couple may prefer a different method. If not, they may need more counseling and follow-up to use the method effectively

4. If you recently stopped using Depo-Provera or combined hormonal methods, are your periods still irregular?

☐ No ☐ Yes If her cycles have not been re-established, she may need to use another method until cycles are regular

5. Do you have any infections or diseases that may change cervical mucus, basal body temperatures, or menstrual bleeding—such as sexually transmitted disease (STD) or pelvic inflammatory disease (PID) in the last 3 months, or vaginal infection?

☐ No ☐ Yes These conditions may affect fertility signs, making fertility awareness-based methods hard to use. Once an infection is treated and reinfection is avoided, however, a woman can use fertility awareness-based methods

INITIATING METHOD

- Requires several months of data collection and analysis unless using CycleBeads
- Description of methods
- Formal training necessary. Couples may be trained together

BUYER BEWARE A woman considering use of the fertility awareness methods must be aware of several potential pitfalls, summarized in **the five "R's"**:

- **R**estrictions on sexual spontaneity (method requires periodic abstinence or the use of backup method)
- **R**igorous daily monitoring
- **R**equired training
- **R**isk of pregnancy during prolonged training period
- **R**isk of pregnancy high on unsafe days

INSTRUCTIONS FOR PATIENT

- Requires discipline, communication, listening skills, full commitment of both partners. Mistakes using this method are particularly likely to lead to unintended pregnancies as intercourse is then occurring at the time in the cycle when a woman is *most* likely to become pregnant
- If using FAM, use contraception during fertile days
- If using NFP, abstain from sexual intercourse during fertile days
- Encourage other forms of sexual satisfaction

FOLLOW-UP

- Have you had sexual intercourse during "unsafe" times during your cycle?
- Discuss use of emergency contraception if having sex during "unsafe" times during cycle
- Do you have emergency contraceptive pills at home?

PROBLEM MANAGEMENT

Inconsistent use and risk taking: Educate about emergency contraception when women start using method

FERTILITY AFTER DISCONTINUATION OF METHOD: No effect

CHAPTER 18

Condoms for Men

www.ppfa.org OR condomania.com OR askdurex.com OR www.ansell.com

DESCRIPTION: Condoms for men are sheaths made of latex, polyurethane or natural membranes (usually lamb cecum), which are placed over the penis prior to contact and worn until after ejaculation when the penis is removed from the orifice (vagina, mouth, anus). Latex condoms are available in at least 2 sizes, in a wide variety of textures and thicknesses (0.03-0.09 mm), and come with or without spermicidal coating. Two brands of polyurethane condoms are currently available in the US. When used correctly and consistently, male latex condoms are highly effective in preventing sexual transmission of HIV and can reduce the risk for other STDs (ie gonorrhea, chlamydia and trichomonas). Natural membrane condoms (made from the intestinal cecum of lambs) may not provide the same level of STI protection. Condoms may be used as a primary contraceptive method, as a back up method, or with another method to provide STI risk reduction. **When used as a primary contraceptive method, it is important that condoms be coupled with advance provision/prescription/ advice to buy OTC of emergency contraceptive pills (ECPs) since couples experience a condom break or slippage during approximately 3-5% of acts of intercourse.**

If 14,000 acts of intercourse are protected by condoms, a mishap (breakage, slippage part of the way down the shaft of the penis, or slippage completely off the penis) will occur approximately 5% of the time or 700 times. If couples experiencing breakage or slippage identify this and use Plan B within one hour, only one of those 700 women will experience an unintended pregnancy. The failure rate of Plan B within one hour of unprotected sex is 0.14% or just about 1 in 700 *[Shelton-2002].*

EFFECTIVENESS *[Trussell J IN Contraceptive Technology-2004]*

Perfect use failure rate in the first year of use: 2% (See Table 13.2, page 40)

Typical use failure rate in the first year of use: 18%

- The most common reason for condom failure is not using a condom with every act of intercourse *[Werner-2004] [Steiner-1999]*
- Although comparative testing has shown that latex and polyurethane condoms provide the same pregnancy protection, polyurethane condoms are more likely to slip or break (2.6 to 5 times more likely *[Gallo-2008]*) than latex condoms (1.6-1.7%)
- Dual use of a condom plus another contraceptive may dramatically reduce the risk of both pregnancy and STI. *[Warner-2004][Cates-2002].*
- Recent survey of condom users: the most common reason for nonuse of both condoms (44%) and EC (41%) was that the woman did not perceive she was at risk *[Nelson-2006].*

HOW CONDOMS WORK

- Condoms act as a barrier; they prevent the passage of sperm into the vagina. Sheathing the penis also reduces transmission and acquisition of STIs, including HIV. **Spermicidal condoms are no longer recommended at all as they provide no additional protection against pregnancy or STIs!** Most condom manufacturers have stopped producing spermicidal condoms. Although, a study of 145 couples using over 12,000 condoms found that applying spermicide AFTER the condom is placed on the penis reduces breaks and slips significantly. *[Gabbay-2008]*

COST

- Average retail cost for latex condoms is $0.50, but some designer condoms cost several dollars. Polyurethane condoms cost $.80-$2.00 each
- Public health agencies often offer free condoms. Purchasers of large numbers of condoms may buy condoms for as low as 4 to 6 cents per condom from Ansell and Durex

ADVANTAGES

Menstrual: No direct impact on menses, but couple may feel more comfortable

Sexual/psychological:

- Some men may maintain erection longer with condoms, making sex more enjoyable
- If the woman/partner puts the condom on, it may add to sexual pleasure
- Male involvement is encouraged and is essential!
- Availability of wide selection of condom types and designs can add variety
- Makes sex less messy for the woman by catching the ejaculate
- Intercourse may be more pleasurable because fear of pregnancy and STIs is decreased

Cancers/tumors & masses: Decrease in HIV transmission reduces risks of AIDS-related malignancies

Other:

- Consistent condom use reduces risks of HIV transmission by approximately 10-fold *[Davis-1999] [Pinkerton-1997] [Warner-2004]* See Figure 18.2, page 62
- Consistent condom use reduces risk of cervical and vulvovaginal HPV infection among newly sexually active women *[Winer-2006]*
- Readily available over the counter; no medical visit required
- Usually inexpensive for single use
- Easily transportable. Don't leave in wallet too long; probably ok for 1 month. It has been suggested that a condom be placed between photographs in a wallet to protect against damage
- Opportunity for couples to improve communication and negotiating skills
- Immediately active after placement
- May reduce risk of PID, infertility, ectopic pregnancy and chronic pelvic pain

DISADVANTAGES: May break or fall off. *Options: see Fig. 18.3, p. 62*

Menstrual: None

Sexual/psychological:

- Use may interrupt lovemaking. Requires discipline to resist impulse to progress to intercourse after erection
- May cause man to lose erection
- Blunting of sensation or "unnatural" feeling with intercourse
- Plain condoms may decrease lubrication and provide less stimulation for woman (use water-based or silicone lubricant with latex condoms if this is a problem)
- Requires prompt withdrawal after ejaculation, which may decrease pleasure
- Makes sex messier for the man

Cancers/tumors and masses: None

Other:

- Requires education/experience for successful use
- Either member of couple may have latex allergy or reaction to spermicide; polyurethane condom is appropriate alternative
- Users must avoid petroleum-based vaginal products when using latex condoms (Figure 18.1, p. 61). This is not a problem with polyurethane condoms
- Couples may be embarrassed to purchase or to apply condoms due to taboos about touching genitalia, stigma of concern about STDs/HIV

COMPLICATIONS

- Allergic reactions to latex are rarely life threatening; 2-3% of Americans (men and women) have a latex allergy; up to 14% of individuals working with latex are latex sensitive. Polyurethane condoms do not cause allergic reactions
- Condom retained in vagina (uncommon) exposes woman to risk of infection as well as pregnancy. If this occurs: 1) try to remove by pinching with second and third fingers or 2) enlist partner's help or 3) go to clinician ASAP. Use EC ASAP

PRECAUTIONS

- Men who are unable to maintain erection when they wear condoms; benzocaine condoms by Durex are now available to prevent premature ejaculation, but studies have not proven a benefit
- Men with abnormal ejaculatory pathways not sheathed by condom
- Woman whose partners will not use condoms
- Women who require high contraceptive efficacy should not be using condoms as their primary contraceptive method. They should, at a minimum, add another more effective method
- Couples in which either partner has latex allergy should avoid latex condoms; men can use Durex-Avanti or Trojan-Supra; women can use Reality female condom
- Couples in which either partner has spermicide allergy or is at high risk for HIV should avoid spermicide-coated condoms

CANDIDATES FOR USE

- Anyone at risk for an STI; appropriate for most couples
- May be used alone or coupled with a second contraceptive method

Special applications for infection control:

- Non-monogamous couples (i.e. if either partner has multiple partners)
- During pregnancy as well as at all other times
- After delivery or pregnancy loss to reduce risk of endometritis (although abstinence is preferable)
- Couples with known viral infections (HIV, HPV, HSV-2) in areas completely covered by device

Adolescents: Excellent option, especially when combined with another method

INITIATING METHOD

Couples desiring to use condoms often benefit from concrete instructions. Use a model and actual condom. Counsel new users about:

- Options among condom types
- Storage for safety and ready access
- How to negotiate condom use with partner and when to place condom *[Warner-2004]*
- How to open package and place correct side of condom over penis
- How to unroll and allow space for ejaculate (depending on condom design)

Provide ECPs to couples relying on the condom for birth control to insure immediate use in the event of condom mishap or problem.

- Specific instructions given to men on correct use decreases breakage and slippage *[Steines-2007]*

INSTRUCTIONS FOR PATIENTS (See Figure 18.1, pg. 61)

- Learn how to use a condom long before you need it. Both women and men need to know how. Practice with models: fingers or banana
- Buy condoms in advance, carry with you; Keep extra condoms out of sunlight and heat
- Try new condoms to find favorite size, scent, and texture and to add variety

- Check date on condom carefully. It may be an expiration date OR a date of production. If it is an expiration date, do not use beyond expiration date. If it is a date of production, condom may be used for several years from the date of production (2 years for spermicidal condoms, 5 years for nonspermicidal latex condoms)
- Open package carefully, squeeze condom out, avoid tearing with fingernails, teeth, scissors, etc.
- Use appropriate water-based or silicone-based lubricant with latex condoms (see page 61). Never put lubricant inside the condom
- Place condom over penis before any genital contact. Either partner can put it on!
- Consider placing a second condom (larger size) over lubricated condom if history of previous breakage or if man has any evidence of STI
- If condom used for oral or rectal intercourse replace with a new condom prior to vaginal entry
- Vigorous sex can break the condom. Consider using 2 condoms at once
- Immediately after ejaculation (before loss of erection) hold rim of condom against shaft of penis and remove condom-covered penis from vagina (or anus). One study found only 71% of men held the rim of the condom during withdrawal and only 50% withdrew immediately after ejaculation *[Warner-1999]*
- Remove condom from the penis and inspect carefully for any breaks
- Dispose of used condom. Do not reuse
- If a condom falls off, slips, tears or breaks, start using ECPs as soon as possible. Plan B is available OTC for women and men > 18 y/o. If you do not have ECPs, call 1-888-NOT-2-LATE or check www.not-2-late.com to find out how to get them. You can get EC from a pharmacist without a prescription. If any risk for STIs, seek medical care

FOLLOW-UP

- Are you and your partner comfortable using condoms?
- Have you had any problems with using the condom? Breaking? Slipping off? Decreased sensation? Vaginal soreness with use? Skin irritation or redness during the day after using it?
- Have you had any post-coital "yeast infection" symptoms? (A woman may confuse an allergic reaction to the condom and/or spermicide with a candidal infection)
- Have you had intercourse—even once—without a condom?
- Did you have any questions about ECPs?
- Do you have Plan B ECPs at home?
- Do you plan to have children? OR Do you plan to have more children? When?

PROBLEM MANAGEMENT

Allergic reaction: *[See Warner-2004]*

- Beware that latex can induce anaphylaxis and that the severity of allergic reaction increases with continued exposure. Sometimes a person who says he (or she) is ***"allergic"*** to condoms may mean condoms a) are difficult to put on or b) lead to loss of erection or c) the couple simply doesn't like condoms or d) is being irritated by a spermicide or lubricant or e) an ongoing infection may be causing irritation. Irritation can also be caused by thrusting during sex. Couple may try another brand of latex condoms
- Switch to polyurethane condoms (Durex, 2 Avanti condoms or Trojan-Supra male condoms, Mayer Laboratories eZ-on, or female condom) or stop using spermicide (depending on the suspected allergen or irritant)
- Switch to another approach to reducing STI risk and contraception, such as the female condom for STI risk reduction and a hormonal method for contraceptive effectiveness

Condom breakage: (Figure 18.3, p. 62) (1-2% for latex condoms)

- Insure correct technique. Common problems: pre-placement manipulations (stretching, etc), use of inappropriate lubricant (placement inside condom), and prolonged or extremely vigorous sex

- May need to recommend larger condom. The 18th edition of ***Contraceptive Technology*** (pages 147-152) lists characteriestics of hundreds of U.S. condoms. The largest are: Kimono, Kimono Microthin, Magnum, MAXX, and Trojan Very Sensitive
- If couple using polyurethane, consider switching to latex condom
- May need to switch method
- Confirm that woman is using ECPs and has supply available at home

Condom slippage: (Figure 18.3, p. 62) (More common than condom breakage)

- Ensure correct technique. Common problems: condom not fully unrolled, lubricant placed incorrectly on inside of condom, and excessive delay in removing penis from vagina after ejaculation. Use of proper-sized condom is important (if condom is too large it may slip off). "Snugger fit" condoms are available
- Rule out erectile dysfunction. Condoms may not be appropriate if man loses erection with condom placement or use
- Confirm that woman is using ECPs and has supply available at home

Decreased sensation:

- Common causes: condom too small, too thick or too tightly applied; inadequate lubrication
- Suggest experimentation with different textured condoms or placing second (larger size) condom over inner lubricated condom. Thinner condoms now available
- Integrate condom placement into lovemaking (suggest partner place condom to help arouse/excite man)

FERTILITY AFTER DISCONTINUATION OF METHOD

- Does not affect baseline fertility
- May protect fertility by reducing risk of STIs

Figure 18.1

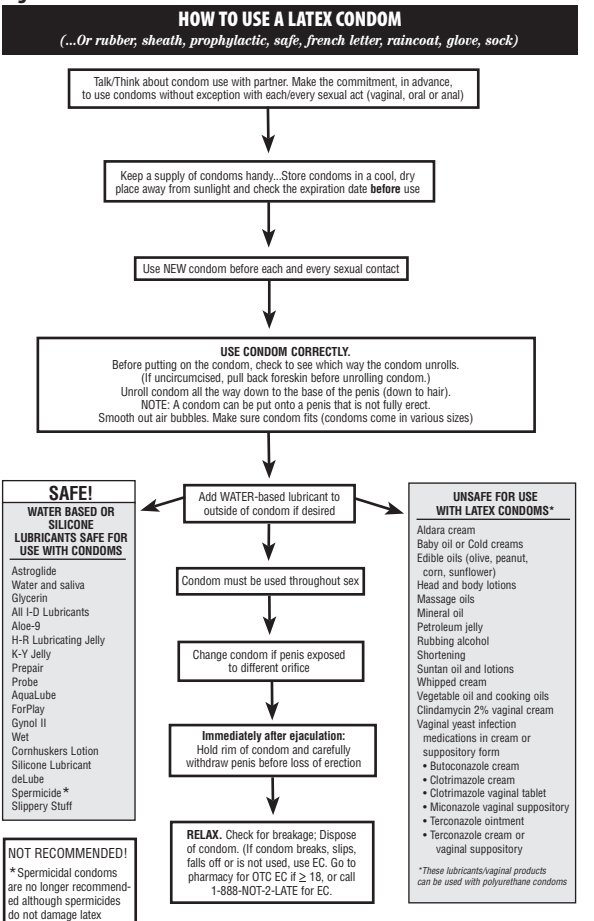
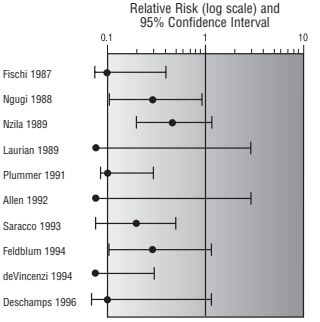
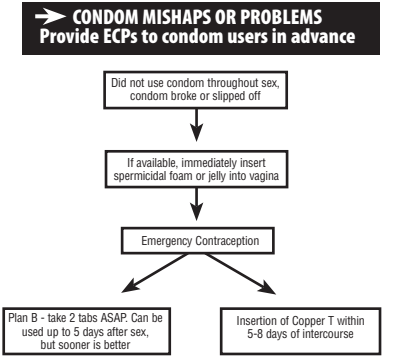

