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Managing Contraception

For Your Pocket

Bridging the Gap Communications

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ABBREVIATIONS USED IN THIS BOOK

ACOG	American College of Obstetricians & Gynecologists	E₂	Estradiol
AIDS	Acquired immunodeficiency syndrome	EE	Ethinyl estradiol
AMA	American Medical Association	EPA	Environmental Protection Agency
ASAP	As soon as possible	EPT	Estrogen-progestin therapy
BBT	Basal body temperature	ET	Estrogen therapy
BCA	Bichloroacetic acid	FAM	Fertility awareness methods
BID	Twice daily	FDA	Food and Drug Administration
BMI	Body Mass Index	FH	Family History
BP	Blood pressure	FSH	Follicle stimulating hormone
BTB	Breakthrough bleeding	GAPS	Guidelines for Adolescent Preventive Services
BTL	Bilateral tubal ligation	GC	Gonococcus/gonorrhea
BV	Bacterial vaginosis	GI	Gastrointestinal
CA	Cancer (if not California)	GnRH	Gonadotrophin-releasing hormone
CDC	Centers for Disease Control and Prevention	HBsAg	Hepatitis B surface antigen
COCs	Combined oral contraceptives (estrogen & progestin)	HAV	Hepatitis A virus
CMV	Cytomegalovirus	HBV	Hepatitis B virus
CT	Chlamydia trachomatis	HCG	Human chorionic gonadotrophin
CVD	Cardiovascular disease	HCV	Hepatitis C virus
D & C	Dilation and curettage	HDL	High density lipoprotein
D & E	Dilation and evacuation	HIV	Human immunodeficiency virus
DCBE	Double contrast barium enema	HPV	Human papillomavirus
DMPA	Depot-medroxyprogesterone acetate (Depo-Provera)	HSV	Herpes simplex virus (I or II)
DUB	Dysfunctional uterine bleeding	H(R)T	Hormone (replacement) therapy
DVT	Deep vein thrombosis	IM	Intramuscular
E	Estrogen	IPPF	International Planned Parenthood Federation
EC	Emergency contraception	IUC	Intrauterine contraceptive
ECPs	Emergency contraceptive pills ("morning-after pills")	IUD	Intrauterine device
ED	Erectile dysfunction	IUP	Intrauterine pregnancy
		IUS	Intrauterine system
		IV	Intravenous

KOH	Potassium hydroxide	PLISSIT	Permission giving
LAM	Lactational amenorrhea method		Limited information
LDL	Low-density lipoprotein		Simple suggestions
LGV	Lymphogranuloma venereum		Intensive
LH	Luteinizing hormone		Therapy
LMP	Last menstrual period	PMDD	Premenstrual dysphoric disorder
LNG	Levonorgestrel	PMS	Premenstrual syndrome
MI	Myocardial infarction	po	Latin: "per os"; orally, by mouth
MIS	Misoprostol	POCs	Progestin-only contraceptives
MMG	Mammogram	POP	Progestin-only pill (minipill)
MMPI	Minnesota Multiphasic Personality Inventory	PP	Postpartum
MMR	Mumps Measles Rubella	PPFA	Planned Parenthood Federation of America
MMWR	Mortality and Morbidity Weekly Report	PRN	As needed
MPA	Medroxyprogesterone acetate	qd	Once daily
MRI	Magnetic resonance imaging	qid	Four times a day
MTX	Methotrexate	RR	Relative risk
MVA	Manual vacuum aspiration	Rx	Prescription
N-9	Nonoxonyl-9	SAB	Spontaneous abortion
NFP	Natural family planning	SHBG	Sex hormone binding globulin
NSAID	Nonsteroidal anti- inflammatory drug	SPT	Spotting
OA	Overeaters Anonymous	SSRI	Selective Serotonin Reuptake Inhibitors
OB/GYN	Obstetrics & Gynecology	STD	Sexually transmitted disease
OC	Oral contraceptive	STI	Sexually transmitted infection
OR	Operating Room	Sx	Symptoms
OTC	Over the counter	TAB	Therapeutic abortion/elective abortion
P	Progesterone or progestin	TB	Tuberculosis
Pap	Papanicolaou	TCA	Trichloroacetic acid
PCOS	Polycystic ovarian syndrome	tid	Three times a day
PE	Pulmonary embolism	TSS	Toxic shock syndrome
PET	Polyester (fibers)	URI	Upper respiratory infection
PG	Prostaglandin	UTI	Urinary tract infection
pH	Hydrogen ion concentration	VTE	Venous thromboembolism
PID	Pelvic inflammatory disease	VVC	Vulvovaginal candidiasis
		WHO	World Health Organization
		ZDV	Zidovudine

CHAPTER 1

The Menstrual Cycle

www.noperiod.com



SEVERAL KEY POINTS ON MENSTRUAL PHYSIOLOGY:

- **What initiates menses (and the next cycle)** is atrophy of the corpus luteum on or about day 25 of a typical 28 day cycle. This atrophy is initiated by a decline in LH release from the anterior pituitary gland and results in a fall in serum estrogen (E) and progesterone (P) levels. Without hormonal support, the endometrium sloughs. This drop in hormonal levels is also detected by the hypothalamus and pituitary, and FSH levels increase to stimulate follicles for the next cycle (Fig. 1.1 and 1.2).
- **Anovulation in women NOT on hormonal contraception leads to prolonged cycles, oligomenorrhea or amenorrhea or to irregular bleeding.** The absence of progesterone in anovulatory women *not* on hormones or birth control places these women at risk for endometrial hyperplasia and cancer. Recovery of ovarian function and return of ovulation has been demonstrated in women with functional hypothalamic amenorrhea who have been treated with cognitive behavioral therapy designed to improve coping skills for circumstances and moods that exacerbate stress [Berga-2003]. Similar results have also been achieved in women treated with hypnotherapy [Tschugguel-2003]
- **The two-cell, two gonadotrophin theory:** At the very beginning of the cycle, the outer theca cells can only be stimulated by LH and produce androgens (testosterone and androstenedione) and the inner granulosa cells can only be stimulated by FSH. Androgens diffuse toward the inner layer *granulosa* cells where they are converted into estradiol (E₂) by FSH-stimulated aromatase (see Figure 1.3).
- In a developing follicle, **low androgen levels** not only serve as the substrate for FSH-induced aromatization, but also stimulate aromatase activity. On the other hand, **high levels of androgens** (an “androgen-rich” environment as in some women with polycystic ovaries) lead to inhibition of aromatase activity and to follicular atresia.
- The female infant is born with 1-2 million follicles, most of which undergo atresia before puberty. Only about 10-20 follicles each month are recruited by rising FSH levels. The recruitment actually occurs during the late luteal phase of the preceeding cycle. Of those 10-20 follicles, usually only one dominant follicle ovulates. The number of follicles stimulated each month depends on the number of follicles left in the residual pool.
- FSH levels are low before ovulation as a result of negative feedback on FSH of E₂ and inhibin B. The dominant follicle “escapes” the effects of falling FSH levels before ovulation, because it has more granulosa cells, more FSH receptors on each of its granulosa cells, and increased blood flow. Cut off from adequate FSH stimulation, the other nondominant follicles undergo atresia.
- When E₂ production is sustained at sufficient levels (about 200 pg/ml) for more than 50 hours, negative feedback of E₂ on LH reverses to positive feedback. The LH surge occurs, and about 12 hours later an oocyte is extruded.
- About 50,000 granulosa cells form the corpus luteum. Some granulosa cells continue to produce E₂ and inhibins but many join the outer layers of theca cells to produce progesterone (P). Inhibin selectively suppresses FSH, not LH. The highest levels of inhibin are during the mid-luteal phase (primarily inhibin A now), causing FSH levels to be the lowest in the mid-luteal phase. At the end of the cycle (10-14 days after ovulation) if the corpus luteum is not rescued by HCG produced by the implanted trophoblast (pregnancy), the corpus luteum will undergo programmed atresia. Falling E₂, P, and inhibin levels induce the release of FSH to initiate another cycle.

Figure 1.1 Menstrual cycle events - Idealized 28 Day Cycle

[Hatcher RA, et al. *Contraceptive Technology*. 18th ed. New York: Irvington, 2004:69]

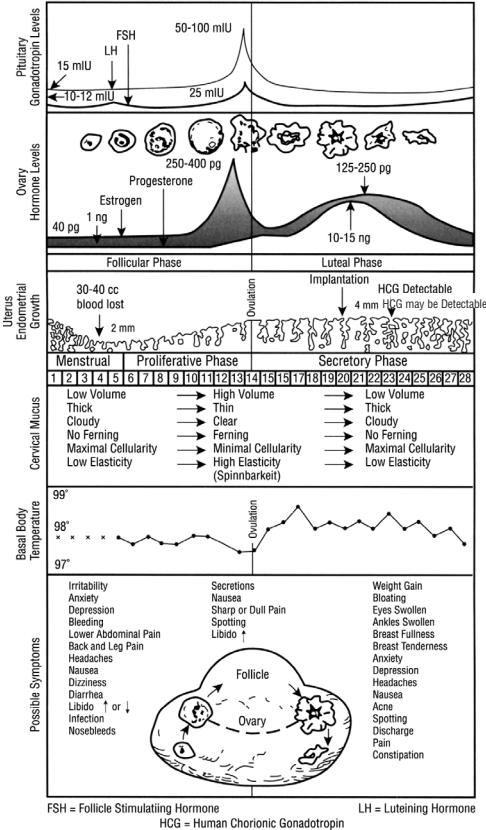
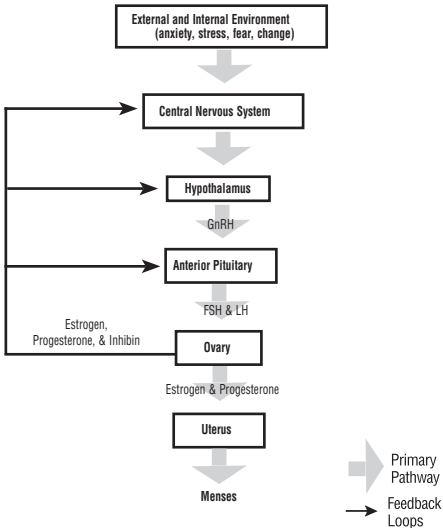


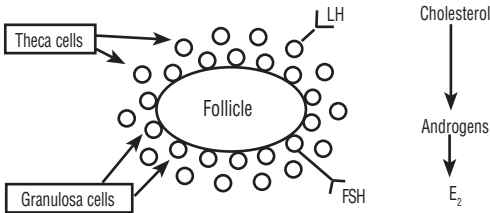
Figure 1.2 Regulation of the menstrual cycle

[Hatcher RA, et al. *Contraceptive Technology*. 18th ed. New York: Irvington, 2004:68]



Primary hormone pathways (➡) in the reproductive system are modulated by both negative and positive feedback loops (→). Prostaglandins, secreted by the ovary and by uterine endometrial cells, also play a role in ovulation, and may modulate hypothalamic function as well.

Figure 1.3 The two-cell, two gonadotrophin theory



Is Menstruation Obsolete? Who Needs a Period?

The extended or continuous use of pills causes women to have fewer "pill periods". Most, but not all, women like this [Ropes-2002]. Decreased periods or no periods at all is important to discuss with women considering use of continuous pills, Depo-Provera injections, the Mirena IUD or the implant, Implanon. A 2003 Gallop poll found that 99% of female gynecologists consider menstrual suppression safe.

What is "natural" — 50, 150, or 450 menstrual periods in a woman's lifetime?

In prehistoric times women had 50 menstrual cycles or fewer. In Colonial America, when women were having an average of 8 babies and nursing each baby for 2-3 years, women averaged 150 menstrual periods per lifetime. Currently in America women average 450-480 menstrual cycles per lifetime. [Segal, 2001]

Some women find regular menses reassuring, positive, "natural" or important evidence that they are still capable of reproducing. Many women regularly experience inconvenience, messiness, blood loss, painful menses, cyclic migraines, depression, ovarian cysts, and/or breast tenderness, would be happier having periods less often, or not at all (see discussion of extended use of COCs on page 100).

Many women feel both positively and negatively about their periods. Close to half of all visits to gynecology clinicians are for difficulties women experience at the time of their menses. [Segal, 2001] Women experiencing symptoms associated with their menses may benefit from contraceptives that alter the likelihood of ovulation, the amount of blood lost each month, or the extent of menstrual cramping and pain. In some instances, women may benefit from contraceptives that completely eliminate monthly periods. This is particularly likely to be true for women with any of the following cyclic symptoms: PMS, endometriosis, dysmenorrhea, depression, headaches, seizures, nausea, vomiting, breast enlargement or tenderness or very heavy bleeding. Unfortunately, few women are aware of the noncontraceptive benefits of contraceptives [Peipert, 1993] or of basic contraceptive knowledge [Davis, 2006]. ←

Clearly some women choose contraceptives to gain relief from symptoms related to their menstrual cycles. Others discontinue contraceptives due to undesirable effects on the patterns of their menses. In the pages ahead, the advantages and disadvantages of each contraceptive related to the menstrual cycle are described.

A provocative book by Coutinho and Segal raises the question: ***Is Menstruation Obsolete?*** [Coutinho, 1999] These two individuals played pivotal roles in the research leading to the approval of a number of our current contraceptives. Here is a comment on their book:

Kate Miller, MPH, of the University of Pennsylvania states: *One of the difficulties of regular menstruation is the usual assembly of monthly symptoms - cramps, headache, fatigue, irritability - which are often dismissed as part of "the curse" that women must simply endure. Since women tolerate these symptoms so regularly, they may not automatically include them in the "risks" of monthly menstruation. The reader is encouraged to recognize what may have previously gone unnoticed: that this monthly discomfort is simply not obligatory. In fact, it can be a startling exercise for a woman to imagine her life without the hassles and ailments of regular menstruation. This is a message whose time has come.*

CHAPTER 2

Recommended Screening/Risk Assessment by Age**

AGES 13-18 YEARS

SCREENING

History

- Reason for visit
- Health status: medical, surgical, family, menstrual
- Dietary/nutrition assessment
- Physical activity
- Use of complementary and alternative medicine
- Tobacco, alcohol, other drug use
- Abuse/neglect
- Sexual practices

Physical Examination

- Height and Weight
- Blood pressure
- Body Mass Index
- Secondary sexual characteristics (Tanner staging)
- Pelvic examination (when indicated by the medical history) and skin*

LABORATORY TESTS

Periodic

- Cervical cytology (annually beginning at approximately 3 years after initiation of sexual intercourse)
- Chlamydia and gonorrhea testing if sexually active

High-Risk Groups*

- Hemoglobin level assessment
- Bacteriuria testing
- Sexually transmitted disease testing
- Human immunodeficiency virus (HIV) testing
- Genetic testing/counseling
- Rubella titer assessment
- Tuberculosis skin testing
- Lipid profile assessment
- Fasting glucose testing
- Hepatitis C virus testing
- Colorectal cancer screening†

EVALUATION AND COUNSELING

Sexuality

- Development
- High-risk behaviors
- Preventing unwanted/unintended pregnancy
 - Postponing sexual involvement
 - Contraceptive options, including emergency contraception
- Sexually transmitted diseases
 - Partner selection
 - Barrier protection

Fitness and Nutrition

- Dietary/nutritional assessment (including eating disorders)
- Exercise: discussion of program

- Folic acid supplementation (0.4 mg/d)
- Calcium intake

Psychosocial Evaluation

- Suicide: depressive symptoms
- Interpersonal/family relationships
- Sexual identity
- Personal goal development
- Behavioral/learning disorders
- Abuse/neglect
- Satisfactory school experience
- Peer relationships
- Date rape prevention

Cardiovascular Risk Factors

- Family history
- Hypertension
- Dyslipidemia or obesity
- Diabetes mellitus

Health/Risk Behaviors

- Hygiene (including dental); fluoride supplementation
- Injury prevention
 - Safety belts and helmets
 - Recreational hazards/firearms
 - Hearing
 - Occupational hazards
 - School hazards
 - Exercise and sports involvement
- Skin exposure to ultraviolet rays
- Tobacco, alcohol, other drug use

IMMUNIZATIONS*

Periodic

- Tetanus-diphtheria booster (once between ages 11 and 16 years)
- Hepatitis B virus vaccine (one series for those not previously immunized)
- HPV vaccine (one series for those not previously immunized)
- Meningococcal vaccine (before high school for those not previously immunized)

High-Risk Groups*

- Influenza vaccine
- Hepatitis A virus vaccine
- Pneumococcal vaccine
- Measles, mumps, rubella vaccine
- Varicella vaccine

Leading Causes of Death**:

- Accidents
- Malignant neoplasms
- Homicide
- Suicide
- Congenital anomalies
- Diseases of the heart

†Only for those with a family history of familial adenomatous polyposis or 8 years after the start of pancolitis. For a more detailed discussion of colorectal cancer screening, see Smith RA, von Eschenback AC, Wender R, Levin B, Byers T, Rothenberger D, et al. American Cancer Society guidelines for the early detection of cancer: update of early detection guidelines for prostate, colorectal, and endometrial cancers. Also: update 2001-guidelines for early lung cancer detection [published erratum appears in CA Cancer J Clin 2001;51:150]. CA Cancer J Clin 2001;51:38-75; quiz 77-80.

*See Table 1.

**See box at end

*NOTE: the vaccine against HPV is being recommended by many public health groups for women 9 to 26 years of age 5

Leading Causes of Morbidity:

- Acne
- Asthma
- Chlamydia
- Diabetes mellitus or obesity
- Headache
- Infective, viral, and parasitic diseases
- Mental disorders, including affective and neurotic disorders
- Nose, throat, ear and upper respiratory infections
- Sexual assault
- Sexually transmitted diseases
- Urinary tract infections
- Vaginitis

* Please see page 10 for High-Risk Factors

AGES 19-39 YEARS

SCREENING

History

- Reason for visit
- Health status: medical, surgical, family
- Dietary/nutrition assessment
- Physical activity
- Use of complementary and alternative medicine
- Tobacco, alcohol, other drug use
- Abuse/neglect
- Sexual practices
- Urinary and fecal incontinence

Physical Examination

- Height and weight
- Body mass index
- Blood pressure
- Neck, adenopathy, thyroid
- Breasts/abdomen
- Pelvic examination
- Skin*

LABORATORY TESTING

Periodic

- Cervical cytology (annually beginning no later than age 21 years; every 2-3 years after 3 consecutive negative test results if age 30 years or older with no history of cervical intraepithelial neoplasia 2 or 3, immunosuppression, human immunodeficiency virus (HIV) infection, or diethylstilbestrol exposure in utero)*

High-Risk Groups *

- Hemoglobin level assessment
- Bacteriuria testing
- Mammography
- Fasting glucose testing
- Sexually transmitted disease testing
- Human immunodeficiency testing
- Genetic testing/counseling
- Rubella titer assessment
- Tuberculosis skin testing
- Lipid profile assessment
- Thyroid-stimulating hormone screening
- Hepatitis C virus testing

- Colorectal cancer screening
- Bone density screening

EVALUATION AND COUNSELING

Sexuality

- Discussion of a reproductive health plan
- High-risk behaviors
- Contraceptive options for prevention of unwanted pregnancy, including emergency contraception
- Preconceptional and genetic counseling for desired pregnancy
- Sexually transmitted diseases
 - Partner selection
 - Barrier protection
- Sexual function

Fitness and Nutrition

- Dietary/nutritional assessment
- Exercise: discussion of program
- Folic acid supplementation (0.4 mg/d)
- Calcium intake

Psychosocial Evaluation

- Interpersonal/family relationships
- Intimate partner violence
- Work satisfaction
- Lifestyle/stress
- Sleep disorders

Cardiovascular Risk Factors

- Family history
- Hypertension
- Dyslipidemia or Obesity
- Diabetes mellitus
- Lifestyle

Health/Risk Behaviors

- Hygiene (including dental)
- Injury prevention
 - Safety belts and helmets
 - Occupational hazards
 - Recreational hazards/firearms
 - Hearing
 - Exercise and sports involvement
- Breast self-examination
- Chemoprophylaxis for breast cancer (for high-risk women ages 35 years or older)
- Skin exposure to ultraviolet rays
- Suicide: depressive symptoms
- Tobacco, alcohol, other drug use

IMMUNIZATIONS

Periodic

- Tetanus-diphtheria booster (every 10 years)
- HPV vaccine (one series for those ≤ 26 years with no prior immunization)

High-Risk Groups *

- Measles, mumps, rubella vaccine
- Hepatitis A virus vaccine
- Hepatitis B virus vaccine
- Influenza vaccine
- Pneumococcal or Varicella vaccine
- Meningococcal vaccine

* Please see page 10 for High-Risk Factors

Leading Causes of Death:

- Malignant neoplasms
- Accidents
- Diseases of the heart
- Suicide
- Human immunodeficiency virus infection
- Homicide

Leading Causes of Morbidity:

- Acne
- Arthritis/Asthma
- Back symptoms
- Cancer/Chlamydia
- Depression
- Diabetes mellitus
- Gynecologic disorders
- Headache/migraines
- Hypertension
- Joint disorders
- Menstrual disorders
- Mental disorders, including affective and neurotic disorders
- Nose, throat, ear, and upper respiratory infections
- Obesity
- Sexual assault/domestic violence
- Sexually transmitted diseases
- Skin rash/dermatitis
- Substance abuse
- Urinary tract infections

AGES 40-64 YEARS

SCREENING

History

- Reason for visit
- Health status: medical, surgical, family
- Dietary/nutrition assessment
- Physical activity
- Use of complementary and alternative medicine
- Tobacco, alcohol, other drug use
- Abuse/neglect
- Sexual practices
- Urinary and fecal incontinence

Physical Examination

- Height, Weight, Blood pressure, BMI
- Oral cavity, Neck: adenopathy, thyroid
- Breasts, Axillae, Abdomen, Pelvic examination
- Skin*

LABORATORY TESTING

Periodic

- Cervical cytology (every 2-3 years after 3 consecutive negative test results if no history of cervical intraepithelial neoplasia 2 or 3, immunosuppression, human immunodeficiency virus (HIV) infection, or diethylstilbestrol exposure in utero)*
- Mammography (every 1-2 years beginning at age 40 years; yearly beginning at age 50 years)
- Bone density screening (if no risk factors; ← no more frequent than every 2 years)

- Lipid profile assessment (every 5 years beginning at age 45 years)
- Beginning at age 50 years, yearly fecal occult blood testing or flexible sigmoidoscopy every 5 years or yearly fecal occult blood testing plus flexible sigmoidoscopy every 5 years or double contrast barium enema every 5 years or colonoscopy every 10 years
- Fasting glucose testing (every 3 years after age 45)
- Thyroid-stimulating hormone screening (every 5 years beginning at age 50 years)

High-Risk Groups*

- Hemoglobin level assessment
- Bacteriuria testing
- Fasting glucose testing
- Sexually transmitted disease testing
- Bone density screening
- HIV/TB testing
- Lipid profile assessment
- Thyroid-stimulating hormone screening
- Hepatitis C virus testing
- Colorectal cancer screening

EVALUATION AND COUNSELING

Sexuality*

- High-risk behaviors
- Contraceptive options for prevention of unwanted pregnancy, including emergency contraception
- Sexually transmitted diseases

Partner selection

Barrier protection

- Sexual functioning

Fitness and Nutrition

- Dietary/nutrition assessment
- Exercise: discussion of program
- Folic acid supplementation (0.4 mg/d until age 50 years), Calcium intake

Psychosocial Evaluation

- Family relationships, Intimate partner violence
- Work satisfaction, Retirement planning
- Lifestyle/stress, Sleep disorders

Cardiovascular Risk Factors

- Family history
- Hypertension
- Dyslipidemia or Obesity
- Diabetes mellitus
- Lifestyle

Health/Risk Behaviors

- Hygiene (including dental)
- Hormone therapy
- Injury prevention
 - Safety belts and helmets
 - Occupational hazards
 - Exercise and sports involvement
 - Firearms
 - Hearing

*Preconceptional counseling is appropriate for certain women in this age group.

* Please see page 10 for High Risk Factors.

- Breast self-examination***
- Chemoprophylaxis for breast cancer (for high risk women)
- Skin exposure to ultraviolet rays
- Suicide: depressive symptoms
- Tobacco, alcohol, other drug use

IMMUNIZATIONS

Periodic

- Influenza vaccine (annually beginning at age 50)
- Tetanus-diphtheria booster (every 10 yrs)

High-Risk Groups *

- Measles, mumps, rubella vaccine
- Hepatitis A virus vaccine, Hepatitis B virus vaccine
- Influenza vaccine, Pneumococcal vaccine
- Varicella vaccine
- Meningococcal vaccine ←

Leading Causes of Death:

- Malignant neoplasms
- Diseases of the heart
- Cerebrovascular diseases
- Chronic lower respiratory disease
- Accidents
- Diabetes mellitus
- Chronic liver disease and cirrhosis
- Suicide
- Human immunodeficiency virus (HIV) disease

Leading Causes of Morbidity:

- Arthritis/osteoarthritis
- Asthma
- Back symptoms
- Cancer
- Cardiovascular disease
- Depression
- Diabetes mellitus
- Headache/migraine
- Hypertension
- Menopause
- Mental disorders, including affective and neurotic disorders
- Musculoskeletal ←
- Nose, throat, and upper respiratory infections
- Obesity
- Sexually transmitted diseases
- Ulcers
- Vision impairment

AGE 65 YEARS AND OLDER

SCREENING

History

- Reason for visit
- Health status: medical, surgical, family
- Dietary/nutritional assessment
- Physical activity
- Use of complementary and alternative medicine
- Tobacco, alcohol, other drug use, and concurrent medication use
- Abuse/neglect
- Sexual practices
- Urinary and fecal incontinence

Physical Examination

- Height, Weight, Blood pressure, BMI
- Oral cavity,
- Neck: adenopathy, thyroid
- Breasts, axillae
- Abdomen
- Pelvic examination
- Skin*

LABORATORY TESTING

Periodic

- Cervical cytology (every 2-3 years after 3 consecutive negative test results if no history of cervical intraepithelial neoplasia 2 or 3, immunosuppression, human immunodeficiency virus (HIV) infection, or diethylstilbestrol exposure in utero)*
- Urinalysis
- Mammography
- Lipid profile assessment (every 5 years)
- Yearly fecal occult blood testing *or* flexible sigmoidoscopy every 5 years *or* yearly fecal occult blood testing plus flexible sigmoidoscopy every 5 years *or* double contrast barium enema every 5 years *or* colonoscopy every 10 years
- Fasting glucose testing (every 3 years)
- Bone density screening (if no new risk factors, no more often than every 2 years) ←
- Thyroid-stimulating hormone screening (every 5 years)

High-Risk Groups *

- Hemoglobin level assessment
- Sexually transmitted disease testing
- Human immunodeficiency virus testing
- Tuberculosis skin testing
- Thyroid-stimulating hormone testing
- Hepatitis C virus testing
- Colorectal cancer screening

* Please see page 10 for High Risk Factors

*** Despite a lack of definitive data for or against breast self-examination, breast self-examination has the potential to detect palpable breast cancer and can be recommended.

EVALUATION AND COUNSELING

Sexuality

- Sexual functioning
- Sexual behaviors
- Sexually transmitted diseases
 - Partner selection
 - Barrier protection

Fitness and Nutrition

- Dietary/nutrition assessment
- Exercise: discussion of program
- Calcium intake

Psychosocial Evaluation

- Neglect/abuse
- Lifestyle/stress
- Depression/sleep disorders
- Family relationships
- Work/retirement satisfaction

Cardiovascular Risk Factors

- Hypertension
- Dyslipidemia or Obesity
- Diabetes mellitus
- Sedentary lifestyle

Health/Risk Behaviors

- Hygiene (including dental)
- Hormone therapy
- Injury prevention
 - Safety belts and helmets
 - Prevention of falls
 - Occupational & Recreational hazards
 - Exercise and sports involvement
 - Firearms
- Visual acuity/glaucoma; Hearing
- Breast self-examination
- Chemoprophylaxis for breast cancer (for high risk women)
- Skin exposure to ultraviolet rays
- Suicide: depressive symptoms
- Tobacco, alcohol, other drug use

IMMUNIZATIONS

Periodic

- Tetanus-diphtheria booster (every 10 yrs)
- Influenza vaccine (annually)
- Pneumococcal vaccine (once)

High-Risk Groups *

- Hepatitis A virus vaccine
- Hepatitis B virus vaccine
- Varicella vaccine
- Meningococcal vaccine

Leading Causes of Death:

- Diseases of the heart
- Malignant neoplasms
- Cerebrovascular diseases
- Chronic lower respiratory diseases
- Alzheimer's disease
- Influenza and pneumonia
- Diabetes mellitus
- Accidents and adverse effects
- Alzheimer's disease

Leading Causes of Morbidity:

- Arthritis/osteoarthritis
- Asthma
- Cancer
- Cardiovascular disease
- Chronic obstructive pulmonary diseases
- Diabetes mellitus
- Diseases of the nervous system and sense organs
- Hearing and vision impairment
- Hypertension
- Mental disorders, including affective and neurotic disorders
- Musculoskeletal symptoms
- Nose, throat, and upper respiratory infections
- Obesity/Osteoporosis
- Pneumonia/Septicemia
- Ulcers
- Urinary tract infections
- Urinary tract (other conditions, including urinary incontinence)
- Vertigo

* Please see page 10 for High Risk Factors

Sources of Leading Causes of Mortality & Morbidity

Leading causes of mortality are provided by the Mortality Statistics Branch at the National Center for Health Statistics. Data are from 2002, the most recent year for which final data are available. The causes are ranked.

Leading causes of morbidity are unranked estimates based on information from the following sources:

- National Health Interview Survey, 2004
- National Ambulatory Medical Care Survey, 2004
- National Health and Nutrition Examination Survey III, 2003-2004
- National Hospital Discharge Survey, 2004
- National Nursing Home Survey, 1999
- U.S. Department of Justice National Violence Against Women Survey, 2006
- U.S. Centers for Disease Control and Prevention Sexually Transmitted Disease Surveillance, 2004
- U.S. Centers for Disease Control and Prevention HIV/AIDS Surveillance Report, 2004

INTERVENTIONS FOR HIGH-RISK FACTORS

Intervention	High-Risk Factor
• Bacteriuria testing	Diabetes mellitus
• Bone density screening	Postmenopausal women younger than 65 years: personal history of fracture as an adult; family history; Caucasian; dementia; poor nutrition; smoking; low weight and BMI; estrogen deficiency caused by early (age <45 years menopause, bilateral ovariectomy, or prolonged (>1 year) premenopausal amenorrhea; low life-long calcium intake; alcoholism; impaired eyesight despite adequate correction; history of falls; inadequate physical activity. All women: certain diseases or medical conditions and those who take certain drugs associated with an increased risk of osteoporosis
• Colorectal cancer screening	Colorectal cancer or adenomatous polyps in first-degree relative younger than 60 years or in two or more first-degree relatives of any ages; family history of familial adenomatous polyposis or hereditary nonpolyposis colon cancer; history of colorectal cancer, adenomatous polyps, or inflammatory bowel disease, chronic ulcerative colitis, or Crohn's disease
• Fasting glucose test	Overweight (body mass index ≥ 25 kg/m ²); family history of diabetes mellitus; habitual physical inactivity; high-risk race/ethnicity (eg, African American, Hispanic, Native American, Asian, Pacific Islander); have given birth to a newborn weighing more than 9 lb or history of gestational diabetes mellitus; hypertension; high-density lipoprotein cholesterol level ≤ 35 mg/dL; triglyceride level ≥ 250 mg/dL; history of impaired glucose tolerance or impaired fasting glucose; polycystic ovary syndrome; history of vascular disease
• Fluoride supplementation	Live in area with inadequate water fluoridation (<0.7 ppm)
• Genetic testing/counseling	Considering pregnancy and: patient, partner, or family member with history of genetic disorder or birth defect; exposure to teratogens; or African, Cajun, Caucasian, Eastern European (Ashkenazi) Jewish, French Canadian Mediterranean, or Southeast Asian ancestry
• Hemoglobin level assessment	Caribbean, Latin American, Asian, Mediterranean, or African ancestry; history of excessive menstrual flow
• Hepatitis A vaccination	Chronic liver disease; clotting factor disorders; illegal drug users; individuals who work with HAV infected nonhuman primates or with HAV in a research laboratory setting; individuals traveling to or working in countries that have high or intermediate endemicity of hepatitis A
• Hepatitis B vaccination	Hemodialysis patients; patients who receive clotting factor concentrates; health care workers and public safety workers who have exposure to blood in the workplace; individuals in training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions; injecting drug users; individuals with more than 1 sexual partner in the previous 6 months; individuals with a recently acquired STD; all clients in STD clinics; household contacts and sexual partners of individuals with chronic HBV infection; clients and staff of institutions for the developmentally disabled; international travelers who will be in countries with high or intermediate prevalence or chronic HBV infection for more than 6 months; inmates of correctional facilities
• Hepatitis C virus (HCV) testing	History of injecting illegal drugs; recipients of clotting factor concentrates before 1987; chronic (long-term) hemodialysis; persistently abnormal alanine aminotransferase levels; recipient of blood from a donor who later tested positive for HCV infection; recipient of blood or blood-component transfusion or organ transplant before July 1992; occupational percutaneous or mucosal exposure to HCV-positive blood
• Human immunodeficiency virus (HIV) testing	More than one sexual partner since most recent HIV test or a sex partner with more than one sexual partner since most recent HIV test; Seeking treatment for STIs; drug use by injection; history of prostitution; past or present sexual partner who is HIV positive or bisexual or injects drugs; long-term residence or birth in an area with high prevalence of HIV infection; history of transfusion from 1978-1985; invasive cervical cancer. Adolescents entering detentional facilities. Offer to women seeking preconceptional evaluation. Adolescents who are or whoever have been sexually active.