HOW TO USE A LATEX CONDOM
(...Or rubber, sheath, prophylactic, safe, french letter, raincoat, glove, sock)
Talk/Think about condom use with partner. Make the commitment, in advance, to use condoms without exception with each/every sexual act (vaginal, oral or anal)
Keep a supply of condoms handy...Store condoms in a cool, dry place away from sunlight and check the expiration date **before** use
Use NEW condom before each and every sexual contact
USE CONDOM CORRECTLY.
Before putting on the condom, check to see which way the condom unrolls.
(If uncircumcised, pull back foreskin before unrolling condom.)
Unroll condom all the way down to the base of the penis (down to hair).
NOTE: A condom can be put onto a penis that is not fully erect.
Smooth out air bubbles. Make sure condom fits (condoms come in various sizes)
SAFE!
WATER BASED OR SILICONE LUBRICANTS SAFE FOR USE WITH CONDOMS
Astroglide
Water and saliva
Glycerin
All I-D Lubricants
Aloe-9
H-R Lubricating Jelly
K-Y Jelly
Prepair
Probe
AquaLube
ForPlay
Gynol II
Wet
Cornhuskers Lotion
Silicone Lubricant
deLube
Spermicide*
Slippery Stuff
NOT RECOMMENDED!
*Spermicidal condoms are no longer recommended although spermicides do not damage latex
Add WATER-based lubricant to outside of condom if desired
Condom must be used throughout sex
Change condom if penis exposed to different orifice
Immediately after ejaculation: Hold rim of condom and carefully withdraw penis before loss of erection
RELAX. Check for breakage; Dispose of condom. (If condom breaks, slips, falls off or is not used, use EC. Go to pharmacy for OTC EC if ≥ 18, or call 1-888-NOT-2-LATE for EC.
UNSAFE FOR USE WITH LATEX CONDOMS*
Aldara cream
Baby oil or Cold creams
Edible oils (olive, peanut, corn, sunflower)
Head and body lotions
Massage oils
Mineral oil
Petroleum jelly
Rubbing alcohol
Shortening
Suntan oil and lotions
Whipped cream
Vegetable oil and cooking oils
Clindamycin 2% vaginal cream
Vaginal yeast infection medications in cream or suppository form
• Butoconazole cream
• Clotrimazole cream
• Clotrimazole vaginal tablet
• Miconazole vaginal suppository
• Terconazole ointment
• Terconazole cream or vaginal suppository
*These lubricants/vaginal products can be used with polyurethane condoms

Figure 18.2 10 Studies demonstrating protective effect of latex condoms against HIV transmission in heterosexual couples



[Feldblum et al., 1995]

Figure 18.3



CHAPTER 19

Female-Controlled Barrier Methods

www.femalehealth.com, www.cervcap.com, www.femcap.com, www.lea.com, www.plannedparenthood.org

DESCRIPTION

- Two cervical caps are FDA approved and currently available in the US: FemCap and Lea's Shield. Both caps are made of silicone rubber (latex-free), cover the cervix completely, and create suction between the cervix and the cap.
- The Ortho All-FlexTM diaphragm is now made of silicone; a dome-shaped device placed to cover the cervix, and held in place by the vagina. Currently, diaphragms must be fitted by a clinician. Both caps and the diaphragm are reusable, but should be replaced with any signs of wear and tear, or damage.
- The TodayTM contraceptive sponge is no longer being produced as of 2008. Sponges made before production stopped may still be available for purchase.
- The female condom: a disposable, single use, polyurethane (FC) or nitrile (the FC2) sheath placed in the vagina.
- When used as a primary method, these barrier methods should be coupled with counseling to have ECP on hand at home.

EFFECTIVENESS

- The failure rate for the FemCap in the package insert is 29%
- A small study of women using Lea's Shield showed an 8.7% failure rate over 6 months with typical use *[Mauck-1996]*
- A recent Cochrane Review conducted by FHI found pregnancy rates during one year of use to be 11% to 13% for the diaphragm

Diaphragm:	***Perfect use failure rate in first year:***	6%
	Typical use failure rate in first year:	16% *[Trussell]*
Female Condom:	***Perfect use failure rate in first year:***	5%
	Typical use failure rate in first year:	21% *[Trussell]*

HOW THEY WORK: Act both as a mechanical barrier to sperm migration into the cervical canal and as a chemical agent by applying spermicide directly to the cervix

ADVANTAGES

Menstrual: none

Sexual/psychological:

- Intercourse may be more pleasurable because fear of pregnancy is reduced
- Controlled by the woman
- Can be inserted several hours before sexual intercourse to permit spontaneity
- Can remain in place for multiple acts of intercourse up to 24 hours (diaphragm) to 48 hours (cervical cap) total from time of placement (except for female condom)

Cancers, tumors and masses

- Follow-up studies of earlier cervical caps show no associated increase in cervical dysplasia with use. Labeling of current cervical caps or diaphragms does not require additional pap smears

Other:
- May reduce risk of cervical infections, including gonorrhea, Chlamydia, and PID, but offers no protection against HIV infection
- Immediately active after placement
- May be used during lactation

DISADVANTAGES

Menstrual: none
Sexual/psychological:
- Requires placement prior to genital contact, which may reduce spontaneity of sex
- Some women do not like placing fingers or a foreign body into their vagina

Other:
- Lack of protection against HIV and some STD's. Must use condoms if at risk
- Higher failure rates than with hormonal contraception
- Odor may develop if left in place too long or if not appropriately cleaned (if reusable)
- Severe obesity or arthritis may make insertion/removal difficult

COMPLICATIONS

- UTI's may increase
- Superficial cervical erosion may occur causing vaginal spotting and/or cervical discomfort and discontinuation
- No cases of toxic shock syndrome have been reported, but theoretically, the risk may be increased if these methods are left in too long or used during menses

CANDIDATES: Women NOT at high risk of HIV

- Women willing and able to insert device prior to coitus and remove it later
- Highly motivated women willing to use with every coital act
- Women with pelvic relaxation are better candidates for cap than for diaphragm
- Woman who is sensitive to use of hormones
- Women and partner(s) who have no sensitivity to spermicides

Adolescents: Appropriate, but requires discipline and preparedness to use consistently and correctly. If at risk for STI's use condoms in addition.

INITIATING METHOD

- Given the high failure rates for these methods, it is important to provide ECP's in advance for use if needed or recommend purchase OTC for adults
- A speculum and bimanual exam is recommended before initiating use. Should not be used in the presence of vaginal infections, or vaginal or cervical abrasions
- Patient labeling for each device explains how to insert and remove. Demonstrate placement and removal during your exam, and allow the patient to demonstrate placement and removal before she leaves the office/clinic
- Additional spermicide is not necessary for additional acts of intercourse
- Encourage use of a back-up method for the first few uses until she is confident with correct use. Continual use of male condoms with these methods will reduce pregnancy and STI risk
- If device dislodges during use, EC should be used ASAP.
- For reusable devices, instruct the woman to wash with mild soap and water after each use, dry, and store in container until next use. The sponge and female condom should be disposed of after removal
- Recent gel use with a diaphragm, such as Replens, does not inhibit testing for HPV, urine GC/CT, or cervical cytology quality

FOLLOW-UP

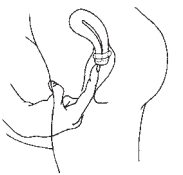
- Are you or your partner noticing any discomfort during sex?
- Do you notice an odor when you remove the device?
- Have you had any burning with urination, vaginal irritation or itching?
- Do you use the device every single time you have sexual intercourse?
- For the cap or diaphragm, do you always apply spermicide before insertion?
- Do you have ECP at home?

PROBLEM MANAGEMENT

- Spotting/cervical or vaginal discomfort/erosion: Rule out infection; stop use to allow healing; consider different size or alternative method
- Urinary tract infections: Urinate postcoitally to reduce bladder contamination with vaginal bacteria. Check fit to be sure there is not excessive urethal pressure
- Odor upon removal: Rule out infection. Try Listerine soaks if reusable, shorten time left in place, or replace
- Dislodged during sex (ensure proper fit) or other failure to use correctly: Use EC. Provide ECPs to have on hand. Consider alternative method

FERTILITY AFTER DISCONTINUATION

- Immediate return to baseline fertility



CERVICAL CAPS

Lea's Shield:

- Lea's Shield is held in place by the vaginal walls and muscles, so one size fits all
- Requires a prescription for use

Femcap:

- Three sizes available. Approximately 85% of women can be assigned the correct size of FemCap based on their obstetrical history: nulligravid women using the small (22mm) size, parous women who have not delivered vaginally using the medium (26 mm) size, and women who have delivered vaginally using the largest (30 mm) size
- Proper fit can be confirmed in the office or clinic by checking that: insertion instructions have been followed, the cervix is covered entirely, and the device is comfortable for the woman
- FemCap may be bought over the internet at www.femcap.com with recommendation for fit to be checked by clinician

Instructions for Use:

Instructions for use are similar for both types of cervical caps. Detailed instructions specific to each type can be found online at http://www.leasshield.com or www.femcap.com

- Can be placed anytime before sex
- Coat the inside of the bowl and the rim with spermicide. Place a small amount of spermicide along the outer part of the cap.
- In the squatting, leg-up or reclining position, press the rims on each side of the bowl together and hold with the dome of the bowl pointing downward.
- Insert long/thick side first as far into the vagina as possible. Push the device over your cervix so that it covers the cervix completely. Then press upwards to create suction between the cap and your cervix. You might feel air venting out as the suction is created between the cap and the cervix.
- The device should be left in place for at least 6-8 hours after the last act of intercourse, up to 48 hours total.
- To remove, use fingers to grasp loop, twist or push on cap to break the suction (hearing a "pop"), and remove device from the vagina

DIAPHRAGM

- As of 2008, the Ortho All-FlexTM diaphragm is now made of silicone (latex-free). Generic versions are no longer available in the U.S.
- Available only through manufacturer. Current diaphragms need to be fitted by a clinician. The latest version has 4 sizes available.
- On bimanual exam, determine degree of version of uterus; not a good method for extremely anteverted or retroverted uterus. Introduce your third finger into the posterior fornix and and tilt your wrist upward to mark where your index finger/hand contacts the symphysis. Use that measurement as a guide and place a fitting diaphragm in the vagina
- Have woman walk around in your office to test its comfort
- Recheck the fit of the diaphragm each year during annual exam, and whenever there is a 20% weight change and/or pregnancy

Instructions for Use:

- Can be placed up to 6 hours before sex
- Fill inner surface of diaphragm 2/3 full with 2 teaspoons of spermicide
- In the squatting, leg-up or reclining position, press the rims on each side of the diaphragm together and hold with the dome of the bowl pointing downward.
- Insert with the dome side down as far into the vagina as possible. Push the diaphragm over your cervix so that it covers the cervix completely. Prior to each act of coitus, reconfirm correct placement. **For the second and each subsequent act, do not remove the diaphragm but use a condom for additional protection**
- Check to ensure diaphragm is lodged behind symphysis and completely covers the cervix. Bear down and digitally check to ensure that diaphragm does not move from behind pubic arch
- The diaphragm should be left in place for at least 6 hours after the last act of intercourse, up to 24 hours total from the time it was placed

Figure 21.1
Risk of pregnancy increases when a spermicide is not used. Put spermicide on outside and on inside

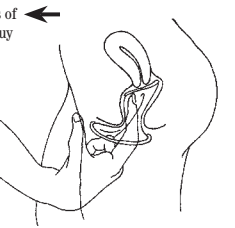
TODAY™ CONTRACEPTIVE SPONGE

- The contraceptive sponge is no longer being produced as of 2009. Sponges made before production stopped may still be available for purchase over the counter.
- The sponge is pre-filled with spermicide that is continuously released into the vagina during use

Instructions for Use:

- Hold the sponge "dimple" side up and thoroughly wet sponge with tap water before insertion. Squeeze the sponge to produce suds
- In the squatting, leg-up or reclining position, press the rims on each side of the sponge together with the dimple still pointing upward
- Insert with the dimple first and loop last as far into the vagina as possible. Push the sponge over your cervix so that the dimple covers the cervix completely. To check positioning, squat or bear down to be sure it does not move
- The Today™ sponge should be left in place for at least **6** hours after the last act of intercourse, up to **24** hours total
- To remove, use fingers to grasp loop and remove device from the vagina. Dispose of sponge after use

THE FC - FEMALE CONDOM



- The "FC" is a polyurethane sheath. The FC2, available as of 2008, is a nitrile sheath that is cheaper to produce and buy
- Sold over-the-counter, without need for prescription ($3.30 - $6.00; $1.50 in public clinic)

Instructions for Use:

- Can be inserted up to 8 hours before sex to allow for spontaneity
- In squatting, leg-up, reclining or lithotomy position, compress inner ring and introduce into vagina guiding sheath high into vagina until outer ring rests against vulva. Rotate inner ring to stabilize device in vault
- Manually place penis in sheath
- Excessive friction between penis and device can cause breakage or device inversion
- Remove condom immediately after intercourse. Twist outer ring to seal off contents and then pull out of vagina. Test condom for patency, then discard
- If condom dislodges or breaks, or if any spillage of ejaculate occurs, use EC ASAP
- If a male latex condom is used with a FC, theoretically, there can be increased risk of breakage of either or both condoms

CHAPTER 20

Spermicides

www.fhi.org OR www.avsc.org/contraception/cspe1.html OR www.microbicide.org

DESCRIPTION: The search for an effective vaginal microbicide that would also kill sperm remains an important research priority, perhaps the most important research priority, in reproductive health. In the USA, nonoxynol-9 (N-9) is available over the counter. In addition to N-9, patients around the world use menfegol, benzalkonium chloride, sodium docusate, and chlorhexidine (but these compounds are not available in the U.S.). Spermicides are available as vaginal creams, films, foams, gels, suppositories, sponges and tablets.

Women at high risk of HIV should not use spermicides (CDC:4). Nor should women who are HIV-infected (CDC:4) *[CDC Medical Eligibility Guidelines-2010]* Condoms without nonoxynol-9 lubrication are effective and widely available. Women at high risk of HIV infection should also avoid using diaphragms and cervical caps to which nonoxynol-9 is added (CDC:3). The contraceptive effectiveness of diaphragms and cervical caps without nonoxynol-9 has been insufficiently studied and should be assumed to be less than that of diaphragms and cervical caps with nonoxynol-9. There is good evidence that N-9 does not protect against STI's and some evidence that it may be harmful by increasing genital irritation *[Cochrane Review-2008]*.

EFFECTIVENESS (See Trussell's failure rates, Table 13.2, p. 40)

Perfect use failure rate in first year: 15%

Typical use failure rate in first year: 28% *[Trussell J IN Contraceptive Technology, 2004]*

While an application of a spermicide into the vagina is an appropriate backup contraceptive (including use with a condom), **spermicidal condoms are no longer recommended at all** as they provide no additional protection against pregnancy or STIs vs. condoms without spermicide. *[Warner-2004]*

- Cochrane review of spermicides for contraception found the probability of pregnancy varied widely in trials. A gel with 52.5 mg N-9 was significantly less effective than gels with higher N-9 doses (100 mg, 150 mg). Gel was liked more than film and suppositories in largest trial *[Grimes-2005]*

MECHANISM: As barriers, the vehicles prevent sperm from entering the cervical os. As detergents, the chemicals attack the sperm flagella and body, reducing motility

ADVANTAGES

Menstrual: None

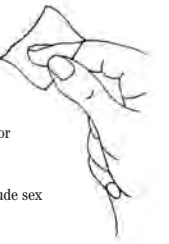
Sexual/psychological:

- Lubrication may heighten satisfaction for either partner
- Ease in application prior to sexual intercourse
- Either partner can purchase and apply; requires minimal negotiation

Other:

- Available over the counter; requires no medical visit
- Inexpensive and easy to use
- Foam and spermicidal jelly are immediately active with placement
- May be used during lactation

DISADVANTAGES



Menstrual: None

Sexual/psychological:

- Films and suppository spermicides require 15 minutes for activation, which may interrupt or delay lovemaking
- Must feel comfortable inserting fingers into vagina
- Insertion is not easy for some couples due to embarrassment or reluctance to touch genitalia
- Some forms, e.g., foam, become "messy" during intercourse
- Possible vaginal, oral, and anal irritation can disrupt or preclude sex
- Taste may be unpleasant

Cancers, tumors, and masses: None

Other:

- Relatively high failure rate among perfect and typical users and does not protect against transmission of HIV, GC or chlamydia (see p. 146 - statement from 2006 CDC STI Treatment Guidelines). Spermicides may, in women having frequent intercourse with multiple partners, enhance transmission of HIV by irritation of vaginal mucosa and by destroying vaginal flora, e.g., lactobacilli, in nonoxynol-9 concentrations as low as 0.1% *[Van Dame, Durban, 2000 found 1.7 RR of HIV transmission in users of spermicidal vaginal gel with 52.5 mg N-9] [Kreiss - 1992]*
- Allergic reactions and dermatitis in women and men that could decrease compliance

COMPLICATIONS

- Women and men have confused fruit jelly, e.g., grape jelly, for spermicidal "jelly"
- Women and men have attempted to use cosmetics or hair products containing non-spermicidal octoxynols and nonoxynols (nonoxynol 4, 10, 12, and 14) in lieu of nonoxynol-9

CANDIDATES FOR USE

- Willing to accept high failure rates
- Any woman and partner who presents with no prior allergy or reaction to spermicides

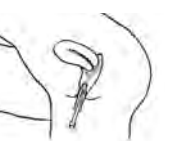
Adolescents:

- Readily available and not contraindicated for teens unless at high risk for HIV infection
- High failure rate should discourage long-term use as primary method

INITIATING METHOD

- Except in cases where the patient, or partner, presents with pregnancy, allergy, or irritation, women can begin these methods at any time following product instructions
- Ensure ECPs are on hand at home

INSTRUCTIONS FOR PATIENT



- Inserting person should wash and dry hands
- Spermicide has its greatest efficacy near the cervical os
- Water exposure, e.g. bathing or douching, within 6 hours after insertion or post-coitally can minimize effectiveness; reapply before next penetrative act
- Keep spermicides in cool, dry places; tablets or foam can tolerate heat, film melts at 98.6° F

Creams/foams/gels

- Apply less than 1 hour prior to sexual intercourse. With foam, shake canister vigorously. Fill plastic applicator with spermicide. Insert applicator deeply into vagina and depress plunger. Immediately active. Finish sexual intercourse within 60 minutes of application

Film, suppositories and tablets

- Insert at least 15 minutes before sexual intercourse: with film, fold the sheet in quarters and then half again (this aids insertion). Using fingers or an applicator, the inserting partner places the spermicide applicator or film deep in the vagina, near cervix. Finish sexual intercourse within 60 minutes of application

FOLLOW-UP

- Have you or your partner(s) experienced any rash or discomfort after using spermicides?
- Have you changed partners since beginning spermicides?
- Have you had sex—even once—without using spermicides?
- Would you like a more effective method?
- Did you have questions about ECPs?
- Do you have Plan B emergency contraceptive pills at home?
- Do you plan to have children? OR Do you plan to have more children? If yes, when?

PROBLEM MANAGEMENT

Dermatitis: Discontinue spermicides and offer another method. If spermicide was used as lubricant, recommend a water-based or silicone-based lubricant without nonoxynol-9

Changed partners: Explain STI prevention, check for STIs, and recommend condoms

FERTILITY AFTER DISCONTINUATION OF METHOD

- No effect on baseline fertility

CHAPTER 21

Coitus Interruptus (Withdrawal)

www.managingcontraception.com

DESCRIPTION: Man withdraws penis completely from the vagina before ejaculation

EFFECTIVENESS

Perfect use failure rate in first year: 4% (See Trussell's failure rates, Table 13.2, p. 40)
Typical use failure rate in first year: 27%
[Trussell J IN Contraceptive Technology, 2004]

MECHANISM: Withdrawal prior to ejaculation reduces or eliminates sperm introduced into vagina. Preejaculatory fluid is not generally a problem unless two acts of sexual intercourse are close together. It is very important that the penis is away from the introitus after withdrawal.

Are there sperm in pre-ejaculate fluid?

Some concern exists that the pre-ejaculate fluid may carry sperm into the vagina. In itself, the pre-ejaculate, a lubricating secretion produced by the Cowper's glands, contains no sperm. Two studies examining the pre-ejaculate for the presence of spermatozoa found none. However, a previous ejaculation may have left some sperm hidden within the folds of the urethral lining. In examinations of the pre-ejaculate in one small study, the pre-ejaculate was free of spermatozoa in all of 11 HIV-seronegative men and 4 of 12 seropositive men. Although the 8 samples containing spermatozoa revealed only small clumps of a few hundred sperm, these could theoreticallly pose a risk of fertilization. In all likelihood, the spermatozoa left from a previous ejaculation could be washed out with the force of a normal urination; however, this remains unstudied. *[Kowal D. Coitus interruptus (withdrawal) IN Hatcher, RA Contraceptive Technology 18th edition. Page 314] [3 references]*

COST: None

ADVANTAGES

Menstrual: None
Sexual/psychological:
- No barriers
- Readily available method which encourages male involvement

Cancers, tumors, and masses: None
Other: Surprisingly effective if used correctly

DISADVANTAGES

Menstrual: None
Sexual/psychological
- May not be applicable for couples with sexual dysfunction such as premature ejaculation or unpredictable ejaculation
- Requires man's cooperation and control
- May reduce sexual pleasure of woman and intensity of orgasm of man
- Encourages "spectatoring" or thinking about what is happening during sexual intercourse

Cancers, tumors, and masses: None
Other: **Relatively high failure rate among typical users and does not adequately protect against STIs. It may reduce risk of fluid-born infection**

COMPLICATIONS: None

MEDICAL ELIGIBILITY CHECKLIST
- Man must be able to predict ejaculation in time to withdraw penis completely from vagina and move away from woman's external genetalia
- Premature ejaculation makes method less effective
- Appropriate for couples not at risk for STIs

CANDIDATES FOR USE
- Couples who are able to communicate during sexual intercourse
- Disciplined men who can ignore the powerful instinct, urging them to continue thrusting
- Couples in stable, mutually monogamous relationship
- Couples without religious or cultural prohibitions against withdrawal
- Women willing to accept higher risk of unintended pregnancy

Adolescents: Compliance may be a problem (as it is for couples of all ages); teens may have less control over ejaculation; advise use of condoms for better protection against pregnancy and STIs. While withdrawal is a relatively poor contraceptive option, especially if pregnancy prevention and infection control are very important, withdrawal is definitely better than using no contraceptive at all

INITIATING METHOD: Can begin at any time; provide ECPs in advance

INSTRUCTIONS FOR PATIENT
- Practice withdrawal using backup method until both partners master withdrawal
- Wipe penis clean of the pre-ejaculation fluid prior to vaginal penetration
- Use coital positions that ensure that the man will be capable of withdrawing easily at the appropriate time
- Use emergency contraception if withdrawal fails

FOLLOW-UP
- Does your partner ever ejaculate/begin to ejaculate before withdrawing?
- Do you want to use a more effective method?
- Did you have any Plan B at home?
- Do you plan to have children? OR Do you plan to have more children?

PROBLEM MANAGEMENT

Failure to withdraw: Use ECPs everytime withdrawal does not work! Consider another method

FERTILITY AFTER DISCONTINUATION OF METHOD: No adverse effects on fertility (except the method does not adequately protect against STIs)

CHAPTER 22

Emergency Contraception

www.not-2-late.com OR www.go2planb.com
1-800-330-1271

Plan B One-Step & Next Choice now available!

Emergency contraceptive pills can be provided from behind the counter (i.e. directly from the pharmacist without a prescription) for people ages 17 and older. An identification card is required. Even if providers do not have to write a prescription, they play a significant part in increasing patient education about emergency contraception and access to ECPs. Many pharmacies do not stock ECPs so having it in advance is important. *[French AC, Kauntiz AM]*

- Good news: Some data show increased availability after Plan B was awarded OTC status *[Geere-2008]*
- Tell **ALL** your patients about emergency contraception (EC)
- Provide EC pills or prescriptions in advance to your patients or advise to buy OTC
- Continue to write prescriptions for:
  - Women younger than 17
  - Women 17 and older with insurance coverage for EC
  - Women who may not have a government issued ID stating their age
  - Women who may be embarrassed to ask for EC without a prescription

OVERVIEW

Plan B and Next Choice now available OTC for people ≥ 17 years old. These should routinely be used as EC rather than combined pills. The states with EC available direct from pharmacies for people of any age are Washington, California, Vermont, Alaska, Massachusetts, New Hampshire, New Mexico, Hawaii and Maine. In 34 countries, EC is available directly from pharmacies. Emergency contraception (EC) includes any method used after intercourse to prevent pregnancy. None of the current methods is an abortifacient and none disturbs an implanted pregnancy. There are currently 3 methods in widespread use worldwide:

- High-dose progestin-only contraceptive pills (POPs). PLAN B or Next Choice preferable to Ovrette or COCs
- Yuzpe Method 13 brands of combined oral contraceptive pills (COCs)
- Copper IUD insertion (Paragard)

An estimated 51,000 pregnancies were averted by EC use in 2000 accounting for 43% of the decrease in abortions since 1994 *[Finer-2003]*. Only the two hormonal methods are utilized to any significant degree in the U.S. (all combined and progestin-only pills that may be used are on p. 80 of this book and in diagram on A-20). It is more effective to provide ECPs to patients in advance than to give them a prescription with refills in advance, but always do one or the other.

- Studies have found women getting EC in advance are not more likely to have unprotected sex
- Women in EC studies often underutilize EC. Inconvenience and fear of the side effects were reasons for non-use cited in one study *[Rocca-2007]*
- Increased access to EC enhances use but does not decrease pregnancy rates *[Raymond-2007]*

Table 24.1 Overview of Postcoital Methods Currently Available in U.S.

Characteristic	POPs	COCs *	Copper IUD
Timing of initiation after intercourse	ASAP but ***can*** be used up to 120 hours (5 days); Sooner is better	ASAP but ***can*** be used up to 120 hours (5 days); Sooner is better	Up to 8 days after ovulation. In practice, usually given up to 5 days after intercourse
Pregnancies/ 100 women	Early start: 0.4% (<12 h) Late start: 2.7% (1-3 days) Average: 1.1%	Early start: 0.5% (<12 h) Late start: 4.2% (1-3 days) Average: 2 - 3.2%	0.1%
Advantages	Fewer side effects than COCs; Product available for advance prescription: Plan B® **Both pills can be taken at once**	Wide range of COCs available for use	Effective long-term contraceptive for appropriate women
Disadvantages	Less available than COCs that can be used to create an off-label EC regimen. Check for availability of Plan B at pharmacies near you at www.go2planb.com	Gastrointestinal side effects – can be reduced with antiemetic pretreatment No dedicated product	Expensive; must be appropriate candidate for IUD; Timing issues: counseling, testing, etc. Insertion procedure required
Side effects	Spotting. Same hormonal side effects as COCs, but significantly less frequent and less severe	Nausea, vomiting, spotting headache, breast tenderness, moodiness, change in next menses	Pain, bleeding, expulsion
Avoid use in pregnant women and women with other prescribing precautions	Do not use in women with known pregnancy because the treatment will not be effective. Not a teratogen	Do not use in women with known pregnancy or current severe migraine. POPs a better option for all women with a history of DVT or PE	Prescribing precautions for IUD use (see page 80)

For more information about EC, phone numbers of EC providers, or **to become listed as an EC provider**, check out the web site www.not-2-late.com or call the EC Hotline at 1-888-NOT-2-LATE. Other good sources of information about EC are www.go2planB.com or call 800-330-1271.

* COCs using norgestrel are better studied. COCs with norethindrone may be used as ECPs, but failure rates are slightly higher as compared with COCs with norgestrel

EMERGENCY CONTRACEPTION WITH ORAL CONTRACEPTIVE PILLS

DESCRIPTION

POPs: more effective than COCs and less side effects

- EITHER: Both Plan B or Next Choice tabs at once ←
  OR: Tab #1 followed by #2 in 12 hours ←
- EITHER: within 72 hours or 120 hours (5 days) ←
- BEST: 2 tabs at once as soon as possible or Plan B One-Step ←

- Plan B One-Step has both doses in a single pill ←
- Next Choice

Yuzpe Method using any of the levonorgestrel-containing COCs:

- Two large doses of COCs with at least 100 µg of ethinyl estradiol and either 100 mcg of norgestrel or .50 mg of levonorgestrel in each dose. Norethindrone pills have slightly less effectiveness as ECPs. Take first dose ASAP within 120 hours after inadequately protected sex; take second dose 12 hours later (second dose may be more than 120 hours after unprotected sex). Try to provide ECPs to women in advance (actual pills or prescription with refills if < 17 years old) (see Figure 24.1, p. 80)

EFFECTIVENESS

• In this large trial, starting treatment with a delay of 4-5 days did not significantly increase the failure rate compared to the efficacy of treatment begun within 3 days of unprotected intercourse. *[von Hertzen-2002].* Failure rate was slightly higher when ECPs were taken on days 4 or 5. **Emergency contraceptive pills should be taken as soon as possible after unprotected sex**

• Taking more than number of pills specified is *not* beneficial and may increase risk of vomiting

EC with POPs ***PLAN B*** ***Next Choice***	Only 1.1% of 967 women using POPs for EC became pregnant in a WHO multi-center study *[WHO task force on Postovulatory Methods of Fertility Regulation. Lancet Aug 8, 1998]*	89% average reduction of pregnancy rate based on WHO perfect-use study population	12 pregnancies per 1000 unprotected acts of sexual intercourse followed by POPs
EC with COCs	2-3% failure rate	74% average reduction of pregnancy rate (WHO perfect-use study)	20-32 pregnancies per 1000 unprotected acts of sexual intercourse followed by Preven or COCs

Plan B, Next Choice and other emergency contraceptive pills are NOT recommended for routine use as a contraceptive

HOW EMERGENCY CONTRACEPTIVE PILLS WORK:

• ECPs act by preventing pregnancy and never by disrupting an implanted pregnancy, i.e. never as an abortifacient

• If taken before ovulation, ECPs disrupt normal follicular development and maturation, blocks LH surge, and inhibit ovulation; they may also create deficient luteal phase and may have a contraceptive effect by thickening cervical mucus

• If taken after ovulation, ECPs have little effect on ovarian hormonal production and limited effect on endometrial maturation

• ECPs may affect tubal transport of sperm or ova

COST

POPs:

• Plan B is available OTC in retail pharmacies for about $40- $50. Next Choice is less costly

• Non-profit and Title X agencies may purchase POPs at $4.50 - $8.00 per treatment

• Pharmacists in those states that may dispense without a prescription charge $50-$55 for counseling and medication

Yuzpe method with COCs:

• One cycle of COCs may vary from a few dollars to more than $50

Other costs:

• Cost prior to obtaining pills may vary from nothing (if already given) to cost of full exam and pregnancy test. This may increase total cost of EC to $45 to over $100

ADVANTAGES

Menstrual: None

Sexual/Psychological:

- Offers an opportunity to prevent pregnancy after rape, mistake, or barrier method failure (condom breaks or slips, diaphragm dislodges, etc.)
- Reduces anxiety about unintended pregnancy prior to next menses
- Process of getting EC may lead woman to initiate ongoing contraception

Cancers, tumors and masses: None

Other:

- Estimated 40% of reduction in teen pregnancies ('95 to '99) due to EC

DISADVANTAGES

Menstrual:

- Next menses may be early (especially if taken before ovulation), on time, or late
- Notable changes in flow of next menses seen in 10-15% of women
- **If no menses within 3 weeks (21 days) of taking ECPs, pregnancy test should be done**

Sexual/psychological:

- Women who are uncomfortable with post-fertilization methods might need reassurance that use of EC with COCs or POPs is consistent with their beliefs if taken during the follicular phase. They also may need to be warned that if taken after ovulation, ECPs may work as an interceptive (ie prevent implantation of fertilized egg)
- No STI protection

Cancers, tumors and masses: None

Other:

- Breast tenderness, fatigue, headache, abdominal pain and dizziness
- No protection against STIs; consider treatment for possible STIs following exposure