• Influenza vaccination	Anyone who wishes to reduce the chance of becoming ill with influenza; chronic cardiovascular or pulmonary disorders including asthma; chronic metabolic diseases, including diabetes mellitus, renal dysfunction, hemoglobinopathies, and immunosuppression (including immunosuppression caused by medications or by HIV); residents and employees of nursing homes and other long-term care facilities; individuals likely to transmit influenza to high risk individuals (eg, household members and caregivers of elderly, children aged from birth to 59 months, adults with high risk conditions, health-care workers; day-care workers)
• Lipid profile assessment	Family history suggestive of familial hyperlipidemia; family history of premature (age <50 years for men, <60 years for women) cardiovascular disease; diabetes mellitus; multiple coronary heart disease risk factors (eg, tobacco use, hypertension)
• Mammography	Women who have had breast cancer or who have a first-degree relative (ie, mother, sister, or daughter) or multiple other relatives who have a history of premenopausal breast or breast and ovarian cancer
• Measles, mumps, rubella vaccine	Adults born in 1957 or later should be offered vaccination (one dose of MMR) if there is no proof of immunity or documentation of a dose given after first birthday; persons vaccinated in 1963-1967 should be offered revaccination (2 doses); health-care workers, students entering college, international travelers, and rubella-negative postpartum patients should be offered a second dose
• Meningococcal vaccine	→ Adults with anatomic or functional asplenia or terminal complement component deficiencies, first year college students in dormitories, microbiologists routinely exposed to <i>Neisseria meningitidis</i> , military recruits, travel to hyperendemic or endemic areas. Any condition (eg cognitive dysfunction, spinal cord injury, seizure or other neuromuscular disorder) that compromises respiratory function or the handling of respiratory secretions or that increases risk of aspiration
• Pneumococcal vaccine	Chronic illness such as cardiovascular disease, pulmonary disease, diabetes mellitus, alcoholism, chronic liver disease, cerebrospinal fluid leaks, functional asplenia (eg, sickle cell disease) or splenectomy; exposure to an environment where pneumococcal outbreaks have occurred; immuno-compromised patients (eg, HIV infection, hematologic or solid malignancies, chemotherapy, steroid therapy); Revaccination after 5 years may be appropriate for certain high-risk groups
• Rubella titer assessment	Childbearing age and no evidence of immunity
• STD testing	History of multiple sexual partners or a sexual partner with multiple contacts, sexual contact with persons with culture-proven STI, history of repeated episodes of STIs, attendance at clinics for STIs; developmental disabilities, routine screening for chlamydial infection for all sexually active women aged 25 years or younger and other asymptomatic women at high risk for infection; routine screening for gonorrheal infection for all sexually active adolescents and other asymptomatic women at high risk for infection, syphilis testing for sexually active adolescents who exchange sex for money, use IV drugs, entering a detention facility, or live in a high prevalence area →
• Skin examination	Increased recreational or occupational exposure to sunlight; family or personal history of skin cancer; clinical evidence of precursor lesions
• Thyroid-stimulating hormone test	Strong family history of thyroid disease; autoimmune disease (evidence of subclinical hypothyroidism may be related to unfavorable lipid profiles)
• Tuberculosis skin test	HIV infection; close contact with persons known or suspected to have TB; medical risk factors known to increase risk of disease if infected; born in country with high TB prevalence; medically underserved; low income; alcoholism; intravenous drug use; resident of long-term care facility (e.g., correctional institutions, mental institutions, nursing homes and facilities); health professional working in high-risk health-care facilities
• Varicella vaccine	All susceptible adults and adolescents, including health-care workers; household contacts of immunocompromised individuals; teachers; day-care workers; residents and staff of institutional settings, colleges, prisons, or military installations; adolescents and adults living in households with children; international travellers; non-pregnant women of childbearing age

American College of Obstetricians and Gynecologists. Primary and preventive care: periodic assessments. ACOG Committee Opinion, No. 357. Nov. 2006.

*For a more detailed discussion of bone density screening, see osteoporosis. ACOG Practice Bulletin 50. American College of Obstetricians and Gynecologists. Obstet Gynecol 2004; 103: 203-16.

**For a more detailed discussion of colorectal cancer screening, see Smith RA, von Eschenback AC, Wender R, Levin B, Byers T, Rothenberger D, et al. American Cancer Society guidelines for the early detection of cancer: update of early detection guidelines for prostate, colorectal, and endometrial cancers. Also: update 2001-testing for early lung cancer detection [published erratum appears in CA Cancer J Clin 2001;51:150]. CA Cancer J Clin 2001;51:38-75; quiz 77-80.

CHAPTER 3

Counseling Guidelines

www.gmhc.org, www.plannedparenthood.org

Advantages of counseling:

- Goal is reducing unintended pregnancies, now 50% of U.S. pregnancies ←
- Involves patient in his/her own care and dispels misconceptions, myths and rumors
- Improves success with complicated regimens
- Advises change of risky behaviors
- Facilitates the decision-making process regarding contraception and STI prevention
- Explains possible side effects, which reduces anxiety, increases success with method and encourages clients to contact if problems occur, reducing severity of complications
- Strengthens the provider/patient relationship
- Encourages patient responsibility for his/her health decisions
- Ensures and maintains *confidentiality*

Principles of good counseling: Allow plenty of time: important and difficult!

- Know what you are talking about!
- *Listen*, look at your patients, allow them to speak freely, paraphrase what you hear
- Remember LISTEN and SILENT use the same letters!
- *Respect*, recognize and accept each individual's unique situation
- Accept and anticipate that behavior change occurs slowly and incrementally.
- Remain *sensitive*; acknowledge that sex/sexuality are very personal
- Be *nonjudgmental* and encourage *self-determination*; avoid *false reassurance*
- ***Urge all your patients to know their HIV status***; each encounter offers opportunity to counsel about STI/HIV prevention and contraception
- Inquire about problems patients may have had with previous medical recommendations
- Realize your patient will remember only 1-4 points from each visit. Avoid information overload and provide written information at appropriate reading level for later reference

The GATHER method suggests the following steps:

- **Greet** patient in a warm, friendly manner; help her or him to feel at ease
- **Ask** patient about her or his needs and reproductive goals; ask about risk for STIs
- **Tell** patient about her or his choices, explaining the advantages and disadvantages of all options
- **Help** patient to choose
- **Explain** the correct use of the method or drug being prescribed
- **Repeat** important instructions to the patient and clarify time and conditions of return visit; give written instructions to patient to review later

Reproductive/Contraceptive Goals:

GOAL:	MAIN CONTRACEPTIVE CONCERNS MAY BE:
Delaying birth of first child	Effectiveness of method, future fertility and STIs; explain EC
Avoiding abortion	Need for maximal effectiveness; Tell about ECs; May want to use 2 methods consistently
Spacing births	Balance of efficacy & convenience; explain EC; safety with breastfeeding
Completed childbearing	Needs effective method for long term

STRUCTURED COUNSELING

Carefully planned structured counseling may include:

- Repetition of a specific message at the time of the initial visit
- Having the patient repeat back her understanding of a message
- Use of a clear, concise videotape
- Asking the patient if she has questions about the videotape
- Written information and instructions that highlight key messages
- Repetition at each follow-up visit
- Checklist for patient to fill out at **each** follow up visit

*Example: Structured counseling for Depo-Provera**

- **The message: Depo-Provera will change your periods.** No woman's periods stay the same as they were before starting Depo-Provera. Ask: ***"Will you find it acceptable if there are major changes in your periods?"*** If no, steer clear of DMPA (as well as progestin-only pills, Implanon, Mirena)
- Have the patient repeat back her understanding of the message, particularly that **over time women stop having periods most months.** Women tend to have very irregular menses almost immediately
- Use of a clear, concise videotape
- Asking the patient if she has questions about the videotape
- Written instructions that clearly highlight the key messages
- Asking at each 3-month visit what has happened to a woman's pattern of bleeding, whether amenorrhea has begun and how she feels about her pattern of bleeding

Checklist for Depo-Provera patient to fill out at each follow up visit. Please check yes or no. Tell us if you have/are:

Spotting or irregular vaginal bleeding	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Missed periods or very, very light periods	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Concern over your pattern of vaginal bleeding	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Depression, severe anxiety or mood changes	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Gained 5 pounds or more	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Questions you want to ask us about Depo-Provera injections	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Any wrist, hip or other fractures	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Using calcium supplements	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Regular exercise ←	<input type="checkbox"/> Yes	<input type="checkbox"/> No

* Continuation rates for women started on Depo-Provera are only 40-60% at one year. Structured counseling has been shown to improve these rates. See p. 126 for details. Structured counseling is also important for women starting any method of contraception, including barrier methods.

CHAPTER 4

Taking a Sexual History

www.siecus.org

Taking Sexual Histories

Explain to the patient that obtaining sexual information is necessary to provide complete care, but reassure her/him that she/he has the right to discuss only what she/he is comfortable divulging. Ask patients less direct questions in the beginning to build trust, then ask the questions that explicitly address sexual issues once you have their confidence. Be cautious about what **information** you place on the chart. Medical records are not necessarily confidential and can be reviewed by insurance companies (**may also be subpoenaed in legal proceedings**)

Suggestions for Initiating the Sexual History

- I will be asking some personal questions about your sexual activity to help me make more accurate diagnoses. This is a normal part of the exam I do with all patients
- To help keep accurate medical records, I will be writing down some of your responses.
If there are things you do not want me to record, please tell me
- Some patients have shared concerns with me related to their risks of infections or concerns about particular sexual activities. If you have any concerns, I would be happy to discuss them with you

Sexual History Questions

- **What are you doing to protect yourself from HIV and other infections? OR What are you doing that puts you at risk for HIV?**
- Do you have questions regarding sex or sexual activity?
- How old were you when you had your first sexual experience?
- Do you have sex with men, women or both?
- Do you need contraception? How are you protecting yourself from unwanted pregnancy?
- How many sex partners have you had in the last 3 months? in the last 6 months? in your lifetime?
- How many sex partners does your partner have?
- Do you have penis in vagina sex? penis in mouth sex? penis in rectum sex?
- Do you drink alcohol or take drugs in association with sexual activity?
- Have you ever been forced or coerced to have sex?
- Are you now in a relationship where you feel physically, sexually, or emotionally threatened or abused?
- When you were younger, did anyone touch your private body parts or ask you to touch theirs?
- Have you ever had sex for money, food, protection, drugs or shelter?
- Do you enjoy sex? Do you usually have orgasms? Do you ever have pain with sex?
- Do you or your partner(s) have any sexual concerns?
- Do you awaken from sleep and you are having intercourse? (If this happens often, condoms and other barrier methods may not be the best method for you.)

Avoid Assumptions: Making assumptions about a patient's sexual behavior and orientation can leave out important information, undermine patient trust and make the patient feel judged or alienated, causing her to withhold information. This can result in diagnostic and treatment errors. Do not assume that patients:

- ARE sexually active and need contraception
- Are NOT sexually active (e.g., older patients, young adolescents)
- Are heterosexual, homosexual or bisexual OR know if their partners have other partners
- Have power (within a relationship) to make or implement their own contraceptive decisions

CHAPTER 5

Sexual Dysfunction

www.herhealth.com, www.newshe.com or www.assect.org

FEMALE

Dyspareunia

- **Definition:** Pain during vaginal intercourse or vaginal penetration
- **Key questions:** Do you have pain with vaginal penetration? Do you have pain with early entry or in the mid vaginal area? Is there pain with deep thrusting? Is pain occasional or consistent? With every partner? Does the pain change with different sexual positions? Are you aroused and lubricated before penetration?
- **Causes:** Organic - vestibulitis, urethritis/UTI, vaginitis, cervicitis, vulvodynia, vulvar dystrophy, interstitial cystitis, traumatic deliveries (forcep or vacuum extractions), hypoestrogenism, PID, endometriosis, surgical scars or adhesions, pelvic injuries, tumors, hip joint or disc pain, female circumcision, orgasmic spasm, lack of foreplay, lubrication
Psychological - current or previous abuse, relationship stress, depression, anxiety, fear of sex or fear of pregnancy
- **Treatment:** Directed to underlying pathology including depression. If dyspareunia is chronic, consider supplementing medical management with supportive counseling and sex therapy

Vaginismus (special case of dyspareunia)

- **Definition:** Painful involuntary spastic contraction of introital and pelvic floor muscles
- **Causes:** Organic - may be secondary to current or previous dyspareunia and its causes.
Psychological - sexual abuse, fears of abnormal anatomy (e.g. terror that vagina will rip with penile or speculum introduction), negative attitudes about sexuality
- **Treatment:** Education is critical. Insight into underlying causes helps. After source is recognized, start progressive desensitization exercises, which may include self manipulation, dilators and/or biofeedback and pelvic floor physical therapy. Sex therapist/psychologist intervention may be needed to deal with unconscious fears unresponsive to education

Decreased Libido (Hypoactive Sexual Desire)

- **Definition:** Relative lack of sexual desire defined by individual as troublesome to her sexual relationship (there is no absolute "normal" level)
- **Causes:** **Organic** - may be due to acute or chronic debilitating medical condition (e.g., diabetes, stroke, spinal cord injury, arthritis, pain, cancer, chronic obstructive pulmonary disease, coronary artery disease, etc.), medications (e.g. sedatives, narcotics, hypnotics, anticonvulsants, centrally-acting antihypertensives, tranquilizers, anorectics, oral contraceptives, Depo-Provera, and some antidepressants), dyspareunia, incontinence, alcohol, hormonal imbalance, or healing episiotomy or other surgical scars; Sexual practices - inadequate sexual stimulation or time for arousal. Sexual desires discordant with partner's desires
Psychological - depression, anxiety, exhaustion, life stress (finances, relationship problems, etc.), poor partner communication, lack of understanding about impacts of aging. Change in body image (breast-feeding, postpartum, weight gain, cancer, or post mastectomy or hysterectomy)
- **Treatment:** Treat underlying causes where possible. Rule out hyperactive sexual desire disorder of partner. Reassure about normalcy, if appropriate. Help patient create time and special space for sexual expression - no distractions from children, telephone, household chores. Suggest variety in sexual practices perhaps with aid of fantasies (romantic novels, films, etc). Exogenous testosterone therapy has yielded mixed results in studies and is not FDA approved. New drugs and creams, causing increased blood flow to the clitoris, may increase sexual arousal for those women whose problems started after developing a

medical disorder and had normal function previously. Consider referral to sex therapist. Read *For Each Other* by Lonnie Barbach and *Women, Sex & Desire* by Elizabeth Davis or *Our Bodies, Ourselves* by the Boston Women's Health Collective

Excessive Sexual Desire (Hyperactive Sexual Desire)

- **Definition:** Excessive sexual activity resulting in social, psychological and physical problems. See Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV)
- **Cause:** Low self esteem; abuse; attention seeking; acting out; mania; bipolar disease
- **Treatment:** Refer for psychological counseling and therapy and Sex Addicts Anonymous

Orgasmic Disorders: Anorgasmia or Primary Anorgasmia

- **Definitions:**
 - **Preorgasmia or Primary Anorgasmia:** Never experienced orgasms and desires to be orgasmic
 - **Secondary Anorgasmia:** Orgasmic in past, no orgasms currently, desirous of orgasm
- **Cause:** Organic - may be secondary to dyspareunia, neurological, vascular disease, medications (e.g. sedatives, narcotics, hypnotics, anticonvulsants, centrally-acting antihypertensives, tranquilizers, anorectics, and some antidepressants - particularly SSRI class antidepressants), or poor sexual techniques of partner (painful, rapid ejaculation)
Psychological - negative attitude about sexuality, chronic relationship stress; lack of knowledge about body and sexual response, depression, life stress
- **Treatment:** Treat underlying organic causes, if possible. Explain sexual response (suggest reading *Our Bodies, Ourselves* or *For Yourself*). Add behavioral/psychological approach using PLISSIT model (see Abbreviations, p. x), and sensate focusing exercises. Help couple set alternative pleasuring goals. Refer to sex therapist if initial interventions not successful. Have woman learn how to have an orgasm on her own in comfortable environment and then she can teach her partner how to pleasure her. Recommend use of lubricants, vibrators and sex toys.

MALE

Decreased Libido (Hypoactive sexual desire disorder)

- No absolute level is "normal"; "decreased libido" is usually related to previous experience, partner's expectations, or perceived societal norms
- Evaluation and treatment similar to female's (see above)

Excessive Sexual Desire (Hyperactive Sexual Desire)

- **Definition:** Excessive sexual activity resulting in social, psychological and physical problems.
- **Cause:** Abuse at young age; attention seeking; acting out; mania; other such as bipolar disease
- **Treatment:** Refer for psychological counseling and therapy, Sex Addicts Anonymous after therapy

Premature (Rapid) Ejaculation

- **Definition:** Recurrent ejaculation before or shortly after vaginal penetration or ejaculation occurs earlier than patient or partner desires. Average time from entry to ejaculation in "normal" couples is 2 minutes; shorter interval is consistent with diagnosis.
- **Causes:** Organic - urethritis, prostatitis, neurological disease (e.g. multiple sclerosis).
Psychological - learned behavior, anxiety (especially among teens)
- **Treatment:** Education and reassurance is important. If goal is pleasuring of partner, teach other techniques to arouse her or him prior to intercourse and/or to achieve orgasm. "Start and stop" technique can be used to prolong erection; man stops stimulation for at least 30 seconds when he feels ejaculation imminent. "Squeeze" technique helpful; when man feels impending ejaculation, partner firmly squeezes the head of the penis beneath the glans for 4-5 seconds to decrease erection. Selective serotonin reuptake inhibitors (SSRIs) in low doses may be helpful if these other techniques are not adequate. Refer to sex therapist (or urologist if cause organic) for additional treatment if needed. Condoms are available with benzocaine to decrease sensation and reduce premature ejaculation

Delayed (Retarded) Ejaculation/Anorgasmia

- **Definition:** Inability to or difficulty in experiencing orgasm and ejaculation with a partner
- **Cause:** usually psychological; learned behavior; may occur when a man has masturbatory patterns that cannot be duplicated with partner; overemphasis on sexual performance; medications such as SSRI's. Rule out organic problems carefully
- **Treatment:** referral to sex therapist recommended

Erectile Dysfunction/Disorders (ED) (Impotence)

- **Definition:** Inability to attain or sustain an erection that is satisfactory for coitus
- **Primary:** never achieved erection
- **Causes:** Organic - low testosterone levels due to hypothalamic-pituitary-testicular disorder; severe vascular compromise. Psychological - usual cause
- **Secondary:** current inability to attain or maintain erection (may be situational)
- **Causes:** Organic - diabetes mellitus, alcohol abuse, hypothyroidism, drug dependency, medications (e.g. sedatives, narcotics, hypnotics, anticonvulsants, centrally-acting antihypertensives, tranquilizers, anorectics, illegal drugs, and some antidepressants), hypopituitarism, penile infections, atherosclerosis, aortic aneurysm, multiple sclerosis, spinal cord lesions, orchiectomy or prostatectomy
Psychological - depression, relationship stress, prior abuse, etc. Suspect when patient has morning erection or is able to masturbate to ejaculation
- **Treatment:** Treat underlying cause. Switch medications if possible. Same measures that help women's sexual desire may be useful. Medical or mechanical treatments available:
 1. **Testosterone.** Shown to be useful in wasting diseases (AIDS) and other low testosterone conditions. Available in patches for ease of use
 2. **Phosphodiesterase inhibitors:** Viagra, Cialis, Levitra. Use caution in patients with cardiovascular disease. Not to be used when taking nitrates
 3. **Alprostadil injections (Edex or Caverject)** prostaglandin E1 ~ 1 cc injected into corpus cavernosa (strengths 125 µg - 1000 µg). Excessive injection may cause priapism. Erection achieved with stimulation lasts 30-60 minutes. Avoid in anticoagulated patients and with vasoactive medications.
 4. **Alprostadil suppository (Muse)** prostaglandin pellet E1 (125-1000 µg) placed inside urethra. Erection occurs as drug absorbed. 70% successful. Contraindications - anatomical penile abnormalities (strictures, hypospadias, etc.), and thrombosis risk factors. Limit 2/day
 5. **Yohimbine hydrochloride.** Prescription pill composed of indole alkaloid. Modestly successful. Avoid in psychiatric patients.
 6. **Vacuum Erection Device (VED).** Use of a vacuum pump and different size rubber bands maintains an erection for 30 minutes. Safe and effective (90% success rate).
 7. **Penile implants (protheses).** Permanent bendable rods or inflatable reservoirs implanted surgically into penis. Activated/inflated for intercourse. Success rate high, but associated with surgical risks and the risk that natural erections disappear
 8. **Microsurgery.** Used in men with atherosclerosis of penile arteries or venous pathology; over 50% success rate

CHAPTER 6

Adolescent Issues

advocatesforyouth.org, youngwomenshealth.org, teenwire.com,
arhp.org/arhpframepated.htm, www.askdurex.com

Talking to adolescent patients about the benefits of delaying sexual activity, the correct use of contraceptives, and the need for protection for STI's and HIV is important:

- The teen pregnancy rate among all teens has decreased since 1990 due to more teens delaying sex and sexually active teens using contraception more consistently [*Santelli-2004*]
- However, the pregnancy rate remains very high among sexually experienced teen girls (31%), especially among teens who start having sex before age 15 (46%), Hispanic teens (52%), and teens who have more than 1 partner (37%) [*National Survey of Family Growth-2002*]
- Teens who used a method of contraception the first time they had sex are less likely to have been involved in a pregnancy than those who did not [*NSFG-2002*]
- HPV vaccine has the potential for the most benefit when used prior to the onset of sexual activity

COUNSELING CHALLENGES POSED BY ADOLESCENTS

Teens are not "young adults." Developmentally appropriate approaches are needed

- Age 11-14 – teens are very concrete, egocentric (self-focused) and concerned with personal appearance and acceptance, and have a short attention span. They will start sexual maturation and abstract thinking in this period
- Age 14-15 – teens are peer oriented and authority resistant (challenge boundaries), and have very limited images of the future
- Age 16-17 – teens are developing logical thought processes and goals for the future. Develop a stronger sense of identity. Thinking becomes more reflective
- Age 18 and above – development of distinct identity and more settled ideas and opinions

Nonjudgmental, open-ended and reflective questions are better than direct yes-no inquiries. Try reflective questions such as "What would you want to tell a friend who was thinking about having sex?" instead of "You're not having sex, are you?"

CONFIDENTIALITY: Adolescents are often afraid to obtain medical care for contraception, pregnancy testing or STI treatment because they fear parental reaction. Over two-thirds of teens never discuss sexual matters with their parents; over one-half feel that their parents could not handle it. All teens should be entitled to confidential services and counseling, but billing systems and/or laws in some states affect their confidential access to family planning services. Know your local laws and refer to sites that may be able to meet all the teen's needs if your practice can not.

ADOLESCENTS AND THE LAW: This table provides information on an adolescent's right to consent to reproductive health, contraception, and abortion services.

Table 6.1 Adolescents and the Law - www.guttmacher.org/sections/adolescents.php 

AL *■□★	DE ●■□◆	IN *■★	MA ●■★	NV *■◆	OH ○■★	TX *■□★
AK ●■☆	DC ●■+	IA ●■◆	MI *■□★	NH *■+	OK *■□◆★	UT *■★◆
AZ ●■★	FL *■◆	KS *■□◆	MN ●■□◆	NJ *■□+	OR ●■+	VT *■+
AR ●■□★	GA ●■□◆	KY ●■□★	MS *■★	NM ●■☆	PA *■★	VA ●■★
CA ●■☆	HI *■□+	LA *■□★	MO *■□★	NY ●■+	RI ○■★	WA ●■+
CO ●■◆	ID ●■★	ME *■□+	MT ●■□◆	NC ●■★	SC *■★	WV *■◆
CT *■+	IL *■□◆	MD ●■□◆	NE *■◆	ND ○□★	SD *■◆	WI ○■★
					TN ●■★	WY ●■★

- = All minors may consent to contraceptive service
- * = Some minors may consent (e.g. married, pregnant, age)
- = No explicit policy related to minors' access to contraceptive services
- = Minor may consent to testing and treatment for STDs. Some states specify age (e.g. 12 or 14)
- = Physician may inform parents about STD testing and treatment but is not required to
- ★ = Parental consent required before a minor may obtain an abortion
- ☆ = Parental consent law exists but not in effect (e.g., declared unenforceable by courts)
- ◆ = Parental notification required before a minor may obtain an abortion. In some states, parental notification is not necessary if a risk for the minor is perceived (i.e. telling parents may result in harm to minor)
- ◇ = Parental notification law exists but not in effect (e.g., declared unenforceable by courts)
- ⊕ = Does not require parental involvement before a minor may obtain an abortion

Sources: *State Policies in Brief: An Overview of Minors' Consent Law: As of 2008.* Guttmacher Institute.




Note: Many of the laws contain specific clauses that affect their meaning and application.

The authors encourage readers to consult the above documents (updated monthly) for more details: www.agi-usa.org.

TEENS AND CONTRACEPTION

The pelvic exam may be a barrier to initiating contraceptive use. It is not necessary to perform a pelvic exam prior to prescribing any contraceptive other than an IUD [Stewart-2001]

ADOLESCENTS AS RISK TAKERS

- Full evaluation of behaviors is important to personalize counseling. Teens must move away from parental authority figures to become independent adult individuals, but, along the way, they may take excessive risks in many areas, including sexuality
- HEADSS interview technique helpful as an organized approach. Ask each teen about Home, Education, Activities, Drugs, Sexuality (activity, orientation and abuse) and Suicide
- Look for the female athletic triad: eating disorders, amenorrhea and osteoporosis. This triad of symptoms may also occur in women who do not exercise excessively
- Discuss keeping emergency contraceptive pills at home and provide a prescription if needed or desired
- The single-rod implant is a highly effective method for use in this age group 
- Both copper and levonorgestrel IUDs are safe and effective methods for nulliparous and parous adolescents (CDC category 2) 
- As in adults, bone mineral density quickly recovers after discontinuation of DMPA use to levels as high as non-users by 12 months [Curtis-2006]. DEXA scans are NOT indicated in this age group as the scores cannot predict fracture risk in adolescents 

HEALTH CARE SCREENING FOR ADOLESCENTS (SEE CHAPTER 21) ←

- Initiate pap smear screening annually beginning 3 years after sexual debut or at age 21, whichever comes first
- HPV typing is not indicated in this age group since low-risk HPV infections are so common and resolve spontaneously (ASCCP, ACOG Guidelines)
- Teaching self breast examination is not recommended in women younger than 19 years old as it leads to many false positives and takes time from higher priority counseling issues

SEX EDUCATION

Sex education has been abbreviated in most U.S. schools, sometimes focusing entirely on an “abstinence-only” message. Abstinence-only sex ed programs have been found ineffective in preventing or delaying teenagers from having sexual intercourse, and have no impact on likelihood that if they do have sex, they will use a condom. Moreover, sex education, contraception and STIs curricula offered in many schools are not medically correct. The information teens obtain from peers is also often inaccurate. Common **MYTHS** are:

- *You cannot get pregnant the first time you have intercourse*
- *You cannot get pregnant if you douche after sex*
- *Having sex or having a baby makes you a woman, makes your boyfriend love you, and gets you the attention you deserve*
- *Making a girl pregnant means that you are a man*

Adolescents need very concrete information and opportunities to role play and practice:

- How to open and place a condom and where to carry it
- How to negotiate NOT having sex and, in other cases, condom use
- How to punch out the pills, where to keep the pack, and how to remember them
- The remarkable advantages of extended use of pills, as well as the disadvantages
- Dual protection: condoms and another contraceptive
- How to access and use emergency contraception

TEENS AND SEXUALLY TRANSMITTED INFECTIONS ←

- Although adolescents and young adults 15-24 years old account for 25% of the sexually active population, they experience almost half of the newly acquired cases of STIs annually [Guttmacher-2008]
- HPV infections account for half of the newly acquired STIs in this age group. The HPV vaccine, Gardasil, provides immunity against types 6, 11, 16 and 18, and is recommended for all girls and young women aged 9-26 [CDC-2007]
- Gardasil is also now approved for use in boys and men ages 9-26 for the prevention of warts ←
- Cervarix, another HPV vaccine for females ages 10-25 approved. Targets HPV types 16 ← and 18. Also given as series of 3 injections
- Annual screening for gonorrhea, Chlamydia, and HIV is recommended for all sexually active people in this age group. Treatment for gc and ct should be followed by a test for reinfection in 2 months.

TEEN BIRTH RATES AND ABORTION RATES

U.S. teens have more partners than teens in many other developed countries. Teen birth, teen abortion, and sexually transmitted infection (STI) rates are higher than in most other industrialized countries. In 2002, 75 out of 1000 U.S. women ages 15-19 got pregnant— ← a rate 11 times greater than in the Netherlands and four times higher than in Germany. The teen abortion rate in the U.S. is more than three times that of France and nearly seven times that of the Netherlands. [Advocates for Youth-2005]

CHAPTER 7

Male Reproductive Health

www.nlm.nih.gov/medlineplus/teenhealth.html

Reproductive health is a term generally associated with women. Efforts are being made to include males in health education and outreach programs, acknowledging that men have important reproductive and sexual health needs of their own. Including men in discussions of contraception and STIs benefits their female partners as well.

MEN AND SEXUAL EXPERIENCE ←

- Most adult men and almost half of adolescent men (46%) have had sexual intercourse. This has decreased from previous years [*Guttmacher Inst.- 2008*]
- For men in the United States: Average age of first intercourse – 17.5
- 2/3 had physical exams in the past year, and less than 20% received reproductive health counseling [*NSFG-2002*]
- In 2002, only 25% of adolescent males who had ever had sex had ever been tested for HIV
- 5% of males aged 15-19 have had sexual contact with another male. These young men may or may not have female partners as well
- 37% of 9th grade boys report being sexually experienced [*Youth Risk Behavior Survey-2003*]

WHERE MEN GET THEIR REPRODUCTIVE HEALTH INFORMATION

- Of 15-19 year old males, 71% had physical exams in the past year but only 39% received reproductive health services. (*Porter, 2000*)
- One survey showed men get most of their STD/AIDS prevention information from the media rather than from a healthcare provider. (*Bradner, 2000*)
- Although most men get some form of sexuality education while they are in high school, for 3 out of 10 men this instruction comes too late – after they have begun having sexual intercourse. (*Sonfield, 2002*)

What can healthcare providers do?

- Make sure to talk to men about reproductive health at school and work physicals. Start early – many adolescents have sexual intercourse before age 17.
- When appropriate, talk to men about reproductive health issues such as STIs and contraception at doctor's visits for unrelated complaints – this may be the only time they visit a physician this year
- HPV vaccine, Gardasil, now approved for males ages 9-26 ←

MEN AND CONTRACEPTION

- Among sexually experienced adolescent males, 14% have made a partner pregnant and 2-7% are fathers. (*Marcell, 2003*)
- As men get older, condom use declines. 7 out of 10 men age 15-17 use condoms, compared to 4 out of 10 men in their 20s, and 2 out of 10 men in their 30s. (*Sonfield, 2002*)
- Vasectomy is a very effective male option for permanent birth control. However, it is estimated that approximately 500,000 men receive a vasectomy in the U.S. each year, in contrast to 700,000 women who have a female sterilization procedure. (*Hawes, 1998*) In only 4 countries throughout the world, Great Britain, Netherlands, New Zealand and Bhutan, do vasectomies exceed tubal sterilization as a method of birth control. Vasectomy has not been found to cause any long-term adverse effects

Men's support of women's birth control methods matter

- Education of adolescent males about birth control (including female methods) leads to improvement in use of the method by their partner(s) (*Edwards, 1994*)

MEN AND SEXUALLY TRANSMITTED INFECTIONS

How many men acquire sexually transmitted infections?

- 17% of men aged 15-49 have genital herpes
- Among men in their 20s, there are 500-600 new cases of gonorrhea and chlamydia per year, per 100,000 men (*Sonfield, 2002*)
- 8 out of 10 Americans living with HIV are men (*Sonfield, 2002*)
- Rates of STIs are higher among young, poor, and minority men

Decreasing STI rates in men helps their female partner(s)

- Treating men decreases initial infection rate and reinfection rate in women, which could decrease female complications such as pelvic inflammatory disease, ectopic pregnancy, and infertility.

Decreasing STI rates in men helps themselves

- While the link between gonorrhea and chlamydia infection and infertility in men has not been proven, there is some clinical evidence that it does have some effect:
gonorrhea/chlamydia infection ➤ urethritis ➤ epidymo-orchitis ➤ infertility
 - If urethritis is treated promptly, there is less likelihood it will proceed to epidymo-orchitis (*Ness, 1997*)
 - The most common cause of epidymo-orchitis in men younger than 35 years old is gonorrhea and chlamydia infections (*Weidner, 1999*)

MEN AND REPRODUCTIVE CANCERS

Testicular cancer

- "Testicular cancer is the most common solid malignancy affecting males between the ages of 15 and 35, although it accounts for only 1% of all cancers in men." (*Michaelson, 2004*)
- The number of deaths from testicular cancer has dropped recently from advances in therapy.
- Some signs or symptoms of testicular cancer are testicular enlargement, a dull ache in the abdomen or groin, scrotal pain, and fluid in the scrotum.
- The patient information website sponsored by the American Urological Association says that monthly testicular self exams are the most important way to detect a tumor early.
- The treatment for testicular cancer can be removal of the affected testicle. Removal of one testicle does not make a man infertile.

Prostate cancer

- The most important risk factor for prostate cancer is age. The older a man is, the greater his risk.
- Prostate cancer is screened for by digital rectal exam and prostate-specific antigen level.
- Some of the treatments for prostate cancer can affect male fertility. For instance, surgery to remove the prostate causes the male ejaculate to become "dry" so the ability to have children is usually lost. Prostate surgery can also cause erectile dysfunction

CHAPTER 8

Perimenopause and Menopause

www.menopause.org or www.nams.org

PERIMENOPAUSE: Perimenopause is marked by changes in the menstrual cycle and is a time that lasts through menopause. Characterized by fluctuations in ovarian hormones resulting in intermittent vasomotor symptoms, menstrual changes and reduced fertility. A perimenopausal woman should use contraception until she is truly menopausal (amenorrheic for one year).