Nausea and vomiting:

	Nausea	Vomiting	Pretreatment with antiemetic
POPs	23%	6%	Many clinicians use only if Hx of past problems with nausea or vomiting
COCs	50%	19%	Can reduce symptoms by 30-50%

COMPLICATIONS

- Several cases of DVT reported in women using COCs as ECPs. No increased DVT risk with POPs

CANDIDATES FOR USE

- All women who have had or who may be at risk for unprotected sex (sperm exposure) are candidates for ECPs for immediate or future use.
- As a backup method for barrier methods
- Forgotten pills, late for contraceptive reinjection, NFP miscalculation, failed withdrawal
- Failure to use methods: clouded judgment, sexual assault
- For the woman who has intercourse infrequently (1-2x/yr) Particularly effective if taken within one hour of otherwise unprotected sex
- NOTE: ECPs do not protect against pregnancy as well as ongoing methods

Adolescents: appropriate back-up option. Having EC available does NOT make teens less likely to use regular contraception or more likely to have unprotected sex. *[Glasier-1998] [Raine-2000] [Ellertson-2001]*

PRECAUTIONS

Plan B/Next Choice:

- Pregnancy (no benefit; no effect)
- Hypersensitivity to any component of product
- Undiagnosed abnormal vaginal bleeding

Use of COCs for EC should be allowed for all women except those who:

- Are pregnant; no benefit but also no dangers
- Are known to be hypersensitive to any component of the product
- Have acute migraine headaches at the time ECPs are to be taken (Use Plan B/Next Choice)
- Have history of DVT or PE (use Plan B/Next Choice)

INITIATING METHOD: Pregnancy testing is optional, not required:

- Getting POPs OTC requires an ID. No evaluation is done by the pharmacist
- Offer ECPs routinely to all women who may be at risk for unprotected intercourse: POPs (levonorgestrel) is better than combined pills
  - Advance provision and prescription increases use of EC but does not diminish use of primary method of contraception
  - Availability directly through pharmacists led to a thousand-fold increase in use of ECPs in selected pharmacies in the state of Washington
- Provide EC for all women who present after-the-fact, acutely in need. If you dispense off-label pills remove the inactive pills to reduce risk of mistake
- Patient history for prescribing EC after-the-fact:
  - LMP, previous menstrual period, dates of any prior unprotected intercourse this cycle, and date and time of last unprotected intercourse
  - Any problems with previous use of ECPs, COCs or POPs?
  - Breast-feeding or severe headaches now? History of DVT or PE? (Use POPs not COCs)
  - Any foreseeable problems if antiemetic causes drowsiness?
- No physical exam/labs needed on a routine basis:
  - No pelvic exam is necessary, now or in the past; No BP measurements needed
  - Pregnancy testing useful only if concerned that prior intercourse may have caused pregnancy. ***ACOG, IPPF and CDC do not include routine pregnancy testing in their protocols***
- Advise patient about possible side effects and consider other EC options (Copper IUD)
- If prescribing COCs, offer premedication with long-acting antiemetic one hour prior to first ECP dose. Take two 25 mg tablets of meclizine hydrochloride (over-the-counter Dramamine or Bonine). Other agents work, but do not have same duration of action. Avoid antiemetic if drowsiness will pose safety hazard. Antiemetics not needed prior to Plan B
- Tell her how to use appropriate number of tablets for particular ECP brand to reach adequate dose (see Figure 24.1, p. 80 and p. A-20).
- **Both Plan B tabs may be taken at once.** If using COCs, encourage patient to take first dose ASAP and second dose approximately 12 hours after first dose. It is ok to take second dose in slightly less or more than 12 hours; realize that 72 hours after unprotected intercourse is NOT the absolute limit. ECP may be taken for up to 120 hours after unprotected sex
- Encourage patient to have available at home in case she has another need to use EC again OR provide prescription with refills if < 18 years old
- Inquire about desire to be checked for STI's (especially in cases of rape)

STARTING REGULAR USE OF CONTRACEPTIVE AFTER USE OF ECPs

- Start using regular method immediately. ECPs offer no lingering reliable protection
- If missed OCs, restart day after ECPs taken (no need to catch up missed pills)

- If starting COCs, patch or ring, see COC precautions and then:
  - May wait for next menses or
  - Start OCs, patch or ring next day with 7-day backup method (this will affect timing of next menses). In office she may punch out a few pills at the beginning of a pill pack to correspond with the day of the week you are seeing her. This may reduce confusion
- If starting DMPA injections, can start immediately. If so, consider having patient return in 2-3 weeks for pregnancy test
- If starting barrier methods, start immediately.
- If starting NFP, use abstinence (or barrier/spermicide) until next menses

SPECIAL ISSUES/FREQUENT QUESTIONS

- Give your patient a supply of EC at her annual visit. EC is more likely to be used if she already has it and need not visit a pharmacy *(Glasier 2001; Jackson 2003; Raine 2005)*
- When in cycle should EC be offered? Anytime
- How many times a year can a woman use ECPs? No limit, but be sure to ask her why her primary method is not working
- What if a patient has had unprotected intercourse earlier in the cycle? Do urine test to confirm no obvious pregnancy. Offer EC. If concerned that your test may miss an early pregnancy, give EC and have her return in 3 weeks (if no menses) for another pregnancy test. EC will not adversely affect a developing pregnancy
- What if she used EC earlier in the month? Offer it again; she may have just delayed ovulation. Review why her primary contraceptive is failing her and remedy the situation (perhaps with a new method). Consider performing pregnancy test in this setting even though it may be too early to have become positive; counsel her about this possibility
- What if the pharmacy is closed or does not carry EC? Plan ahead. Encourage her to have EC on hand at home. Check with local 24-hour pharmacies

INSTRUCTIONS FOR PATIENT

- **EC works best if taken as soon as possible after sex. Women at risk of pregnancy need Plan B or Next Choice at home!** For advance prescription, have her fill her prescription (or obtain OTC) in advance and keep readily available.
- **It is now recommended that both doses of Plan B or Next Choice be taken at once**
- An antiemetic need not be taken prior to Plan B or Next Choice
- Start using contraception right away. ECPs do not reliably protect you beyond the day they are used
- Re-evaluate primary contraceptive method to make it more reliable
- Have her return for pregnancy testing if she has not had her menses 21 days after using ECPs

FOLLOW-UP

- No routine follow-up needed
- Have patient return for pregnancy testing if no menses in 3 weeks
- If patient has persistent irregular bleeding or abdominal pain, she should return to rule out ectopic pregnancy

PROBLEM MANAGEMENT

Nausea/vomiting:

- Antiemetic may be prescribed before or after taking combined COCs as ECPs (does not work as well when taken after EC)
- Vomiting that occurs due to ECPs probably indicates that enough hormones reached the bloodstream to have the desired contraceptive effect. Most experts (but NOT all) recommend a repeat dose of ECPs if vomiting occurs within 30 minutes of taking ECPs. ACOG recommends a repeat dose if vomiting occurs within two hours *[ACOG 2005]*

- POPs are preferable to COCs, but if repeating dose because of severe vomiting, switch from COCs to POPs or consider placing pills in vagina rather than mouth (off-label) or use of a copper IUD. Although uptake is slower with vaginal administration, this may also be possible for woman who has experienced extreme nausea while taking COCs in the past as her regular contraceptive. No data on effectiveness of vaginal COCs used as EC
- If severe vomiting occurs, consider IUD as emergency contraceptive

Amenorrhea: If menses do not occur in 21 days (or more than 7 days beyond expected day for menses to begin), pregnancy test recommended

Pregnancy in spite of using ECPs: If there is a pregnancy, the woman may be reassured that there is evidence that ECPs do not increase the risk of fetal anomalies, ectopic pregnancy or miscarriage

FERTILITY AFTER DISCONTINUATION OF METHOD: Must provide contraception for rest of cycle and beyond. If she starts using birth control pills or a vaginal ring, use a back-up (condoms) for the first 7 days. If she uses patches, use a back-up (condoms) for 9 days

EMERGENCY CONTRACEPTION WITH COPPER IUD

DESCRIPTION

- Insert Copper IUD, following the usual procedures, within 5 days after unprotected or inadequately protected sexual intercourse. May be used up to 8 days after intercourse, if ovulation is known to have occurred 3 days or more after the unprotected sex
- More frequently used outside the U.S., where IUD costs are lower
- In the US, this method is generally restricted to use by women who intend to continue to use the IUD as an ongoing method
- Levonorgestrel IUD (Mirena) is NOT effective for use as EC

EFFECTIVENESS

- **Most effective postcoital contraceptive**
- Failure rate < 1% (only about 6 pregnancies per 1000 insertions in world's literature)

MECHANISM: In the month it is inserted as an emergency contraceptive, it may act by interfering with implantation (see pages 83 and 90 for mechanisms of action of IUDs as routine, long-term contraceptive)

COST: In U.S. about $500. In Europe postcoital IUD insertion costs just $25 (Belgium) or is covered by health plan. Inexpensive in Europe or in the United States in comparison with costs (emotional and financial) of an unintended pregnancy

ADVANTAGES

- The most effective post-coital method and may be used 2 days later than ECPs
- Provides long-term protection against pregnancy following insertion
- In one EC study, >80% continued use of IUD as their contraceptive *[Zhou-2001]*

DISADVANTAGES: Same as using Copper IUD as contraceptive (See Chapter 23)

- Very expensive, if only used for EC and removal expected soon
- Timing constraints of EC use may make it difficult to properly screen patients for IUD insertion (counseling, preinsertion cultures, etc.)

COMPLICATIONS, CANDIDATES FOR USE, PRESCRIBING PRECAUTIONS, INITIATING METHOD, INSTRUCTIONS FOR PATIENT FOLLOW-UP, PROBLEM MANAGEMENT, FERTILITY AFTER USE: Same as using Copper IUD as ongoing contraceptive (See Chapter 23)

Figure 24.1

EMERGENCY CONTRACEPTION USING EMERGENCY CONTRACEPTIVE PILLS (ECPs)

1-888-NOT-2 LATE; www.opr.princeton.edu/ec; www.go2planB.com

POPs (Plan-B/Next Choice): Behind the counter for men, women > 17 years old.
Educate/prescribe/provide emergency contraceptive pills (ECPs) **prior to the need** for them so that women and men have them available at home (or rapid access to them) in case they are needed. This is particularly important since some pharmacies will not dispense ECPs

↓

Start ECPs as soon as possible, after unprotected or inadequately protected sexual intercourse.
Can be used up to 5 days, but sooner is better; most effective if taken immediately or within 12 hours

↓

No need to use anti-nausea medication if using POPs. If using a COC, first, take anti-nausea medication: 50 mg oral meclizine* has 24-hour duration of action

↓

BRAND**	DOSE	
Plan B or Next Choice	2 white tablets all at once***	
One hour after antiemetic, take first dose of ECPs. Choose one of the following:		
Ogestrel, Ovral	2 white tablets per dose	If vomiting occurs within 1 hour, repeat dose
Levora, Low-Ogestrel, Lo/Ovral	4 white tablets per dose	
Levlen, Nordette	4 light-orange tablets per dose	
Tri-Levlen, Triphasil	4 light-yellow tablets per dose	
Trivora	4 pink tablets per dose	
Alesse, Levlite	5 pink tablets per dose	

CALL: 1-888-NOT-2 LATE if you have any questions about emergency contraception OR if you need to hear about EC in Spanish or if you need phone numbers of 5 clinicians nearest you who will provide EC if you need a prescription (are < 17 years old).

↓

If using one of the other COC options, repeat the same dose of ECPs 12 hours later. In the case of Plan B or Next Choice, both tabs may be taken at once

↓

Patient should (re)start ongoing method immediately and restock ECPs at home

↓

Pregnancy test if no period in 3 weeks

NOTE: if anti-nausea medication is NOT taken prior to first dose of ECPs (which is recommended), it may be taken after the first dose, should nausea be severe or should woman vomit. Anti-nausea medication is usually not needed for women using POPs, as they do not contain estrogen.

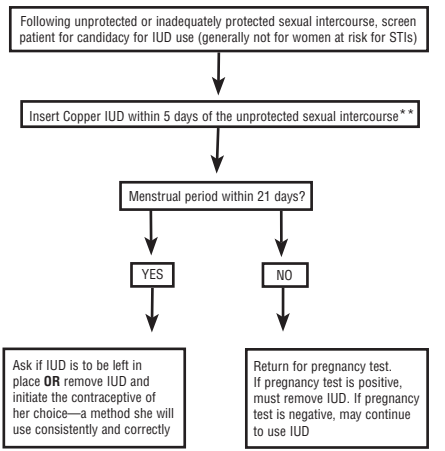
* Meclizine hydrochloride is recommended because it has a 24-hour duration of action. It is available over the counter as Bonine and as Dramamine 2. Other medications to prevent nausea may be prescribed instead.

**Norethindrone pills recently shown to be effective but less than these levonorgestrel products.

***Labeling recommends one Plan B or Next Choice tablet now and one in 12 hours, but new studies show that taking 2 tablets at once is equally effective (and more convenient). Two Plan B or Next Choice tablets ASAP within 5 days is becoming the instruction for women using Plan B or Next Choice.

Figure 24.2

EMERGENCY CONTRACEPTION USING COPPER IUD*
www.opr.princeton.edu/ec



* **There is no evidence that the levonorgestrel IUD, is effective for EC**

** The Copper IUD may be inserted up to the time of implantation—about 5 days after ovulation—to prevent pregnancy. Thus, if a woman had unprotected sexual intercourse 3 days before ovulation occurred in that cycle, the IUD could be inserted up to 8 days after intercourse to prevent pregnancy

Postcoital ParaGard insertion is the most effective emergency contraceptive. If a woman can use a Copper T 380 A IUD as her emergency contraceptive and leave it in as her ongoing long-term contraceptive, she may receive 10 or more years of excellent contraceptive protection.

CALL: 1-888-NOT-2 LATE if you have any questions about emergency contraception OR if you need to hear about EC in Spanish or if you need phone numbers of 5 clinicians nearest you who will provide EC.

CHAPTER 23

Intrauterine Contraceptives

www.popcouncil.org, www.engenderhealth.org, www.berlex.com, www.arhp.org, www.paragard.com

OVERVIEW: Two intrauterine contraceptives are available in the U.S.: the ParaGard® T 380A Intrauterine Copper IUD and the Mirena® levonorgestrel-releasing intrauterine system (LNG-IUS). IUC is among the most effective methods, yet is underutilized in the U.S. IUD insertion immediately after suction aspiration or placental delivery are practices that could lead to many more IUD insertions. Educating clinicians has been shown to increase IUD utilization *[Postlethwaite-2007]*. Post-abortal insertion and clinician education/ training increased utilization by over 300% and decreased repeat abortion in a California Planned Parenthood *[Goodman-2008]*

WOMEN MAY USE IUC IF:

- are nulliparous or multiparous
- are young or older until menopause
- immediately after abortion or miscarriage
- have had an STI in past
- have had an ectopic pregnancy in past
- are not in a monogamous relationship
- have fibroids that do not distort the uterine cavity
- immediately post-partum in the delivery room
- Copper IUD for EC
- Hormonal IUD to help manage endometriosis, adenomyosis, fibroids and dysfunctional uterine bleeding

Women must continue to:

- protect themselves from STI's if not in mutually monogamous relationship

CHOOSING BETWEEN THE TWO IUDS AVAILABLE:

Your patient wants an IUD. Counsel her thoroughly about the advantages and disadvantages of each IUD available. Women need to know either IUD can be removed at any time.

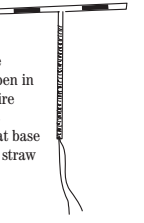
Copper IUD:

- effective for at least 10 years
- no hormones, therefore, no hormonal side effects
- may cause heavier periods and/or more cramping
- can be used as an EC

Hormonal IUD:

- effective for at least 5 years
- releases levonorgestrel, therefore, lighter to no periods. Irregular bleeding common in early months
- may cause hormonal side effects
- treats menorrhagia and dysmennorhea

INTRAUTERINE COPPER CONTRACEPTIVE (ParaGard T 380A)



DESCRIPTION: T-shaped intrauterine contraceptive made of radiopaque polyethylene, with two flexible arms that bend down for insertion but open in the uterus to hold solid sleeves of copper against fundus. Fine copper wire wrapped around stem. Surface area of copper = 380 mm². Monofilament polyethylene tail string threaded through and knotted below blunt ball at base of stem creates double strings that protrude into vagina. This IUD has 2 straw colored strings

EFFECTIVENESS: ***Think of IUDs/IUCs as "reversible sterilization"***

• Approved for 10 years use; effective for 12 years at least

Perfect use failure rate in first year: 0.6% (see Table 13.2, p. 40)

Typical use failure rate in first year: 0.8%

[Trussell J IN Contraceptive Technology, 2004]

Cumulative 10-year failure rate: 2.1 - 2.8%

Use of IUDs decreases the risk of ectopic pregnancy by 70-80% vs. women not using contraception. But, if a woman gets pregnant with an IUD, you must rule out ectopic pregnancy. Of pregnancies with ParaGard in FDA trials, one out of 16 pregnancies was ectopic (WHO trial 1:9). For Mirena, 1 out of 2 was ectopic *[Furlong-2002]* although pregnancies rare

HOW COPPER IUD WORKS:

The intrauterine copper contraceptive works primarily as a spermicide. Copper ions inhibit sperm motility and acrosomal enzyme activation so that sperm rarely reach the fallopian tube and are unable to fertilize the ovum. The sterile inflammatory reaction created in the endometrium phagocytizes the sperm. Experimental evidence suggests that the copper IUDs do not routinely work after fertilization. They are not abortifacients. They primarily prevent pregnancy by killing sperm (spermicidal), and thereby preventing fertilization

COST: $475.00

• ParaGard units that are contaminated during insertion or are expelled or removed within first 3 months may be replaced free of cost. Contact Duramed 877-727-2427. See Ordering and Stocking Chapter 28 p. 144

ADVANTAGES: Effective long-term contraception from a single decision

Menstrual: Period cycles remain regular

Sexual/psychological

• Convenient; permits spontaneous sexual activities. Requires no action at time of use

• Intercourse may be more pleasurable with risk of pregnancy reduced

Cancers, tumors and masses

• Probable protection against endometrial cancer (6 of 7 case control studies) *[Hubacher-Grimes-2002]*

• Possible 40% protection against cervical cancer *[Grimes-2004]*

Other

• Very effective

• Good option for women who cannot use hormonal methods

• Rapid return to fertility and private

• Convenient - single insertion provides up to 12 years protection (package labeling says 10 years)

• **Cost effective. Provides greatest net benefits of any contraceptive over a 5 year period.**

• Risk for ectopic pregnancy decreased

• **IUDs lead to highest level of user satisfaction of any contraceptive** *[Forrest-1996]*

• Can be used as an emergency contraceptive (see p. 79)

DISADVANTAGES:

Menstrual

• Average monthly blood loss increased by up to 50%; this may be diminished by NSAIDs

• May increase dysmenorrhea (removal rates for bleeding and pain first year = 11.9%)

• Spotting and cramping with insertion and intermittently in weeks following insertion

Sexual/psychological

- Some women uncomfortable with concept of having "something" (foreign body) placed inside them
- Some women are not at ease checking strings
- Strings palpable; if strings cut too short, may cause partner discomfort

Cancers, tumors and masses: None

Other

- Requires office procedure for insertion and removal; both can be uncomfortable
- Some programs/protocols recommend a chlamydia/gonnorrhea check before insertion, others do not
- Some do a wet mount and test for GC/CT. Amplified PCR tests of cervix or urine can provide immediate results. If bacterial vaginosis or trichomonas, may still insert IUD and start treatment on the same visit (CDC 2010 MEC)
- Increased risk of infection in first 20 days after insertion (approximately 1/1000 women will get PID)
- Offers no protection from HIV/STIs; PID: see data in box below
- May be expelled obviously (with cramping and bleeding) or silently (unknowingly placing woman at risk for pregnancy). Rate of expulsion declines over time. At 5 years cumulative explusion rate (partial or complete) is 11.3%. Expulsion rate for the 5th year is 0.3%. Women who have expelled one IUD have about a one in three chance of expelling an IUD if another is inserted *[Grimes-2004]*

COMPLICATIONS: See PROBLEM MANAGEMENT section for details

Complication	*Frequency*	*Risk factors*
PID within 20 days	1/1000	BV, cervicitis, contamination with insertion
Uterine perforation	1/1000	Immobile, markedly verted uterus Breast-feeding woman Inexperienced, unskilled inserter
Vasovagal reaction or Fainting with insertion	Rare	Stenotic os, pain Prior vasovagal reaction
Expulsion		Insertion on menses, immediately postpartum, not high enough in fundus or nulliparous
Pregnancy		Poor placement, expulsion

CANDIDATES FOR USE: ***Think of IUDs as reversible sterilization***

- See 2010 CDC Medical Eligibility Criteria, pages A-1 through A-8
- Currently recommended patient profile includes women who are not at high risk of STI's. The copper IUD and LNG IUD are best for women seeking longer-term ($\geq$ 1 year) pregnancy protection due to their high initial cost
- Nulligravid women at low risk for STIs are candidates
- Women with history of PID are candidates if they currently are not at high risk
- Good option for women who cannot or do not want to use hormones

Adolescents: Adolescents often do not meet all the criteria for IUD use

PRESCRIBING PRECAUTIONS: See CDC Eligibility Criteria, **pages A1-A8**

- Pregnancy
- Uterus < 6 cm or > 9 cm (package insert, but may be able to use if >9 cm. Some clinicians use an upper limit of 10-12 cm) or greater especially if post abortion or delivery
- Undiagnosed abnormal vaginal bleeding
- Severe anemia (relative contraindication) (levonorgestrel IUD would be a good choice)
- Active cervicitis or active pelvic infection or known symptomatic actinomycosis
- Women with current STI, STI within 3 months or women at risk (multiple sex partners)
- Recent endometritis (last 3 months); See CDC recommendations, A-6
- Allergy to copper; Wilson's disease
- Uterine anomaly or fibroid(s) distorting uterine cavity (CDC 2010) preventing fundal placement of IUD
- AIDS (CDC: 3), HIV-infected (CDC: 2), AIDS, clinically well on antiretoviral therapy (CDC: 2), high risk of HIV (CDC: 2) IUDs do not increase complications in women with HIV/AIDS *[Curtis - 2002]*
- Known or suspected uterine or cervical CA - Insertion (CDC: 4), continuation (CDC: 2)

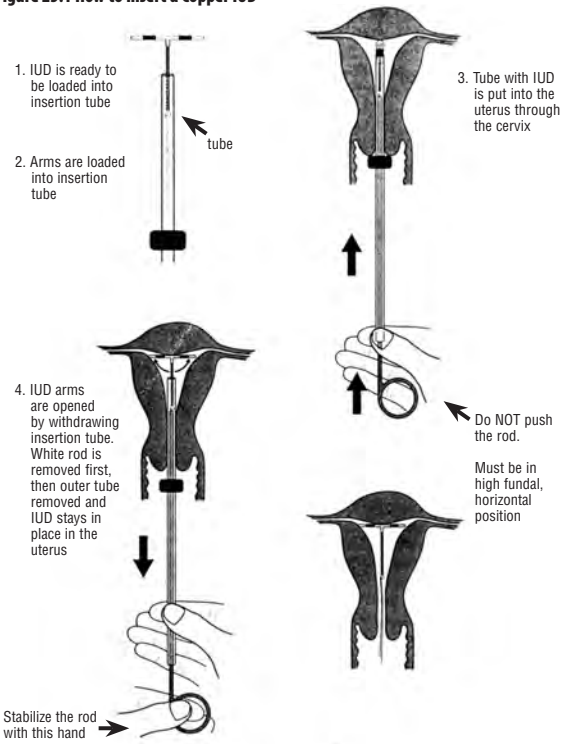
INITIATING METHOD

- Requires insertion by trained professional
- May be inserted at any time in cycle when pregnancy can be ruled out; lowest overall rates of expulsion are when insertion is at midcycle. No backup needed
- May be inserted immediately after induced, therapeutic spontaneous abortion if no infection (increased risk of expulsion if > second trimester)
- May be inserted immediately after delivery of the placenta or may await complete uterine involution postpartum, usually after 4 weeks
- May be inserted following second or third trimester loss (increased risk of expulsion)
- One IUD may be removed and a second inserted at the same visit
- Test for cervical infection, if indicated. Rule out BV; can start BV or trichomonas Rx and insert IUD the same day (CDC 2010)

INSERTION TIPS: Each step should be performed slowly and gently

- All clinicians wanting to insert IUDs would benefit from training in IUD insertion
- Signed consent form
- May give NSAIDs one hour prior to insertion
- Be sure patient is not pregnant
- Routine antibiotic prophylaxis is not warranted; American Heart Association requires **no** antibiotic treatment for mitral valve prolapse, except for women at high risk for bacterial endocarditis
- Recheck position, size and mobility of uterus prior to insertion
- Cleanse upper vaginal, outer cervix, and cervical os and canal thoroughly with antiseptic
- Local anesthesia at tenaculum site: 3 approaches are 1) no anesthesia 2) apply benzocaine 20% gel first at tenaculum site then leave a gel-soaked cotton-tipped applicator in cervical canal for 1 minute before proceeding with IUD insertion 3) inject 1 ml of local anesthetic into the cervical lip into which the tenaculum will be placed
- Most women will NOT need a cervical anesthetic. However, can give 5 cc of local anesthetic at 3 and 9 o'clock
- Place tenaculum to stabilize cervix and straighten uterine axis.
- Sound uterus to fundus with uterine sound or pipelle; uterus should be between 6-9 cm.
- After insertion, trim strings to about 2" (3 1/2 cm). Mark length of strings on chart for later follow-up visits to confirm that length is the same. Also chart lot number
- If in doubt that IUD is at the fundus check with sonography

Figure 25.1 How to insert a Copper IUD



[Speroff L, Darney P. A clinical guide for contraception.4th ed. Baltimore: Lippincott, Williams & Wilkins, 2005:246.]

POSTPLACENTAL & IMMEDIATE POSTPARTUM INSERTION

- Postplacental (preferably within 10 minutes after expulsion of the placenta) is a convenient, effective and safe time to insert Copper IUDs and can be done at ceserean section. ← Most studies are from developing countries
- Easiest to do in women with an epidural in place
- Expulsion rates for post-placental are higher (7- 15% at 6 months) and require that women receiving an IUD very soon after delivery be told how to detect expulsions and are instructed to return for reinsertion
- Unplanned pregnancy rates of post placental IUD insertion range from 2.0 - 2.8 per 100 users at 24 months *[O'Hanley-1992]*. After 1 year, one study found a failure rate of 0.8% following post-placental IUD insertion, comparable to interval insertions *[Thiery-1985]*
- The risk of infection is low following post-placental IUD insertion, with rates of 0.1% to 1.1% *[Lean-1967][Dharmeapanij-1970][Snidvongs-1970][Cole-1984]*. Rates of perforation are very low during post-placental IUD insertion, approximately 1 perforation in each study with patient populations ranging from 1150 to 3800 women *[Cole-1984][Edelman-1979][Phatak-1970]*
- Trim strings at level of cervix ←

Figure 25.2 Two techniques of postplacental IUD insertion and proper location of IUD after insertion

A) IUD strings placed in palm of hand

B) Manual insertion at top of fundus

C) Use of ring forceps to insert IUD

INSTRUCTIONS FOR PATIENT

- Give patient trimmed IUD strings to learn what to check for after menses each month (strings may not be apparent until a few months after post-placental insertion)
- Advise patients to return if any symptoms of pregnancy, infection or IUD loss develop:

PAINS: "Early IUD Warning Signs"	
P	Period late (pregnancy); abnormal spotting or bleeding
A	Abdominal pain, pain with intercourse
I	Infection exposure (STI); abnormal vaginal discharge
N	Not feeling well, fever, chills
S	String missing, shorter or longer

- Counsel patient on anticipated menstrual changes. Ask ***"Will a change in your menstrual bleeding pattern be acceptable to you?"***

FOLLOW-UP: Ask about risk for STIs. Provide condoms if at risk

- Have patient return for post-insertion check about 2 1/2 months after insertion to rule out partial expulsion or other problems requiring removal. Return earlier if any problems
- May be left in place during evaluation and treatment for cervical dysplasia
- Can you feel your IUD strings? Have they changed in length?
- Have you or your partner had any new partners since your last visit?

PROBLEM MANAGEMENT

Uterine perforation: All perforations occur or begin at insertion but may go unrecognized

- Clinical signs: pain, loss of resistance to advancement of instrument and instrument introduced deeper than uterus thought to be on bimanual exam
- Perforation by uterine sound usually occurs in midline posterior uterine wall when there is marked flexion:
  - Remove uterine sound
  - Observe for several hours. Administer antibiotics. If no bleeding seen, stable BP and pulse, patient pain free and hematocrit stable for next several hours, she may be sent home. Provide alternate contraception
  - If any persistent pain or signs of other organ damage, take or refer immediately for laparoscopic evaluation (extremely rare)
- If IUD perforates acutely, attempt removal by gently pulling on strings
  - If resistance encountered, stop and do pelvic ultrasound and/or send to surgery for immediate laparoscopic IUD removal
- If IUD perforation noted and confirmed by ultrasound at later date, if asymptomatic, arrange for elective laparoscopic removal. Provide interval contraceptive. Can have IUD inserted later (i.e. not a contraindication to future IUDs)

Spotting, frequent or heavy bleeding, hemorrhage, anemia:

- Rule out pregnancy. If pregnant, rule out ectopic pregnancy
- Rule out infection, especially if post-coital bleeding
- Rule out expulsion or partial expulsion of IUD (see below)
- If anemic, provide iron supplement and deal with cause
- Consider replacement with the LNG-IUD

Cramping and/or pain:

- Rule out pregnancy, infection, IUD expulsion
- Offer NSAIDs with menses or just before menses every month to reduce cramping
- Consider IUD removal and use of LNG IUD or another method if problem persists

Expulsion/partial expulsion:

- If expulsion confirmed (IUD seen by patient or clinician), rule out pregnancy. May place a new IUD
- If expulsion suspected, use ultrasound to determine IUD absence or presence and location. Probe endocervical canal for IUD, remove if not properly placed. May replace immediately if patient not pregnant
- If not seen on ultrasound, do abdominal x-ray to rule out extrauterine location
- If partial expulsion, remove IUD. If no infections and not pregnant, may replace with new IUD. If IUD not replaced, provide new contraceptive

Finding missing strings in non-pregnant patients:

- Check vagina for strings. Assess string length. If normal, reassure and re-instruct patient how to feel for strings
- Twist cytobrush inside cervix to snag strings which may have become snarled in canal
- Ultrasound to determine IUD presence and location
- If IUD in endocervix, remove and offer to replace
- If IUD correctly in uterus, IUD may be left in place or removed.
- If decision is made to remove IUD after paracervical block, attempt to remove with IUD hook or alligator forceps (some clinicians obtain signed consent after reviewing risks of procedure) or refer for ultrasound to localize prior to attempted removal (provide interim birth control). A 5mm Novak currette (much more painful than alligator forceps) and/or concurrent sonography may be useful in removal of IUDs. In non-pregnant patients, removal may also be done under hysteroscopy

Pregnancy with visible strings:

- Visible strings in first trimester: advise removal of IUD to reduce risk of spontaneous abortion and premature labor
- Patient having miscarriage: Remove IUD. Consider antibiotics for 7 days

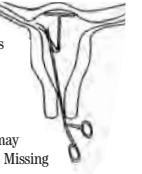
Missing strings in pregnant patients:

- Rule out ectopic pregnancy: 5-8% of all failures with the copper IUD are ectopic
- If intrauterine pregnancy, obtain ultrasound to verify IUD in situ
- If IUD is in uterus, advise patient she is at increased risk for preterm labor and spontaneous abortion but reassure her that fetus is not at increased risk for birth defects. May remove IUD at surgery if patient desires elective abortion. Otherwise, plan for removal at delivery

Infection with IUD use:

- *BV or candidiasis:* treat routinely
- *Trichomoniasis:* treat and stress importance of condoms to prevent STIs
- *Cervicitis or PID:* Give first dose of antibiotics to achieve adequate serum levels before removing IUD. IUD removal not necessary unless no improvement after antibiotic Rx. Patient may not be candidate for continued IUD use. (CDC: 2 for continuation for both STI and PID)
- *Actinomycosis:* Cultures of asymptomatic women without an IUD AND of women with an IUD find that 3-4% of both are positive for Actinomyces *[Lippes, J. Am J Obstet Gyn-1999; 180-2 65-9]*. Often suggested by Pap smear report of "Actinomycosis-like organisms". True upper tract infection with this organism is very serious and requires prolonged IV antibiotic therapy with penicillin. However, less than half of women with such Pap smear reports have actinomyces and those that do usually have asymptomatic colonization only. Examine patient for any signs of PID (it can be unilateral). If signs of upper tract involvement, remove IUD and treat with antibiotics x 1 month. If patient has no clinical evidence of upper tract involvement, 3 options are available depending on patient's wishes and risk of infection:
  1. Conservative. Annual pap smears only. Advise patient to return as needed or if she develops PID symptoms or
  2. Treat with antibiotic penicillin G (500 mg qid p.o. x 2 weeks) or a tetracycline(tetracycline 500 mg qid p.o. for a month OR doxycyline 100 mg bid x 2 weeks) and repeat Pap smear or remove if no clearance of organism or
  3. Treat with antibiotic, remove IUD, and repeat Pap smear in 1 month. Reinsert if colonization cleared

REMOVAL



Indications: Expelling IUD, infection, pregnant, expired IUD, complications with IUD, anemia, no longer candidate for IUD, patient request.