- Average age of onset: 45
- Average duration: 3-5 years
- Women over 40 have second highest abortion ratio due to unintended pregnancy (# abortions/1000 live births), second to women under 15
- All methods of birth control are available to healthy, nonsmoking women until menopause
- In US, 50% women >40 have been sterilized and another 18% have a partner with vasectomy
- Combined hormonal contraceptives have specific benefits for perimenopausal women: May regulate cycles, prevent osteoporosis, treat hot flashes. Should not be used for women >35 who smoke or have significant cardiac risk factors
- Smokers > 35 or women with hypertension may use any non-estrogen containing methods, POPs, DMPA, IUDs or barriers unless they have other risk factors

MENOPAUSE: cessation of spontaneous menses x12 months. Retrospective diagnosis.

- Avg age: 51.1-51.4, earlier in smokers

Common Physiologic Changes after Menopause:

- Hot flashes (~ 75% women – only 15% severe) /sleep disturbances, mood swings
- Thinning of genitourinary tissue (atrophic vaginitis, urinary incontinence)
- Osteopenia, osteoporosis, increased risk for fracture
- Increased risk for cardiovascular disease, unfavorable lipid profiles

One health recommendation to make to all patients, with increasing importance to the aging, is to add regular exercise for its health benefits

BENEFITS OF EXERCISE:

- To decrease risk, gradually add exercise to daily routine rather than immediately starting strenuous activity
- Decreased all-cause mortality
- Decreased CVD: ▼ VLDL, ▲ HDL, ▼ BP, ▼ risk stroke
- Glycemic control: better glycemic control, insulin sensitivity. May prevent development of type 2 DM in high risk populations
- Cancer prevention: may reduce risk of developing breast and prostate cancer
- Prevents obesity: greater reduction in body fat and enhanced preservation of lean body mass than a weight loss diet alone
- Smoking cessation: vigorous exercise aids smoking cessation, and prevents weight gain
- Gallstones: decreases risk
- Function and cognition: improved in elderly who exercise

HORMONE THERAPY:

- Most effective treatment for hot flashes
- Recommended for relief of vasomotor sx and GU atrophy to be used at lowest dose that is effective for short durations. Short duration is not defined (some say 2-5 yrs); re-evaluate every 6 months or year. Not recommended for prevention of CVD
- Combination HT using premarin (0.625mg) and provera (2.5mg) per day associated with a small inc relative risk of CVD (1.29), stroke (1.41), invasive breast cancer(1.26), VTE (2.13) and a small protection against fractures (0.66) and colorectal CA at an average of 5 years of use (WHI data)

- Estrogen therapy alone 0.625mg associated with small increased risk of stroke (1.39) and DVT and small decreased risk of fracture (.61). No increased risk of CVD, PE or breast cancer, which had a small nonsignificant decreased risk 0.77 (0.59-1.01) (WHI data)

PRESCRIBING PRECAUTIONS FOR HT:

- Pregnancy, undiagnosed abnormal vaginal bleeding, active liver disease
- Recent or active thrombophlebitis or thromboembolic disorders
- Breast cancer or known or suspected estrogen-dependent neoplasm
- Recent MI or severe CVD

STARTING HORMONES FOR MENOPAUSAL WOMEN:

- Patient counseling is key to success with HT. May takes weeks for relief of hot flashes. Explain risks and side effects especially vaginal spotting and bleeding
- Usual well woman care measures should be provided – mammogram, pap test, lipid profile – but are not essential (except mammogram) prior to providing HT. Endometrial biopsy not needed except when evaluating abnormal vaginal bleeding
- ➔ • Consider starting with low doses and transdermal preparations (transdermal may have less of a risk for VTE)
- Re-evaluate need for HT/ET annually. The current products are:

Generic names - Estrogens	Brand names
Conjugated estrogen tablets, USP	Premarin®
Synthetic conjugated estrogens, A tablets	Cenestin®, Enjuvia
Esterified estrogens tablets	Menest®
Estropipate tablets	Ogen®, Ortho-est®
Estradiol tablets	Estrace® (micronized), Femtrace
Matrix estradiol transdermal systems	Alora®, Climara®, FemPatch®, Vivelle™, Esclim, Menostar, Vivelle-dot
Reservoir estradiol transdermal systems	Estraderm®
Topical estradiol ➔	Estrasorb®, Estrogel®, Divigel®, Elestrin® ➔
Transdermal spray ➔	Evamist®
Vaginal estradiol	Vagifem® (tablet), Estrace® (cream), Estrin® (ring), Femring® (ring)
Vaginal conjugated estrogen	Premarin®

Generic names - Progestins	Brand names
Medroxyprogesterone acetate (MPA) tablets	Provera®
Megestrol acetate tablets	Megace®
Norethindrone tablets	Micronor®, Nor-QD®, Errin®, Camila® ➔
Norethindrone acetate tablets	Aygestin®
Micronized progesterone capsules	Prometrium®
Progesterone vaginal gel	Crinone®
Levonorgestrel IUS	Mirena

Generic names - Combined Products	Brand names
Estradiol and norgestimate tablets	Prefest®
Conjugated estrogens and MPA tablets	Premphase®, Prempro®
Esterified estrogens and methyl testosterone tablets	Estrate®, Estratest® H.S.
Ethinyl estradiol and norethindrone acetate tablets	Femhrt®
Estradiol and norethindrone acetate tablets	Activella™
Estradiol/ norethindrone acetate transdermal systems	CombiPatch™
Estradiol + levonorgestrel	Climara Pro®
Estradiol + drospirenone ➔	Angeliq

FOLLOW-UP

- Be available to answer questions when there are media reports about HT
- Have the woman keep a menstrual calendar of any breakthrough bleeding or spotting
- If hot flashes continue, consider thyroid dysfunction and other causes before increasing dose or using other therapeutic approaches to hot flash treatment

CHAPTER 9

Prepregnancy Planning and Preparation

www.plannedparenthood.org or www.aidsinfo.nih.gov

Women in the reproductive years should take 0.4 mg (400 micrograms) of synthetic folic acid daily. This easy, safe step significantly reduces the risk of neural tube defects in a developing fetus. All prenatal vitamins contain this minimum FA dose ←

- 400 micrograms of folic acid daily

- Women with a history of spina bifida, women on antiseizure medication and insulin dependent diabetics need 4 mg folic acid daily

Prepregnancy visit assess:

- Reproductive, family and personal medical and surgical history with attention to pelvic surgeries
- Smoking, drug use, alcohol use: advise to stop and refer for help if needed
- Nutrition habits: identify excesses and inadequacies
- Medications: make adjustments in those that may affect fertility and/or pregnancy outcome. Advise patient not to make any changes without clinician's knowledge

Review Medical History: ←

- Glucose control in diabetics before conception and in early pregnancy decreases birth defects and pregnancy failure
- Hypertensive women on ACE inhibitors need to switch meds
- Some antiepileptics are more teratogenic than others
- Women on coumadin need to be transitioned to heparin or lovenox (low molecular weight heparin)
- Risk for sexually transmitted infection/infertility in both partners
- Impacts of any medications (over-the-counter, prescription, herbal). For example, Accutane and tetracycline (which are teratogenic) for acne requires extremely effective contraception and strong consideration of the use of 2 contraceptives correctly. Advise that patient delay pregnancy for at least one year after last Accutane. See p. 39. Helpful online databases include micromedex.com/products/hcs/demos/Part3.html ←
- Risk factors for preterm birth

RISK FACTORS FOR PRETERM BIRTH:

- | | |
|--|--|
| • non-white race | • vaginal bleeding in more than one trimester |
| • age < 17 or > 35 | • excessively physically stressful job (controversial) |
| • low socioeconomic status | • smoking |
| • low prepregnancy weight | • twins |
| • maternal history of preterm birth - especially in second trimester | |

Reference: ACOG Practice Bulletin, 2001

Offer Screening and/or Counseling for:

- Infections (TB, gonorrhea, chlamydia, HIV, syphilis, hepatitis B & C, HSV as per CDC guidelines). Vaginal wet mount if discharge present
- Neoplasms (breast, cervical dysplasia, warts, etc.)
- Immunity (rubella, tetanus, chicken pox, HBV) HPV if applicable
- Alcohol use, tobacco use, substance abuse, obesity
- Advanced maternal and paternal age

Provide Genetic Counseling:

- For all women, but may need additional specialized counseling if going to be ≥ 35 y.o. when she delivers or has a significant personal or family history of genetic disorders, poor pregnancy outcome or partner of advanced paternal age
- Family history of mental retardation or genetic disorders such as sickle cell anemia, thalassemia, cystic fibrosis, Tay-Sachs, Canavan disease, neural tube defect
- High risk ethnic backgrounds: African Americans, Ashkenazi Jews, French Canadian, Cajun, etc
- Seizure disorders, Diabetes
- Other heritable medical problems

Assess Environmental Hazards:

- Chemical, radioactive and infectious exposures at workplace, home, hobbies
- Physical conditions, especially workplace
- Assess male partner as well!

Assess Psychosocial Factors:

- Readiness of woman and partner for parenthood
- Mental health (depression, etc.) and domestic violence
- Financial issues and support systems

Recommend:

Ideally, planning a pregnancy should involve both a woman and her partner

- Balanced diet
- Do not eat shark, swordfish, mackerel, tilefish or fish caught in local waters
- Eat up to 12 oz (2 average meals) of fish lower in mercury, which can include up to 6 oz of albacore tuna per week. Non albacore tuna has less mercury. ←
- Vitamin with folic acid 0.4 mg for all women planning pregnancy or at risk for unintended pregnancy (women with previous pregnancy with a neural tube defect, insulin dependent diabetic, alcoholic, malabsorption or on anticonvulsants need 4 mg folic acid daily) ←
- Minimize STI exposure risk
- Weight loss, if obese (gradual loss until conception)
- Special planning for women with prior gastric bypass or current obesity ←
- Moderate exercise
- Avoiding exposure to cat feces (toxoplasmosis) if no known immunity
- Early in process of discussing pregnancy encourage breastfeeding as the best way to feed her baby
- Early prenatal care when pregnancy occurs ←

Avoid

- Raw meat (including fish) and unpasteurized dairy products
- Abdominal/pelvic X-rays, if possible
- Excesses in diet, vitamins, exercise
- Non-foods (pica), unusual herbs
- Sex with multiple partners or sex with a partner who may be HIV-positive, have other STI or have other sex partner(s). Use condom if any question.

CHAPTER 10

Pregnancy Testing

www.plannedparenthood.org, www.ovulation.com & 1-800-230-PLAN

Early testing gives a woman time to pursue pregnancy options

- Prenatal care can be initiated promptly
- Unhealthy behaviors/exposures can be stopped sooner
- Ectopic pregnancies may be detected earlier
- Medical and surgical methods of abortion are safest at earlier gestations

PREGNANCY TESTS

Urine tests:

- *Enzyme-linked immunosorbent assay (ELISA) test:*
 - Immunometric test uses antibody specific to placentally-produced HCG and another antibody to produce a color change. Commonly used in home pregnancy test and in offices and clinics. Performed in 1-3 minutes using urine samples
 - Most tests positive at levels of 25 mIU/ml. This level can be detectable 7-10 days after conception. May require 5-7 days after implantation to detect all pregnancies
 - Test results are positive for 98% of women 7 days after implantation ←
 - Urine pregnancy tests are used in most clinical settings and are available for women to purchase over-the-counter; teach patients that no lab test is 100% accurate and that false negative tests (tests read as negative when a woman actually is pregnant) usually occur when done too early in the pregnancy and are far more common than false positive tests (tests read as positive when a woman actually is NOT pregnant)
- 29 one-step urine tests sensitive to 10-25 mIU/ml beta hCG are outlined in table 26-2 on pages 636 and 637 of 18th edition of *Contraceptive Technology*.

Serum tests (blood drawn):

- *Radioimmunoassay:*
 - Uses colorimetry, which detects HCG levels as low as 5 mIU/ml
 - Results available in 1-2 hours
 - Offers ability to quantify levels of HCG to monitor levels over time when clinically indicated as for ectopic pregnancy diagnosis and treatment

HCG QUICK FACTS

- β -HCG can be detected as early as 7-10 days after conception thereby, “ruling in” pregnancy, but pregnancy cannot be “ruled out” until 7 days after expected menses
- If needed for evaluation of early pregnancy, serial HCG testing should be done every 2 days until levels reach discriminatory levels of 1800-2000 mIU/ml, when a gestational sac can be visualized reliably by vaginal ultrasound. In normal gestations the levels of HCG double about every 2 days [Stenchever MA-2001]
- Average time for HCG levels to become non-detectable after first trimester surgical abortion ranges from 31-38 days

MANAGEMENT TIPS

- Home tests can be misused or misinterpreted.
- Any test can have false-negative results at low levels. If in doubt, repeat urine test in 1-2 days or obtain serum tests with a quantitative HCG
- Recommend folic acid, 0.4 mg/day: every woman, every day (pregnancy test positive or negative)

PREGNANCY TEST NEGATIVE: A TEACHABLE MOMENT

A negative pregnancy test for a woman not wanting to become pregnant clearly provides the counselor or clinician with a teachable moment and a time to offer a woman a better contraceptive and ECPs for future acts of intercourse that might be unprotected.

“What a relief! The pregnancy test is negative.” This must have been scary to worry that you might be pregnant.

1. If you haven't been using contraception, this is your “wake-up call.” What contraceptive method would work best for you now? You may be able to start your contraceptive without a pelvic exam.
2. Don't try to become pregnant in order to see if you can become pregnant.
3. Don't take a chance from this moment on: never, just never, have intercourse without knowing that you are protected against both infection and unintended or unwanted pregnancy, unless you want to get pregnant.
4. Remember, your negative urine pregnancy test does not rule out conception from acts of intercourse in the past 2 weeks.

For Clinicians:

5. Learn about emergency contraceptive pills and emergency IUD insertion.
6. Discuss keeping emergency contraceptive pills at home for future use; can buy OTC if ≥ 17 years. Otherwise, provide prescription

PREGNANCY TEST POSITIVE: A TEACHABLE MOMENT

The pregnancy test is positive and she wants to continue the pregnancy. Whether or not this pregnancy was planned and prepared for,* your patient has decided to continue this pregnancy, providing you, the counselor or clinician, with a teachable moment.

The pregnancy test is positive and she is continuing her pregnancy to term

1. Start vitamins containing folic acid (0.4 mg) today. Buy vitamins on the way home.
2. Stop drinking alcohol or using any recreational drugs today.
3. Stop smoking today.
4. Ask: “Are you on any medication? Are you taking OTC products?”
5. Use condoms if at any risk for HIV or other STIs.
6. Eat healthy foods. Gain 25-30 pounds during your pregnancy (if your weight is now normal).
7. Review current medical problems.
8. Learn about EC for the future
9. Establish prenatal care. Provide referral if needed

* If she doesn't want to continue pregnancy, discuss other options including adoption or pregnancy termination or refer her to someone who feels comfortable doing this.

➡ Find out what's new in *Managing Contraception 2010-2012* by scanning this pocket guide for arrows!

CHAPTER 11

Postpartum Contraception

www.avsc.org or www.fhi.org

Planning for postpartum (PP) contraception should begin during pregnancy and use should be initiated as early as possible postpartum. A newborn can place many demands on a woman's time, so her method should be as convenient for her to use as possible. In some women who are not breastfeeding, ovulation may return postpartum before a woman realizes she is at risk, which may be before her first period. The 6-week postpartum visit is too late. The visit should be at 2-4 weeks. By 6 weeks postpartum, 50% of women as early as 26-28 days postpartum have had vaginal intercourse. Involve her partner as often as possible. Advance provision of EC is always appropriate

- Pregnancies spaced at least 18-23 months apart are less likely to have: preterm delivery, low birth weight, and small for gestational age infants *[2hr-2005]*

AT DELIVERY

- Tubal sterilization may be performed (at C-section or after vaginal delivery)
- Copper or levonorgestrel IUD may be inserted within 20 minutes of delivery of placenta (requires learning new technique) but rates of expulsion are higher than with insertion after uterine involution

PRIOR TO LEAVING HOSPITAL

- Encourage breastfeeding. Reinforce education about lactational amenorrhea if patient is interested (see Chapter 15, p. 47-50)
- Pelvic rest (no douching, no sex, no tampons) is generally recommended for 4-6 weeks and/or until lochia stops. Many women choose NOT to follow this advice in spite of increased risk for infection. Some clinicians encourage women to become sexually active when they feel comfortable and ready
- At this time, sex may be the last thing the woman is thinking about. Nevertheless, encourage her to have a contraceptive plan for when she does initiate sexual activity. Options:

- Tubal sterilization, vasectomy
 - Progestin-only methods: Depo-Provera (DMPA), progestin-only pills (POPs), Implanon
- NOTE:** There are three approaches to starting these progestin-only methods:
- 1) When the patient leaves the hospital (off-label) start POPs, DMPA or receive Implanon
 - 2) Since progestin-only methods may prolong bleeding wait 2-3 weeks to start them (no data). Women with history of or high risk for postpartum depression may also benefit from a delay in starting progestin-only methods. In breastfeeding women, progestin-only methods have no effect on milk production or composition or long-term growth of the infant *(Truit-2003)*
 - 3) Start at 6 weeks which is what labels recommend. Use condoms if intercourse prior to 6 weeks

Label does not include use in first 6 weeks because many studies did not include such women not because there is an established contraindication.

- Male or female condoms to reduce risk of sexually transmitted infections
- Estrogen containing contraceptive may be prescribed for nonlactating women to start 3 weeks postpartum (increased risk of thrombosis associated with pregnancy reduced by that time). Recommend to start the Sunday after 21st day PP. Give a prescription when she leaves the hospital (to be started in 3 weeks)
- Provide EC in advance or advise to buy OTC

AT POSTPARTUM VISIT (2-6 WEEKS) - see CDC MEC A-3

- Best time is likely at 2 weeks to coincide with infant's first exam. Waiting 6 weeks will miss important issues like resumption of sex, problems with breastfeeding, postpartum depression and adaptation at home to having a baby
- Ask if woman has resumed sexual intercourse
- Pregnancy is possible 3 months after delivery even if she is fully breastfeeding and 3 weeks if she is not
- Support continued breastfeeding if applicable
- Lactational amenorrhea follow-up. Provide condoms as transitional method and discuss other methods before transition to decreased breastfeeding
- Emergency contraception may be given if needed
- Progestin-only methods may be provided (Depo-Provera, progestin-only pills, Mirena, Implanon). Provide backup method as needed if initiated when not on menses
- COCs, patch or ring may be started after 3 weeks in non-breastfeeding women*. For breastfeeding women, start CHCs at 1 month PP, now a CDC category 2. Provide backup method as needed
- IUD may be inserted if uterus well involuted (whether or not she is breast-feeding). Usually at 4 + weeks
- Condoms (male or female) may be given as primary or backup contraceptive to provide STI risk reduction; withdrawal can be used at any time
- Tubal sterilization via laparoscopy or transcervical (Essure) may be provided after uterine involution, or vasectomy anytime
- Diaphragm, cervical cap may be fitted after pelvis/cervix return to normal configuration
- NFP and FAM should await resumption of normal cycles for at least 3 months
- Screen for postpartum depression

A HARD LOOK AT MISTAKES MADE OVER AND OVER AGAIN

Often we see patients/clients who have made repeated mistakes; A postpartum woman who has already had several unplanned pregnancies, an individual with repeated infections who almost never uses a condom, a smoker, an abuser of alcohol or drugs, a person who eats far too much and exercises far too little. When this happens and the problem is inconsistent or incorrect use of a contraceptive we may want to share a message like this with our patient:

"If you have made a mistake using a contraceptive method in the past, you may be able to learn to use it correctly in the future. BUT, you may also make the same mistake over and over again in the future. Such is human nature. We are creatures of habit. So, be very careful going back to a method that you have failed to use correctly in the past. Similarly, if you have had a certain side effect from using a method in the past, you may experience the same side effect in the future."

—Robert A. Hatcher



*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 12

Elective Abortion

www.prochoice.org/naf or www.earlyoptionpill.com

OVERVIEW


Surgical abortion, accounting for 95% of abortions, are very safe with serious morbidity in less than 1% of procedures and a death rate of 4 per million if performed ≤ 8 weeks increasing to ~ 9 per 100,000 for those done at ≥ 21 weeks (less than 2% of procedures) [Bartlett-2004] (compared to maternal mortality with a continued pregnancy of approximately 11.8/100,000 deliveries [MMWR-2005]). 60% of the 1.3 million U.S. abortions are done at < 9 weeks and 27% are less than 7 weeks. The estimated mortality rate for early medical abortions in the U.S. is $\sim 1/100,000$ procedures. The introduction of several agents for early medical abortion have added new options.  

Safe, legal, elective abortion procedures are important for fertility control since 48% of pregnancies in the U.S. are unintended and 25% of pregnancies end in induced abortion [Jones-2002].

Despite having one of the highest abortion rates among developed countries, 87% of U.S. counties had no abortion providers or facilities, an increase from 78% in 2000. Many state laws impose mandatory restrictions, waiting periods, and consent requirements. For current information on your state's abortion laws, contact Pro Choice America 202-973-3000 or www.nara.org/.

- 47% of all women in the US have had one or more elective abortions
- In 2002, about 2% of all women aged 15-44 had an abortion [Fines, Hershaw-2005]
- Each year about 10,000-15,000 abortions occur as a result of rape or incest

Features of Medical Compared to Surgical Abortion

Medical	Surgical
Generally avoids invasive procedure	Involves invasive procedure
Requires multiple visits	Usually requires one visit
Days to weeks until complete	Usually complete in a few minutes
Available during very early pregnancy	Available during early and later pregnancy
High success rate (94% - 97%)	Higher success rate (99%)
Requires follow-up to ensure completion of abortion	Does not require follow-up in most cases
May be more private in some circumstances; will vary for each individual patient	May be more private in some circumstances; will vary for each individual patient
Patient participation in multi-step process	Less patient participation in a single-step process
Analgesia available if desired	Allows use of sedation or anesthesia if desired
Does not require surgical training, but does require surgical back-up 	Requires surgical training and sometimes licensed facility

ELECTIVE SURGICAL ABORTION

DESCRIPTION

Voluntary termination of pregnancy using uterine aspiration in early intrauterine gestations. In later gestations (after 14 weeks) using instruments for tissue removal (standard dilation and evacuation [D & E] or intact dilation & extraction [D & X]). ←

EFFECTIVENESS

- 98-99% effective; failures are mostly incomplete abortions with small amounts of retained tissue; rarely does the pregnancy continue

PROCEDURE

- After informed consent obtained according to local law, type of procedure is determined by gestational age and patient preference
- Perform careful bimanual exam to assess size and position of uterus ←
- In second trimester, dilate the cervix with an osmotic dilator (laminaria, dilapan) OR with a prostaglandin analogue (misoprostol) with or without an osmotic dilator
- Peri-operative antibiotics reduce the risk of post-procedure infection. However, no studies demonstrate if a single regimen is better than others. The best study supports use of doxycycline. If chlamydia infection likely, a 7-day course of doxycycline, or a single dose of azithromycin 1 g may be given. If BV is present, treat with appropriate antibiotics
- Cleanse ectocervix and endocervix
- Administer cervical anesthesia; if desired, adjunctive sedation can also be used. NSAIDs are typically administered pre-operatively and post-operatively
- Place tenaculum and mechanically dilate cervix if not previously dilated adequately
- Using sterile technique, insert a plastic cannula and apply suction to aspirate products of conception either with a machine, or manually with a manual vacuum aspiration (MVA) syringe
- May confirm adequacy of procedure by checking uterine cavity with a sharp curette (optional)
- Evaluate tissue to confirm presence of placental villi/gestational sac if early pregnancy. If more than 9 weeks should be able to visualize fetal tissue. If no villi, consider possibility of ectopic pregnancy
- Administer Rh immune globulin if woman is Rh negative

ADVANTAGES

- Provides woman complete control over her fertility
- Ability to prevent an unwanted or defective birth or halt a pregnancy that poses risk to maternal health or other aspects of her life
- Safe and rapid; preoperative evaluation and procedure can usually be done in a single visit from a medical perspective (local legal restrictions may affect this)
- No increase in risk of breast cancer, infertility, cervical incompetence, preterm labor, or congenital anomalies in subsequent pregnancy after uncomplicated first-trimester abortion
- Fewer risks to maternal health than continuing pregnancy
- Can be provided as early as intrauterine pregnancy is diagnosed

DISADVANTAGES

- Cramping and pain with procedure; the noise of the vacuum machine (if electrical vacuum used) may cause anxiety.
- Possibility of later regret (regret is equally possible for undesired pregnancy that is continued)

COMPLICATIONS

- Infection <1%, with an uncommon complication of infertility
- Incomplete abortion 0.5%-1.0%; Failed abortion 0.1%-0.5%
- Hemorrhage 0.03%-1.0%
- Post-abortion syndrome (hematometra) <1%
- Asherman's syndrome rare (more likely with septic abortion), with an uncommon complication of infertility
- Mortality: Elective surgical abortion deaths <1 per 100,000 and medical ~ 1 per 100,000

CANDIDATES FOR USE

- Any woman requesting abortion. State laws often limit gestational age (typically available through 24 weeks). State laws may also affect access and consent procedures

Adolescents: State laws vary regarding requirements and consent requirements (See p. 19)

INITIATING METHOD

- Carefully discuss all pregnancy options, including prenatal care for continuing pregnancy or for adoption and programs available for assistance with each option
- If patient chooses abortion, discuss available techniques when applicable (surgical versus medical)
- Obtain informed consent after answering all questions
- Offer emotional support, education, pre- and post-procedural instructions, and contraception
- Usually perform procedure in outpatient setting unless woman has severe medical problems requiring more intense monitoring or deeper anesthesia
- Initiate contraception immediately after procedure including intrauterine contraception

INSTRUCTIONS FOR PATIENT

- Keep telephone number(s) nearby for any emergencies
- May resume usual activities same day if procedure done under local anesthesia
- One week pelvic rest (no tampons, douching or sexual intercourse)
- Use NSAIDs or acetaminophen for cramping, ergotamine (methergine) for heavy bleeding
- Showers are permitted immediately
- Seek medical care urgently if heavy bleeding, excessive cramping, pain, fevers, chills, or malodorous discharge
- After 1 week of abstinence, use contraception with every single act of intercourse and keep EC available for future use

FOLLOW-UP

- Have you had a temperature >100.4°F
- What has your bleeding been like since the procedure?
- Have you had any new abdominal or pelvic pain?
- Are you using a contraceptive?

PROBLEM MANAGEMENT

Infection

- Always evaluate possibility of retained products and need for reaspiration
- Patients who develop endometritis can generally be treated using outpatient PID therapies described in the CDC Guidelines (see Chapter 30 p. 159 - PID)
- Cases that are more complicated may require hospitalization and IV antibiotics (uncommon)

Persistent or excessive bleeding

- *Possible causes* : uterine atony, retained products, uterine perforation, cervical laceration
- *Treat likely cause(s)*: Use uterine-contracting agents for atony (methergine, hemabate, misoprostol). Reaspirate if retained products. If uterine perforation, give antibiotics, and evaluate surgically if there is concern for bowel or vascular injury. Suture external cervical lacerations; tamponade endocervical lacerations
- *For significant hemorrhage (rare)*: transfuse if large blood loss. Provide blood factors to patients with coagulopathies. In extremely rare cases, uterine artery embolization, further surgery or hysterectomy may be necessary

ELECTIVE MEDICAL ABORTION

DESCRIPTION

- The first medication (mifepristone or methotrexate) is given to interrupt the further development of the pregnancy
- Misoprostol is then given to induce expulsion of the products of conception (see protocol p. 35)
- Misoprostol is a prostaglandin analogue which causes the cervix to soften and the uterus to contract. May be taken orally, vaginally or buccally, either at home or in the office. (Not as effective when given alone as when given with either mifepristone or methotrexate) [Goldberg, Greenberg, and Darney-NEJM 2001]

INITIATING METHOD

- Discuss all pregnancy options, including prenatal care for continuing pregnancy or for adoption, and highlight programs available for assistance with each option
- If patient chooses elective abortion, discuss available techniques (surgical vs. medical)
- Review protocol, risks, benefits, and visit schedule
- Assess patient's access to provider if D&C is needed. Explain need for D&C if incomplete or if continuing pregnancy (some women think they can avoid surgery altogether)
- Obtain informed consent after all questions are answered
- Vaginal ultrasound to confirm dates if available

Mifepristone (Ru-486) And Misoprostol (Mis)

Most medical abortions in the U.S. and abroad now use mifepristone rather than methotrexate. Mifepristone used as an abortifacient in France since 1988

Mechanism - Mifepristone acts as an antiprogesterone to block continued support of the pregnancy. It blocks progesterone receptors. This causes decidual necrosis and detachment of products of conception. Mifepristone also causes cervical softening

Dose of mifepristone - 600 mg is FDA approved dose - but 200 mg is just as effective in clinical trials

Effectiveness - 92-98% effective depending on gestational age and MIS doses used: for gestational age up to 49 days if using oral MIS, up to 63 days if vaginal or buccal MIS. Process is generally more rapid than alternative regimens

Contraindications - Not effective for ectopics. Not for use by chronic corticosteroid users, chronic adrenal failures, porphyrias, or with history of allergy to mifepristone or prostaglandins

Protocol - (evidence-based regimens)

- **Screening:** Baseline labs including Rh, hemoglobin
- **Mifepristone:** administer 200 mg orally. Give Rh immune globulin if Rh negative at this time. Provide misoprostol for home use
- **Misoprostol:** can be used vaginally, buccally or orally. Timing should be based on the woman's needs/schedule (see table)
- **Follow-up:** Can be performed 2-14 days after misoprostol use. If assessed at 14 days, can be just history and exam with ultrasound as indicated. If assessed at one week or less, ultrasound to establish absence of gestational sac. Alternative follow-up with serum hCG testing can be used. Perform D&C for heavy bleeding, signs of infection or continuing pregnancy. If gestational sac not expelled, can perform D&C or repeat misoprostol with return evaluation in 1-2 weeks.

MIFEPRISTONE MEDICAL ABORTION AND INFECTION

Serious infections and bleeding (rarely, fatal) occur following spontaneous, surgical, and medical abortions, including following mifepristone use. No causal relationship between the use of mifepristone and misoprostol and these events has been established. Ensure that the patient knows whom to call and what to do, including going to an Emergency Room if none of the provided contacts are reachable, if she experiences *sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope*, or if she experiences *abdominal pain or discomfort or general malaise* (including weakness, nausea, vomiting or diarrhea) more than 24 hours after taking misoprostol.

Atypical Presentation of Infection: Patients with serious bacterial infections (e.g. *Clostridium sordellii*) and sepsis can present without fever, bacteremia or significant findings on pelvic examination following an abortion. *Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise.* A high index of suspicion is needed to rule out serious infection and sepsis.

ALTERNATIVE REGIMENS:

Medical Abortion with Methotrexate (MTX) and Misoprostol (MIS)

Methotrexate prevents reduction of folic acid to tetrahydrofolate by binding to dihydrofolate reductase, which interferes with DNA synthesis. This action, in early pregnancy, prevents continued implantation (inhibits syncytialization of the cytotrophoblast). MTX 50 mg/m² IM or 50 mg PO is combined with MIS 800 mcg vaginally 3-7 days later in women up to 49 days gestation. Efficacy within 1 week is typically 70-80%. If the remaining non-continuing pregnancies are managed expectantly, the overall success rate is as high as 95%. Because of the significant delay in abortion for many women and the limit of efficacy to gestations only up to 49 days, the combination of MTX and MIS is generally not recommended for medical abortion.

EARLY MEDICAL ABORTION WITH MISOPROSTOL ALONE

Misoprostol, when used without mifepristone or MTX, can cause abortion after 1-3 doses in women up to 56 days gestation. Treatment regimens typically include MIS 800 mcg vaginally at intervals ranging from every 8 hours to every 24 hours. Efficacy rates are generally around 70% with one dose of misoprostol, 80% after two doses and near 90% after three doses. Given the existence and availability of safe alternative regimens, MIS alone is generally not recommended for medical abortion. However, in situations where mifepristone is unavailable, MIS alone is an option

CONTRACEPTION AFTER ABORTION ←

- All methods may be started on the day of an abortion procedure
- Advantages of starting immediately: know patient is not pregnant, immediate contraceptive protection
- If inserting IUD after second-trimester abortion procedure, may have slightly higher expulsion rate
- For medication abortions, start contraceptives on day of follow-up visit when termination of pregnancy confirmed.
- Vaginal rings were inserted within 1 week following surgical and medical abortions in 81 women and were found to be highly acceptable [*Fine-2007*]

CHAPTER 13

Choosing Among Contraceptive Methods

www.managingcontraception.com/choices, www.plannedparenthood.org/library

THE BEST METHOD IS THE ONE THAT IS MEDICALLY APPROPRIATE AND IS USED EVERY TIME BY SOMEONE HAPPY WITH THE METHOD

- Each contraceptive method has both advantages and disadvantages
- Be aware of your own biases
- Effectiveness and safety are important (see pages 38, 40)
- Convenience and ability to use method correctly influences effectiveness
- Protection against STIs/HIV needs to be considered for women and men at risk
- Effects of method on menses may be very important to a woman
- Ability to negotiate with partner may help determine method selected
- Religion, privacy, friend's advice and frequency of sex may influence decision
- Discuss all methods with patient, even those you may not use in your own practice
- Is partner supportive of contraception/condoms and will he help pay for them?
- Consider discussing with couple, particularly if there appears to be conflict

EFFECTIVENESS: measured by failure rates in 2 ways (see Table 13.2, p. 40)

Correct and consistent use first year failure rate: The percentage of women who become pregnant during their first year of use when they use the method perfectly.