Procedure: Grasp the strings close to external os and steadily retract until IUD removed

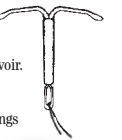
Complications

- Embedded IUD: Gentle rotation of strings may free IUD. If still stuck, may use alligator forceps removal with or without sonographic guidance (see Missing strings, p. 88). Hysteroscopic removal may be indicated in rare cases. A paracervical block reduces pain from removal of an embedded IUD
- Broken strings: Remove IUD with alligator forceps, IUD hook or Novak curette (more painful)

FERTILITY AFTER DISCONTINUATION OF METHOD

Immediate return to baseline fertility

LEVONORGESTREL INTRAUTERINE SYSTEM (Mirena®)



DESCRIPTION: T-shaped intrauterine contraceptive placed within uterine cavity that initially releases 20 micrograms/day of levonorgestrel from its vertical reservoir. Release falls to 14 mcg per day after 5 years. Concentrations of LNG are much higher in the endometrium than in the myometrium and the circulating blood *[Nilsson-1982]*. Product information/ordering: 1-866-647-3646. IUD has 2 gray strings

EFFECTIVENESS: Effective for up to 5 years (label)

Perfect use failure rate in first year: 0.1% (See Table 13.2, p. 38)
Typical use failure rate in first year: 0.1% *[Trussell J. IN CT, 2004]*
5-year cumulative failure rate: 0.7%
7-year cumulative failure rate: 1.1% *[Sivin-1991]*

- 1-year continuation rate in Finland: 93%; 2 years: 87% *[Bachman-BJOG, 2000]*

Now indicated as contraceptive for women with heavy menstrual bleeding

HOW LEVONORGESTREL IUD WORKS: Levonorgestrel causes cervical mucus to become thicker, so sperm can not enter upper reproductive tract and do not reach ovum. Changes in uterotubal fluid also impair sperm and ovum migration. Alteration of the endometrium prevents implantation of fertilized ovum. This IUD has some anovulatory effect (5-15% of treatment cycles; higher in first years)

COST: $843.60. See p. 144 (Ordering and Stocking Device chapter) ←

- **The ARCH Foundation supplies Mirena intrauterine contraceptives to providers caring for economically disadvantaged women whose insurance does not cover Mirena. They also provide funds for removal to qualifying individuals. Go to www.archfoundation.com**
- **Mirena units that are contaminated or must be removed in first 3 months or are expelled *may* be replaced free of cost. Contact Berlex: 1-877-393-9071; Fax: 704-357-0036**

ADVANTAGES

Menstrual: **Dysmenorrhea generally improves**

- Menorrhagia improves (at 12 months, 90% less blood loss with LNG IUS; 50% with COCs; 30% with prostaglandin inhibitors). Among 44 menorrhagic women receiving Mirena, only 2 were still menorrhagic at 3 months. At 9 and 12 months 21 of 44 were amenorrheic *[Monteiro-2002]*
- After 3 to 6 months of menstrual irregularities (mostly spotting), Mirena decreases menstrual blood loss more than 70% (97% reduction in blood loss in one study) *[Monteiro-2002]*
- Amenorrhea develops in approximately 20% of users by 1 year and in 60% by 5 years
- Decreased surgery (hysterectomies, endometrial ablation, D & C) for menorrhagia, endometriosis, idiopathic causes of bleeding, leiomyomata or adenomyosis
- Indicated by product labeling for heavy menstrual bleeding ←

Sexual/psychological:

- Convenient: permits spontaneous sexual activity. Requires no action at time of intercourse
- Reduced fear of pregnancy can make sex more pleasurable

Cancers, tumors and masses: Protective effect against endometrial cancer, fibroids ←

Other: Extremely effective; as effective or more effective than female sterilization

- May be used as the progestin for endometrial protection with menopausal estrogen treatment
- ***Decreased*** risk for ectopic pregnancy by 80% *[Anderson-1994]*
  - Several studies show decreased PID, endometritis and cervicitis in LNG-IUS users
- Reduces symptoms e.g. pain of endometriosis *[Petta-2005]*

DISADVANTAGES

Menstrual: **(Removal for any bleeding problem in first year: 7.6%)**

- Number of spotting and bleeding days is significantly higher than normal for first few months and lower than normal after 3 to 6 months of using levonorgestrel intrauterine system
- Amenorrhea (a negative if not explained, a positive for some women if explained well in advance) occurs in about 20% of women at one year of use

- May cause cramping following insertion
- Expulsion: 2.9% in women using Mirena exclusively for contraception; 8.9% to 13.6% in women using Mirena to control heavy bleeding *[Diaz-2000] [Monteiro-2002]*

Sexual/psychological:
- Same as Copper IUD except when spotting and bleeding may interfere with sexual activity
- Loss of menses means hard to keep track of menstrual cyclicity symptoms (e.g. PMS)

Other:
- Offers no protection against viral STIs like HPV or HIV
- Persistent unruptured follicles may cause ovarian cysts; most regress spontaneously
- Hormonal side effects: headaches, acne, mastalgia, moodiness
- Brief discomfort after insertion or removal

COMPLICATIONS: See 2010 CDC MEC - Appendix: A1 - A8 **and page 84**
- PID risk transiently increased after insertion (highest in first 3 weeks)
- Perforation of uterus at time of insertion (less than 1 in 1000)

CANDIDATES FOR USE: ***Think of Mirena as reversible sterilization***
- Women wanting effective, reversible long-term contraception including nulliparous women and women wanting to avoid tubal sterilization. While in place, as effective as laparoscopic or transcervical tubal sterilization
- Can be used in women with heavy menses, endometriosis, fibroids, cramps or anemia
- Menopausal women using estrogen, with intact uteri, who are unable to tolerate oral progestins are protected against endometrial carcinoma by using a levonorgestrel intrauterine contraceptive (off-label) *[Raudaskoski, 1995] [Luukkainen, Steroids - 2000]*
- Formal FDA approval is being sought for the use of the LNG IUS to treat menorrhagia
- 2010 CDC practice recommendations include post placental insertion of LNG-IUS up to 48 hours in women. Only a pilot study of 20 women is published on this topic *[Hayes-2007]*. Probably associated with a higher expulsion rate than interval insertion.

PRESCRIBING PRECAUTIONS: See CDC Precautions in Appendix: A-1 - A-8
- May be used by woman with past history of ectopic pregnancy (CDC:1)

INITIATING METHOD: ***Each step should be performed slowly and gently***
- ***The one-hand insertion technique is different from current Copper IUDs. Training sessions may be set up by calling 1-866-LNG-IUS1.*** See Figure 25.3, pages 92-93
- If inserted within 7 days from LMP, no backup needed. She can have it inserted any other time of cycle if reasonably certain not pregnant, but add backup or abstinence x 7 days
- Insertion tube is 2 mm wider than for copper intrauterine contraceptives; may rarely need to dilate cervix
- Paracervical block may be required, especially for nulliparas
- Counsel in advance to expect menstrual cycle changes, including amenorrhea. Women using levonorgestrel contraceptive system who received information in advance about possible bleeding changes and amenorrhea were significantly more likely to be highly satisfied with the contraceptive. *[Backman-2002]*
- Advise NSAIDs for post-insertion discomfort. If pain persists, she must return

INSTRUCTIONS FOR PATIENT: Similar to copper intrauterine contraceptive, p. 87

FOLLOW-UP: Same as Copper IUD

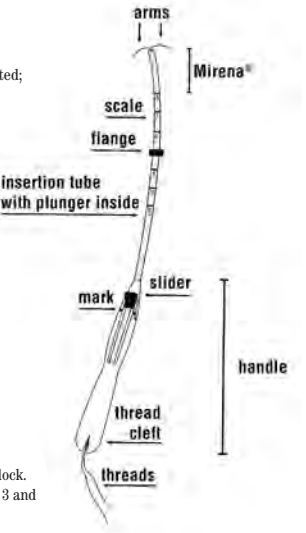
PROBLEM MANAGEMENT: Similar to Copper T 380-A; see p. 88-89
- ***Perforation:*** A case report from Israel actually looked at serum LNG levels from Mirena in the omentum following uterine perforation. They were higher than POP serum levels. So, theoretically, an abdominal Mirena IUD still provides adequate contraceptive effect until it is removed. Condoms and removal of IUD still recommended!

FERTILITY AFTER DISCONTINUATION OF METHOD: Immediate return to baseline fertility

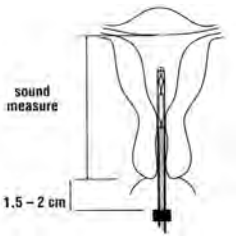
Figure 25.3 INSERTION TIPS: Each step should be performed slowly and gently

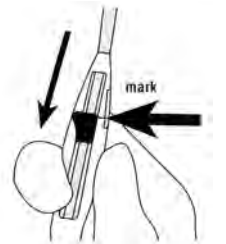
- All clinicians wanting to insert IUDs would benefit from training in IUD insertion
- Reconfirm signed consent
- May give NSAIDs one hour prior to insertion
- Be sure patient is not pregnant
- Routine antibiotic prophylaxis is not warranted; American Heart Association requires **no** antibiotic treatment for mitral valve prolapse, except for women at high risk for bacterial endocarditis
- Recheck position, size and mobility of uterus prior to insertion
- Cleanse upper vaginal, outer cervix, and cervical os and canal thoroughly with antiseptic
- Local anesthesia at tenaculum site: 3 approaches are 1) no anesthesia 2) apply benzocaine 20% gel first at tenaculum site then leave a gel-soaked cotton-tipped applicator in cervical canal for 1 minute before proceeding with IUD insertion (Speroff/Darney p. 245) 3) inject 1 ml of local anesthetic (1% chloroprocaine) into the cervical lip into which the tenaculum will be placed
- Most women will NOT need a paracervical block. However, can give 5 cc of local anesthetic at 3 and 9 o'clock
- Place tenaculum to stabilize cervix and straighten uterine axis.
- Sound uterus to fundus with uterine sound or pipelle; uterus should be at least 6 cm, but no strict limits.
- Pick up Mirena and release the threads from slider so they hang freely
- Push slides in the furthest position away from you while pulling threads to load Mirena making sure arms stay horizontal
- Fix threads in cleft
- Set flange to depth measured by sound
- Keep thumb on slider as you insert Mirena into uterus
- Advance Mirena until the flange is 1.5 - 2 cm from external os
- Pull back slider until it reaches mark while holding inserter steady. Wait 30 seconds to allow arms to open within uterus
- Advance Mirena until flange touches cervix allowing Mirena to reach fundus

MIRENA® and Inserter



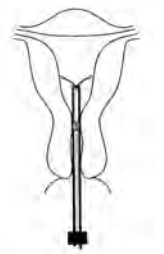
- Hold inserter in position while pulling slides down all the way. The threads should be released automatically from cleft. If not, manually remove the strings from the cleft
- Withdraw Mirena inserter from uterus
- Cut threads to 2 inches; requires care and sharp scissors to avoid dislodging Mirena
- Hand patient cut strings so she knows what to feel for during string check





Pulling the slider back to reach the mark

Flange adjusted to sound depth



The arms of the MIRENA® being released

CHAPTER 24

Combined (Estrogen & Progestin) Contraceptives

www.managingcontraception.com OR www.plannedparenthood.org OR www.noperiod.com

This chapter will describe the methods that provide both an estrogen and a progestin: combined birth control pills (p. 94), the patch (p. 112) and the vaginal ring (p. 114)

PILLS - DAILY "THE PILL" COMBINED PILLS

DESCRIPTION: Each hormonally active pill in combined pills contains an estrogen and a progestin. Ethinyl estradiol (EE) is the most commonly used estrogen; it is in most 50 µg pills and all of the sub-50 µg formulations. Mestranol, which must be metabolized to EE to become biologically active, is found in two 50 µg formulations (rarely prescribed). At least 7 progestins are used in the different pill formulations. Traditional packs have 21 active combined pills, with or without 7 additional pills (usually placebo pills or pills with iron). Many newer formulations have varying numbers of active pills and hormone free pills. For example, Seasonale has 84 consecutive hormonal pills followed by 7 placebo pills. Yaz and Loestrin-24 have 24 days of hormonal pills followed by 4 days of placebo pills. New pill, Lybrel, has no hormone free pills. Monophasic formulations contain active pills with the same amount of hormones in each tablet. Multiphasic formulations contain active pills with varying amounts of progestin and/or estrogen in the hormonal pills. All of the recently approved pills have less than 7 inactive pills per cycle ←

EFFECTIVENESS

Perfect use failure rate in first year: 0.3% (of every 1,000 women who take pills for 1 year, 3 will become pregnant in the first year use) (See Table 13.2, p. 40)
Typical use failure rate in first year: 9% *[Trussell J IN Contraceptive Technology, 2004]*

HOW PILLS WORK: Ovulation suppression (90% to 95% of time). Also causes thickening of cervical mucus, which blocks sperm penetration and entry into the upper reproductive tract. Thin, asynchronous endometrium inhibits implantation. Tubal motility slowed.

COST

- Cost of one cycle: from a few dollars to more than $50. Most pharmacies charge $20-$42/cycle
- Costs differ from region to region, and pills with 50 mcg of estrogen often cost more.
- Generic brands are generally less expensive. They are not required to have clinical testing; they must only prove blood level equivalency (80–125% of parent compound's blood levels).
- Wal-Mart sells Tri Sprintec for $9.00 per cycle ←
- Most major insurance companies cover at least some brands of pills
- The co-pay for Seasonale is as much as $60 per a package (3 months supply)

ADVANTAGES

Menstrual:

- Decreased blood loss and decreased anemia may decrease menstrual cramps/pain, and more predictable menses
- Eliminates ovulation pain (Mittelschmerz)
- Can be used to manipulate timing and frequency of menses (see Choice of COC, p. 103 & 108)
- Reduces risk of internal hemorrhage from ovulation (especially important in women with bleeding diatheses or women using anticoagulants)
- Regulates menses and provides progestin for women with anovulation/PCOS (reducing risk of endometrial cancer)

Sexual/psychological:

- No interruption at time of intercourse; more spontaneous activity
- Intercourse may be more pleasurable because of reduced risk of pregnancy

Cancers/tumors/masses:

- Low dose OCs offer the same 50% reduction in ovarian cancer risk as higher-dose formulations *[Ness-2000].* COC users for 5 years have 50% reduction in risk; users for 10 years have 80% reduction. Protection extends for 30 years beyond last pill use; Significant reduction in risk also seen in some high risk women carrying BRCA mutations
- Decreased risk for **endometrial cancer** *[Grimes-2001]* (30 µg and higher dose pills)
  - COC users for 1 year have 20% reduction in risk; users for 4 years have 60% reduction
  - Protection extends for 30 years beyond last pill use *[Ness, AmJEpidemiol-2000]*
  - Particularly important for PCOS women, obese women, and perimenopausal women
- Decreased risk of death from **colorectal cancer** *[Beral-1999]*
- Decreased risk of corpus luteum cysts and hemorrhagic corpus luteum cysts
- *Breast masses:* reduce risk of **benign breast disease** (including fibroadenomas)

DO BIRTH CONTROL PILLS CAUSE BREAST CANCER?