Typical use first year failure rates: The percentage of women who become pregnant during their first year of use. This number reflects pregnancies in couples who use the method correctly and consistently and of those who do not. **This typical use failure rate is the relevant number to use when counseling new start users.**

- In spite of many very effective options, the U.S. has a high rate of unintended pregnancy. Just under 50% of all pregnancies in the U.S. are not planned. The U.S. also has the lowest rate of IUD use in the developed world. Our challenge is to help women and couples use available methods effectively

Counseling about effectiveness:

- Methods are divided into 3 groups:
 - A) *Highly effective:* female and male sterilization, Implants, IUDs, DMPA
 - B) *Moderately effective:* pills (COCs and POPs), ring, patch
 - C) *Slightly effective:* male latex condoms, diaphragm, cervical cap (no previous births or previous births), female condoms, spermicides (gel, foam, suppository, film), withdrawal, natural family planning (calendar, temperature, cervical mucus)

KEY QUESTIONS

- **What contraceptive did you come to this office today wanting to use?** Data show that giving the method they ask for is more likely to result in continuation. [Pariani S. et al. *Stud Fam Plann*, 1991]
- **When (if ever) do you want to have your next child?** Helps teach need for preconceptional care and guides in selection of method. Consider IUDs for spacing. After first 2 years of use, most cost-effective method. If she definitely wants no further pregnancies, be sure to discuss sterilization in addition to the highly effective reversible methods

- *Does your partner want to have children in the future? When?*
- *Will your partner help you using condoms and/or paying for contraceptives?*
Using abstinence when you do not have another method?
- *What would you do if you had an accidental pregnancy? Is abortion an option or not?* When abortion is not an option, highly effective methods should be stressed. ←
- *What method(s) did you use in the past? What problems did you have with it/them?*
- *What are you doing to protect yourself from STIs/AIDS?* Inclusion of counseling about safer sex practices and condoms may be critical
- *Do you know what emergency contraception is?* Encourage her to purchase a package of ECPs to have on hand while encouraging use of a highly effective contraceptive ← thereby minimizing the potential need for EC
- *Do you have any serious medical problems?*
- *What side effects are you willing to accept?*

Comparing Typical Effectiveness of Contraceptive Methods

This chart available at www.who.int/reproductive-health/family-planning/tool.htm

More effective
Less than 1 pregnancy per
100 women in 1 year



Less effective
About 30 pregnancies per
100 women in 1 year

How to make your method more effective

Implants, IUD, female sterilization: After procedure, little or nothing to do or remember

Vasectomy: Use another method for first 3 months

Injectables: Get repeat injections on time

Lactational amenorrhea method, LAM (for 6 months): Breastfeed often, day and night

Pills: Take a pill each day

Patch, rings: Keep in place, change on time

Condoms, diaphragm: Use correctly every time you have sex

Fertility awareness methods: Abstain or use condoms on fertile days. Newest methods (Standard Days Method and TwoDay Method) may be easier to use.

Withdrawal, spermicides: Use correctly every time you have sex



Sources:
Steiner MJ, Trussell J, Mahta N, Condon S, Subramaniam S, Boorne D. Communicating contraceptive effectiveness: a randomized controlled trial to inform a World Health Organization family planning handbook. *Am J Obstet Gynecol* 2006;195(1):85-91.
World Health Organization/Department of Reproductive Health and Research (WHO/RHR), Johns Hopkins Bloomberg School of Public Health (JHSPH)/Center for Communication Programs (CCP). *Family Planning: A Global Handbook for Providers*. Baltimore, MD and Geneva: CCP and WHO, 2007.
Trussell J. Choosing a contraceptive: efficacy, safety, and personal considerations. In: Hatcher RA, Trussell J, Stewart F, Nelson AL, Cates W Jr, Gostel F, Kowal D, eds. *Contraceptive Technology*. Nineteenth Revised Edition. New York: Ardent Media, Inc., in press.

2007

TABLE 13.1 Comparative risk of unprotected intercourse on unintended pregnancies and STI infections*

Unintended pregnancy/coital act	PID per woman infected with cervical gonorrhea
17%-30% midcycle <1% during menses	40% if not treated 0% if promptly and adequately treated
Gonococcal transmission/coital act	Tubal infertility per PID episode
50% infected male, uninfected female 25% infected female, uninfected male	8% after first episode 20% after second episode 40% after three or more episodes

*Cates W Jr. *Reproductive tract infections*. In: Hatcher RA, et al. *Contraceptive Technology*. 18th ed. New York: Ardent Media, 2004:193.

ACCUTANE SHOULD BE USED VERY CAUTIOUSLY IN REPRODUCTIVE AGE WOMEN



Accutane (isotretinoin) is a vitamin A isomer used in the treatment of extremely severe acne. If taken by a woman who is pregnant, it may cause a wide range of teratogenic effects including:

CNS: hydrocephalus, facial nerve palsy, cortical blindness and retinal defects

Craniofacial: low-set ears, microcephaly, triangular skull and cleft palate

Cardiovascular: transposition of the great vessels, atrial and ventricular septal defects

Important contraceptive messages for women considering Accutane use, in view of the fact that no method of birth control is 100% effective:

- **Use Two Methods:** In addition to compulsive, careful and consistent use of a very effective hormonal contraceptive, also use condoms consistently and correctly. Use of any combined (E/P) method is likely to have a beneficial effect on acne.
- **Repeated Pregnancy Tests:** Pregnancy tests are essential prior to initiating and on a monthly basis thereafter. This is particularly important since the critical time of exposure to Accutane is believed to be 2-5 weeks after conception [Briggs-2002]
- **Consider Abortion if Contraceptive Failure:** Should pregnancy occur, strongly consider an abortion. In the 22 months following its introduction, the manufacturer, FDA and CDC received reports on 154 Accutane-exposed pregnancies, of which 95 (61.7%) were electively aborted. Another 12 (7.8%) aborted spontaneously. 26 were born without major defects and 21 had major malformations [Briggs-2002] **Many clinicians will not provide this drug unless the woman agrees to have an abortion should a pregnancy occur**
- **Use Accutane Sparingly:** This drug is dangerous to a developing fetus and should not be used unless other approaches to managing acne have been used first AND unless the reproductive-age woman using it agrees to use contraception consistently and correctly.

Table 13.2 Percentage of women experiencing an unintended pregnancy within the first year of typical use and the first year of perfect use and the percentage continuing use at the end of the first year: United States*

Method	% of Women Experiencing an Unintended Pregnancy within the First Year of Use		% of Women Continuing Use at One Year ¹
	Typical Use ²	Perfect Use ³	
No Method ⁴	85	85	
Spermicides ⁵	28	18	42
Withdrawal	28	4	43
Periodic Abstinence			51
Calendar	25	9	
Ovulation Method	25	3	
Symptothermal ⁶	25	2	
Post-ovulation	25	1	
Cervical Cap with spermicide			
Parous Women	32	26	46
Nulliparous Women	16	9	57
Diaphragm with spermicide ⁷	11.5	6	57
Condom ⁸			
Reality Female Polyurethane condom	21	5	49
Male (Latex or polyurethane)	18	2	53
Pill (COCs and POPs)	9	0.3	68
Ortho Evra patch [*]	8	0.3	68
NuvaRing [*]	8	0.3	68
Depo-Provera injections - q.3 months	5	0.3	56
Lunelle monthly injection	3	0.05	56
Implanon	0.2	0.1	
IUD			
Copper T (Paragard)	0.8	0.6	78
Levonorgestrel-releasing (Mirena)	0.1	0.1	81
Female Sterilization	0.5	0.5	100
Male Sterilization	0.15	0.10	100

Emergency Contraceptive Pills: Treatment with COCs initiated within 120 hours after unprotected intercourse reduces the risk of pregnancy by at least 60-75%⁹. Pregnancy rates lower if initiated in first 12 hours. Progestin-only EC reduces pregnancy risk by 89%.

Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception.¹⁰

¹ Among couples attempting to avoid pregnancy, the percentage who continue to use a method for 1 year

² Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason

³ Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any other reason

⁴ The percentages becoming pregnant in columns 2 and 3 are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within 1 year. This estimate was lowered slightly (to 85) to represent the percentages who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether

⁵ Foams, creams, gels, vaginal suppositories, and vaginal film

⁶ Cervical mucus (ovulation) method supplemented by calendar in the pre-ovulatory and basal body temperature in the post-ovulatory phases

⁷ With spermicidal cream or jelly

⁸ With or without spermicides (No difference in efficacy)

⁹ The treatment schedule is one dose within 72 hours after unprotected intercourse, and a second dose 12 hours after the first dose. See page 70 for pills that may be used

¹⁰ However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breast-feedings is reduced, bottle feeds are introduced, or the baby reaches 6 months of age

^{*}Adapted from Trussell J, Kowal D. The essentials of contraception. In: Hatcher RA, et al. *Contraceptive Technology*, 18th ed. New York: Ardent Media, 2004.

Updated from Trussell J et al. *Contraception* Volume 78, Issue 1, July 2008.

^{*}Numbers for typical use failure of Ortho Evra and NuvaRing are not based on data. They are estimates based on pill data.

Table 13.3 Major methods of contraception and some related safety concerns, side effects, and noncontraceptive benefits

*Trussell J, Kowal D. The essentials of contraception. IN: Hatcher RA, et al. *Contraceptive Technology*. 17th ed. New York: Ardent Media, 1998:235. Slight adaptations from CT table.

METHOD	NONCONTRACEPTIVE BENEFITS *	SIDE EFFECTS	COMPLICATIONS (RARE)
Combined pills, injections, patch and ring	Decreased dysmenorrhea, PMS, and blood loss; protects against symptomatic PID requiring hospitalization, ovarian and endometrial carcinomas; some benign tumors (leiomyomata, benign breast masses), ectopic pregnancies and ovarian cysts; reduces acne	Nausea, vomiting, headaches, dizziness, mastalgia, chloasma, spotting and bleeding, mood changes, including depression (rare)	Cardiovascular complications (DVT, PE, MI, hypertension), depression, hepatic adenoma, slight increase in adenocarcinoma of cervix
Progestin-only pills	Lactation not disturbed. Decreased menstrual pain & blood loss	Spotting, breakthrough bleeding, amenorrhea, mood changes, headaches, hot flashes	None
Progestin-only implants	Lactation not disturbed. Less blood loss per cycle. Reduced risk of ectopic pregnancy	Menstrual changes, mood changes, weight gain or loss, headaches, hair loss	Infection at implant site, reaction to anesthesia, complicated removal, depression
Progestin-only injections	Lactation not disturbed. Reduces risk of sickle cell crises, endometrial cancer, ovarian cysts, mittelschmerz. May reduce risk of PID, seizures, ovarian cancer. Can be used with anti-convulsants	Menstrual changes, weight gain, headaches, hair loss, adverse impact on lipids, mood changes, including depression (rare)	Allergic reaction, excessive weight gain, glucose intolerance, severe depression
IUD	Lactation not disturbed. Copper T & levonorgestrel IUDs reduce risk for ectopic preg. LNG IUD reduces cramping & pain & treats bleeding from DUB, menorrhagia, & fibroids	Copper-IUD increases menstrual flow, blood loss and cramping. LNG IUD causes irregular bleeding/amenorrhea/decreased flow	PID following insertion, uterine perforation, bleeding with expulsion
Sterilization	Women: reduced risk of ovarian cancer, endometrial cancer, ectopic pregnancy, PID Men: none known	Pain at surgical site, adhesion formation, subsequent regret	Surgical complications: hemorrhage, infection, organ damage, anesthetic complications, pain, ectopic pregnancy
Male latex condom	Reduces risk of STIs and cervical dysplasia	Decrease in spontaneity or sensation; allergic reaction to latex, skin irritation	Rare anaphylactic reactions to latex (use polyurethane condoms)
Female condom	May reduce STI and cervical dysplasia risk	Difficult to use, vaginal and bladder infection	Toxic shock syndrome (although no cases reported)
Diaphragm Cervical cap	Reduces risk of cervical STIs, PID and possibly cervical dysplasia	Vaginal and bladder infection, vaginal erosions from poorly fit device, allergy to spermicide/latex	Toxic shock syndrome, anaphylactic reaction to latex

TIMING:

Couples considering contraceptives and their health care providers face myriad questions about the timing of contraceptive use. Sometimes our clients come to us with mistaken ideas. Sometimes we providers are actually the source of arbitrary misinformation about timing. In either case, timing errors, misconceptions, rigidity and oversimplifications can cause trouble; and trouble in family planning often can be spelled “unintended pregnancy”. In most instances, more important than advice about the timing of contraceptives is rapid initiation and then correct, **consistent** use of contraceptives. Below are several suggestions to consider in helping patients with timing questions:


1. For many women, a practical way to start pills, the patch or the ring is on the first day of the next period. Even easier, sometimes, is the Quick Start method which is to start pills on the day you first see a patient if you can be reasonably certain that she is not pregnant [Westhoff-2002]. Recommend backup method for 7 days unless pills started during the five days after the start of menses or within 5 days of miscarriage. Women with unprotected intercourse in preceeding 5 days should also receive EC
2. Switching from one hormonal method to another can be done immediately as long as the first method is used consistently and correctly, or if it is reasonably certain that she is not pregnant

Reasonably certain a woman is not pregnant - no symptoms and signs of pregnancy AND meets any of following criteria:

- no intercourse since last menses
- has been using a method consistently and correctly
- within first 7 days of normal menses
- within 4 weeks postpartum, non-lactating
- within first 7 days post abortion or miscarriage
- fully or near fully breastfeeding, amenorrheic and < 6 months postpartum

Ref: WHO - selected practice recommendations, 2004: Some experts recommend relying on lactational amenorrhea only through 3 months because 20% of fully nursing mothers ovulate at 3 months

3. Healthy women who tolerate pills well and do not smoke can continue pills indefinitely and/or until menopause unless a woman develops a complication or a contraindication to pill use. Periodic “breaks” from taking pills is still inappropriately recommended by some clinicians and is an unwise practice that can lead to unintended pregnancies
4. Extended use of combined pills with no pill free interval is an acceptable way for some women to take pills, with no increased risk of endometrial hyperplasia [Anderson-2003]. See p. 4
5. The first Depo-Provera injection may be given at any time in the cycle if reasonably certain a woman is not pregnant (see box above). If the day of the first shot is NOT within 5 days of the start of a period, recommend that patient use a back-up contraceptive for 7 days; give EC and repeat pregnancy test in 2-3 weeks if recent unprotected intercourse

6. Avoid overly dogmatic advice regarding when postpartum women should start progestin-only pills and the progestin-only injection, Depo-Provera. CDC category 1 for using progestin-only methods in the first month PP for non-breastfeeding women. CDC category 2 for using progestin-only methods within the first month PP in breastfeeding women. There are clinicians and entire programs starting these two methods in each of the following 3 ways: 
- At discharge from hospital
 - 2-3 weeks postpartum
 - 6 weeks postpartum
7. Recommend that condoms be placed onto the erect penis OR onto the penis before it becomes erect. There are clear advantages and disadvantages to both approaches.
8. Offer Plan B (emergency contraceptive pills) to women in advance. Advance prescription of Plan B is one approach. Better yet, hand her the actual pills and instructions, or instruct her to purchase OTC and keep at home
9. Intrauterine contraceptives may be inserted at any time in a woman's menstrual cycle if she is not pregnant. If using an LNG-IUD, back-up is recommended for 7 days if not inserted in the first 10 days of the cycle. No back-up is needed for Copper IUD because of its high efficacy as an emergency contraceptive.
10. If in doubt about any timing question, use condoms until your timing questions have been resolved

CHAPTER 14

Abstinence or Delaying Sexual Intercourse

www.managingcontraception.com or www.sexrespect.com

DESCRIPTION

Surveys reveal a wide variety of opinions about what constitutes sexual activity. However, from a family planning perspective, the definition of abstinence is clear: it is delaying genital contact that could result in a pregnancy (i.e. penile penetration into the vagina). Some authors argue that abstinence is not a form of contraception, but is a lifestyle choice because a person not having intercourse needs no contraception. Regardless, abstinence is an important means of reducing unintended pregnancies and sexually transmitted infections. A woman or a man may return to abstinence at any time. Abstinence-only-until-marriage education programs receive more than \$100 million annually in U.S. government funding, most of it stemming from the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. There is currently little to no evidence that any of these programs, which promote sexual abstinence and restrict information about contraception, actually achieve their intended purposes.

EFFECTIVENESS

When abstinence is adhered to, there is no pregnancy ←

HOW ABSTINENCE WORKS

Sperm excluded from female reproductive tract, preventing fertilization

COST: None

ADVANTAGES: Can be used as an interval method

Menstrual: none

Sexual/psychological: May contribute to positive self image if consistent with personal values

Cancers, tumors, and masses: Risk of cervical cancer far less if no vaginal intercourse has ever occurred

Other:

- Reduces risk of STIs (unless vaginal intercourse replaced with oral/anal)
- Many religions and cultures endorse

DISADVANTAGES

Menstrual: None

Sexual/psychological: Frustration or possible rejection if abstinence not adhered to

Cancers, tumors, and masses: None

Other:

- Requires commitment and self control; nonunderstanding partner may seek other partner(s)
- Patient and her partner may not be prepared to contracept if they stop abstaining

COMPLICATIONS

- No medical complications
- Person may be in situation where she/he wants to abstain, but partner does not agree.
Women have been raped/beaten for refusing to have intercourse

CANDIDATES FOR USE

- Individuals or couples who feel they have the ability to refrain from sexual intercourse

Adolescents:

- Very appropriate method but need maturity to effectively use abstinence. Obtain information about contraceptive methods for future, understand the consequences of various sexual activities
- Counseling may include discussions on masturbation (solo or mutual) and also “outercourse” alternative ways of expressing affection/attraction/sexuality with partner

MAINTAINING ABSTINENCE USUALLY REQUIRES OPEN COMMUNICATION

- Provide negotiating skills, how to say no or “not now”, and how to resist peer (societal) pressures
- Recommend that patient ensure that partner explicitly agrees to abstain
- Stress that abstinence may just be a decision to delay intercourse. It may mean “not now”, instead of “never”. Remind her that she may use or return to abstinence at any time in life
- Prepare for time when (or if) decision to stop abstaining arises, contraceptive education
- Advise her to consider having condoms and emergency contraception in case of need

PROBLEM MANAGEMENT

Partner does not want to abstain:

- Recommend continued communication and be available to discuss options with couples together
- Provide counseling in other forms of sexual pleasuring if patient interested (masturbation or outercourse)
- Seriously consider birth control method or another partner

FERTILITY ISSUE

- Protects against upper reproductive tract infection preserving a woman's fertility

Are Abstinence-Only Education Programs Effective?

In a review by Kirby (2001), only three evaluation studies of abstinence-only programs met the criteria established for inclusion in the review (e.g. random assignment, large sample size, long-term follow-up, measurement of behavior). **None of the studies demonstrated a significant programmatic effect on the initiation of sex, frequency of sexual activity, or the number of sexual partners.** A report released 4/07 of a long-term study commissioned by Congress, found that abstinence-only sex ed programs are not effective in preventing or delaying teenagers from having sexual intercourse, and have no impact on the likelihood that if they do have sex, they will use a condom.

In addition, these programs often provide misinformation and withhold important information, e.g. about contraception, needed to make informed choices [Santelli-2006].

Another recent study found the sexual behaviour of teenage virginity pledgers did not differ from matched non-pledgers, but were less likely to protect themselves from pregnancy and infection [Rosenbaum-2009]

Source: Kirby, D. (2001). *Emerging Answers: Research Findings on Programs to Reduce Teen Pregnancy*. Washington, DC: The National Campaign to Prevent Teen Pregnancy.

- Recent survey of parents in NC found they overwhelmingly support (89%) comprehensive sexual education yet their state mandates abstinence education [Ito-2006]
- Society for adolescent medicine position paper (2006) states: Abstinence is a healthy choice for adolescents, but this choice should not be coerced. Instead, teens should be informed about sexual risk reduction including abstinence, correct and consistent condom use and contraception

WAYS TO ENCOURAGE ABSTINENCE

Ways to Think About Abstinence

1. **Primary Abstinence** for a very long period of time
2. **Return to Abstinence** for a very long time
3. **Abstinence “for a while” - for example, until**
 - a) effective contraception has been achieved
 - b) STD tests are negative and effective approach to prevention of STDs carefully discussed and agreed upon by both partners
 - c) until 2, 4, or 6 week postpartum visit
 - d) trust and communication (and monogamy) well established in relationship and consequences of sex including unplanned pregnancy can be negotiated
4. **Abstinence right now - tonight or today.** Every day there are some 10 million acts of intercourse in couples NOT wanting to become pregnant and 700,000 of those acts of intercourse are completely unprotected acts of sexual intercourse. Today 700,000 couples could decide NOT to have intercourse.

With each of those 4 time frames for abstinence (avoiding penis-in-vagina intercourse), couples may or may not choose any of a variety of sexual interactions sometimes called **outercourse** (holding hands, hugging, kissing, deep kissing, petting, mutual masturbation, oral-genital contact).

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 infections, 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	<ul style="list-style-type: none"> • Immediately 	No effect
Cervical Cap, Diaphragm	<ul style="list-style-type: none"> • 4-6 weeks postpartum, after cervix and vagina normalized (need to be refitted for postpartum women) 	No effect
Progestin-Only Methods <ul style="list-style-type: none"> • Depo-Provera • Progestin - Only Pills • Implanon 	<ul style="list-style-type: none"> • 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. → 	<ul style="list-style-type: none"> • No significant impact on milk quality or production • Breast-feeding prolonged • Breast-fed children of DMPA users grow at normal rate
Combined Pills <ul style="list-style-type: none"> Patch Vaginal Ring 	<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Copper • Levonorgestrel 	<ul style="list-style-type: none"> • 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)

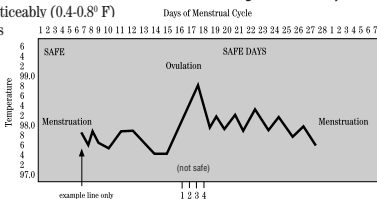
4. TwoDay Method

- 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° 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° C or 0.4° 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 non-spermicidal 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 characteristics 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

*To purchase the 19th edition of **Contraceptive Technology**, with an excellent chapter on condoms by David Lee Warner (CDC) and Markus Steiner (FHI), call (770) 887-8383 or go to www.managingcontraception.com*

Figure 18.1

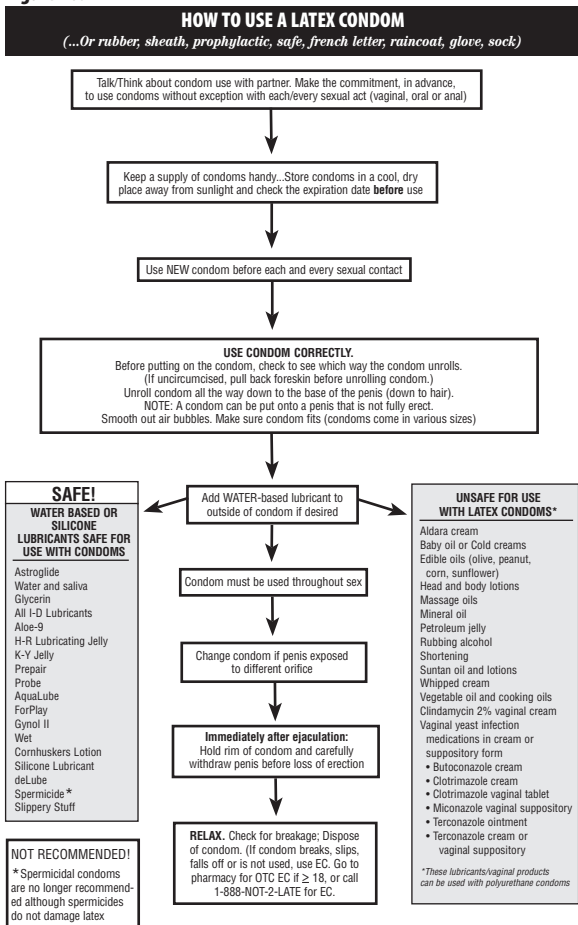


Figure 18.2 10 Studies demonstrating protective effect of latex condoms against HIV transmission in heterosexual couples

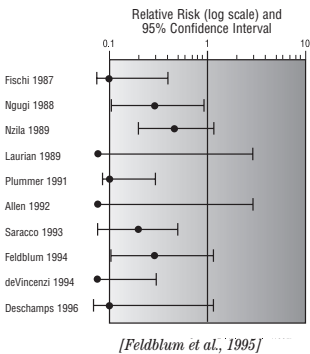
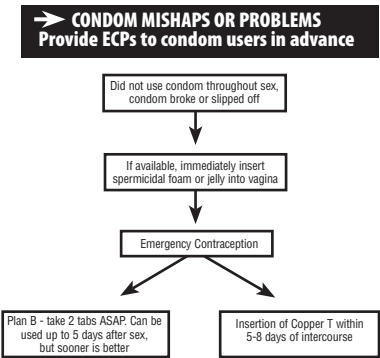


Figure 18.3



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-Flex™ 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 Today™ 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 urethral 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

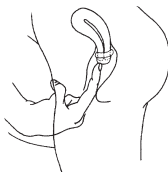
CERVICAL CAPS

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 ←



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-Flex™ 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



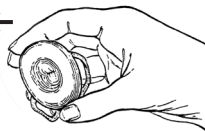
Figure 21.1

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:

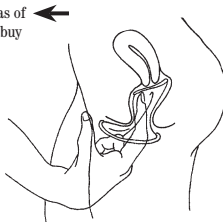
- Hold the sponge “dimple” side up and thoroughly wet sponge with tap water before insertion. Squeeze the sponge to produce suds
- In the squatting, leg-up or reclining position, press the rims on each side of the sponge together with the dimple still pointing upward
- Insert with the dimple first and 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:

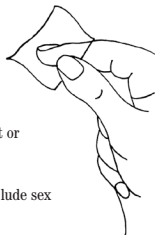
- Available over the counter; requires no medical visit
- Inexpensive and easy to use
- Foam and spermicidal jelly are immediately active with placement
- May be used during lactation

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

**To buy this book for students or staff, call (770) 887-8383 or go to
www.managingcontraception.com**

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 theoretically 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-borne 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 genitalia
- 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)

The 19th edition of *Contraceptive Technology* can be on your desk within a week! Call (770) 887-8383 or go to www.managingcontraception.com

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

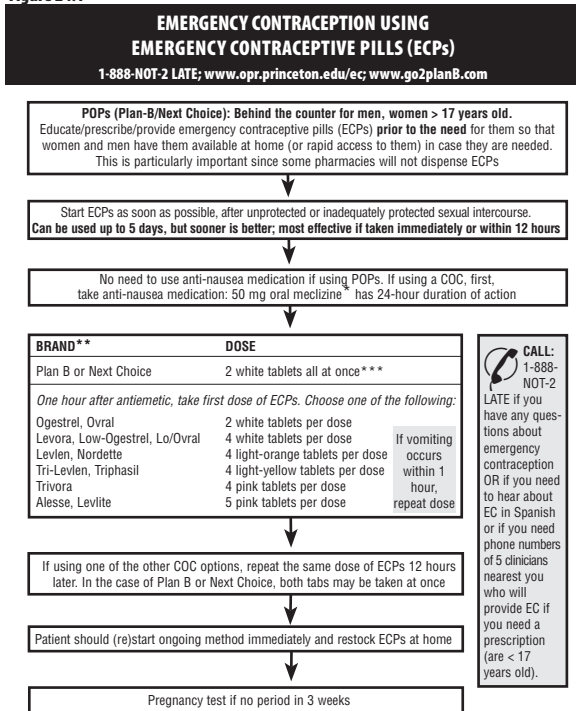
- The most effective post-coital method and may be used 2 days later than ECPs
- Provides long-term protection against pregnancy following insertion
- In one EC study, >80% continued use of IUD as their contraceptive [Zhou-2001]

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



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.

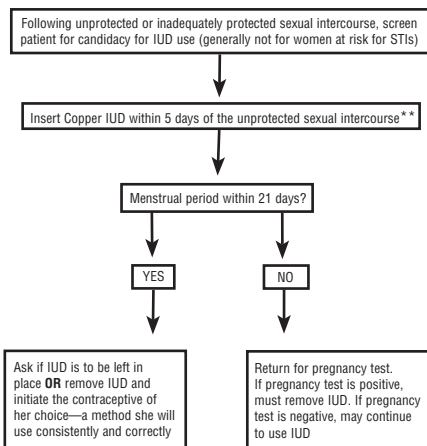
* Meclizine hydrochloride is recommended because it has a 24-hour duration of action. It is available over the counter as Bonine and as Dramamine 2. Other medications to prevent nausea may be prescribed instead.

**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-abortion 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:

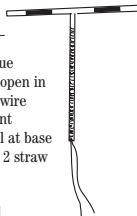
- effective for at least 10 years
- no hormones, therefore, no hormonal side effects
- may cause heavier periods and/or more cramping
- can be used as an EC

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 dysmenorrhea

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/gonorrhea 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 expulsion 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

<i>Complication</i>	<i>Frequency</i>	<i>Risk factors</i>
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 (≥ 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 antiretroviral 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)

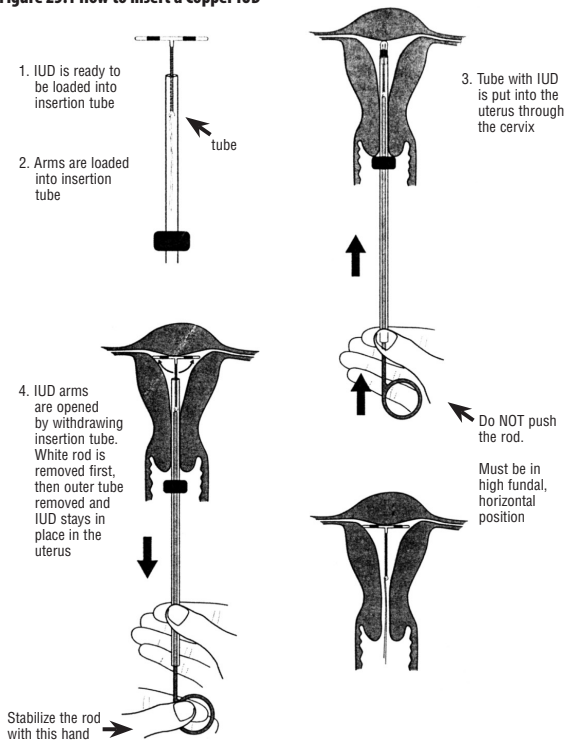
INITIATING METHOD

- 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

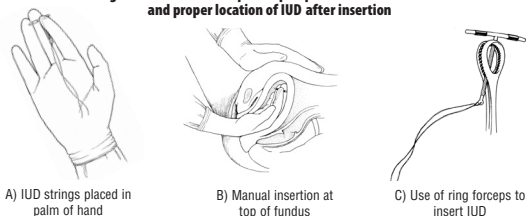


[Speroff L, Darney P. *A clinical guide for contraception*. 4th ed. Baltimore: Lippincott, Williams & Wilkins, 2005:246.]

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 cesarean 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][Dharmapanij-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



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 curette (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)
- *Actinomyces:* 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 "Actinomyces-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 doxycycline 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

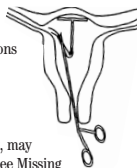
REMOVAL

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)

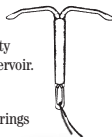


FERTILITY AFTER DISCONTINUATION OF METHOD

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 uterine 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

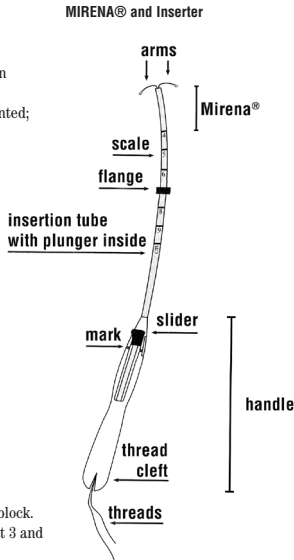
PROBLEM MANAGEMENT: Similar to Copper T 380-A; see p. 88-89

- **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!