- After more than 50 studies and 50 years, most experts believe ***that pills have little, if any, effect on the risk of developing breast cancer.***
- The Women's Care Study of 4575 women with breast cancer and 4682 controls found no increased risk for breast cancer (RR: 1.0) among women currently using pills and a decreased risk of breast cancer (RR: 0.9) for those women who had previously used pills. Use of pills by women with a family history of breast cancer was not associated with an increased risk of breast cancer, nor was the initiation of pill use at a young age *[Marchbanks - 2002]*
- However, several studies have shown that current users of pills are slightly more likely to be ***diagnosed*** with breast cancer (Relative Risk: 1.2). *[Collaborative Group; Lancet 1996]*
- Two factors may explain the increased risk of breast cancer being diagnosed in women currently taking pills: 1) a ***detection bias*** (more breast exams and more mammography) or 2) ***promotion*** of an already present nidus of cancer cells
- Ten years after discontinuing pills, women who have taken pills are at no increased risk for having breast cancer diagnosed. *[Collaborative Group; Lancet 1996]*
- Breast cancers diagnosed in women currently on pills or women who have taken pills in the past are more likely to be localized ***(less likely to be metastatic)***. *[Collaborative Group; Lancet 1996]*
- By the age of 55, the risk of having had breast cancer diagnosed is the same for women who have used pills and those who have not
- The conclusion of the largest collaborative study of the risk for breast cancer is that women with a strong family Hx of breast cancer do not further increase their risk for breast cancer by taking pills. *[Collaborative Group; Lancet 1996]* This was also the conclusion of the Nurses Health Study *[Lipmick-1986] [Colditz-1996]* and the Cancer and Steroid Hormone (CASH) study. *[Murray-1989] [The Centers for Disease Control Cancer and Steroid Hormone Study-1983]*
- While there are still unanswered questions about pills and breast cancer. The overall conclusion is that pills do not cause breast cancer. ***"Many years after stopping oral contraceptive use, the main effect may be protection against metastatic disease."*** *[Speroff and Darney-2001] [Collaborative Group; Lancet 1996]*

NOTE: Many of the symptoms women complain of after starting pills (nausea, headaches, bloating) occur more frequently during the days a woman is on placebo pills. Therefore, ask women ***when*** they have these symptoms. **Symptoms occurring primarily during the placebo days may be an indication for extended or continuous use of pills** *[Sulak-2002]*

Other:

- Reduces risk of ectopic pregnancy and risk of hospitalization with diagnosis of PID
- Treatment for acne, hirsutism and other androgen excess/sensitivity states
- Reduced vasomotor symptoms and effective contraception in perimenopausal women
- Possible increased bone mineral density. Pills with 35 micrograms of estrogen used by women in their 40s; have been associated with fewer postmenopausal hip fractures *[Michaelsson-1998; Lancet, 353:1481-1484]*. However, low dose pills do not affect fracture risk *[Vestergaard-2006]*
- Decreased pain and frequency of sickle cell disease crises

DISADVANTAGES

Menstrual:

- Spotting, particularly during first few cycles and with inconsistent use
- Scant or missed menses possible, not clinically significant but can cause worry
- Post-pill amenorrhea (lasts up to 6 months). Uncommon and usually in women with history of irregular periods prior to taking pills

Sexual/psychological:

- Decreased libido and anorgasmia ARE possible.
- Mood changes, depression, anxiety, irritability, fatigue may develop while on COCs, but no more frequent than with placebos. Rule out other causes before implicating COCs
- In a longitudinal survey of over 9000 women in Australia, OCP use was not associated with depressive symptoms *[Duke-2007]*
- Daily pill taking may be stressful (especially if privacy is an issue)

Cancers/tumors/masses: **Breast cancer - see comprehensive answer on p. 95**

- ***Cervical cancer:***
  - No consistent increased risk seen for squamous cell cervical carcinoma (85% of all cervical cancer) after controlling for confounding variables, such as number of sex partners, smoking and parity
  - Risk of adenocarcinoma, a relatively uncommon type of cervical cancer, is increased 60%, but no extra screening required other than recommended Pap screening
- ***Hepatocellular adenoma:*** risk increased among COC users (only in $\geq$ 50 µg formulations). Risk of hepatic carcinoma not increased, even in populations with high prevalence of hepatitis B

Other:

- No protection against STIs, including HIV.
- Shedding of HIV may be slightly increased with use of some antiretrovirals
- Nausea or vomiting, especially in first few cycles
- Breast tenderness or pain
- Headaches: may increase
- Increased varicosities, chloasma, spider veins
- Daily dosing is difficult for some women
- Average weight gain no different among COC users than in placebo users (see NOTE below)
- See COMPLICATIONS section below

Most women on antiretrovirals should use condoms since:

1) the meds may decrease the pill effectiveness if the antiretroviral induces cytochrome p 450 metabolism
2) GI side-effects from drugs may decrease OC effectiveness
3) It is important to avoid other infections that may facilitate HIV transmission

NOTE: Medical problems and symptom complaints are frequently attributed by patients and providers to COC use. While some women may be particularly sensitive to sex steroids, a recent placebo-controlled study found that the incidence of all of the frequently mentioned hormone-related side effects was not significantly different in the COC group than it was in the placebo group *[Redmond, 1999]* For example, headaches occurred in 18.4% of women on Ortho Tricyclen and in 20.5% of women in the placebo group. Nausea occurred in 12.7% of women on Ortho Tricyclen and in 9.0 % of women on placebo pills. Weight gain occurred in 2.2% of women on Ortho Tricyclen and in 2.1 % of women on placebo pills. For some women, however, these complaints may actually be related to pill use

COMPLICATIONS

- *Venous thromboembolism (VTE)*
  - The risk of VTE with COC use is less than with pregnancy:

No COC use	50/100,000 women per year
COC use	100/100,000 women per year
Pregnancy/Postpartum	200/100,000 women per year

  - DVT risk is associated with the dose of estrogen; the risk of VTE in 50 µg pills is greater than in 20-35 µg pills. The type of progestin may ***slightly*** influence DVT risk. A meta-analysis by Hennessy et al (2001) included 12 observational studies and found a summary relative risk of 1.7 (1.3) - 2.1; heterogeneity p = 0.09) but could not rule out confounding given nature of observational studies. If read, the excess risk was 11 per 100,000 women per year. The current labeling for desogestrel pills states that "several epidemiologic studies indicate that third generation OCs, including those containing desogestrel, are associated with a higher risk of venous thromboembolism than certain second generations OCs. In general, these studies indicate an approximate 2-fold increased risk. However, data from additional studies have not shown this 2-fold increase in risk." Neither the FDA nor ACOG recommends switching current users of desogestrel containing pills to other products. Underlying blood dyscrasias such as Factor V_{Leiden} mutation and Protein S or C abnormalities increase risk of VTE significantly. However, in the absence of strong family history (see boxed message on p. 99), screening is not necessary. A very large well-designed prospective study of the risk of VTE with drospirenone, found no relative increase in risk with the use of DRSP compared with LNG pills *(Dinger)*. Two recent large studies (one case-control, and one retrospective cohort) did find small increases in risk with the use of DRSP pills compared with LNG pills *(Lidegaard, A van Hylckand Vlieg)*. A debate about whether these studies adequately controlled for confounding factors is ongoing
- *Myocardial infarction (MI) and stroke*
  - There is no increased risk of MI or stroke for young women who are using low-dose COCs who do not smoke, do not have hypertension and do not have migraine headaches with neurological findings
  - Women at risk:
    - Smokers over 35 shouldn't use COCs; all smokers should be encouraged to stop smoking. Smokers over 35 have MI rate of 396 per million COC users per year vs. 88 per million non-COC users per year
    - Women with hypertension, diabetes, hyperlipidemia or obesity
    - Women with migraine with aura (only stroke risk increases)
- *Hypertension:* 1% of users develop hypertension which (usually) is reversible within 1-3 months of discontinuing COCs. Most users have a very small increase if any in blood pressure
- *Neoplasia:* COC users using early high dose pills are at higher risk of developing adenocarcinoma (rare) of the cervix and hepatic adenomas (rare). See boxed message on p. 95 for an answer to the question: Do birth control pills cause breast cancer?

ELEVATED BLOOD PRESSURE: A TEACHABLE MOMENT

Each time you find an elevated blood pressure, several messages should reach the ears of your patient:*

1. If you smoke, stop smoking. This is by far the most important step you can take
2. Moderate exercise for 20-30 minutes each day, every day reduces blood pressure!
3. If overweight, lose weight. Reduce fat in your diet
4. Use salt in moderation
5. If you are on antihypertensive medications, take them regularly!
6. Work on reducing stress in your life (may be difficult and may take time)

* *In addition to deciding if pills can be used*

- *Cholelithiasis/cholecystitis:* higher dose formulations were associated with increased risk of symptomatic gallbladder disease
  - Sub-50 mcg formulations may be neutral or have a slightly increased risk
  - Use COCs with caution in women with known gallstones. Asymptomatic (CDC:2), treated by cholecystectomy (CDC:2), symptomatic and being treated medically (CDC:3), current and symptomatic (CDC:3)
- *Visual changes:* Rare cases of retinal thrombosis (must stop pills). Contact lens users may have dry eyes. May need to recommend eye drops or need to switch methods

CANDIDATES FOR USE: See 2010 CDC Medical Eligibility Criteria, p. A-1 through A-8

- Most healthy reproductive aged women are candidates for COCs
- Use of COCs is often decided on the basis of a balance of benefits and side effects
- In addition to medical precautions, real world considerations such as the need for privacy, affordable access to COCs, and the requirement for daily administration need to be considered when evaluating a woman for COC use

Adolescents

- May be excellent candidates for contraceptive benefits if patient is able to take a pill each day.
- Many of the non-contraceptive effects of OCs are particularly important for adolescent women – e.g. decreased dysmenorrhea (the most common cause of lost days of school and work among women under 25), and decreased acne, hirsutism, or hypoestrogenism due to eating disorders, excessive exercise, stress, etc.
- Failure rates are higher in teens using COCs. Help teens integrate pill taking into daily rituals (tooth brushing, cell phone, watch alarm, application of makeup, putting on earrings). Ask teenager how she will create a way to be successful. Suggest having her write down a plan. Ask if parents are aware that she is using contraception and if they are supportive. Consider continuous COC use. See p. 100
- Encourage teens to use condoms consistently and correctly
- Be sure she has a package of Plan B at home

SPECIAL CONSIDERATIONS FOR USE

- Women with medical conditions that improve with COCs may find COCs a particularly attractive contraceptive option. This includes women with dysmenorrhea, endometriosis, menstrual migraine without aura, iron deficiency anemia, acne, hirsutism, polycystic ovarian syndrome (PCOS), ovarian or endometrial cancer risk factors, eating disorders or activity patterns that increase risk of osteoporosis. Consider continuous or extended COC use with a monophasic pill. See p. 100
- Women whose reproductive health would be improved by ovulation suppression or decreased menstrual blood loss should also consider COCs. This includes women with chronic amenorrhea (unopposed estrogen), and women who suffer menorrhagia or dysmenorrhea and some anticoagulated women (COCs decrease risk of internal hemorrhage with ovulation and menorrhagia)
- Women whose quality of life would be improved by reducing frequency of or eliminating menses with extended cycles or continuous COC use: See p. 100
- Women who have difficulty swallowing pills may benefit from the chewable formulation of Ovcon-35. OCs may potentially also be placed in the vagina for systemic absorption. Large studies are lacking

PRESCRIBING PRECAUTIONS

See CDC Eligibility Criteria Appendix A1 - A8

- Thrombophlebitis, thromboembolic disease or history of deep venous thrombosis or pulmonary embolism (unless anticoagulated)
- Family history of close family members with unexplained VTE at early age (eg Factor V_{Leiden} mutation)

The questions to ask are as follows:

- Has a close family member (parents, siblings, grandparents, uncles, aunts) ever had unexplained blood clots in the legs or lungs?
- Has a close family member ever been hospitalized for blood clots in the legs or lungs? If so, did this person take a blood thinner? (If not, it is likely that the family member had a nonsignificant condition such as superficial phlebitis or varicose veins)
- What were the circumstances in which the blood clot took place (eg. pregnancy, cancer, airline travel, surgery, obesity, immobility, postpartum, etc.)? *[Grimes - 1999]*

"If the family history screening is positive - one or more close family members with a definite strong VTE history (young first - or second - degree relatives with spontaneous VTE) clinician might consider further laboratory screening for genetic conditions. Another alternative is to suggest progestin-only OCs or another non-estrogen-containing birth control method." *[Grimes - 1999]*

- Cerebral vascular disease or coronary artery disease
- Current breast cancer (CDC: 4)
- Past breast cancer and no evidence of current disease for 5 years (CDC: 3)
- Endometrial carcinoma or other estrogen dependent neoplasia (excluding endometriosis and leiomyoma)
- Unexplained vaginal bleeding suspicious for serious condition (before evaluation) (CDC: 2)
- Cholestatic jaundice of pregnancy or jaundice with prior pill use
- Hepatic adenoma or carcinoma or significant hepatic dysfunction
- Smoking after age 35. CDC defines heavy smoking as $\geq$ 15 cigarettes/day (see p. A3)
- Complicated or prolonged diabetes, systemic lupus erythematosus (if vascular changes)
- Severe migraine with aura or other neurologic symptoms
- Breastfeeding women (without supplementation) until breastfeeding well established COCs have no adverse effects on babies of OC-using, nursing mothers
- Hypersensitivity to any components of pills
- Daily use of certain broadspectrum antibiotics. Although CDC (see p. A8) states that women using antibiotics other than grisiofulvin or rifampicin may use COCs (CDC:1), patients are exposed to conflicting information. Many clinicians explain the differing opinons and let patient decide for herself. There are not convincing data that broad spectrum antibiotics increase the failure of COCs. Doxycycline and fluconazole *[Hilbert-2001]* do not lower the effectiveness of COCs *[Murphy AA-1991] [Neely JL-1991]*
- Hypertension with vascular disease $\frac{140\text{-}159}{90\text{-}99}$ = 3 (CDC) $\frac{\geq 160}{\geq 100}$ = 4 (CDC)

EXTENDED USE OF PILLS MAY MEAN:

A. Manipulation of a cycle to delay one period for a trip, honeymoon, or athletic event
B. Use of active hormonal pills for more than 21 consecutive days) followed by 2 to 7 hormone-free days.
C. Continuous daily COCs for at least 21 pills, but after that, may break for 2-7 days if spotting or breakthrough bleeding is bothersome
D. Use of a monophasic pill indefinitely. BTB can occur at any time with this regimen. Eventually she develops an atrophic endometrium and breakthrough bleeding decreases.

Cyclic symptoms that may improve from the extended use of pills:

Symptoms usually occurring at the time of menses: (predicted benefits)

- Abdominal, back or leg pain, dysmenorrhea
- If cyclic pills do not control symptoms of endometriosis *[Havada-2007]* continuous pills may work *[Vercellini-2003]*
- Bleeding abnormalities including menorrhagia
- Irritability or depression. Decreased libido
- Headaches including both menstrual migraine and other cyclic headaches *[Sulak-2000] [Kwiecien-2003]*
- Nausea, dizziness, vomiting or diarrhea
- Cyclic yeast or other infections or cyclic nosebleeds
- Cyclic seizures, arthritis, or recurrences of asthma at the time of menses
- Changes in insulin requirements
- Cyclic symptoms associated with polycystic ovarian disease

Symptoms usually occurring at midcycle:(predicted benefits)

- Spotting due to sudden fall in estradiol
- Sharp or dull pain (that precedes ovulation and is caused by high midcycle PG levels)

Symptoms usually occurring just prior to menses: (predicted benefits)

- Slight to more dramatic weight gain, bloating, swollen eyes or ankles
- Breast fullness or tenderness
- Anxiety, irritability or depression, nausea or headaches due to dropping estrogen
- Acne, spotting, discharge, breast fullness or tenderness
- Pain or cramping or constipation

Most important advantages & disadvantages of taking COCs continuously:

Advantages:

- May be more effective as a contraceptive when taken daily
- May be easier to remember (do the same thing every day)
- Women wanting to avoid bleeding for an athletic event, special trip or any other reason
- Less frequent menstruation *[Sulak-2000] [Glasier-2003]* and less blood loss
- Recent Harris survey: three quarters of women prefer less frequent periods, although only 8% tried continuous pills. *[Harris-2008] Accessed at www.healthywomen.org/Documents/MenstrualManagementReport.pdf*
- Decreased expenses from tampons, pads, pain meds, and days of work missed

Disadvantages:

- More expensive and the extra packs of pills required may not be covered by insurance
- Unscheduled spotting or bleeding and the absence of regular menses
- Clinician must explain the difference: amenorrhea, while taking a progestin every day, is not harmful *[Miller-2003]*. Ammenorhea for a woman on no hormonal contraceptive, may lead to endometrial hyperplasia or cancer.

MEDICAL ELIGIBILITY CHECKLIST: Ask a woman on pills the questions below. If she answers NO to ALL of the questions and has no other contraindications, then she can use low-dose COCs if she wants. If she answers YES to a question below, follow the instructions

1. Do you think you are pregnant?

☐ No ☐ Yes Assess if pregnant. If she might be pregnant, give her male or female condoms to use until reasonably certain that she is not pregnant. Then she can start COCs. If unprotected sex within past 5 days, consider emergency contraception if she is not pregnant

2. Do you smoke cigarettes and are you age 35 or older?

☐ No ☐ Yes Urge her to stop smoking. If she is 35 or older and she will not stop smoking, do not provide COCs. Help her choose a method without estrogen

3. Do you have high blood pressure? (see Appendix)

☐ No ☐ Yes If BP below 140/90, OK to give COCs if no other comorbidities exist even if taking antihypertensive drugs. If BP is elevated, see Appendix, p. A-3. Consider IUD or progestin-only methods

4. Are you breast-feeding your baby?

☐ No ☐ Yes If yes, non-estrogen containing contraceptives are preferable. ← However, according to new CDC Medical Eligibility Criteria 2010 (see appendix) use of COCs in breastfeeding women is given a catagory 2 at 1 month PP meaning advantages outweigh disadvantages. CDC considering change to category 2 or 3 for the 3-6 week post partum period depending on a woman's risk factors for VTE.

5. Do you have serious medical problems such as a heart disease, severe chest pain, blood clots, high blood pressure or diabetes? Have you ever had such problems?

☐ No ☐ Yes Do not provide COCs if she reports heart attack or heart disease due to blocked arteries, stroke, blood clots (except superficial clots), severe chest pain with unusual shortness of breath, diabetes for more than 20 years, or damage to vision, kidneys, or nervous system caused by diabetes. Help her choose a method without estrogen. Consider POPs, LNg IUD, Copper T 380 A, Implanon, barriers, DMPA

6. Do you have or have you ever had breast cancer? (see Appendix)

☐ No ☐ Yes Do not provide COCs if current or less than 5 years ago. Help her choose a method without hormones. If disease free x 5 years, may consider COCs if there are no better option for her (CDC: 3)

7. Do you often get bad headaches with blurred vision, nausea or dizziness?

☐ No ☐ Yes If she gets migraine headaches with blurred vision, temporary loss of vision, sees flashing lights or zigzag lines, or trouble speaking or moving, or has other neurologic symptoms, do not provide COCs. Consider POPs, LNG IUD, Copper T 380 A, Implanon, barriers. Help her choose a method without estrogen. If she has only menstrual migraines without abnormal neurologic findings, consider COC use.

8. Are you taking medicine for seizures or are you taking rifampin, griseofulvin or St. John's Wort?

☐ No ☐ Yes If she is using St. John's Wort, rifampin, griseofulvin, topiramate (Topomax) phenytoin, carbamazepine, barbiturates, or primidone, guide her to a non-estrogen containing method or strongly encourage condom use as backup contraceptive. Use of valproic acid does NOT lower the effectiveness of COCs. See discussion p. 104

9. Do you have vaginal bleeding that is unusual for you? (see Appendix)

☐ No ☐ Yes If she is not likely to be pregnant but has unexplained vaginal bleeding that suggests an underlying medical condition, evaluate condition before initiating pills. Treat as appropriate or refer. Reassess COC use based on findings

10. Do you have jaundice, cirrhosis of the liver, an acute liver infection or tumor? (Are her eyes or skin unusually yellow?) (see Appendix)

☐ No ☐ Yes If she has serious active liver disease (jaundice, painful or enlarged liver, active viral hepatitis, liver tumor), do not provide COCs. Refer for care as appropriate. Help her choose a method without hormones

11. Do you have gallbladder disease? Ever had jaundice while taking COCs or during pregnancy?

☐ No ☐ Yes If she has acute gallbladder disease now or takes medicine for gallbladder disease, or if she has had jaundice while using COCs or during pregnancy, do not provide COCs. Consider a method without estrogen. Women with known asymptomatic cholelithiasis may use COCs with caution

12. Are you planning surgery with a recovery period that will keep you from walking for a week or more? Have you had a baby in the past 21 days?

☐ No ☐ Yes Help her choose a method without estrogen. If planning surgery or just had a baby, provide COCs for delayed initiation and another interim method

13. Have you ever become pregnant on the pill?

☐ No ☐ Yes Ask about pill-taking habits. Consider longer dosing hormonal methods or shortening or eliminating the pill-free interval while using COCs

INITIATING METHOD (see INSTRUCTIONS FOR PATIENT, p. 104)

- In asymtomatic women, **a pelvic examination is not necessary to start pills** *[Stewart-2001]*
- *Counseling is critical in helping women successfully use the pill*
  - Patients who are counseled well about how to use pills and what side effects may develop are usually better prepared and may be more likely to continue use
- *Timing of initiation* (see Table 26.2, p. 107)
  - First day of next menstrual period start
  - **"Quick Start"** (starting the day of the counseling clinic visit) is quite feasible to help women adapt to COCs *[Westoff-2002].* Provide 7 day backup. Bleeding is not increased in "quick starters". This is now the preferred method of starting pills
  - If using Sunday start, recommend back-up method x 7 days. Sunday start can result in no periods on weekends
- *Choice of pill*
  - The pill that will work best for the woman is the one that she will take regularly!
  - For special situations, some formulations offer advantages over others (see CHOOSING COCs FOR WOMEN IN SPECIAL SITUATIONS, p. 103)
    - In general, use the lowest dose of hormones that will provide pregnancy protection, deliver the non-contraceptive benefits that are important to the woman, and minimize her side effects

- Monophasic formulations are preferable if women are interested in controlling cycle lengths or timing by eliminating any or all pill-free intervals for medical indications or personal preference (see Choosing COCs, Figure 26.2 p. 108)
- Triphasic formulations are preferred by some clinicians to reduce some side effects (such as premenstrual breakthrough bleeding) when it is not desirable to increase hormone levels throughout the entire cycle or when it is desirable to reduce total cycle progestin levels (e.g. acne treatment). There are no studies that support the superiority of triphasic pills for women with BTB

- *Choice of pattern of COC use*
  - 28-day cycling: Most common use pattern. Women have monthly withdrawal bleeding during placebo pills
  - *"First day start" each cycle:* Women can start each new pack of pills on first day of menses each cycle
  - *"Bicycling" or "tricycling":* Women skip placebo pills for either 1 or 2 packs and then use the placebo pills and have withdrawal bleeding after 6 weeks (end of 2nd pack) or after 9 weeks (end of 3rd pack). **Use monophasic pills**
  - You may prescribe 4 packs of low dose monophasic pills omitting the placebo pills or use Seasonale, Seasonique, LoSeasonique, Jolessa or Lybrell all pre-packaged for extended cycles
  - *"Continuous use":* Women take only active pills and have no withdrawal bleeding. Often women must transition through bicycling or tricycling to achieve amenorrhea. Must use monophasic pills. Need to counsel regarding BTB and spotting
  - Studies of extended cycles have found no increased risk of endometrial hyperplasia *[Johnson-2007]*

  NOTE: the last three options may be particularly good for:
  - Women with menstrually-related problems (menorrhagia, anemia, dysmenorrhea, menstrual mood changes, menstrual irregularity, endometriosis, menstrual migraine, PMS, PMDD)
  - Women on medications that reduce COC effectiveness (e.g. anticonvulsants, St. John's Wort). See further description on p. 104
  - Women who have conceived while on COCs or who forget to take them regularly
  - Women who are ambulatory but disabled and for whom menstrual bleeding may be particularly problematic
  - Women who want to control their cycles for their own convenience
- Provide or recommend EC for when/if needed

CHOOSING COCs FOR WOMEN IN SPECIAL SITUATIONS

- *Endometriosis:* Pills taken continuously are most effective in reducing symptoms. Continuous use (no break) of ring may also be effective. See p. 116
- *Functional ovarian cysts:* higher dose monophasic COCs may be slightly more effective. Extended or continuous use of pills may also be more effective
- *Androgen excess states:* all COCs are helpful but pills with higher estrogen/progestin ratios are preferable to reduce free testosterone and inhibit 5 alpha-reductase activity.
- *Breastfeeding women:* progestin-only methods preferable to COCs in breastfeeding women. However, according to new CDC Medical Eligibility Criteria 2010 (see appendix) gives use of COCs in breastfeeding women a catagory 2 at 1 month PP meaning advantages outweigh disadvantages.

- *Hypercholesterolemia:* Selection of pill depends on type of dyslipidemia:
  - Screening for lipids not necessary prior to prescribing COCs
  - Elevated LDL or low HDL: consider estrogenic pill (high estrogen/androgen rates)
  - Elevated triglycerides: Some clinicians recommend not prescribing COCs if triglycerides > 350 mg/dL because COCs increase triglycerides by approximately 30% and risk of pancreatitis increased (norgestimate may increase triglycerides less)
- *Hepatic enzyme-inducing agents (e.g. anticonvulsants except valproic acid and St. John's Wort):* Options:
  - Prescribe high-dose COC (containing 50 µg EE)
  - Prescribe 30-35 µg pill with reduced pill-free interval (first-day start, bicycling with first day start, or continuous use)
- *Antibiotic use:* Concern that without intestinal flora to unconjugate the hormonal compounds produced by first hepatic processing, subsequent reabsorption of estrogen and progestin would not be possible. However, research on current dose pills suggests no significant difference in circulating serum levels of hormones when women used broad-spectrum antibiotics *[Murphy AA-1991][Neely-1991]*. Class OC labeling warns about potential antibiotic interactions. If patient has other risk factor (vomiting, diarrhea, forgetfulness) or is worried, do suggest back-up method for duration of antibiotic use. Rifampin **does** and griseofulvin **may** decrease pill effectiveness and a backup or alternative contraceptive is recommended. Check PDR for effects of antiretrovirals on steroid levels. Antiretrovirals receive a 2 (generally use the method) in the CDC Medical Eligibility Criteria
- *Obese patients:* Current data do not suggest different prescribing for markedly overweight women but some studies show a higher failure rate and increased risk of DVT

INSTRUCTIONS FOR PATIENT: Periodic "breaks" from pills are NOT recommended!

- Key to successful pill use is a well-informed patient. Provide new-start patients with:
  - Clear instructions on pill initiation, preferably written and in her primary language. If reasonably certain that she is not pregnant, use Quick Start technique *[Westhoff - 2002] (See p. 102)*. Have her take the first hormonally active pill immediately and use all pills. This *may* delay onset of next period. This will not increase the number of days of menstrual bleeding nor the number of days of spotting. The 3 month continuation rate among Quick Start women was markedly better than women starting pills at later times
  - Help her plan where to store pills, how to remember to take them and where to obtain refills
  - Explanation about possible transitional side effects (spotting, breast tenderness, headaches, etc.) and encouragement to call or return should any become troublesome (see PROBLEM MANAGEMENT). Also highlight noncontraceptive benefits
  - Warning about serious complications
  - There is no clinical data that suggests that generic OC's are less effective than branded OC's. Use the pill that is easiest to obtain (which may be the cheapest) *[ACOG Comm Opinion, Aug 2007]*
- Backup method: ensure patient has and knows how to use method if she needs to use one for interim protection, back-up, or as an alternate method if she ever discontinues COC use.
- Have patient return in 3 months for BP check and follow-up of any complaints (there is some debate about this recommendation especially if a woman can get the blood pressure determination elsewhere). Subsequently, only annual routine gynecologic exams are offered to low-risk patients
- Each woman on birth control pills needs a package of Plan B at home

CHECKLIST FOR EACH RETURN VISIT FOR WOMEN USING PILLS

Before you are seen by a counselor or clinician, please tell us your response to the following questions. Please check yes or no. Tell us if you have:

Any problem you think could be caused by pills	Yes____	No____
Nausea or vomiting	Yes____	No____
Spotting or irregular vaginal bleeding	Yes____	No____
Occasional missed periods (no bleeding)	Yes____	No____
Breast tenderness or a breast lump	Yes____	No____
Any symptoms of pregnancy	Yes____	No____
Depression, severe anxiety or mood changes	Yes____	No____
Decreased interest in sex	Yes____	No____
Decreased ability to have orgasms	Yes____	No____
Gained 5 pounds or more	Yes____	No____
High blood pressure	Yes____	No____
Been smoking at all	Yes____	No____
Been taking medicines for seizures	Yes____	No____
Been taking over-the-counter herbs	Yes____	No____
Ever forgotten to take your pills	Yes____	No____
Forgotten to take pills quite often	Yes____	No____
Changed sexual partners	Yes____	No____
Experienced any of the following pill danger signals:		
__**A**bdominal pain?	Yes____	No____
Yellow skin or eyes?	Yes____	No____
__**C**hest pain?	Yes____	No____
__**H**eadaches which are severe?	Yes____	No____
__**E**ye problems: blurred vision or loss of vision?	Yes____	No____
__**S**evere leg pain?	Yes____	No____

"ACHES" is a way for you to remember the pill danger signals.
Please explain any question you have answered "yes" to:

PROBLEM MANAGEMENT

Nausea/vomiting: **Rule out pregnancy, reassure that nausea usually improves**

- Prescribe lower estrogen formulation
- Suggest taking pills at night (evening meal or bedtime) to allow patient to sleep through high serum levels of hormones. Suggest taking pills with morning meal if experiencing bothersome nausea during the night
- If patient vomits within one hour of taking pill, suggest antiemetic prior to taking replacement pill. Use backup method for 7 days
- Consider change to a non-estrogen containing method
- Abdominal pain problems possibly related to COCs: thombosis of major intra-abdominal vessels, gallstones, pancreatitis, liver adenoma, Crohn's disease or porphyria

Spotting and/or breakthrough bleeding:

- See Fig. 26.3, p. 109 for women taking pills in the traditional 21/7 manner
- Do not double-up on pills!

Women taking pills for an extended period of time:

- Take first 21 pills every single day whether or not spotting occurs
- Thereafter, one approach to spotting is to stop active hormonal pills on first day of spotting (after having taken pills for at least 21 days). Take no pill for 2 or 3 days. Then restart pills daily until the next spotting day (again as long as pill has been taken for at least 21 days). With any pill taken continuously, the number of days with BTB will decrease over time

Missed one pill: **Instruct patient to take missed pill ASAP and take next pill as usual**

Missed two pills:

- For 30-35 mcg pills, same instructions as missed one pill (above)
- For 20 mcg pills follow instructions below for missed > 2 pills

Missed more than two pills:

- Take an active pill and continue taking 1 pill daily
- Use condoms or abstinence x 7 days
- If missed in week 3, finish active pills in current pack and start new pack the next day. Skip current pack's inactive pills
- If missed pills in first week and had sex, use EC

If patient uses ECPs: Instruct patient to resume taking pills in pack the next day after she finishes ECPs

Missed withdrawal bleed on COCs (not on extended or continuous cycles):

- Offer pregnancy test, especially if she missed any pills in last cycle or if she has any symptoms of pregnancy
- Offer emergency contraception if any intercourse in last 5 days
- Advise patient that there are no adverse clinical impacts of amenorrhea from COCs
- If patient prefers monthly withdrawal bleeding, consider switching to formulation with higher estrogen or lower progestin
- Otherwise, have her continue her COCs on usual schedule

New onset or significant worsening of headaches on COCs: (see Figure 26.4, p. 110)

Hot flashes on placebo-pill week:

- Suggest starting on first day of withdrawal bleeding or continuous use of monophasic pills OR
- Offer low-dose of transdermal or oral estrogen during placebo-pill week (Mircette provides 5 days of estrogen during 4th week)
- Offer Seasonique, a new formulation with 84 days of active pills, followed by 7 days of pills with 10 mcg EE or Lybrel, a formulation where all pills have hormones

If patient ≥ 50 years old, consider checking FSH level at least 2+ weeks off the pill (make sure she is using condoms) - see algorithm on p. 111