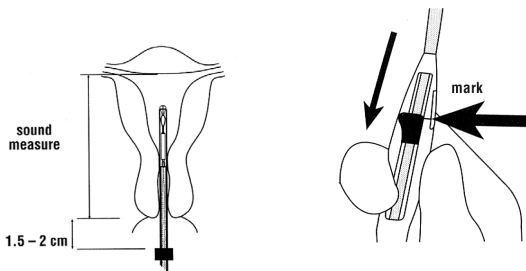
FERTILITY AFTER DISCONTINUATION OF METHOD: Immediate return to baseline fertility

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% chlorprocaine) 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

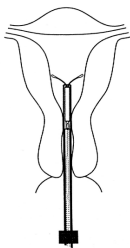


- Hold inserter in position while pulling slides down all the way. The threads should be released automatically from cleft. If not, manually remove the strings from the cleft
- Withdraw Mirena inserter from uterus
- Cut threads to 2 inches; requires care and sharp scissors to avoid dislodging Mirena
- 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 [Lipnick-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 ≥ 50 μ g 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 ≥ 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 griseofulvin or rifampicin may use COCs (CDC:1), patients are exposed to conflicting information. Many clinicians explain the differing opinions 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 $\frac{140-159}{90-99} = 3$ (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]. Amenorrhea 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 category 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 asymptomatic 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 category 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:		
<u>A</u> bdominal pain?	Yes _____	No _____
Yellow skin or eyes?	Yes _____	No _____
<u>C</u> hest pain?	Yes _____	No _____
<u>H</u> eadaches which are severe?	Yes _____	No _____
<u>E</u> ye problems: blurred vision or loss of vision?	Yes _____	No _____
<u>S</u> 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: thrombosis 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

MAKING THE TRANSITION FROM COCs TO HRT: (See Figure 26.5, p. 111)

FERTILITY AFTER DISCONTINUATION OF METHOD

- Immediate return of fertility: Average delay in ovulation 1-2 weeks. Post-pill amenorrhea more common in women with a past history of very irregular menses; rarely persists for up to 6 months
- Women should initiate another method immediately after discontinuing COCs
- Women can be surprised to learn that their pattern of menses **prior to starting pills** (frequency, duration, flow, dysmenorrhea) **tends to return** once they stop COCs
- Taking pills for many years prior to trying to become pregnant may actually protect a woman from some of the causes of infertility such as endometriosis, endometrial cancer, uterine fibroids, polycystic ovarian disease and ovarian cancer

Table 26.2 Starting Combined Oral Contraceptives*

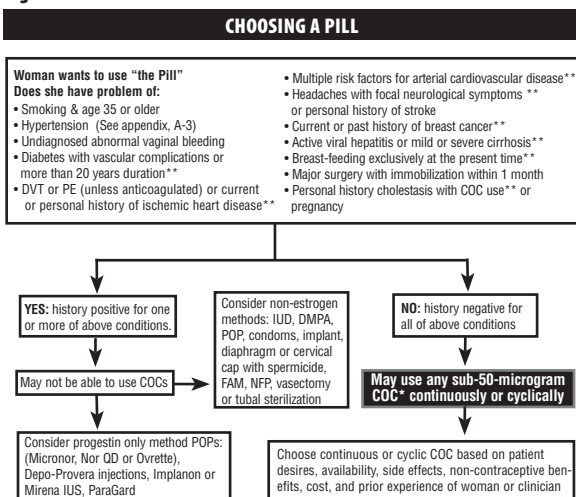
CONDITION BEFORE STARTING	WHEN TO START COCs?
Starting (restarting) COCs in menstruating women	<ul style="list-style-type: none"> • Immediately, if pregnancy excluded start with first pill in package; backup needed x 7 days "QUICK START" [Westhoff - 2002] See p. 102 • First day of next menses • If within 5 days after start of her menstrual bleeding, no backup required.** • First Sunday after next menses begins. ** Backup needed x 7 days
Starting (restarting) in amenorrheic women	Anytime if it is reasonably certain that she is not pregnant; abstain from sex or use backup method for next 7 days
Postpartum and breastfeeding	According to new CDC Medical Eligibility Criteria 2010, use of COCs in breastfeeding women is a category 2 at 1 month postpartum meaning advantages outweigh disadvantages***
Postpartum and not breastfeeding (after pregnancy of 24 or more weeks)	<ul style="list-style-type: none"> • Wait 3 weeks after delivery to allow hypercoagulable state of pregnancy to abate
After 1st or 2nd trimester (≤ 24 weeks) pregnancy loss or termination	<ul style="list-style-type: none"> • Immediately - start the same day • No backup needed
Switching from another hormonal method	<ul style="list-style-type: none"> • Start COCs immediately if she has been using hormonal method correctly and consistently, or if it is reasonably certain she is not pregnant. No need to wait until next period. No additional contraceptive needed • If previous method was an injectable, start COCs at the time repeat injection would have been given
Switching from a non-hormonal method (other than IUD)	<ul style="list-style-type: none"> • Can start immediately or at any other time if it is reasonably certain that she is not pregnant. Use backup method for the next 7 days unless it is the first day of menses
Switching from an IUD (including hormonal)	<ul style="list-style-type: none"> • Start pills within 5 days of start of menstrual bleeding, no additional contraceptive needed & IUD can be removed at that time • Start pills at any other time if it is reasonably certain she is not pregnant. If sexually active in this menstrual cycle and more than 5 days since menstrual bleeding started, remove IUD at time of next menstrual period OR give EC, then start COCs immediately; backup x 7 days
After taking ECPs	<ul style="list-style-type: none"> • Day after ECP** • First day of next menses • Sunday of next menses** } if using other interim method until menses

* World Health Organization. Selected Practice Recommendations for Contraceptive Use. 2004

** Back-up method needed for 7 days after starting COCs if it has been more than 5 days since menstrual bleeding started

*** 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.

Figure 26.2



- The World Health Organization and the Food and Drug Administration both recommend using the **lowest dose pill** that is effective. All combined pills with less than 50 µg of estrogen are considered "low-dose" and are effective and safe
- There are no studies demonstrating a decreased risk for deep vein thrombosis (DVT) in women on 20-µg pills. Data on higher dose pills have demonstrated that the less the estrogen dose, the lower the risk for DVT
- All COCs lower free testosterone. Class labeling in Canada for all combined pills states that use of pills may improve acne
- To minimize discontinuation due to spotting and breakthrough bleeding, warn women in advance, reassure that spotting and breakthrough bleeding become better over time. (See Figure 26.3, p. 109)

*The package insert for women on Yasmin and Yaz states [Berlex-2001]: "Yasmin is different from other birth control pills because it contains the progestin drospirenone. Drospirenone may increase potassium. Therefore, you should not take Yasmin if you have kidney, liver or adrenal disease, because this could cause serious heart and health problems. Other drugs may also increase potassium. If you are currently on daily, long-term treatment for a chronic condition with any of the medications below, you should consult your healthcare provider about whether Yasmin is right for you, and during the first month that you take Yasmin, you should have a blood test to check your potassium level: NSAIDs (ibuprofen [Motrin®, Advil®], naproxen [Naprosyn®, Aleve®, and others] when taken long-term and daily for treatment of arthritis or other problems); potassium-sparing diuretics (spironolactone and others); potassium supplementation; ACE inhibitors (Capoten®, Vasotec®, Zestril® and others); Angiotensin-II receptor antagonists (Cozaar®, Diovan®, Avapro® and others); heparin"

**These are conditions that receive a CDC:3 or a CDC: 4 (See appendix pages A-5 and A-7)

Figure 26.3

SPOTTING/BREAKTHROUGH BLEEDING ON COCs 21/7*

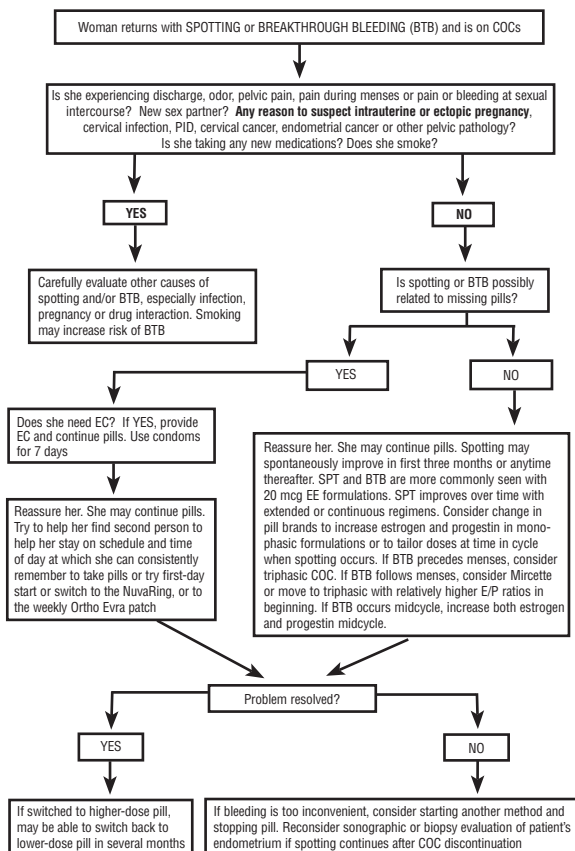


Figure 26.4

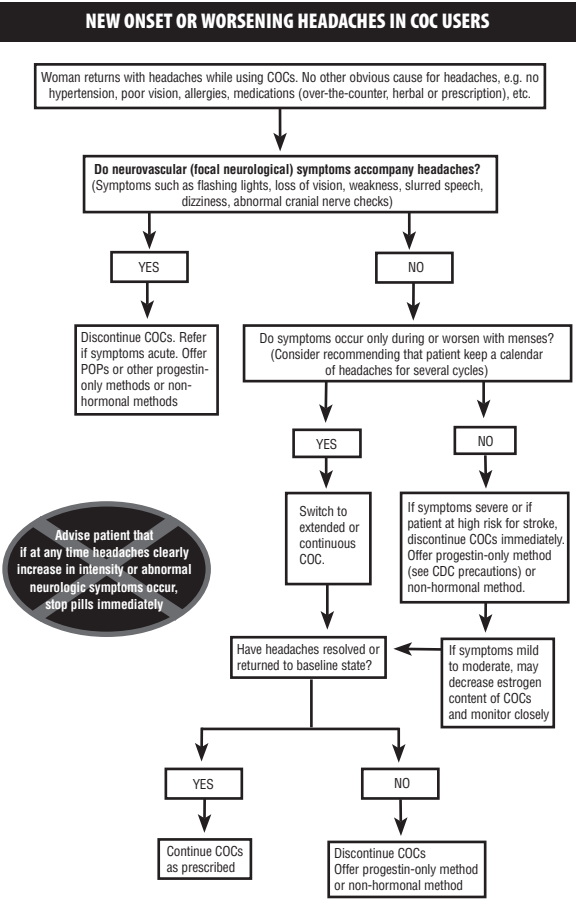
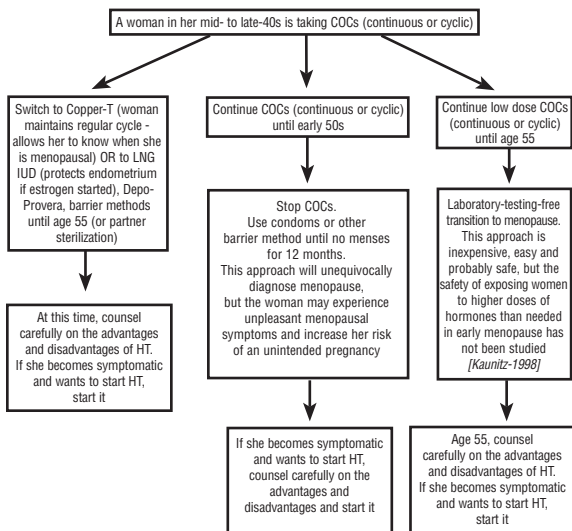


Figure 26.5

MAKING THE TRANSITION FROM COCs TO MENOPAUSE, WITH OR WITHOUT HORMONE THERAPY (HT)

The transition from COCs to menopause, with or without HT may be accomplished in a number of ways. Some reviewers of this algorithm switch to a 20 or 25-mcg pill if the patient is going to use COCs into their early 50s. A major concern is unintended pregnancy. Work together to determine a method for pregnancy prevention that is acceptable and effective

*This algorithm does NOT include testing for a woman's menopausal status using FSH or LH tests**



*FSH and LH testing are problematic because they show current status only.

A perimenopausal woman can seem to be menopausal according to lab tests but ovulate unpredictably after that. See precautions about the provision of hormones to menopausal women on p. 24.

PATCHES - WEEKLY - ORTHO EVRA PATCH

DESCRIPTION: One Ortho Evra patch is worn for one week for each of 3 consecutive weeks, on the lower abdomen, buttocks, upper outer arm or to the upper torso (except for the breasts). The fourth week is patch-free to permit withdrawal bleeding. This 4.5 cm square patch delivers 20 micrograms of ethinyl estradiol and 150 mcg of the progestin, norelgestromin (the active metabolite of norgestimate) daily. [Grimes-2001] It takes 3 days to achieve steady states or plateau levels of hormones after application of the patch and the patch contains sufficient hormone for 9 days though prescribing info states to remove after 7 days. The patch delivers about 60% more estrogen over a 21-day period than a 35 mcg EE COC and 3 times more than the ring

MECHANISM: The patch prevents pregnancy in the same manner as combined pills

COST: 3 patches are slightly more expensive than one cycle of brand pills

EFFECTIVENESS: Among perfect users (users who apply transdermal contraceptive patches on schedule and each patch remains in place for the full week), only 3-6 in 1,000 women (0.3-0.6%) are expected to become pregnant during the first year (Table 13.2 on p. 40). Pooled data from three contraceptive efficacy studies (22,155 treatment cycles) using life table analysis found an overall failure rate of about 1% (0.8% or 8 pregnancies per 1000 women through 13 cycles). [Zieman-2001]

Of 15 pregnancies in the 3 clinical trials of the Ortho Evra Patch, 5 were in women who were markedly overweight (women more than 90 kilograms or 198 pounds). [Zieman-2001] (30% of failures in 3% of women) There are no reliable data available about typical failure rates, thus the typical failure rate is presumed similar to COCs [Audet-2001]

ADVANTAGES

Menstrual: Like combined pills

Sexual/Psychological:

- May enhance sexual enjoyment due to diminished fear of pregnancy
- Attractive for women who forget to take pills
- Does not interrupt intercourse

Cancers/tumors and masses: No data yet; benefits probably comparable to combined pills

Other:

- Option throughout the reproductive years: Age is not a reason to avoid the Patch. Compliance among teens using patch is good. For some women compliance may be easier than taking a pill every day [Audet-2001]. Each patch contains enough hormone to suppress ovulation for up to 9 days.
- May bathe, swim and do normal activities

DISADVANTAGES

Menstrual: In the first cycle, about one-fifth of patch users experienced breakthrough bleeding or spotting. This improved with time

Sexual/Psychological: Similar to pills, but use may be more obvious than pills. See p. 95

Cancers/tumors and masses: Same as COCs

Other:

- Lack of protection against sexually transmitted infections (STIs)
- Among 812 women on the patch, 3 serious adverse events were considered possible or likely related to use of the patch, including 1 case of pain and paraesthesia in the left arm, 1 case of migraine and 1 case of cholecystitis [Audet-2001]

- Must remove and replace patch weekly. Application site problems include partial detachment (2.8%) or complete detachment (1.8%) and skin irritation (1.1%) [Audet-2001]. **Pigment changes (hyper and hypo) have been noted under the site of patch application.** In a study of patch wear under conditions of physical exertion and variable temperatures and humidity, less than 2% of patches were replaced for complete or partial detachment. 2.6% of women discontinued using the patch because of application site reactions. Problems did not increase over time [Audet-2001]. Border of patch may become dirty, picking up lint, hairs or fabric. Able to remove with baby oil after patch is changed
- Nausea occurred in 20.4% of women on patch vs 18.3% of women using oral contraceptives; patch was discontinued by 1.8% of women because of nausea [Audet-2001]
- Breast discomfort was greater in women using the patch than in women on the pill. The difference was significant only in cycles 1 and 2 (15.4% vs 3.5% in cycle 1 and 6.6% vs 1.5% in cycle 2). For cycles 3-13, breast discomfort occurred in 0 to 3.2% of women using the patch and in 0 to 1.7% of women on pills (not statistically significant) [Audet-2001]
- Headaches were as likely in women on patch (21.9%) as in women on pills (22.1%)
- Irritation or an allergic skin reaction while using the patch (19%)

COMPLICATIONS (See p. 114)

- Data demonstrate that patch users had average concentrations of EE at steady state that were ~60% higher than women using COCs with 35 mcg EE. They also had ~25% lower peak levels of EE. Based on data from oral contraceptives, higher levels of estrogen are associated with an increased risk of VTE and CV events. Epidemiologic data on the patch are limited so far. Several case control studies have reported odds ratios for VTE ranging from 0.9 to 2.4 meaning that there may be no increased risk or an approximate doubling of risk [Jick-2006, 2007 Package Insert] [Cole-2007]. Currently available data do not show an increased risk of MI or stroke. Women choosing the patch should be informed of the **possibility** of an increase in risk of adverse events, particularly VTE.
- Other complications similar to COCs

PRESCRIBING PRECAUTIONS

- Precautions for the patch are the same as those for combined pills (see p. 108 and A1-A8)
- **Women weighing more than 90 kg (198 lbs)** should be told that the patch is less effective as compared to its use in women < 198 lbs and that they should consider using a backup or another method. Should not be a “first-line” method for woman over 198 pounds

CANDIDATES FOR USE

- Women wanting to avoid daily pill-taking or a sex-related method like condoms
 - Women wanting regular menstrual periods. May be used by individuals allergic to latex
- Adolescents: Excellent option, particularly for teenage women unable to remember to take pills daily [Archer-2002]**

INITIATING METHOD

- With the 1st pack of patches, the patient is eligible for up to three free replacement patches. Write prescription for “replacement patch” with the first box of patches
- **A pelvic examination is not necessary prior to starting this method [Stewart-2001]**
- Ask patient, “What day of the week is the easiest for you to remember?” and start then if you are reasonably certain she is not pregnant. Unlike pills, the time of day doesn’t matter!
- Women switching from pills can switch to the patch any time in cycle. They need not wait to complete pack of pills
- Women switching from DMPA should start when the next injection is due
- But as with pills, the patch can be started anytime with backup for 7 days, if you are reasonably sure the woman is not pregnant. If started on day one of cycle, backup not needed
- Quick Start initiation of the patch resulted in no increase in pregnancy or BTB [Murthy-2005]
- Provide or recommend EC for when/if needed

INSTRUCTIONS FOR PATIENT

- If the PATCH-FREE interval is more than 9 days (late restart), apply a new patch and use backup contraception for 7 days
- No band-aids, tatoos, or decals on top of patch as this might alter absorption of hormones
- Smooth the edges down when you first put it on
- Avoid placing patch on exactly the same site 2 consecutive weeks
- Location of patch should not be altered in mid-week
- Women should check the patch daily to make sure all edges remain closely adherent to skin
- Single replacement patches are available through pharmacists. The manufacturer will reimburse a woman for up to \$12 for the replacement patch
- Disposal: fold over self. Place in solid waste, preferably in a sealed plastic bag to minimize hormone leakage into waste site. Do not flush down toilet

FOLLOW UP

- What is happening to your menstrual periods?
- Have you experienced skin irritation?
- Has your patch ever come off partially or completely?
- Have you had problems remembering to replace your patch on schedule

PROBLEM MANAGEMENT (See p. 106)

FERTILITY AFTER DISCONTINUATION OF METHOD: Likely the same rapid return of fertility as COCs

VAGINAL CONTRACEPTIVE RING - MONTHLY - NuvaRing

DESCRIPTION: (also see www.nuvaring.com) The NuvaRing is a combined hormonal contraceptive consisting of a 5.4 cm (2 inches) diameter flexible (not hard) ring, 4 mm (1/8 inch) in thickness. The ring is made of ethylene vinylacetate polymer. It is left in place in the vagina for 3 weeks (or 1 month) and then removed for a week to allow withdrawal bleeding. It may be used continuously with no hormone-free days, but this is off-label. **It is generally recommended that it not be removed for intercourse. If it must be, however, it should be replaced within 3 hours.** Douching is discouraged but topical therapies (antifungal agents, spermicides, etc) are allowed. NuvaRing releases low doses of ethinyl estradiol (15 micrograms daily) and etonogestrel, the active form of desogestrel (120 micrograms daily). With oral hormones there is a daily spike in hormone levels after the woman swallows each dose, followed by a gradual drop throughout the rest of the day. A single vaginal ring maintains a steady, low release rate for 35 days while in place and releases less estrogen daily at a steadier rate than pills or patches

HOW CONTRACEPTIVE VAGINAL RINGS WORK: *contraceptive effects similar to combined pills.* This method suppresses ovulation for 35 days, while in place [Mulders-2001]. Also see COCs, p. 94

COST: Each ring costs approximately the same as one cycle of pills. It is possible to get some free rings via the website at www.nuvaring.com. Public health programs pay much less for each NuvaRing

EFFECTIVENESS: Overall pregnancy rate of 0.3 [Trussell-2004] to 0.65 [Roumen-2001] per 100 woman-years (all first-year users). There is no information about typical use failure rate, so a typical use failure rate of 9% is used by Trussell in the 18th edition of *Contraceptive Technology* (same figure as for combined pills). It is likely that since the method needs to be remembered once per month rather than once per day, that the typical user failure rate would be lower

ADVANTAGES: No daily fluctuation in hormone levels**Menstrual:**

- Withdrawal bleeding occurs in 98.5% of cycles, and bleeding at other times in only 5.5% of cycles [Dieben-2002]; much better withdrawal/spotting pattern than COCs probably due to NOT forgetting pills and the steady even blood levels that are achieved
- Irregular bleeding is low in the first cycle of use (6%) and continues to be low throughout subsequent cycles [Dieben-2002]

Sexual/Psychological: Decreased fear of pregnancy may increase pleasure from intercourse

Cancers/tumors and masses: No published data; probably similar to COCs

Other: There are only 2 tasks for ring users to remember: insertion and removal once a month so compliance may be easier (92% vs. 75% for pills in one study) [Bjarnadottir-2002]

- 85% of women and 71% of partners say they cannot feel it [Dieben-2002]
- The lowest serum levels of estrogen and progestin in any combined hormonal method
- Privacy - no visible patch or pill packages. Particularly helpful for some teens
- Little weight gain associated with ring use [O'Connel-2005] ←

DISADVANTAGES

Menstrual: Withdrawal bleeding continued beyond the ring-free interval in about one quarter of cycles (20% to 27%) [Roumen-2001]. However, most of the time it is just spotting. Although not necessary, some women may rinse the ring. Also, ring can be accidentally pulled out by a tampon

Sexual/Psychological: Some women dislike placing/removing objects into/out of vagina. Some women or men may feel ring during intercourse. If bothersome, ring may be removed and reinserted within 3 hours

Cancers/tumors and masses: None

Other: Adverse events reported by vaginal contraceptive ring users that were judged by the investigators to be possibly device related are headache (6.6%), nausea (2.8%), weight increase (2.2%), dysmenorrhea (1.8%), depression (1.7%), leukorrhea (5.3%), vaginitis (5.0%), and vaginal discomfort (2.2%) [Roumen-2001]

COMPLICATIONS: Similar to combined pills

PRESCRIBING PRECAUTIONS

- The CDC Medical Eligibility Criteria for the NuvaRing are the same as for combined pills
- Women who are hesitant about touching their genitalia or who have difficulty inserting or removing ring may not be good candidates
- Women with pronounced pelvic relaxation

CANDIDATES

- Women wanting to avoid having to do something daily, or at the time of intercourse
- Women wanting regular menstrual periods
- Women satisfied with OCs but willing to try the patch or ring were happier with the ring than their OC [Creinin-2007] ←

Adolescents: Excellent option; requires less discipline than taking pills daily

INITIATING METHOD: *Best approach - teach women to insert and remove ring in office. Ask women if they would like you to insert a ring after you do an exam to demonstrate just how little she will feel the ring*

- A new ring is inserted any time during the first 5 days of a normal menstrual cycle and backup for 7 days is recommended in package insert
- New ring can be inserted at any time in cycle if reasonably certain woman is not pregnant; use backup x 7 days (CDC)
- Provide or recommend EC for when/if needed
- Quick Start of Nuvaring has been studied with high levels of satisfaction by users [Schafer-2006]. See p. 102 for description ←

INSTRUCTIONS FOR PATIENT

- The package insert states that backup must be used during the first 7 days that the first ring is in place
- The NuvaRing is removed at the end of 3 weeks of wear; then, after one ring-free week, the woman inserts a new ring
- The woman's menstrual period (withdrawal bleed) occurs during the ring-free week
- Ring removal during intercourse is not recommended; however, women who want to remove it during intercourse may do so without having to use a backup method as long as it is not removed for longer than 3 hours a day
- Although it is intended to be a once a month method, check for presence frequently, especially after intercourse since 20% of women experience expulsion in the first 3 months ←
- No special accuracy is required for ring placement; absorption is fine from anywhere in the vagina
- Because the ring is small and flexible, **most women do not notice any pressure or discomfort**, and it is not likely to be uncomfortable for their partners during intercourse
- Always have 2 rings on hand in case one is lost
- Avoid douching with ring in place. Douching is not recommended for any woman
- Tampons, lubricants and vaginal yeast creams can be used with the ring in place
- Rings may be stored at room temperature avoiding extreme heat for up to 4 months. If a woman has more than a 4-month supply of rings, they may be stored in a refrigerator. Rings kept in a refrigerator should not freeze
- A ring that falls into the toilet does float! It can be washed with soap and water and reinserted
- If the ring is left in place longer than three weeks, the user is probably still protected from pregnancy for up to 35 days by the same ring, allowing clinicians flexibility in how often they tell women the ring must be replaced. For example, the ring could be reinserted on the first of the month each month with no hormone-free interval (similar to taking combined pills with no hormone-free days)
- Extended use of the ring has been studied. The number of bleeding and spotting days combined was similar in shorter and extended cycles [Miller-2005]. Extended use decrease menstrual flow and cramping [Sulak-2008]. If breakthrough bleeding occurs, instruct the patient to remove the ring, store it for 4 days, then reinsert [Sulak-2008] ←
- **Dispose of ring with solid waste, preferably in a sealed plastic bag to minimize leakage into waste site**

FOLLOW UP: Ask about difficulty during removal or insertion or frequent expulsion. Women may need closer follow-up if they have: genital prolapse, severe constipation, or frequent vaginal infection (i.e. recurrent yeast infection). Otherwise, similar to women on pills

FERTILITY AFTER DISCONTINUATION: Excellent and immediate. Average return to ovulation: 11 days (range 8-21 d) [Mulders-2002]

CHAPTER 25

Progestin-Only Contraceptives

www.managingcontraception.com

The progestin-only methods are progestin-only pills (p. 117), Depo-Provera (p. 121), and Implanon (p. 130). The LNG IUD is described on p. 90

LOW DOSE PROGESTIN PILLS - DAILY - often called MINI-PILLS OR POPS

DESCRIPTION: Progestin-only pills (POPs) are also known as mini-pills. POPs contain only a progestin and are taken daily with no hormone-free days. POPs have lower progestin doses than combined pills and no estrogen. Each tablet of Micronor and Nor-QD contains 0.35 mg norethindrone.

EFFECTIVENESS [Trussell J IN *Contraceptive Technology* 2004]

Perfect use failure rate in first year: 0.3% (See Table 13.2, p. 40)

(if 300 women take POPs for 1 year, only 1 will become pregnant in the first year of perfect use)

Typical use failure rate in first year: 8.0%

HOW POPS WORK: Thickens cervical mucus to prevent sperm entry into upper reproductive tract (major mechanism). Effect short lived - requires punctual dosing. Other mechanisms include ovulation suppression (in about 50% of cycles), thin, atrophic endometrium which inhibits implantation; and slowed sperm motility. Some POPs in Europe suppress ovulation more than the norethindrone pills used in the USA

COST [Trussell, 1995; Smith, 1993]

- POPs cost more than combined pills both in pharmacies and in sales to public programs

ADVANTAGES

Menstrual:

- Decreased menstrual blood loss, cramps and pain, amenorrhea (10% of women). Amenorrhea is more likely with punctual dosing
- Decrease in ovulatory pain (Mittelschmerz) in cycles when ovulation suppressed

Sexual/physiological:

- May enhance sexual enjoyment due to diminished fear of pregnancy
- No disruption at time of intercourse; facilitates spontaneity

Cancers, tumors and masses:

- Possible protection against endometrial cancer

Other:

- Rapid return to baseline fertility
- Possible reduction in PID risk due to cervical mucus thickening
- Good option for women who cannot use estrogen but want to take pills
- May be used by smokers over age 35. **Discourage smoking, of course!**
- May be used by breastfeeding women

DISADVANTAGES

Menstrual: Irregular menses ranging from amenorrhea to increased days of spotting and bleeding but with reduced blood loss overall

Sexual/psychological:

- Spotting and bleeding may interfere with sexual activity
- Intermittent amenorrhea may raise concerns about pregnancy
- Possible increase in depression, anxiety, irritability, fatigue or other mood changes, but often POPs reduce risk of these disorders

Cancers, tumors and masses:

- May be associated with slightly higher risk of persistent ovarian follicles

Other:

- Must take pill at same time each day (more than 3-hour delay considered by some clinicians to be equivalent to a “missed pill”)
- Effect on cervical mucus decreases after 22 hours and is gone after 27 hours
- No protection against STIs

COMPLICATIONS

- Allergy to progestin pill is rare
- Amenorrheic, Latina, breast-feeding women who had gestational diabetes may be at higher risk of developing overt diabetes in first year postpartum [*Kjos, 1998*]

CANDIDATES FOR USE (See 2010 CDC Medical Eligibility Criteria, A-1 - A-8)

- Virtually every woman who can take pills on a daily basis can be a candidate for POPs
- POPs are particularly good for women with contraindications to or side effects from estrogen:
 - Women with personal history of thrombosis
 - Recently postpartum women
 - Women who are exclusively breast-feeding
 - Smokers over age 35
 - Women who had or fear chloasma, worsening migraine headaches, hypertriglyceridemia or other estrogen-related side effects (e.g. nausea)
 - Women with hypertension, coronary artery disease or cerebrovascular disease
 - Women with lupus

PRESCRIBING PRECAUTIONS

Progestin-only pills can be used by all women willing and able to take daily pills except:

- Suspected or demonstrated pregnancy (although there are no proven harmful effects for the fetus)
- Current breast cancer or breast cancer less than 5 years ago (CDC:3)
- Active hepatitis, hepatic failure, jaundice
- Inability to absorb sex steroids from gastrointestinal tract (active colitis, etc.)
- Taking medications that increase hepatic clearance (rifampin, and the anticonvulsants carbamazepine, oxycarbazepine, phenytoin [Dilantin], phenobarbital, primidone, topiramate and felbamate, [not valproic acid], St. Johns Wort or griseofulvin). Efficacy in combination with Orlistat and other fat-binding agents is not well studied

MEDICAL ELIGIBILITY CHECKLIST: Evidence-based criteria for deciding whether women with 130 different conditions are presented in the appendix, pages A-1 through A-8. These criteria were updated at the World Health Organization in 2004. Ask the client the questions below. If she answers YES to a question below, follow the instructions; in some cases she can still use POPs

1. Do you think you are pregnant?

☐ No ☐ Yes Assess if pregnant. If she might be pregnant, give her latex male condoms to use until reasonably sure that she is not pregnant. Then she can start POPs

2. Do you have or have you ever had breast cancer? (See Appendix)

☐ No ☐ Yes Do not provide POPs. Help her choose a method without hormones. May possibly consider POPs or DMPA if disease-free x 5 years (CDC:3), but only if there is no better alternative

3. Do you have jaundice, severe cirrhosis of the liver, acute liver infection or tumor? (Are your eyes or skin unusually yellow?) (See Appendix)

☐ No ☐ Yes Perform physical exam and arrange lab tests or refer. If she has serious active liver disease (jaundice, painful or enlarged liver, viral hepatitis, liver tumor), may be able to use POPs with more intensive follow-up (CDC:3)

4. Do you have vaginal bleeding that is unusual for you? (See Appendix)

☐ No ☐ Yes If she is not pregnant but has unexplained vaginal bleeding that suggests an underlying medical condition, can provide POPs since neither the underlying condition nor its assessment will be affected. Promptly assess and treat any underlying condition as appropriate, or refer. Reassess POP use based on findings

5. Are you taking medicine for seizures? Taking rifampin (rifampicin), griseofulvin or aminoglutethimide? St. John's Wort? (See Appendix)

☐ No ☐ Yes If she is taking phenytoin, carbamazepine, barbiturate, topiramate, oxycarbamazepine, or primidone for seizures or rifampin, griseofulvin, aminoglutethimide or St. John's Wort, provide condoms or spermicide or help her choose another method that is more effective, such as DMPA. Use of valproic acid does NOT lower the effectiveness of POPs. Discuss ECPs

6. Do you have problems with severe diarrhea or malabsorption or other bowel disorders? Or are you using medications that block fat absorption?

☐ No ☐ Yes Help her choose a non-oral method of birth control.

SPECIAL SITUATIONS

History of pregnancy while using POPs correctly:

- Switch to more effective method e.g. IUD, Implanon or DMPA
- Continue POPs but add condoms or other backup with every act of coitus

Use with a broad-spectrum antibiotic such as tetracycline or erythromycin:

- Few studies support antibiotic's role in contraceptive failure. See 2010 CDC Medical Eligibility Criteria for "other antibiotics," CDC:I, Page A8. Some clinicians encourage backup for first 1-2 weeks, others for full duration of antibiotic use. Explain conflicting advice now being given; let patient decide whether to use backup method.

INITIATING METHOD

- **A pelvic examination is not necessary prior to initiation of this method** [Stewart-2001]
- **New starts:** Offer condoms either for back-up for 2 days or for use should patient stop POPs. Also encourage advance obtaining of PLAN B or give her a package of PLAN B
- **Post-partum:** May initiate immediately regardless of breast-feeding status (PPFA, UCSF, Grady Memorial Hospital)
Note: CDC and IPPF are concerned about theoretical impact of POPs on breast milk production and recommend waiting until 6 weeks to initiate use of DMPA and POPs
- **After miscarriage or abortion:** Start immediately
- **Menstruating women:** Start on menses if possible. No backup if started within 5 days of LMP. May initiate anytime in cycle if woman is not pregnant, but recommend at least 2 day back-up barrier method
- **Switching from IUD, COCs, DMPA, to POPs:** Start immediately. Need for back-up depends on previous method used: **IUD:** start immediately, backup for 7 days; Some clinicians say 48 hours minimum; others say no backup. **COCs:** start immediately if cycle of hormonally active pills completed; backup not necessary if no pill-free interval. **DMPA:** start immediately if switching at or before next DMPA injection due (no backup necessary)

INSTRUCTIONS FOR PATIENT

- Take one pill daily at same time each day until end of pack. Start next pack the next day
- If at risk for infection, use condoms with every act of intercourse
- If you miss a pill by more than 3 hours from regular time, take the missed pill(s) and use backup for 48 hours. Consider using emergency contraception if sex in past 5 days. Obtain a package of Plan B to have at home in case of a mistake

FOLLOW-UP

- How many pills do you typically miss or are late taking per week? Per pack?
- Have you missed any pills in last 5 days? (candidate for EC)
- Have you missed any periods or experienced any symptoms of pregnancy?
- What has your menstrual bleeding been like?
- Have you had any increase in headaches, or change in mood or libido?
- Do you plan to have children? OR Do you plan to have more children?
- What are you doing to protect yourself from STIs?

PROBLEM MANAGEMENT

- **Amenorrhea:** Rule out pregnancy with first episode or whenever symptoms of pregnancy noted. Otherwise, amenorrhea is not harmful when women take progestin-only pills
- **Irregular bleeding:** After finding out if missing pills, rule out STIs, pregnancy, cancer. If not at risk and no evidence of underlying pathology, reassure patient; 3-day course of high dose NSAIDs may help
- **Heavy bleeding:** Rule out STIs, pregnancy, cancer. If no evidence of underlying pathology, rule out clinically significant anemia. Trial of 3 days high dose NSAIDs. If fails, may need estrogen-containing contraceptives (addition of physiologic doses ET only may compromise cervical mucus barrier), Mirena IUS or non-hormonal methods of contraception
- **Abdominal pain:** Consider pelvic pathology (ectopic pregnancy, torsion, appendicitis, PID) and refer for treatment. If ovarian cyst is cause, it may usually be managed conservatively unless pain is severe. Progestin slows follicular atresia. Recheck in 6 weeks and anytime her symptoms worsen

FERTILITY AFTER DISCONTINUATION OF METHOD: Fertility returns to its baseline levels promptly

DMPA INJECTIONS (DEPO-PROVERA) - EACH 3 MONTHS

DESCRIPTION: 1 cc of a crystalline suspension of 150 mg depot medroxyprogesterone acetate injected intramuscularly into the deltoid or gluteus maximus muscle every 13 weeks For more information, call 1-800-253-8600 ext. 38244.

Depo-Provera Subcutaneous - 104, subcutaneous injections of 104 mg of DMPA facilitate women giving themselves Depo-Provera injections at home. Women receive up to 14 weeks of contraceptive protection from an injection of 104 mg of DMPA SQ

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

- Approved labeling indicates each injection effective for up to 13 weeks

Perfect use failure rate in first year: 0.3% (See Table 13.2, p. 40)

Typical use failure rate in first year: 3%

Continuation at 1 year: 23% [Westfall-1996] 42% [Polaneczky-1996] 56% [Trussell-2004]



Subcutaneous Depo-Provera

Despite the lower dose of Sub Q DMPA (104 vs 150 mg), no pregnancies occurred among the 44% of study subjects who were overweight (26%) or obese (18%). In fact, there were no pregnancies at all in 720 women over one year. 55% were amenorrheic at the end of one year. [Jain J, Jakimiuk AJ et al-2004]

HOW DEPO WORKS: Suppresses ovulation by inhibiting LH and FSH surge, thickens cervical mucus blocking sperm entry into female upper reproductive tract, slows tubal and endometrial mobility, and causes thinning of the endometrium

COST: In Washington State, health departments pay \$4.75 for 28 days of contraception for a woman receiving Depo-Provera each 3 months. This is 4 times greater than the cost of pills for the same clinics, \$1.35 per cycle. [Marguties - 2001] The co-pay for DMPA is about \$60/vial

ADVANTAGES

Menstrual:

- Less menstrual blood loss, anemia, or hemorrhagic corpus luteum cysts
- After 1 year of use, 50% of women develop amenorrhea; 80% develop amenorrhea in 5 years. For this to be an advantage, it must be clearly explained at first and subsequent visits. See discussion of structured counseling on page 13
- Decreased menstrual cramps, pain and ovulation pain
- Improvement in endometriosis. **Depo-Provera Subcutaneous 104** was also FDA approved for management of endometriosis pain on March 29, 2005

Sexual/psychological:

- Intercourse may be more pleasurable without worry of pregnancy
- Convenient: permits spontaneous sexual activity; requires no action at time of intercourse

Cancers, tumors, and masses:

- Significant reduction in risk of endometrial cancer
- Possible reduction in risk of ovarian cancer

Benefits for women with medical problems:

- Suppresses ovulation, bleeding and menstrual blood loss in anticoagulated women and women with bleeding diathesis; decreases anemia
- Reduces acute sickle cell crises by 70% [de Abood-1997]
- Excellent method for women on anticonvulsant drugs; **may actually decrease seizures** and effectiveness not compromised
- Amenorrhea and prolonged effective contraception may be very important for severely developmentally or physically challenged women. One reviewer makes home visits for some wheelchair bound patients who love Depo-Provera

Other:

- The drop in teen pregnancies in 1990s, abortions and births, is attributed to Depo-Provera, Norplant, EC, condoms and abstinence promoting programs
- Significantly reduces risk for ectopic pregnancies and slightly decreases risk of PID
- Convenient: single injection provides at least 13 weeks protection
- Most protocols call for administration anytime between 11 and 13 weeks. However, DMPA is usually forgiving of late injections
- Less user-dependent than POPs, COCs
- Good option for women who cannot use estrogen (see CANDIDATES FOR USE)
- Private: no visible clue that patient is using except for impact on menses
- May be used by nursing mothers
- Return to baseline fertility may be delayed, but is excellent

DISADVANTAGES

Menstrual:

- Irregular menses during first several months: many women experience unpredictable spotting and bleeding, occasionally blood loss reported to be heavy but unlikely to cause anemia. After 6-12 months, amenorrhea more likely (50% after 1 year)

Sexual/psychological: Also see weight gain, below

- Spotting and bleeding may interfere with sexual activity
- Amenorrhea may raise patient's fears of pregnancy or myth of "build-up of menses" in uterus if not explained well
- Hypoestrogenism can (infrequently) cause dyspareunia, hot flashes or decreased libido
- Possible increase in depression, anxiety, irritation, PMS, fatigue or other mood changes, but often DMPA reduces risk of these disorders
- Fear of needles may make this an unacceptable choice

Cancers, tumors, and masses: none

Other: (See boxed message: Depo Provera & Bones on p. 123)

- No protection against STIs: must use condoms if at risk
- Must return every 11-13 weeks for injection (difficult for some women) or get injection from person trained to provide injections
- Long acting: **not** immediately reversible
- Slow to return to baseline fertility: average 10 months from last injection
- Occasionally, hypoestrogenism ($E_2 < 25$) may develop as a result of FSH suppression. Potential for decreased bone mineral density if used for prolonged period without opportunity for recovery prior to menopause. May have more effect on teen bones. See box on p. 123
- Severe headaches may occur - rarely attributable to DMPA
- Acne, hirsutism may develop
- Possible increase in diabetes risk in amenorrheic breastfeeding women with diagnosis of gestational diabetes during first year postpartum [*Kjos 1999*]
- Metabolic impacts: glucose (slight rise), LDL (slight rise or neutral), HDL (may decrease)
- Other hormone-related Sx: breast tenderness, bloating, hair loss, vasomotor symptoms
- Associated with modest weight gain in most women [*Westhoff-2007*] ←

COMPLICATIONS

- Progressive significant weight gain possible. Average of 5.4 lbs in first year and 16.5 lbs after 5 yrs [*Schullie-1973*] See p. 125: WEIGHT GAIN: A TEACHABLE MOMENT. Adolescent girls who were obese when starting Depo gained significantly more weight (mean 9.4 kg) than obese girls starting OCs (mean 0.2 kg) and controls (mean 3.5 kg) [*Ziegler-2006*]
- Worsening depression (rare) (average MMPI does not change in women on DMPA).
- Severe allergic reaction, including anaphylaxis (very rare). May consider having women wait in or near office for 20 minutes after injection. (Reviewers disagree about this recommendation, especially for previous DMPA users). Ask patients to report itching at injection site

CANDIDATES FOR USE (See new 2010 CDC Criteria on pages A-1 through A-8)

- Women who want intermediate-to-long-term contraception and can return every 11-13 weeks
- Women who do not plan a pregnancy soon after DMPA discontinuation
- Women who want privacy, convenience, and high efficacy
- Women who want or need to avoid estrogen:
 - Women with personal history of thrombosis (CDC: 2) or strong family history of venous thromboembolism (CDC: 1)
 - Recently postpartum women (CDC: 1)
 - Women who are exclusively breast-feeding beyond 6 weeks postpartum (CDC: 1). There is debate about use of DMPA in breastfeeding women less than 6 weeks PP (see p. 125 under INITIATING METHOD POSTPARTUM)
- Smokers over age 35 (CDC: 1)
- Women who fear chloasma or had vomiting, migraine headaches, hypertriglyceridemia, or other estrogen-related side effects
- Women who use drugs which affect liver clearance (except aminoglutethimide)
- Women with anemia, fibroids, seizure disorder (CDC 1), sickle cell disease (CDC: 1), endometriosis, hypertriglyceridemia (CDC: 2), systemic lupus erythematosus or coagulation disorder (hyper- or hypo-coagulation)
- Physically compromised women for whom bleeding is a nuisance or a problem

Adolescent women: (CDC: 2) Only 4 things to remember to do each year!

- Extremely effective with long carry-over if patient returns late for reinjection (see Figure 27.1, p. 128); Decreases menstrual cramps and pain
- Does not protect against STIs
- Privacy and confidentiality possible
- For some teens may be only acceptable method
- May be associated with significant weight gain, acne, complexion changes
- Requires periodic reinjections

Bone Mineral Density and Depo-Provera

Depo-Provera received a black box warning from the FDA in 11/04 due to this issue. ←
ACOG and AAP recommend no limit to use and no BMD testing. Some reviewers of this book think this was too severe a warning. All DMPA users should have the warning clearly explained to them and a discussion of alternatives if they choose to change methods. Women who used DMPA for more than 2 years have significantly reduced bone mineral density (BMD) of lumbar spine and femoral neck. But effect is largely reversible, even after ≥ 4 years of DMPA use, comparable to the effect and reversal seen after lactation [Petitti-2000]. **All women using DMPA including teens should be taking in sufficient calcium in diet or be encouraged to take calcium supplements. Also encourage to exercise regularly and avoid smoking.** ←
Longitudinal studies of DMPA use in teens found a significant difference in BMD ←
between DMPA users and non-users due to a decrease in users and an increase in nonusers. ←
By 12 months after discontinuation, BMD of former users was the same as for non-users. ←
[Scholes-2005]

PRESCRIBING PRECAUTIONS: Women unwilling to accept a change in their menstrual periods

- Pregnancy
- Undiagnosed abnormal vaginal bleeding
- Unable to tolerate injections; afraid of shots
- History of breast cancer, MI or stroke
- Current venous thromboembolism (unless anticoagulated)
- Active viral hepatitis
- Known hypersensitivity to Depo-Provera

See previous page “Bone Mineral Density and Depo-Provera” about package insert black box warning

DRUG INTERACTIONS: Aminoglutethimide (Cytodren), used to treat Cushing's disease, reduces DMPA efficacy

MEDICAL ELIGIBILITY CHECKLIST

Ask the client the questions below. If she answers NO to ALL the questions, then she CAN use DMPA 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 condoms or spermicide to use until reasonably sure that she is not pregnant. Then she can start DMPA

2. Do you plan to become pregnant in the next year?

☐ No ☐ Yes Use another method with less potential delay in return of fertility

3. Do you have serious medical problems such as heart attack, severe chest pain, or uncontrolled high blood pressure? Have you ever had such problems? (See Appendix)

☐ No ☐ Yes In general, do not provide DMPA if she reports heart attack (CDC:3), stroke (CDC:3), heart disease due to blocked arteries, severe high blood pressure (systolic ≥ 160 or diastolic ≥ 100) (CDC:3), diabetes for more than 20 years (CDC:3), or damage to vision, kidneys, or nervous system caused by diabetes or by HTN. Help her choose another effective method. All the above conditions receive a “3” in the 2010 CDC Medical Eligibility Criteria

4. Do you have or have you recently had breast cancer (CDC: 3 or 4)? (See Appendix)

☐ No ☐ Yes Do not provide DMPA. Help her choose a method without hormones. If cancer-free for 5 or more years, a woman with a history of breast cancer may possibly use DMPA (CDC: 3)

5. Do you have jaundice, cirrhosis of the liver, a liver infection or tumor? (Are her eyes or skin unusually yellow?) (See Appendix)

☐ No ☐ Yes Perform physical exam or refer. If she has serious liver disease (jaundice, painful or enlarged liver, viral hepatitis, liver tumor), do not provide DMPA. Refer for care. Help her choose a method without hormones

6. Do you have vaginal bleeding that is unusual for you? (See Appendix)

☐ No ☐ Yes If she is not pregnant but has unexplained vaginal bleeding that suggest a serious underlying medical condition (CDC:3), assess and treat any underlying condition as appropriate, or refer. Provide DMPA based on findings

INITIATING METHOD (see Figure 27.1, page 128)

A pelvic exam is **NOT** necessary prior to the initiation of this method [Stewart-2001]

Cycling women:

- Preferred start time is during first 7 days from the start of menses
- Alternative: inject anytime in the cycle if not pregnant, back-up x 7 days (see 27.1)

Postpartum women: May give injection prior to hospital discharge. Special considerations:

- After severe obstetrical blood loss, delay injection until lochia stops
- If woman has history or high risk for severe postpartum depression, observe carefully and delay injection at least 4-6 weeks
- Breast-feeding women: May either start DMPA immediately or wait 4-6 week.

Women who have spontaneous or therapeutic abortion: May initiate immediately.

Women switching methods:

- May start anytime patient is known not to be pregnant
- Hormonal method: if she has been using her current method consistently and correctly, may initiate immediately
- If switching from non-hormonal method, offer same options as cycling women

INSTRUCTIONS FOR PATIENT: *Some women may be able to give themselves Depo-Provera injections*

- Do **NOT** massage area where shot was given for a few hours (massaging area may reduce duration of action and thereby effectiveness)
- Expect irregular bleeding/spotting in beginning. Usually decreases over time. Return at any time spotting or bleeding is bothersome. Rx may make bleeding pattern more tolerable
- It is not harmful or dangerous if you do not have periods while you use DMPA

WEIGHT GAIN: A TEACHABLE MOMENT

When you see a patient who is very heavy or has gained enough weight to disturb her, you have a teachable moment. BE PREPARED FOR THAT TEACHABLE MOMENT.

Simple messages to share:

1. Eat less (small, frequent meals helps some to lose weight); eat balanced diet with lots of fruits and vegetables and minimal saturated fats, chips, cookies, pasta and other carbohydrates
2. Exercise more...and every day
3. Find patterns of eating and exercising that you enjoy! You won't do them for long unless you enjoy the process.
4. Call Overeaters Anonymous (OA) - www.overeatersanonymous.org
5. Drink 8-10 glasses of water daily

- Be sure to take in 1000 mg (women over age 25) to 1200 mg (adolescent women) of calcium every day to build your bones. Take calcium tablets like calcium carbonate or TUMS daily if your diet does not include enough calcium. Calcium is best absorbed when 500 mg is taken late in the day with a glass of orange juice. Get weight bearing and muscle-strengthening exercise at least 3 times a week (preferably 20 minutes daily)
- Return in 11-13 weeks for your next injection. Use abstinence, condoms, and EC, if necessary, if you are late coming for your re-injection (more than 13 weeks)
- Pregnancy is rare; return if you develop pregnancy symptoms other than amenorrhea
- Serious complications with DMPA are rare, but return if you develop severe headaches; heavy bleeding; depression or problems at the shot site (pus, pain, allergic reaction)

FOLLOW-UP

- Are you experiencing spotting or irregular bleeding? Have you missed periods or had very light periods? Are you concerned about your pattern of bleeding?
- Did you have pain at the injection site after previous injection?
- Have you felt depressed or had major mood changes?
- Have you gained 5 pounds or more? (See WEIGHT GAIN, A TEACHABLE MOMENT, p. 125)
Be sure to weigh patients at each visit. This means at **each and every visit**
- Consider measuring height and calculating a BMI
- Do you have any increase in your headaches?
- Have you had the feeling that you may be pregnant?
- Did you have any problems returning on time for this injection?
- Do you plan to have children? OR Do you plan to have more children?
- What are you doing to protect yourself from STIs? When appropriate encourage condom use

STRUCTURED COUNSELING FOR DEPO-PROVERA PATIENTS WORKS!

- Discontinuation rates for DMPA users at 1 year are high in the absence of structured counseling: 70% in a New York study of low-income women [Polaneczky-1996]; 43.4% in a rural Mexican study [Canto-DeCetina-2001]
- Importance of focused, structured, repeated counseling at initiation and follow-up visits can't be overstated. See STRUCTURED COUNSELING p. 13
- Structured counseling may include repetition, having patient repeat back instructions, showing videotapes, providing videotapes, audiotapes and written instructions and asking focused questions such as "What has happened to your pattern of bleeding?", "Have your periods become extremely light?", OR "Does your pattern of bleeding bother you?" rather than unfocused questions like "Are you having any problems?"
- Structured counseling in Mexico lowered DMPA discontinuation associated with three bleeding problems: amenorrhea, irregular bleeding and heavy bleeding, from 32% to 8%. Discontinuation from amenorrhea fell from 17 to 3%; from SPT or BTB from 10 to 3%; and from heavy bleeding from 5 to 2% [Canto-DeCetina-2001]
- Weight should be taken at each visit and weight control discussed carefully if there has been weight gain (see progressive weight gain p. 129 and WEIGHT GAIN: A TEACHABLE MOMENT p. 125)

PROBLEM MANAGEMENT

Allergic reaction or vasovagal reaction: In acute setting, provide support as needed. Benadryl may reduce pruritus and swelling. Oxygen and other resuscitation may be needed for severe reactions (extremely rare). Most allergic manifestations subside in 1 week or so. Refer if symptoms severe or do not improve appropriately. Avoid future injections and help her choose a different method

Vaginal dryness (dyspareunia) or atrophic vaginitis: May be due to hypoestrogenism. Consider measuring E_2 levels and giving physiologic replacement dose of estrogen, if needed. May give estrogen as vaginal cream, ring, tablets or systemic estrogen (tablets or patch) supplementation. Dyspareunia may be relieved with water soluble or silicone lubricants

Pain or infection at injection site: Offer anti-inflammatory medications. Rule out infection or needle damage to nerve, etc. Provide appropriate antibiotics if cellulitis present

Patient returns early (<11 weeks) wanting reinjection (eg b/c of travel): May give DMPA

Patient returns late (>13 weeks) for reinjection: See Figure 27.1 on page 135

- WHO guidance: repeat injection of DMPA can be given up to 4 weeks late without requiring additional contraceptive protection. ←

- This does not mean that the regular DMPA interval can be extended by 4 weeks ←

Switching to another method (eg OCs, IUD, etc) from DMPA: Initiate new method at any time convenient for patient. Preferred time would be near end of effectiveness of last DMPA injection unless switching to OCs, patch or vaginal rings to control menstrual disorders on DMPA. **Do NOT wait until next menses to start pills.** She may have amenorrhea for a number of months after DMPA

Transitioning perimenopausal women: See Figure 27.2 on page 129

Weight gain: Advise to watch caloric intake and to increase exercise. Refer to OA, Overeaters Anonymous. **Be ready to discontinue method if weight gain is excessive or unacceptable** (See teachable moment p. 125)

Heavy bleeding:

- Rule out pregnancy, cervical infection or neoplasia and other causes
- Rule out anemia - recommend iron rich foods and/or supplements
- May treat with NSAIDs or low dose estrogen supplements:
 - Ibuprofen 800 mg orally every 8 hours for 3 days
 - Mefenamic acid: 500 mg once, then 250 mg every 6 hours for 2-3 days ←
 - Conjugated equine estrogen (2.5, 1.25 or 0.625 mg) orally once a day up to four times per day for 4-6 days OR ethinyl estradiol x 21 days (expensive)
 - COCs for 1-2 months (in addition to DMPA use)

Irregular bleeding and spotting:

- Reassure that cumulative blood loss is usually less not more
- Rule out infection or cervical lesions as source
- Reassure that irregular spotting and bleeding is to be expected in first several months
- May use same therapies as outlined in heavy bleeding section above

Amenorrhea:

- Reassure her that this is not a medical problem. Do pregnancy test if she has other Sx.
- Switch method if patient desires regular menses (consider patch, ring, COCs). Even if she stops DMPA, menses may not return for months

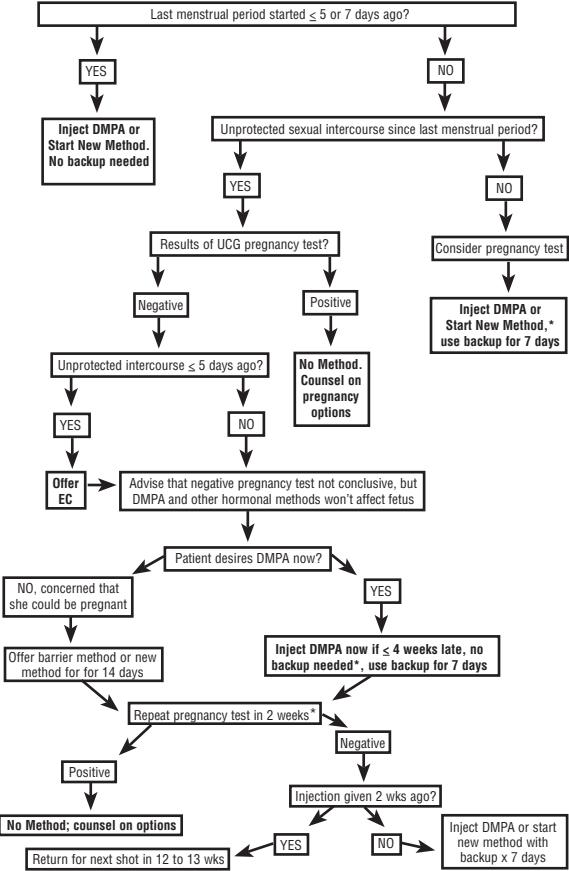
Depression:

- Evaluate suicide potential and refer immediately, if indicated
- Explain that DMPA usually does not worsen depression. Start antidepressant therapy, if needed. Discontinue DMPA if you or your patient has any misgivings about continuing its use

FERTILITY AFTER DISCONTINUATION OF METHOD

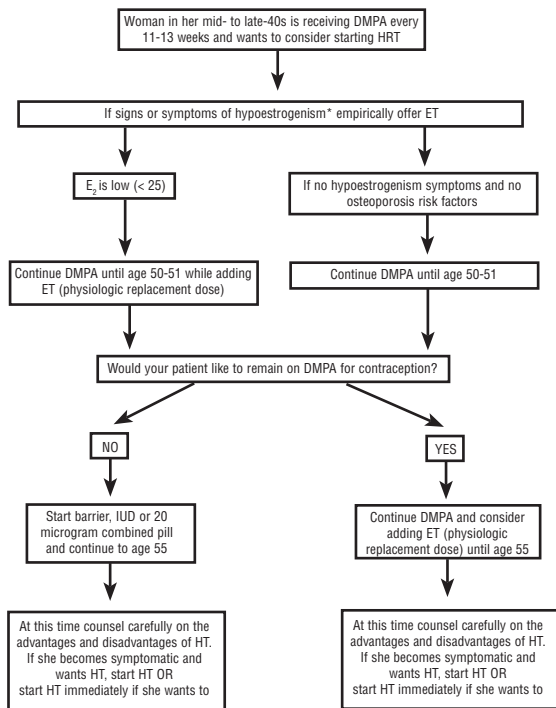
- Because anovulation may last for more than 1 year, women who know they will want to become pregnant within one year of cessation of use would be wise to consider another option, especially women over 35 years of age
- Fertility returns after 3 months; however, the conception rates overall are lower than women discontinuing other contraceptive methods. After last shot, 50% of women are pregnant after 6-7 months (compared to 4 months with other methods). (Delay not increased with increased duration of use). More than 90% of women become pregnant within 2 years
- Women who do not want to await spontaneous return of ovulation will require gonadotrophin therapy to induce ovulation. Gonadotropins will not overcome effect of DMPA on cervical mucus

Figure 27.1 Initial Injection or Late Reinjection (more than 4 weeks since scheduled return visit at 13 weeks) of DMPA or Switching From DMPA to COCs or Another Hormonal Method*



*Steiner MJ, Kwok C, Starback J et al. *Contraception* 2008 77 (2008) 410-414.

Figure 27.2 Making Transition from DMPA to Menopause, With or Without Hormone Replacement Therapy (HRT, EPT, or HT)



* DMPA can suppress gonadotropins, so measuring FSH or LH may not be informative of menopausal state. DMPA use decreases endogenous estrogen levels. Long-term DMPA users in their 40s may benefit from estrogen supplementation [Kaunitz, 1998]. Some researchers recommend that, at age 50, 2 FSH measurements be done at injection visit to assess menopausal status. If 2 consecutive levels are ≥ 35 -40 m IU/ml, this is suggestive of menopause [Juliato-2007]

IMPLANTS: IMPLANON - THE SINGLE ETONOGESTREL IMPLANT

Approved
2006

DESCRIPTION: Single implant is 4-cm long and 2 mm in diameter (5 mm longer than one Norplant implant), with a membrane of ethylene vinyl acetate (EVA) copolymer and with a core of 68 mg of etonogestrel in EVA (the new name for 3-ketodesogestrel). Initially, progestin is released at rate of 60 µg per day decreasing to 25-30 mcg/day by end of year 3. Implanon is effective for at least 3 years. Implant is placed under the skin of upper arm with a 16 gauge disposable, preloaded inserter

EFFECTIVENESS: No pregnancies in earliest studies. Some postmarketing pregnancies. Overall, 82% of women continue to use Implanon for 2 or more years. Women > 30% above ideal body weight excluded from studies. However, serum concentration of ENG remains high enough to suppress ovulation (0.3 ng/ml) even in heavier users

HOW IMPLANON WORKS:

- Within 24 hours of insertion thick cervical mucus prevents normal sperm transport
- Inhibition of ovulation. No ovulation in first 2 years and only 2 women had 4 ovulatory events in third year of Implanon use. However, they did not get pregnant
- Atrophic endometrium

COST: \$595.28 - Private Sector/ \$262.00 - Public Sector

ADVANTAGES

Menstrual: Decreased menstrual and ovulatory cramping or pain; overall, less bleeding than with Norplant and more amenorrhea (15% at one year). Less anemia. Dysmenorrhea decreases by 48% [Affandi-1998]

Sexual/psychological:

- Sexual intercourse may be more pleasurable because fear of pregnancy is reduced
- Usage not linked to sexual intercourse—allows spontaneity

Cancers/tumors and masses: None

Other:

- High continuation rate in clinical trials. Cyclic headaches may improve
- Single implant is easier and faster to insert and remove than multiple implants. Removal is usually accomplished with only a #11 scalpel and gentle finger pressure with < 1.0 cc ml of local anesthetic (use tuberculin syringe)
- Asymptomatic (usually) follicular cysts are less common

DISADVANTAGES

Menstrual:

- Unpredictable/irregular menstrual bleeding frequent and may persist but usually is light and well tolerated
- Amenorrhea and oligomenorrhea common

Sexual/psychological:

- Irregular bleeding may inhibit sexual intercourse
- Insertion and removal require procedures, for which special training is needed

Cancers/tumors and masses: None

Other:

- No STI protection
- Hormonal side effects: headache is most common
- May develop acne (or acne may improve)

- Ovarian cysts; usually resolve without treatment ←
- Dependent on clinician to remove ←

COMPLICATIONS:

- Removal difficulties much less frequent than with Norplant
- Rarely, sonographic or MRI localization is required
- Rare infections ←

CANDIDATES FOR USE:

- Implanon is particularly good for women with contraindications to or side effects from estrogen:
 - Women with personal history of thrombosis
 - Recently postpartum women
 - Women who are exclusively breast-feeding as there are no effects on breast milk or ←
breast-feeding infants associated with Implanon use [Reinprayoon-2000, Taneepanichkul-2005]
 - Smokers over age 35
 - Women who had or fear chloasma, worsening migraine headaches, hypertriglyceridemia or other estrogen-related side effects
 - Women with hypertension, coronary artery disease or cerebrovascular disease

PRESCRIBING PRECAUTIONS, MEDICAL ELIGIBILITY CHECKLIST, INITIATING METHOD:

Same precautions as for progestin-only pills

INITIATING METHOD:

- If inserted within 7 days of LMP, no backup needed. Can be inserted any time of cycle if reasonably certain not pregnant. If later than 7 days from LMP, use backup x 7 days
- If has been on DMPA, insert at time next injection due. No backup needed

INSTRUCTIONS FOR PATIENT: Irregular bleeding is to be expected and persists while rod is in place. If your pattern of bleeding is unacceptable, come back because there are several treatments that may make your bleeding pattern more acceptable (Periodic COC, patch, ring use). Amenorrhea more likely than with Norplant, but less likely than with DMPA

FOLLOW-UP: Routine GYN follow-up

PROBLEM MANAGEMENT:

Amenorrhea: Quite common. Pregnancy test if symptoms of pregnancy

Spotting/breakthrough bleeding: to be expected; not harmful. If bothersome may provide several cycles of low-dose pills, patch or rings or NSAIDs

Arm Pain after insertion

- Rule out nerve damage or infection
- If due to bruising, advise her to make sure bandage is not too tight
- Apply ice packs for 24 hours
- Take acetaminophen or NSAID

Infection in insertion area

- **No abscess:** cellulitis only. Do not remove, Clean infected area with antiseptic. Oral antibiotics for 7 days. (Recheck in 24-48 hours to make sure improving and at end of therapy)
- **Abscess:** Preload with antibiotics; prepare infected area with antiseptic, make incision, drain pus, and remove implant. Continue antibiotic therapy and wound care

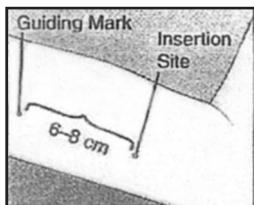
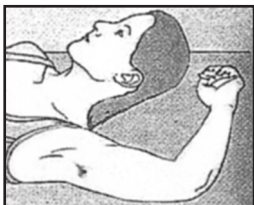
Difficult to locate rod: may be found by ultrasound or MRI. This requires experienced sonographer using transducer of 10 MHz or greater. Rarely, there may be a failure of provider to insert the rod (implant left in inserter) ←

FERTILITY AFTER DISCONTINUATION OF USE: Return to baseline fertility is rapid and complete; 94% ovulate within 3-6 weeks of removal

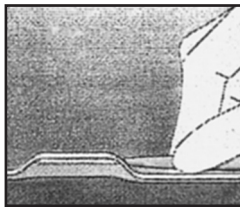
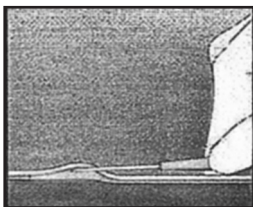
IMPLANON INSERTION

- Implanon can be prescribed only by clinicians who have personally attended a company sponsored training session (Organon - for training, call 1-877-Implanon or visit www.implanon-usa.com)
- For full review, see package insert

1. Patient should lie on her back with her non-dominant arm flexed at the elbow and externally rotated
2. Insert 6-8 cm above the elbow at the inner side of upper arm over the groove between the biceps and triceps muscles

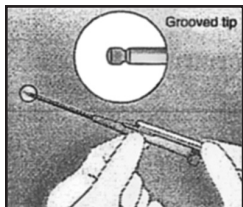


3. Mark planned track with a pen or marker
4. Clean site with antiseptic
5. Anesthetize area with 1-2 cc lidocaine (1%) subdermally along planned track of insertion
6. Carefully remove Implanon applicator from package. While shield is still on needle, look for Implanon rod (white) on tip of applicator. If not seen, carefully tap the top of needle (with shield) against hard surface to bring implant to needle tip
7. Following visual confirmation, lower the Implanon rod back into the needle by tapping it back into the needle tip, then remove the needle shield while holding the applicator upright
8. Note that the Implanon can fall out of the needle. Therefore, keep the applicator upright
9. Apply counter-traction to the skin around the proposed insertion site, and insert the needle at an angle - not greater than 20°, with the beveled side of the needle facing up
10. Keeping the needle in the subdermal tissue, lower the applicator to a horizontal position and insert just under the skin. Tenting of the skin helps to **keep it superficial and parallel to the surface of the skin**



11. When inserted to its full length, press the obturator support to break the seal and turn the obturator 90° in either direction

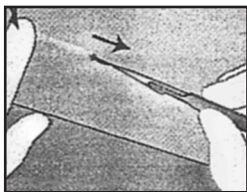
12. Hold the obturator fixed – and fully retract the cannula
13. Confirm that Implanon has been inserted by a) inspecting the needle tip for the absence of Implanon and the visualization of the grooved obturator tip and b) palpating the arm for the Implanon – have patient palpate too.



14. Apply adhesive bandage and pressure bandage. Patient may remove pressure bandage in 24 hours and adhesive bandage in 3-5 days
15. Complete the user card and give to patient to keep and complete patient chart label and affix to medical record

IMPLANON REMOVAL:

1. Palpate arm for Implanon
2. If Implanon not palpable – obtain imaging study. Implanon can be imaged with ultrasound that uses a high frequency linear array transducer – at least 10 MHz, or with MRI. If these imaging methods fail, call 1-877-Implanon for further instructions
3. The prescribing information for Implanon states that Implanon should only be removed by clinicians trained in the Implanon removal technique
4. Palpate the rod, apply antiseptic and anesthetize where the incision will be made. Apply the anesthetic under the tip of the implant closest to the elbow, and make a 2-3 mm incision in the longitudinal direction
5. Apply pressure on the proximal (closest to the head) tip of the implant gently pushing out of the incision. If the implant is encapsulated by fibrous tissue, make an incision in the fibrous sheath and then remove the Implanon with forceps



6. A new Implanon may be inserted in the same incision if desired

The incision can be closed with an adhesive bandage, followed by a pressure bandage. Patient may remove pressure bandage in 24 hours and adhesive bandage in 3-5 days

CHAPTER 26

Female Sterilization: Tubal Ligation or Occlusion

www.engenderedhealth.org, www.plannedparenthood.org or www.essure.com

DESCRIPTION: Surgery to interrupt the patency of fallopian tubes. In 2002 in the USA, 27% of married women reported having had tubal sterilization while 9% of their husbands had a vasectomy [Mosher-2004]. Many single women have sterilization operations. Approximately half of sterilizations in the USA are done in the postpartum period within 48 hours of delivery [Peterson-1998].

EFFECTIVENESS: Failure rates vary depending on sterilization method and patient's age.

Table 28.1 Cumulative 10-year failure rates for some methods of voluntary female sterilization methods*

Method	Failure rate (highest rate)
Postpartum partial salpingectomy	0.8%*
Silastic bands over loop of tube	1.8%*
Interval partial salpingectomy	2.0%*
Bipolar cautery	2.5%*
Spring clip application	3.7%*
Filshie clip (7 years)	0.9%+

For each sterilization method, at least 50% more failures were ascertained AFTER 2 YEARS as had been identified in the 2 years immediately following the sterilization procedure

* U.S. Collaborative Review of Sterilization. The risk of pregnancy after tubal sterilization. Am J Obstet Gynecol 1996;174:1161-70.

+ Filshie clip (0.9% failure rate - 7 years) [Chi-Chen Contraception 1987;35:171-8]

- Younger women had higher failure rates
- All methods require proper application to maximize effectiveness
- Teaching institution rates (above study) may differ from private settings

Hysteroscopic tubal occlusion: 99.74% effective at 5 years (if post-op verified occlusion by hysterosalpingogram) ←

HOW FEMALE STERILIZATION WORKS: Interruption of patency of the fallopian tubes preferably in isthmic region thereby preventing fertilization

LAPAROSCOPIC STERILIZATION: TRANSABDOMINAL

Bipolar cautery:

- Apply to area along fallopian tube with no vessels ascending through broad ligament, where the diameter of tube is similar on either side of selected area (at least 2 cm from uterotubal junction). Thoroughly cauterize tissue using bipolar cutting current of 25 Watts passing through jaws of instrument. Bipolar cautery has the highest risk of subsequent fistulization and ectopic pregnancy.

Silastic band: (Fallope Ring, Yoon Band)

- Apply over knuckle of tube at least 3 cm from utero-tubal junction. Loop of banded tube should clearly contain two complete diameters of tube

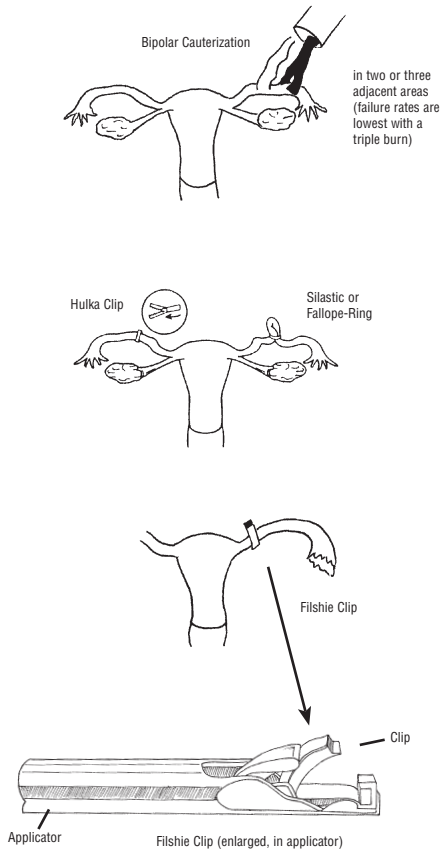
Hulka-Clemens clip (spring clip):

- Spring-loaded clip. Apply to isthmic portion of tube. 1-2 cm distal to cornu at an angle of 90° relative to long axis of tube. Highest failure rate

Filshie clip:

- Hinged titanium clip with cured silicone rubber lining. Apply to isthmic portion of tube, 1 to 2 cm from cornu. Should see hook end of clip through filmy mesosalpinx. May apply postpartum with special applicator (0.9% failure vs. 0.4% failure for interval application)

Figure 28.1 Laparoscopic Technique Diagrams



POSTPARTUM OR INTERVAL MINI-LAPAROTOMY METHODS

Modified Pomeroy:

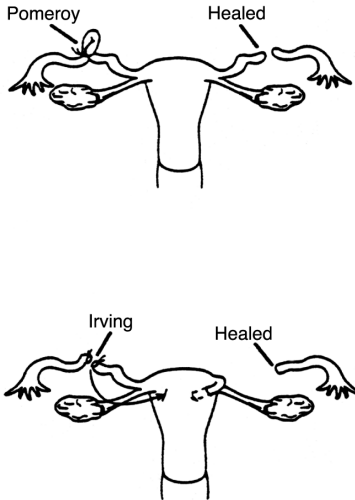
- Ligation at the base of a loop of isthmic portion of tube with plain absorbable catgut suture (2 separate ties) followed by excision of the knuckle of tube. Segment is histologically confirmed to contain tubal ostia.

Modified Parkland:

- Excision of segment of isthmic portion of tube after separate ligation of cut ends, no “knuckle formed”

Irving, Uchida and Fimbriectomy are rarely performed ←

Figure 28.2 Postpartum or Mini-Laparotomy Techniques



ADVANTAGES

Menstrual: None

Sexual/psychological: Enhanced enjoyment of sex by reducing worry of pregnancy

Cancers, tumors, and masses:

- Decreased risk of ovarian cancer. Women with BRCA 1 mutations who have undergone a tubal ligation have a 60% lower risk of developing invasive ovarian cancer. [*Narod-Lancet* 357 (9267): 1467-70, 2001]. Overall 40% reduction in risk of ovarian cancer

Other:

- Permanent and highly effective

DISADVANTAGES

Menstrual:

- Data from 9514 women who underwent tubal sterilization by 6 techniques and followed for up to 5 years suggest no “post-tubal ligation syndrome” and no increases in the amount or duration of menstrual bleeding or menstrual pain. [*Peterson, 2000*]

Sexual/psychological:

- Regret may occur especially with young patients; counsel well and offer reversible methods if any hesitancy (see Fig. 28.5, p. 140)

Cancers, tumors, and masses: None

Other:

- Requires outpatient surgery (usually with general anesthesia); Expensive in short term
- If failure occurs, higher risk of ectopic pregnancy (30%)
- Not readily reversible
- Does not prevent spread of HIV and STIs

COMPLICATIONS [*Peterson, 1997*]

	<i>Minilaparotomy</i>	<i>Laparoscopy</i>
<i>Minor</i>	11.6%	6.0%
<i>Major</i>	1.5%	0.9%

- Minor complications include infection, wound separation
- Major complications include conversion to laparotomy, hemorrhage, viscus injury especially with cautery, anesthetic complications
- Major vessel injury risk with laparoscopy 3-9/10,000 procedures
- Mortality: 1-2/100,000 procedures (leading cause is general anesthesia)

LONG-TERM RISKS

- Statistically higher risk for subsequent hysterectomy, but only in women who had gynecologic complaints prior to sterilization
- Regret (0.9% - 26.0%) Risk factors include: age under 30, low parity, sterilization at time of cearean delivery, change in marital status, poverty, minority status, misinformation about permanence or risks, hurried decision. If sterilized < 30 years old, 40% requested information on reversal, 20% expressed regret but only 1% had a reversal done [*Schmidt-2000*]. **This issue requires careful counseling**

CANDIDATES FOR USE

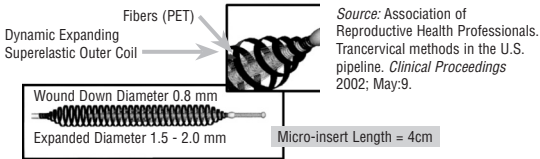
- Woman who is certain she wants no more children
- Woman over age 21 (only required for Medicaid reimbursement, not for medical requirements or for California state funding)
- Woman for whom surgery is considered safe

Adolescents: Not a preferred method, generally higher regret and higher failure rates

ESSURE: HYSTEROSCOPIC STERILIZATION VIA POLYESTER FIBERS

www.essure.com Essure is a new approach to transcervical sterilization that causes tubal blockage by encouraging local tissue growth with polyester (PET) fibers [Valle Fertil Steril 2001]. An attached outer coiled spring is released that molds to the shape of the interstitial (uterine) portion of each fallopian tube. The device costs \$950 [Ballagh, 2003], but it is covered by insurance plans that cover laparoscopic tubal ligation (even Medicaid). It takes 3 months after procedure to occlude tubes. An hysterosalpingogram (HSG) is needed 3 months after surgery to document success

Figure 28.3 Essure System Overview: Micro-Insert Design



ADVANTAGES: "The alternative to incision"

- Provides tubal sterilization in physician's or ambulatory surgery office (average operating time: 13 to 35 minutes)
- No change in a woman's menstrual cycles
- No failures among 453 women relying on Essure for one year following confirmation of tubal blockage at 3 months by hysteroscopy; 99.8% effective. 99.7% effective at 5 years
- There is no need for conscious sedation or general anesthesia (nonsteroidal premedication is strongly recommended to prevent tubal spasm)
- In clinical trial, (Australia, Europe, and the U.S.) 92% of women returned to work in one day, most resumed normal activities the same day as the procedure
- May be preferred for obese women, women with abdominal adhesions, or women with risk factors for anesthesia

DISADVANTAGES: Requires specialized training and equipment

- Hysterosalpingogram must be done at 3 months to confirm blockage. Until that time, couple must use another contraceptive.
- Procedure designed for interval sterilization. It is not to be used at Cesarean delivery or immediately postpartum [Ballagh, 2003]
- Luteal pregnancies occurred in 4 of 466 women in spite of negative urine pregnancy tests on the day of the procedure
- It may not be possible to visualize both tubal ostia (this occurs about 2% of the time)
- May require more than one operative procedure
- In only 446 of 518 women (86.1%) could devices be introduced into both tubes at the time of the first procedure due to difficulty locating tubes, tubal spasm or tube already not patent
- Expulsion of one or both devices (14 of 466 successful procedures or 3.0%)
- Perforation of the uterus occurred during 1% of procedures
- This form of sterilization cannot be reversed

PRESTERILIZATION COUNSELING CHECKLIST*

- Discuss alternative reversible methods and quote their effectiveness. (IUDs and implants are more effective than some forms of tubal sterilization)
- Discuss vasectomy as an alternative
- Insure patient commitment to having no future children, even if something happened to her current family
- Describe details of surgery (informed consent later) and possible intraoperative and long-term complications (risk for ectopic pregnancy)
- Stress that procedure must be considered irreversible and that about 10% of women regret their decision and answer all of her questions
- Discuss that ~ 2% of laparoscopic and transcervical procedures cannot be completed on first attempt. Review the “what if” intended procedure cannot be completed
- Obtain informed consent using locally approved consent forms - No requirement that spouse must be involved

*Adapted from ACOG Technical Bulletin, April 1996.

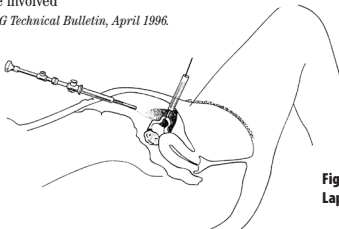


Figure 28.4
Laparoscopy

INITIATING METHOD

- Obtain informed consent. Preferable to involve partner in process, but not necessary
- Any time in cycle with certainty of no conception, otherwise follicular timing preferred. Not true for Essure. With Essure, you want to time when lining will be very thin
- The routine provision of antibiotics is generally NOT recommended [see ACOG Practice Bulletin No. 23, January, 2001]

FOLLOW-UP

- For women having interval occlusion procedure, follow up in two weeks for post-op wound check is typical, but not required. Routine annual gynecology exams
- 3-month follow up visit for Essure (see p. 138)

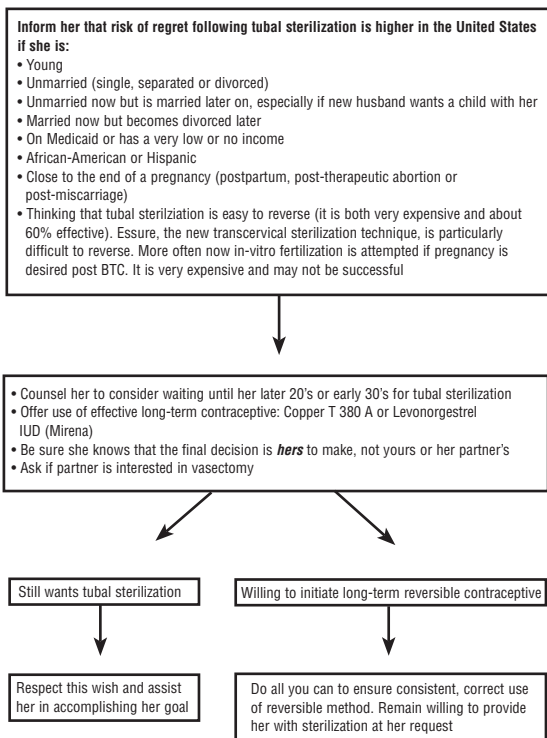
MANAGEMENT OF PROBLEMS

- Anesthesia complications, wound infections, intraperitoneal adhesion formation, hydrosalpinx – managed with standard approaches
- Although some women report irregular menses or dysmenorrhea after tubal sterilization, several studies have demonstrated that a syndrome of irregular menses or dysmenorrhea following tubal sterilization does NOT exist [Peterson-2000]. These problems are **not** apt to develop at any higher rates in sterilized women. They are most likely age-related and inevitable

FERTILITY AFTER TUBAL STERILIZATION

- Women must desire to be permanently sterile because reversal is costly and results are unpredictable. In vitro fertilization may be possible, but many cannot afford this procedure and it is not always successful

Figure 28.5 Sterilization Requested by Young Woman



CHAPTER 27

Male Sterilization: Vasectomy

www.engenderedhealth.org or www.plannedparenthood.org

DESCRIPTION: Permanent male contraception. Outpatient surgical procedure. No-scalpel technique punctures scrotum, delivers vas; ligates or cauterizes vas. Nearly 1 in 5 white U.S. men married to women of childbearing age has had a vasectomy. [Amba-1997]

EFFECTIVENESS (See Table 13.2, p. 40)

Perfect use failure rate in first year: 0.10%

Typical use failure rate in first year: 0.15%

[Trussell J, IN *Contraceptive Technology*, 2004]

Recent analysis of the 540 women in the CREST study who were protected by vasectomy found a cumulative failure rate of 9.4 per 1000 procedures at one year (0.9%) and 11.3 at years 2, 3 and 5. [Jamieson, Costello, Trussell et al-2004]

Although vasectomy is safer and potentially more effective than tubal sterilization, as of mid-2000, there are only 4 nations in the world where vasectomies exceed tubal sterilizations: Great Britain, the Netherlands, New Zealand and Bhutan.

HOW VASECTOMY WORKS: Interrupts vas deferens preventing passage of sperm into seminal fluid and female reproductive tract



Vas deferens isolated following incision with scapel

ADVANTAGES

Sexual/psychological:

- Sexual intercourse may be more enjoyable because fear of pregnancy decreased
- Permits man opportunity to take on an important contraceptive role
- No interference during sexual intercourse and no contraceptive burden for female

Cancers, tumors, and masses: None

Other:

- Simpler, safer and more effective than female sterilization
- More cost-effective than female sterilization and more convenient
- Shares contraception responsibility with partner
- No supplies or further clinic visits needed after sperm count has been documented to be zero
- Only local anesthesia required ←

DISADVANTAGES

Sexual/psychological:

- Some men resist vasectomy fearing that it will interfere with sexual function (it doesn't) or because they feel contraception is solely the woman's responsibility (it isn't)
- Regret at a later time possible (1% of men request a reversal)
- Will need back-up method until there are no motile sperm. Female partner may still need contraception if she has other partner(s) or if STI protection needed

Cancers, tumors, and masses: None

Other:

- Does not reduce risk for STIs; will still need to use condom if at risk
- Short-term post-operative discomfort, bruising, and swelling

COMPLICATIONS

- Surgically related complaints such as hematoma, bruising, wound infection, or adverse reaction to local anesthesia
- Severe chronic pain (2%) [Choe, Kirkema - 1996]. Usually limited to less than 1 year
- Later regret possible

CANDIDATES FOR USE: Men who desire a permanent method

INITIATING METHOD

- Take preoperative history; make general health assessment
- Ask if history of genital infections or anomalies ←
- Obtain informed consent. In general, try to involve partner
- Carefully counsel, especially about permanence of method
- Advise patient to bathe genital area and upper thighs prior to surgery; wear clean, loose-fitting clothes to facility; no food for 2 hours before procedure

PRESCRIBING PRECAUTIONS

- Current infection of penis, prostate, or scrotum
- Fear of needles or scalpels (scalpels not required if no-scalpel vasectomy)

INSTRUCTIONS FOR PATIENT

- Plan to rest for 48 hours and wear scrotal support
- Apply ice pack to incision site to decrease swelling, pain and bruising. Small packages of frozen peas conform well around the scrotum
- Keep area dry for two days – wear snug underwear and pants to provide support where needed
- If any symptoms or signs of infection develop, seek help immediately.
- Return as directed for sperm counts. Results from a new study suggest that azospermia is more likely after 12 weeks (60% azospermia) than after 20 ejaculations (28% azospermic) and that neither endpoint is ideal [Barone-2003]. Use other forms of contraception until two consecutive sperm samples show no motile sperm

FOLLOW-UP: *To avoid failure due to LATE recanalization, repeating semen analysis every few years makes sense*

- Have you had your semen tested? If yes, were motile sperm absent?

PROBLEM MANAGEMENT

Wound infection: Treat with antibiotics. Drain and treat any abscesses

Hematoma: Apply warm moist packs to scrotum. Provide scrotal support

Granuloma: Observe; usually it will resolve itself. Occasionally requires surgery

Pain at site: If no infection, provide scrotal support and analgesics

Excessive swelling: If large and painful, may require surgery. Provide scrotal support if hematoma

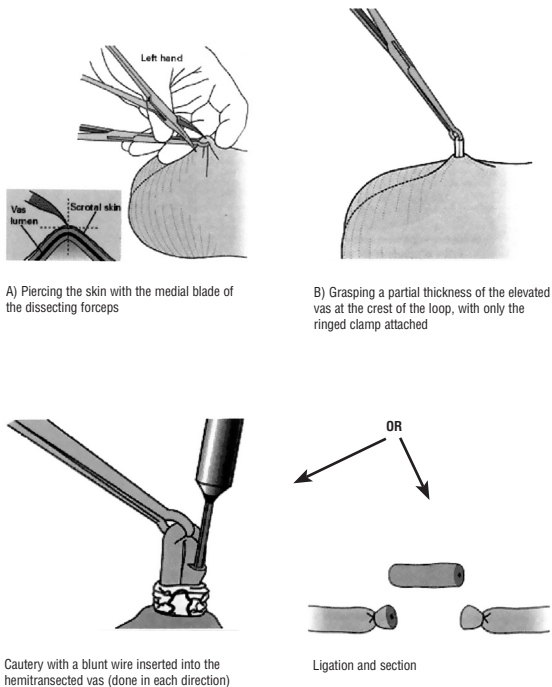
Chronic persistent pain considered to be severe: [2% - Choe, Kirkema - 1996]. IPPF

Handbook states that this pain can often be relieved by vasovasectomy or decompression of the distended vas deferens releasing the sperm into the scrotal cavity [Evans, Huetz IPPF Handbook - 1997]

FERTILITY AFTER VASECTOMY

- Man must accept that vasectomy is irreversible and permanent
- Microsurgical techniques of reversal now result in return of sperm to ejaculate in over 90% of men, but in pregnancy rates of only 50% or above. Reversibility rates decrease as time passed since procedure increases
- Important factors for reversal are
 - skill of microsurgeon
 - length of time since vasectomy
 - presence of antisperm antibodies (man)
 - partner's fertility
 - manner in which vasectomy was performed (amount of vas removed or cauterized)

Figure 29.1 Vasectomy - No-Scalpel Techniques



Cornell No-Scalpel Vasectomy Center. No-Scalpel Vasectomy. <http://www.vasectomy.com/no-scalpel-vasectomy-diagram.html>.2/6/02.

CHAPTER 28

Ordering and Stocking Devices: Implanon, Mirena, ParaGard

www.implanon-usa.com, www.mirena-support.com, www.paragard.com

ORDERING AND STOCKING DEVICES: Telephone numbers below are for ordering devices, speaking with customer service, reporting adverse events.

IMPLANON

- Call 1-877-Implanon, www.implanon-usa.com
- Implanon dispensed by two pharmacies: CuraScript and CVS Caremark ←
- To set up account, need state license number and DEA number
- Pharmacy verifies that health care provider (HCP) has attended a company sponsored Implanon training program
- Implanon is usually a “medical benefit”; sometimes a pharmacy benefit
- If Implanon contaminated prior to insertion or touching the patient – call 1-877-Implanon (option 3) and save the product to ship back to manufacturer for free replacement
- HCPs may complete and fax a benefits search (determine if an individual's insurance covers Implanon) to pharmacy. Search completed within 48-72 hrs. **Cost** of implant alone (if no insurance): \$595.28 ←
- Payment plans available. For information, call 1-877-Implanon and press option #6 ←

MIRENA

- Call 1-866-647-3646, www.mirenasupport.com, www.mirena-us.com, www.archfoundation.com
- To set up an account, clinician needs license. Bayer verifies that the HCP is certified (i.e. trained by a medical specialist, or has attended a company sponsored training program). If not, a training kit will be included in the order ←
- Verify insurance coverage
- If no coverage, patients can pay by credit card with Mirena shipped to HCP.
- Low income patients can apply to the ARCH foundation (1-877-393-9071) or www.archfoundation.com for a subsidized Mirena
- If Mirena is contaminated upon insertion, or removed early for a medical reason, no general replacement policy exists. However, by calling the hotline or their Bayer sales consultant, they will consider each event on a case-by-case basis. ←
- **Cost** (of IUS if no insurance): \$843.60 (single payment). Patient may pay by 4 ← installments: First payment is: \$337.44 and then 3 payments at \$168.72 each or 24 equal payments of \$35.15. Call 1-866-638-8312 to take advantage of one of these plans. Mirena will be ordered by health care provider and shipped to the office within 2 to 3 business days.

PARAGARD

- Call 1-877-727-2427, www.ParaGard.com
- To set up an account, a clinician needs a state license number
- Verify patient insurance coverage prior to insertion
- If no coverage, patients can pay by credit card / ParaGard shipped to HCP
- Replacement policy: If a clinician contaminates the IUD prior to touching the patient (e.g., drops on floor), call the hotline within 7 days AND save the product to ship back to them. They will send a replacement. If the woman has the ParaGard removed for a medical reason within 90 days (and reported within 30 days of removal) they will replace the product if the patient desires. If patient paid for IUD – she will be reimbursed. If she paid and is not ← satisfied with the IUD, she can get a full refund within the first 150 days
- **Cost** (of IUD if no insurance): \$ 494.00. or 12 credit card payments of \$41.17 ←

CHAPTER 29

HPV Vaccine

www.cdc.gov, www.acog.org, www.gardasil.com, www.cervarix.com

HPV VACCINE:

- Quadrivalent vaccine (Gardasil) protects against infection with HPV types 6, 11, 16, 18 which account for 70% of HPV-related cervical cancer and 90% of genital warts
- Vaccine prepared from highly purified virus like particles (VLPs) of the major capsid protein of the HPV
- IM injection to deltoid or thigh
- Designed to prevent the following conditions caused by HPV 6,11,16,18 (these conditions may still occur related to other HPV types): cervical dysplasia and cancer, vulvar or vaginal dysplasia and genital warts
- Now offered to males ages 9-26 also for prevention of warts ←
- 4 Phase 2 and 3 randomized, placebo controlled trials evaluated 20,451 women ages 16-26. Median duration of follow-up was 4,3,2,4 and 2 years
- Vaccine was found to be highly effective in preventing acquisition of disease
- Vaccine is a preventive tool, not a substitution for cervical cancer screening. These recommendations remain unaffected by the vaccine's approval and use
- Administered in a series of 3 inoculations: initial injection, then 2 months and 4 months after that
- Approved for females ages 9-26: Federal Advisory Committee on Immunization Practices (ACIP) recommends administering to girls between ages 11 and 12; may be given from age 9
- Women with previous HPV infection or abnormal cytology can still be vaccinated and may benefit from protection from strains they may not have yet acquired. Benefits in these women may be more limited and women should be informed of this. Benefits may also decrease in women who have had ≥ 5 lifetime sexual partners
- Vaccination is not treatment for genital warts
- Immunosuppression is not a contraindication to vaccination; efficacy may be affected
- Currently not recommended to vaccinate women > 26 y/o
- New HPV vaccine, Cervarix, recently approved for use in females aged 10-25. Protects against HPV types 16, 18 ←

CERVICAL CANCER SCREENING GUIDELINES UNCHANGED

SEE Prescribing Information for full information

Contraindication: hypersensitivity to vaccine components. If sensitivity occurs after first dose, do not administer subsequent doses

Precaution: may not result in protection for all recipients

- Not intended to be given to pregnant women, pregnancy category B. Pregnancy registry: 1-800-986-8999
- Adverse events include pain, swelling, erythema, pruritis at injection site

CHAPTER 30

Sexually Transmissible Infections (STIs) 2006 CDC Guidelines for Treatment*

Complete guidelines at www.cdc.gov/nchstp/od/nchstp.html
www.hab.hrsa.gov www.aidsinfo.nih.gov

Since women and men seeking contraceptives are also at risk for STIs, we have included in this book information on the treatment of many of the most important STIs based on the latest abridged CDC recommendations (2006). Please refer to the full document for comprehensive information

Bacterial Vaginosis.....	p. 155	Human Papillomavirus Infection (HPV).....	p. 161
Candida.....	p. 157	Lymphogranuloma Venereum (LGV).....	p. 150
Chancroid.....	p. 148	Lice.....	p. 169
Chlamydia.....	p. 152	Mucopurulent cervicitis.....	p. 155
Clinical Prevention Guidelines.....	p. 146	Nongonococcal urethritis.....	p. 152
Donovanosis.....	p. 150	Pelvic Inflammatory Disease (PID).....	p. 159
Ectoparasitic Infections.....	p. 163	Pediculosis pubis.....	p. 163
Genital Herpes Simplex Virus (HSV).....	p. 148	Scabies.....	p. 164
Genital Ulcers.....	p. 148	Sexual Assault/STIs: (Inside Back Cover)	
Genital Warts.....	p. 161	Adults/Adolescents.....	p. 164
Gonorrhea.....	p. 153	Syphilis.....	p. 151
Granuloma Inguinale (Donovanosis).....	p. 150	Trichomonas.....	p. 157
Hepatitis A and B.....	p. 169	Urethritis and Cervicitis.....	p. 152
HIV Infection.....	p. 165	Vaccine-Preventable STIs.....	p. 163
		Vaginal Discharge.....	p. 155

CLINICAL PREVENTION GUIDELINES

- The specific recommendations presented here are from that document
- Both partners should be tested for STIs, including HIV, before initiating sexual intercourse
- A new condom should be used for each act of insertive intercourse (oral, vaginal or anal)

Prevention Methods

- *Male Condoms*
 - Used consistently and correctly, latex condoms are effective in preventing the transmission of HIV infection and can reduce the risk for other STIs
 - Failure usually results from inconsistent or incorrect use, rather than condom breakage
- *Female Condoms*
 - Laboratory studies indicate that the Reality female condom is an effective mechanical barrier to viruses, including HIV
 - Used consistently and correctly, the female condom may substantially reduce risk for STIs including HIV
- *Condoms and Spermicides*
 - Condoms lubricated with spermicides are no more effective than other lubricated condoms in protecting against HIV and STDs
 - Use of condoms with N-9 is not recommended for HIV/STD prevention

- Vaginal spermicides containing N-9 are not effective in preventing cervical gonorrhea, chlamydia or HIV infection
- Diaphragm use has been demonstrated to provide some protection against cervical gonorrhea, chlamydia, and trichomoniasis (case control, cross sectional studies)
- Diaphragms are not effective to protect women against HIV infection (Padian 08)
- *Nonbarrier Contraception, Surgical Sterilization, and Hysterectomy*
 - Hormonal contraception (e.g., oral contraceptives, Norplant, and Depo-Provera) offer no protection against HIV or other STDs
 - Women who use hormonal or intrauterine contraception, have been surgically sterilized, or have had hysterectomies should still be counseled on the use of condoms for HIV/STI protection

SPECIAL POPULATIONS

Pregnant Women

- *Recommended Screening Tests*
 - Syphilis: all pregnant women at first prenatal visit; high risk (high areas of syphilis morbidity) retested in early third trimester and at delivery. Some states require all women to be screened at delivery
 - Hepatitis B surface antigen (HbsAg): all pregnant women first visit
 - *Neisseria gonorrhoeae*: first visit for women at risk or living in an area of high prevalence
 - *Chlamydia trachomatis*: all women at first prenatal visit and in the third trimester for women at increased risk (i.e., women aged <25 years and women who have a new or more than one sex partner or whose partner has other partners)
 - HIV screening test: encouraged for all pregnant women as routine prenatal test at the first prenatal visit. If high risk retest in 3rd trimester before 36 weeks
 - Bacterial vaginosis (BV): at the first prenatal visit for patients at high risk for preterm labor (history of prematurity). Current evidence does not support universal testing for BV
 - Papanicolaou (Pap) smear: first visit if no Pap smear has been documented during the preceding year
 - Hepatitis C antibodies at the first prenatal visit for women at high risk (intravenous drug users, blood transfusions, organ transplant)
- *Other Concerns (Other STI-related Concerns are to Be Considered as Follows:)*
 - Pregnant women who have either primary genital herpes infection, HBV, primary cytomegalovirus (CMV) infection, or Group B streptococcal infection and women who have syphilis and who are allergic to penicillin may need to be referred to an expert for management
 - HbsAg-positive pregnant women should be reported to the local and/or state health department; household and sexual contacts of HbsAg-positive women should be tested and immunized if negative
 - In the absence of lesions during the third trimester, routine serial culture for herpes simplex virus (HSV) is not indicated for women who have a history of recurrent genital herpes. Prophylactic cesarean section is not indicated for women who do not have active genital lesions at the time of delivery
 - The presence of genital warts is not an indication for cesarean delivery unless size obstructs delivery in labor (rare)

Adolescents

- With limited exceptions, all U.S. adolescents can consent to the confidential diagnosis and treatment of STIs. See Table 6.1, p. 19
- All children and adolescents should get HBV vaccine and females 9-26 years old, the HPV vaccine

DISEASES CHARACTERIZED BY GENITAL ULCERS

Management of Patients Who Have Genital Ulcers

- In the United States, most young, sexually active patients who have genital ulcers have genital herpes, a smaller percentage have syphilis, or chancroid. Each disease has been associated with an increased risk for HIV infection
- The evaluation of all patients who have genital ulcers should include a serologic test for syphilis and diagnostic evaluation for herpes; in settings where chancroid is prevalent a test for *Haemophilus ducreyi* should be performed. Specific tests (to be used with clinical assessment) for the evaluation of genital ulcers include the following:
 - Serology, dark-field exam or direct immunofluorescence test for *T. pallidum*
 - Culture or antigen test for HSV and
 - Culture for *Haemophilus ducreyi*
- HIV testing should be a) performed in the management of patients who have genital ulcers caused by *T. pallidum* or *H. ducreyi* and b) strongly considered for those who have ulcers caused by HSV

CHANCROID (SHAN-kroyd)

Organism: *H. ducreyi*

Diagnosis: Culture on special medium of *H. ducreyi*, or if all of the following criteria are met: a) patient has 1 or more painful ulcers; b) no evidence of syphilis on lab exam after at least 7 days; c) the clinical picture is typical of chancroid and d) test for HSV is negative.

Treatment: Recommended Regimens

Azithromycin.....1 g orally in a single dose, OR
Ceftriaxone.....250 mg intramuscularly (IM) in a single dose, OR
Ciprofloxacin.....500 mg orally twice a day for 3 days, OR
Erythromycin base.....500 mg orally three times a day for 7 days.

Follow-up: Re-examine in 3-7 days. If no improvement consider whether a) the diagnosis is correct, b) the patient is coinfecting with another STI, c) the patient is infected with HIV, d) the treatment was not taken as instructed, or e) the *H. ducreyi* strain causing the infection is resistant to the prescribed antimicrobial.

- **The time required for complete healing:**
 - Depends on the size of the ulcer; large ulcers may require >2 weeks
 - Healing is slower for some uncircumcised men who have ulcers under the foreskin
 - Resolution of fluctuant lymphadenopathy is slower than that of ulcers and may require drainage, even during otherwise successful therapy
 - Although needle aspiration of buboes is a simple procedure, incision and drainage of buboes may be preferred because of less need for subsequent drainage procedures

Management of Sex Partners: Should be examined and treated regardless of symptoms if they had sexual contact within 10 days of the onset of symptoms

Special Considerations: Pregnancy. The safety of azithromycin for pregnant and lactating women has not been established. Ciprofloxacin is contraindicated during pregnancy and lactation. No adverse effects of chancroid on pregnancy outcome or on the fetus have been reported.

GENITAL HERPES SIMPLEX VIRAL (HSV) INFECTION (Her-pes)

Most persons shed the virus intermittently and are unaware that they are infected and are asymptomatic at the time of transmission.

Organisms: HSV-1 and HSV-2

Diagnosis: See complete 2002 CDC Guidelines or Contraceptive Technology (18th Edition)

Counseling: Counseling of these patients should include the following:

- Patients should be advised to abstain from sexual activity when lesions or prodromal symptoms are present and encouraged to inform their sex partners
- Latex condoms, when used consistently and correctly, might reduce the risk for genital herpes, when the infected areas are covered or protected by the condom
- Sexual transmission of HSV can occur during asymptomatic periods
- Daily use of valacyclovir can reduce transmission
- The risk for neonatal infection should be explained to all patients, including men. Childbearing-aged women who have genital herpes should be advised to inform health-care providers who care for them during pregnancy about the HSV infection
- Patients having a first episode of genital herpes should be advised that a) episodic antiviral therapy during recurrent episodes might shorten the duration of lesions and b) suppressive antiviral therapy can ameliorate or prevent recurrent outbreaks
- Patients may be directed to websites: <http://www.ashstd.org> or www.ihmf.org

Treatment: 5% to 30% of first-episode cases of genital herpes are caused by HSV-1, but clinical recurrences are much less frequent for HSV-1 than HSV-2 genital infection

• HSV, Recommended Regimens for First Clinical Infection

Acyclovir.....400 mg orally three times a day for 7-10 days, OR
Acyclovir.....200 mg orally five times a day for 7-10 days, OR
Famciclovir.....250 mg orally three times a day for 7-10 days, OR
Valacyclovir.....1.0 g orally twice a day for 7-10 days

• HSV, Recommended Regimens for Episodic Recurrent Infection

Acyclovir.....400 mg orally three times a day for 5 days, OR
Acyclovir.....800 mg orally twice a day for 5 days, OR
Acyclovir.....800 mg orally three times a day for 2 days, OR
Famciclovir.....125 mg orally twice a day for 5 days, OR
Famciclovir.....1000 mg orally twice a day for 1 day, OR
Valacyclovir.....500 mg orally twice a day for 3 days
Valacyclovir.....1.0 g orally once a day for 5 days

• HSV, Recommended Regimens for Daily Suppressive Therapy

Acyclovir.....400 mg orally twice a day, OR
Famciclovir.....250 mg orally twice a day, OR
Valacyclovir.....500 mg orally once a day, OR
Valacyclovir.....1.0 g orally once a day

- Valacyclovir 500 mg once a day appears less effective than other valacyclovir dosing regimens in patients who have very frequent recurrences (i.e., >10 episodes per year)

- Valacyclovir and famciclovir appear to be comparable to acyclovir in clinical outcome

Severe Disease: IV therapy should be provided for patients who have severe disease or complications necessitating hospitalization, such as disseminated infection, pneumonitis, hepatitis, or complications of the central nervous system (e.g., meningitis or encephalitis)

• HSV, Recommended Regimen for Persons with Severe Disease

Acyclovir.....5-10 mg/kg body weight IV every 8 hours for 2-7 days until clinical resolution is attained followed by oral therapy to complete 10 days total therapy

Special Considerations:

• Pregnancy

- Available data do not indicate an increased risk for major birth defects in women treated with acyclovir in the first trimester
- Safety of acyclovir, valacyclovir, and famciclovir Rx in pregnant women not established

• *Perinatal Infection*

- The risk for transmission to the neonate from an infected mother is high (30% - 50%) among women who acquire genital herpes near the time of delivery and is low (<1%) among women who have a history of recurrent herpes at term and women who acquire genital HSV during the first half of pregnancy
- Therefore, prevention of neonatal herpes should emphasize prevention of acquisition of genital HSV infection during late pregnancy
- Susceptible women whose partners have oral or genital HSV infection, or those whose sex partners' infection status is unknown, should be counseled to avoid unprotected genital and oral sexual contact during late pregnancy
- At the onset of labor, all women should be examined and carefully questioned about whether they have symptoms of HSV. Infants of women who do not have symptoms or signs of HSV infection or its prodrome may be delivered vaginally
- Cesarean delivery does not completely eliminate the risk for HSV infection in the neonate but is recommended in presence of any lesions (1% recurrent)

GRANULOMA INGUINALE (DONOVANOSIS) (gran-u-LO-ma in-gwi-NAL-e, don-o-van-O-sis)

Organism: *Klebsiella granulomatis*, formerly known as *Calymmatobacterium granulomatis*, is an intracellular, gram-negative bacterium. It is seen rarely in the USA. Presents as a painless, progressive, vascular, ulcerative lesion with regional lymphadenopathy

Diagnosis: Visualization of Donovan bodies from tissue of lesion or biopsy

Treatment: Appears to halt progressive destruction of tissue. Prolonged duration of therapy often required to enable granulation and re-epithelialization of the ulcers. Therapy should be continued at least 3 weeks and until all lesions have healed completely

• *Granuloma Inguinale, Recommended Regimens*

Doxycycline.....100 mg orally twice a day for a minimum of 3 weeks

• *Granuloma Inguinale, Alternative Regimens*

Trimethoprim-sulfamethoxazole.....One double-strength tablet orally twice a day for a minimum of 3 weeks, OR

Ciprofloxacin.....750 mg orally twice a day for a minimum of 3 weeks, OR

Erythromycin base.....500 mg orally four times a day for a minimum of 3 weeks (for use during pregnancy), OR

Azithromycin.....1 g orally per week for at least 3 weeks

NOTE: For any of the above regimens, the addition of an aminoglycoside (gentamicin 1 mg/kg IV every 8 hours) should be considered if lesions do not respond within the first few days of therapy

LYMPHOGRANULOMA VENEREUM (LGV) (lim-fo-gran-u-LO-ma ve-nar-E-um)

This is most frequently manifested in heterosexuals as unilateral tender inguinal nodes and in women and homosexual men with proctocolitis, or inflammatory involvement or perirectal or perianal fistulas or strictures

Organism: Invasive strains L1, L2, or L3 of *Chlamydia trachomatis*

Diagnosis: Serological and exclusion of other ulcerative lesions or those with lymphadenopathy.

Treatment: Treatment cures infection and prevents ongoing tissue damage, although tissue reaction can result in scarring. Buboos may require aspiration through intact skin or incision and drainage to prevent the formation of inguinal/femoral ulcerations.

• **LGV, Recommended Regimen**

Doxycycline.....100 mg orally twice a day for 21 days OR

• **Alternative Regimen**

Erythromycin base.....500 mg orally four times a day for 21 days

SYPHILIS (SIF-i-lis)

Organism: *Treponema pallidum* (tre-po-NE-ma PAL-e-dum)

Diagnosis: See most recent CDC Guidelines or *Contraceptive Technology*

Treatment:

- Parenteral penicillin G is preferred drug for Rx of all stages of syphilis. The preparation(s) used (i.e., benzathine, aqueous procaine, or aqueous crystalline), the dosage, and the length of Rx depend on the stage and clinical manifestations of disease
- Parenteral penicillin G is the only therapy with documented efficacy for syphilis during pregnancy. Patients who report a penicillin allergy, including pregnant women with syphilis in any stage and patients with neurosyphilis, should be desensitized and treated with penicillin
- The Jarisch-Herxheimer reaction is an acute febrile reaction often accompanied by headache, myalgia, and other symptoms that might occur within the first 24 hours after any therapy for syphilis; patients should be advised of this possible adverse reaction

PRIMARY, SECONDARY AND EARLY LATENT SYPHILIS

• **Recommended Regimen for Adults**

Benzathine penicillin G..... 2.4 million units IM in a single dose

Management Considerations: All patients who have syphilis should be tested for HIV infection. In areas in which the prevalence of HIV is high, patients who have primary syphilis should be retested for HIV after 3 months if the first HIV test result was negative

Follow-up: Serologic test titers may decline more slowly for patients who previously had syphilis. Patients should be reexamined clinically and serologically at both 6 months and 12 months; also see complete *2006 CDC Guidelines* for more detail

Management of Sex Partners: *Sexual transmission of T. pallidum has occurred only when mucocutaneous syphilitic lesions are present;* such manifestations are uncommon after the first year of infection. However, persons exposed sexually to a patient who has syphilis in any stage should be evaluated clinically and, according to CDC, serologically

Special Considerations

- **Penicillin Allergy:** Nonpregnant penicillin-allergic patients who have primary or secondary syphilis should be treated with one of the following regimens. Close follow-up of such patients is essential. Limited clinical studies suggest that ceftriaxone may be effective for early syphilis. The optional dose and duration of therapy have not been defined, however, some specialists recommend 1 gm daily IM or IV for 8-10 days
-

• **Recommended Regimens**

Doxycycline.....100 mg orally twice a day for 2 weeks, OR

Tetracycline.....500 mg orally four times a day for 2 weeks

- Pregnant patients who are allergic to penicillin should be desensitized, if necessary, and treated with penicillin.
-

LATENT SYPHILIS:

See most recent CDC Guidelines

TERTIARY SYPHILIS:

See most recent CDC Guidelines

DISEASES CHARACTERIZED BY URETHRITIS AND CERVICITIS

Management of Patients Who Have Nongonococcal Urethritis

Diagnosis: Testing for chlamydia and gonorrhea is strongly recommended because of the increased utility and availability of highly sensitive and specific testing methods and because a specific diagnosis might improve compliance and partner notification

Treatment:

• **Nongonococcal Urethritis, Recommended Regimens**

Azithromycin.....1 g orally in a single dose, OR
Doxycycline.....100 mg orally twice a day for 7 days

• **Nongonococcal Urethritis, Alternative Regimens**

Erythromycin base.....500 mg orally four times a day for 7 days, OR
Erythromycin ethylsuccinate....800 mg orally four times a day for 7 days, OR
Ofloxacin.....300 mg twice a day for 7 days, OR
Levofloxacin.....500 mg orally once daily for 7 days

Follow-up: If symptoms persist, patients should be instructed to return for reevaluation and to abstain from sexual intercourse even if they have completed the prescribed therapy

Partner Referral: Patients should refer all sex partners within the preceding 60 days for evaluation and treatment

• **Recurrent/Persistent Urethritis, Recommended Treatment**

Retreat with initial regimen if noncompliant or reexposed. Otherwise, do culture for T. vaginalis
Metronidazole.....2 g orally in a single dose, OR
Tinidazole.....2 g orally in single dose, OR
Azithromycin.....1 g orally in a single dose (if not used initially)

CHLAMYDIAL INFECTION IN ADOLESCENTS AND ADULTS

Several important sequelae can result from *Chlamydia trachomatis* (kla-MID-e-a tra-KO-ma-tis) infection in women; the most serious of these include PID, ectopic pregnancy, and infertility. Some women who have apparently uncomplicated cervical infection already have subclinical upper reproductive tract infection. Chlamydial infection is much more common in women under age 25 than in older women. Asymptomatic older women need not be screened unless they have risk factors (e.g. new partner), but sexually-active young women should be.

Diagnosis: See complete 2006 CDC Guidelines

Treatment:

- Treatment of infected patients prevents transmission to sex partners and, for infected pregnant women, might prevent transmission to infants during birth
- Treatment of sex partners helps to prevent reinfection of the index patient and infection of other partners
- Coinfection with *C. trachomatis* often occurs among patients who have gonococcal infection; therefore, presumptive treatment of such patients for chlamydia is appropriate (see GONOCOCCAL INFECTION, Dual Therapy for Gonococcal and Chlamydial Infection, p 153)
- The following recommended treatment regimens and the alternative regimens cure infection and usually relieve symptoms:

• **Chlamydia Infection, Recommended Regimens**

Azithromycin.....1 g orally in a single dose, OR (equally effective)
Doxycycline.....100 mg orally twice a day for 7 days

• **Chlamydia Infection, Alternative Regimens**

Erythromycin base.....500 mg orally four times a day for 7 days, OR
Erythromycin ethylsuccinate...800 mg orally four times a day for 7 days, OR
Ofloxacin.....300 mg orally twice a day for 7 days, OR
Levofloxacin.....500 mg orally once daily for 7 days

Follow-up: Patients do not need to be retested for chlamydia after completing treatment with doxycycline or azithromycin unless symptoms persist or reinfection is suspected because these therapies are highly efficacious. Rescreening is recommended for chlamydia infection 3 months after treatment due to high prevalence of reinfection, especially for adolescents

Management of Sex Partners: Patients should be instructed to refer their sex partners for evaluation, testing, and treatment, if they had sexual contact with the patient during the 60 days preceding onset of symptoms in the patient or diagnosis of chlamydia, and the most recent contact should be tested even if > 60 days ago

Special Considerations:

• **Pregnancy:**

- Doxycycline, ofloxacin and levofloxacin are contraindicated for pregnant women
 - Clinical experience and studies suggest azithromycin is safe and effective
 - Repeat testing, preferably NAAT, 3 weeks after completion of therapy with the following regimens is recommended because a) sequelae to mom and infant b) frequent side effects of erythromycin may discourage patient compliance
-

• **Recommended Regimens for Pregnant Women**

Azithromycin.....1 g orally in single dose OR
Amoxicillin.....500 mg orally three times a day for 7 days.

• **Alternative Regimens for Pregnant Women**

Erythromycin base.....500 mg orally four times a day for 7 days, OR
Erythromycin base.....250 mg orally four times a day for 14 days, OR
Erythromycin ethylsuccinate.....800 mg orally four times a day for 7 days, OR
Erythromycin ethylsuccinate.....400 mg orally four times a day for 14 days, OR

NOTE: Erythromycin estolate is contraindicated during pregnancy because of drug-related hepatotoxicity.

GNOCOCCAL INFECTION

DUAL THERAPY FOR GNOCOCCAL AND CHLAMYDIAL INFECTIONS

Patients infected with *N. gonorrhoeae* often are coinfecting with *C. trachomatis*; this finding led to the recommendation that patients treated for gonococcal infection also be treated routinely with a regimen effective against uncomplicated genital *C. trachomatis* infection. CDC no longer recommends use of fluoroquinolones for treatment of gonococcal infections or PID ◀

Uncomplicated Gonococcal Infections of the Cervix, Urethra, and Rectum

• **Recommended Regimens** ◀

Cefixime.....400 mg orally in a single dose or 400 mg by suspension (200mg/5ml)
Ceftriaxone.....125 mg IM in a single dose, AND

TREATMENT FOR CHLAMYDIA IF CHLAMYDIAL INFECTION NOT RULED OUT

Azithromycin.....1 g orally in a single dose, if chlamydia not ruled out OR
Doxycycline.....100 mg orally twice a day for 7 days, if chlamydia not ruled out

Uncomplicated Gonococcal Infections of the Cervix, Urethra, and Rectum**• Alternative Regimens**

Spectinomycin.....2 g IM in a single dose. Spectinomycin is currently not available in the U.S. ←

Single-dose cephalosporin....regimens other than ceftriaxone 125 mg IM and cefixime 400 mg include a) ceftizoxime 500 mg IM, b) cefotaxime 500 mg IM, and c) cefoxitin 2 g IM with probenecid 1 g orally

- Many other antimicrobials are active against *N. gonorrhoeae*
- Azithromycin 2 g orally is effective against uncomplicated gonococcal infection, but it is expensive and causes gastrointestinal distress
- An oral dose of 1 g azithromycin is not recommended

Uncomplicated Gonococcal Infection of the Pharynx

- Gonococcal infections of the pharynx are more difficult to eradicate than infections at urogenital and anorectal sites
 - Few antigonococcal regimens can reliably cure such infections >90% of the time
 - Although chlamydial coinfection of the pharynx is unusual, coinfection at genital sites sometimes occurs. Therefore, treatment for both gonorrhea and chlamydia is suggested
-

• Recommended Regimen ←

Ceftriaxone.....125 mg IM in a single dose, PLUS

TREATMENT FOR CHLAMYDIA IF CHLAMYDIA INFECTION NOT RULED OUT

Doxycycline.....100 mg orally twice a day for 7 days, if chlamydia not ruled out

Management of Sex Partners: All sex partners of patients who have *N. gonorrhea* infection should be evaluated and treated for *N. gonorrhea* and *C. trachomatis* infections if their last sexual contact with the patient was within 60 days before onset of symptoms or diagnosis. Most recent should be notified even if > 60 days prior

Special Considerations:

- Pregnant women should not be treated with quinolones or tetracyclines
- Pregnant women infected with *N. gonorrhoeae* should be treated with a recommended or alternate cephalosporin
- Women who cannot tolerate a cephalosporin should be administered a single 2-g dose of spectinomycin IM
- Either azithromycin or amoxicillin is recommended for treatment of presumptive or diagnosed *C. trachomatis* infection during pregnancy (see CHLAMYDIAL INFECTION, p. 152)

DISEASES CHARACTERIZED BY VAGINAL DISCHARGE

Have Vaginal Infections:

- Vaginitis is usually characterized by a vaginal discharge or vulvar itching and irritation; a vaginal odor may be present
- The three diseases most frequently associated with vaginal discharge are trichomoniasis (caused by *T. vaginalis*), BV (caused by a replacement of the normal vaginal flora by an overgrowth of anaerobic microorganisms and *Gardnerella vaginalis*), and candidiasis (usually caused by *Candida albicans*)
- Mucopurulent cervicitis caused by *C. trachomatis* or *N. gonorrhoeae* can sometimes cause vaginal discharge
- Vaginitis is diagnosed by pH and microscopic examination of fresh samples of the discharge
- The pH of the vaginal secretions can be determined by narrow-range pH paper for the elevated pH typical of BV or trichomoniasis (i.e., pH of >4.5)
- One way to examine the discharge is to dilute a sample in one to two drops of 0.9% normal saline solution on one slide and 10% potassium hydroxide (KOH) solution on a second slide. Always prepare saline slide first
- An amine odor detected immediately after applying KOH suggests BV
- A cover slip is placed on each slide, which is then examined under a microscope at low and high-dry power. The motile *T. vaginalis* or the clue cells of BV usually are identified easily in the saline specimen
- The yeast or pseudohyphae of *Candida* species are more easily identified in the KOH specimen
- The presence of objective signs of vulvar inflammation in the absence of vaginal pathogens, along with a minimal amount of discharge, suggests the possibility of mechanical, chemical, allergic, or other noninfectious irritation of the vulva
- Culture for *T. vaginalis* is more sensitive than microscopic examination
- Laboratory testing fails to identify the cause of vaginitis among a minority of women

BACTERIAL VAGINOSIS (BV)

- BV is a clinical syndrome resulting from replacement of the normal H₂O₂ producing *Lactobacillus* sp. in the vagina with high concentrations of anaerobic bacteria (e.g., *Prevotella* sp. and *Mobiluncus* sp.), *G. vaginalis*, and *Mycoplasma hominis*
- BV is the most prevalent cause of vaginal discharge or malodor
- Half of women whose illnesses meet the clinical criteria for BV are asymptomatic
- Treatment of male sex partner has not been beneficial in preventing recurrence

Diagnostic Considerations: BV can be diagnosed by the use of clinical criteria meeting three of the following symptoms or signs:

- a. A homogeneous, white, noninflammatory discharge that smoothly coats the vaginal walls
- b. The presence of clue cells on microscopic examination
- c. A pH of vaginal fluid >4.5
- d. A fishy odor of vaginal discharge before or after addition of 10% KOH (i.e., the whiff test)

Treatment: The principal goal of therapy in nonpregnant women is to relieve vaginal symptoms and signs of infection. All women **with** symptoms require treatment, regardless of pregnancy status

• *BV, Recommended Regimens for Nonpregnant Women*

Metronidazole.....500 mg orally twice a day for 7 days, OR

Clindamycin cream.....2%, one full applicator (5 g) intravaginally at bedtime for 7 days OR

Metronidazole gel.....0.75%, one full applicator (5 g) intravaginally, once daily for 5 days OR

- Patients should be advised to avoid consuming alcohol during treatment with metronidazole and for 24 hours thereafter. Clindamycin cream is oil-based and might weaken latex condoms and diaphragms for 5 days after use

• **BV, Alternative Regimens**

Clindamycin.....300 mg orally bid x 7 days OR

Clindamycin ovules.....100 mg intravaginally qhs x 3 days

Recommended metronidazole regimens are equally efficacious. The vaginal clindamycin cream appears to be less efficacious than the metronidazole regimens

- Metronidazole 2 g single-dose therapy is an alternative regimen because of its lower efficacy for BV
- FDA has approved both metronidazole 750-mg extended release tablets once daily for 7 days and a single dose of clindamycin vaginal cream. However, data concerning clinical equivalency of these regimens with other regimens have not been published.

Follow-up: Follow-up visits are unnecessary if symptoms resolve. Recurrence is not unusual

- Because treatment of BV in high-risk pregnant women who are asymptomatic might prevent adverse pregnancy outcomes, a follow-up evaluation, at 1 month after completion of treatment, should be considered

Management of Sex Partners: Routine treatment of sex partners is not recommended

Special Considerations:

- **Allergy or Intolerance to the Recommended Therapy:**

- Clindamycin cream is preferred in case of allergy or intolerance to metronidazole. Metronidazole gel can be considered for patients who do not tolerate systemic metronidazole, but patients allergic to oral metronidazole should not be administered metronidazole vaginally

- **Pregnancy:**

- BV has been associated with adverse pregnancy outcomes (i.e., premature rupture of the membranes, preterm labor, and preterm birth)
- Organisms found in increased concentration in BV also are frequently present in postpartum or post-cesarean endometritis
- Treat all symptomatic pregnant women when diagnosed
- Treatment of BV in high-risk pregnant women (i.e., those who have previously delivered a premature infant) who are asymptomatic might reduce preterm delivery. However, the optimal treatment regimens have not been established. Some specialists screen and treat those with BV at first prenatal visit and prefer oral therapy
- The recommended regimen is metronidazole 250 mg orally three times a day for 7 days OR metronidazole 500 mg orally twice a day for 7 days OR clindamycin 300 mg orally twice daily for 7 days
- Low-risk pregnant women (i.e., those who previously have not had a premature delivery) who have symptomatic BV should be treated to relieve symptoms.
- Data are limited concerning the use of metronidazole vaginal gel during pregnancy. Use of clindamycin vaginal cream during the second half of pregnancy is not recommended because three randomized trials indicated an increase in adverse events
- Multiple studies have not demonstrated an association between metronidazole use during pregnancy and teratogenicity in newborns

Other: The bacterial flora that characterize BV have been recovered from the endometria and salpings of women who have PID

TRICHOMONIASIS

Diagnosis:

- Trichomoniasis is caused by the protozoan *T. vaginalis*, easily identified on a wet smear
Most men who are infected do not have symptoms of infection, although a minority of men have nongonococcal urethritis
- Many women do have symptoms of infection, characteristically a diffuse, malodorous, yellow-green discharge with vulvar irritation; many women have fewer symptoms
- Vaginal trichomoniasis might be associated with adverse pregnancy outcomes, particularly premature rupture of the membranes and preterm delivery

Treatment:

• **Trichomoniasis, Recommended Regimen**

Metronidazole.....2 g orally in a single dose, OR

Tinidazole.....2 g orally in a single dose

• **Trichomoniasis, Alternative Regimen**

Metronidazole.....500 mg twice a day for 7 days

- In randomized clinical trials, the recommended metronidazole and tinidazole regimens have resulted in cure rates of approximately 90% - 95%; ensuring treatment of sex partners might increase the cure rate. Treatment of patients and sex partners results in relief of symptoms, microbiologic cure, and reduction of transmission
- Metronidazole gel is < 50% effective
- Patients should be advised to avoid alcohol through 24 hours after completion of Rx with metronidazole and 72 hours after Rx with tinidazole

Follow-up:

- Unnecessary for men and women who become asymptomatic after treatment or who are initially asymptomatic
- Infections with strains of *T. vaginalis* that have diminished susceptibility to metronidazole can occur; however, most of these organisms respond to higher doses of metronidazole or tinidazole
- If treatment failure occurs with metronidazole, the patient should be retreated with metronidazole 500 mg twice a day for 7 days or tinidazole
- If treatment failure occurs repeatedly, the patient should be treated with a single, 2g dose of metronidazole or tinidazole once a day for 3-5 days

Management of Sex Partners: Routine Rx recommended avoid intercourse until Rx is complete and both partners are asymptomatic

Special Considerations:

- **Allergy, Intolerance, or Adverse Reactions:** Effective alternatives to therapy with metronidazole or tinidazole are not available. Patients who are allergic to this class of drugs can be managed by desensitization
- **Pregnancy:** Patients may be treated with 2 g of metronidazole in a single dose; see guidelines
- **HIV Infection:** Patients who have trichomoniasis and also are infected with HIV should receive the same treatment regimen as those who are HIV negative

VULVOVAGINAL CANDIDIASIS (VVC)

- Vulvovaginal yeast infections are caused by *C. albicans* or, occasionally, by other *Candida* sp. or other yeasts
- An estimated 75% of women will have at least one episode of VVC
- Typical symptoms of VVC include pruritus and vaginal discharge
- Other symptoms may include vaginal soreness, vulvar burning, dyspareunia, and external dysuria
- None of these symptoms is specific for VVC

Diagnostic Considerations:

- A diagnosis of *Candida* vaginitis is suggested clinically by pruritus and erythema in the vulvo-vaginal area; a white discharge may occur, as may vulvar edema
- The diagnosis can be made in a woman who has signs and symptoms of vaginitis, and when either a) a wet preparation or Gram stain of vaginal discharge demonstrates yeasts or pseudohyphae or b) a culture or other test yields a positive result for a yeast species
- If culture cannot be done and KOH test is negative, empiric Rx can be considered for symptomatic women
- *Candida* vaginitis is associated with a normal vaginal pH (<4.5)
- Use of 10% KOH in wet preparations improves the visualization of yeast and mycelia by disrupting cellular material that might obscure the yeast or pseudohyphae
- Identifying *Candida* by culture in the absence of symptoms should not lead to treatment because 10%-20% of women usually harbor *Candida* sp. and other yeasts in the vagina. VVC can occur concomitantly with STIs

Treatment: Topical formulations effectively treat VVC. The topically applied azole drugs are more effective than nystatin. Treatment with azoles results in relief of symptoms and negative cultures among 80%-90% of patients who complete therapy

• VVC, Recommended Regimens

• Intravaginal agents:

Butoconazole*2% cream 5 g intravaginally for 3 days, OR
Butoconazole.....	2% cream 5g (butoconazole 1-sustained release), single vaginal application
Clotrimazole*1% cream 5 g intravaginally for 7-14 days, OR
Clotrimazole.....	100-mg vaginal tablet for 7 days, OR
Clotrimazole.....	100-mg vaginal tablet, two tablets for 3 days, OR
Miconazole*2% cream 5 g intravaginally for 7 days, OR
Miconazole*200-mg vaginal suppository, one suppository for 3 days, OR
Miconazole*100-mg vaginal suppository, one suppository for 7 days, OR
Miconazole*1200-mg vaginal suppository, one time dose, OR
Nystatin.....	100,000-u vaginal tablet, one tablet for 14 days, OR
Tioconazole*6.5% ointment 5 g intravaginally in a single application, OR
Terconazole.....	0.4% cream 5 g intravaginally for 7 days, OR
Terconazole.....	0.8% cream 5 g intravaginally for 3 days, OR
Terconazole.....	80-mg vaginal suppository, one suppository for 3 days, OR
• Oral agent:	
Fluconazole.....	150-mg oral tablet, one tablet in single dose.

*** Over-the-counter preparations**

These creams and suppositories are oil-based and may weaken latex condoms and diaphragms

Follow-up: Patients should be instructed to return for follow-up visits only if symptoms persist or recur

Management of Sex Partners: None; VVC usually is not acquired through sexual intercourse

Special Considerations:

- **Pregnancy:** VVC often occurs during pregnancy. Only topical azole therapies applied for 7 days should be used to treat pregnant women.
- **HIV Infection:** Based on available evidence, therapy is same as seronegative women

PELVIC INFLAMMATORY DISEASE (PID) (see Table 13.1, page 39)

- PID comprises a spectrum of inflammatory disorders of the upper female genital tract, including any combination of endometritis, salpingitis, tuboovarian abscess, and pelvic peritonitis
- Sexually transmitted organisms, especially *N. gonorrhoeae* and *C. trachomatis*, are implicated in most cases; however, microorganisms that can be part of the vaginal flora (e.g., anaerobes, *G. vaginalis*, *H. influenzae*, enteric gram negative rods, and *Streptococcus agalactiae*) also can cause PID
- In addition, CMV, *M. hominis* and *U. urealyticum* may also be etiologic agents

Diagnostic Considerations: See complete 2006 CDC Guidelines (www.cdc.gov). Empiric treatment should be initiated in sexually active young women and others at risk for STIs if they are experiencing pelvic or lower abdominal pain, if no other cause can be identified and if **ONE** of the following minimum criteria are present on pelvic exam:

- cervical motion tenderness **OR**
- uterine tenderness **OR**
- adnexal tenderness

Treatment: Must provide empiric, broad-spectrum coverage of likely pathogens
Antimicrobial coverage should include *N. gonorrhoea*, *C. trachomatis*

- Suggested criteria for **HOSPITALIZATION** decision based on discretion of HCP
- Surgical emergencies such as appendicitis cannot be excluded
 - Patient is pregnant
 - Patient does not respond clinically to oral antimicrobial therapy
 - Patient is unable to follow or tolerate an outpatient oral regimen
 - Patient has severe illness, nausea and vomiting, or high fever
 - Patient has a tuboovarian abscess

PID, Parenteral Regimen A

Cefotetan.....	2 g IV every 12 hours, OR
Cefoxitin.....	2 g IV every 6 hours, PLUS
Doxycycline.....	100 mg IV or orally every 12 hours

- Because of pain associated with infusion, doxycycline should be administered orally when possible, even when the patient is hospitalized
- Both oral and IV administration of doxycycline provide similar bioavailability
- When tuboovarian abscess is present, many health-care providers use clindamycin or metronidazole with doxycycline for continued therapy rather than doxycycline alone, because it provides more effective anaerobic coverage

• **PID, Parenteral Regimen B**

Clindamycin.....900 mg IV every 8 hours, **PLUS**

Gentamicin.....loading dose IV or IM (2 mg/kg of body weight) followed by a maintenance dose (1.5 mg/kg) every 8 hours. Single daily dosing may be substituted.

- Although use of a single daily dose of gentamicin has not been evaluated for the treatment of PID, it is efficacious in analogous situations
 - Parenteral therapy may be discontinued 24 hours after a patient improves clinically, and continuing oral therapy should consist of doxycycline 100 mg orally twice a day or clindamycin 450 mg orally four times a day to complete a total of 14 days of therapy
 - When tuboovarian abscess is present, many healthcare providers use clindamycin for continued therapy rather than doxycycline because clindamycin provides more effective anaerobic coverage
-

• **PID, Alternative Parenteral Regimens:** Limited data support the use of other parenteral regimens, but the following has been investigated in at least one clinical trial, and it has broad-spectrum coverage.

Ampicillin/Sulbactam.....3 g IV every 6 hours, **PLUS** doxycycline 100 mg IV / orally every 12 hours **OR**

Oral Treatment: Can be considered for mild to moderately severe acute PID. Patients who do not respond to oral therapy within 72 hours should be reevaluated to confirm the diagnosis and be administered parenteral therapy on either an outpatient or inpatient basis.

• **PID, Recommended Oral Regimen**

Ceftriaxone.....250 mg IM once, **OR**

Cefoxitin.....2 g IM plus probenecid, 1 g orally in a single dose concurrently once, **OR**

Other parenteral third-generation cephalosporin (e.g., ceftriaxone or cefotaxime), **PLUS**

Doxycycline.....100 mg orally twice a day for 14 days with or without metronidazole 500 mg orally twice daily for 14 days.

• **PID, Alternative Oral Regimens:** If parenteral cephalosporin therapy is not feasible, use of fluoroquinolones (levofloxacin 500 mg orally once daily or ofloxacin 400 mg twice daily for 14 days) with or without metronidazole (500 mg orally twice daily for 14 days) may be considered if the community prevalence and individual risk (see “Gonococcal Infections in Adolescents and Adults” in Sexually Transmitted Disease Treatment Guidelines, 2006) of gonorrhea is low. Tests for gonorrhea must be performed prior to instituting therapy and the patient managed as follows if the test is positive:

- If NAAT test is positive, parenteral cephalosporin is recommended
 - If culture for gonorrhea is positive, treatment should be based on results of antimicrobial susceptibility. If isolate is QRNG, or antimicrobial susceptibility can't be assessed, parenteral cephalosporin is recommended
-

Follow-up:

- Patients receiving oral or parenteral Rx should demonstrate substantial clinical improvement (i.e., defervescence; reduction in direct or rebound abdominal tenderness; and reduction in uterine, adnexal, and Cx motion tenderness) within 3 days after initiation of Rx
- Patients who do not improve within 3 days usually require additional diagnostic tests, surgical intervention, or both

Special Considerations:

- **Pregnancy:** Pregnant women who have suspected PID should be hospitalized and

160 treated with parenteral antibiotics.

HUMAN PAPILLOMAVIRUS INFECTION (HPV)

Genital Warts: Vaccine now available. See page 145

- More than 30 types of HPV can infect the genital tract. Most HPV infections are asymptomatic, subclinical, or unrecognized. Visible genital warts usually are caused by HPV types 6 or 11. Other HPV types in the anogenital region (i.e., types 16, 18, 31, 33, and 35) have been strongly associated with cervical dysplasia
- HPV types 16, 18, 31, 33, and 35 are found occasionally in visible genital warts and have been associated with external genital (i.e., vulvar, penile, and anal) squamous intraepithelial neoplasia (i.e., squamous cell carcinoma in situ, bowenoid papulosis, erythroplasia of Queyrat, or Bowen's disease of the genitalia). These HPV types have been associated with vaginal, anal, and cervical intraepithelial dysplasia and squamous cell carcinoma. Patients who have visible genital warts can be infected simultaneously with multiple HPV types

Treatment:

- The primary goal of treating visible genital warts is the removal of symptomatic warts
- Treatment can induce wart-free periods in most patients. Genital warts often are asymptomatic
- **No evidence indicates that currently available treatments eradicate or affect the natural history of HPV infection.** The removal of warts may or may not decrease infectivity
- If left untreated, visible genital warts may resolve on their own, remain unchanged, or increase in size or number. No evidence indicates that presence of visible warts or their treatment is associated with the development of cervical cancer

Regimens:

- Treatment of genital warts should be guided by the patient's preference, the available resources, and the experience of the health-care provider.
- None of the available treatments is superior to other treatments, and no single treatment is ideal for all circumstances. The treatment modality should be changed if a patient has not improved substantially. The majority respond within 3 months of therapy

• External Genital Warts, Recommended Treatments:

• Patient-Applied

Podofilox.....0.5% solution or gel OR

Imiquimod.....5% cream

- Patients may apply **podofilox** solution with a cotton swab, or podofilox gel with a finger, to visible genital warts twice a day for 3 days, followed by 4 days of no therapy
- This cycle may be repeated as necessary for a total of four cycles
- The total wart area treated should not exceed 10 cm², and a total volume of podofilox should not exceed 0.5 mL per day
- If possible, the health-care provider should apply the initial treatment to demonstrate the proper application technique and identify which warts should be treated.
- The safety of podofilox during pregnancy has not been established.
- Patients should apply **imiquimod** cream with a finger at bedtime, three times a week for as long as 16 weeks
- The treatment area should be washed with mild soap and water 6-10 hours after the application
- The safety of imiquimod during pregnancy has not been established

- **Provider-Administered:**

Cryotherapy with liquid nitrogen or cryoprobe. Repeat applications every 1 to 2 weeks **OR** Trichloroacetic acid (TCA) or BCA 80%-90%. May place petroleum jelly around wart to reduce spread of medication to normal mucosa. Apply a small amount only to warts and allow to dry, at which time a white "frosting" develops; powder with talc or NaHCO₃ to remove unreacted acid if an excess amount is applied. Repeat weekly if necessary. **OR** Podophyllin resin.....10%-25% in tincture of benzoin

- A small amount should be applied to each wart and allowed to air dry
- To avoid the possibility of complications associated with systemic absorption and toxicity, application should be limited to <0.5 mL of podophyllin or <10 cm² of warts per session and no open wounds should exist nearby
- Some experts suggest that the preparation should be thoroughly washed off 1-4 hours after application to reduce local irritation. Repeat weekly if necessary
- *The safety of podophyllin during pregnancy has not been established*
- *Surgical removal* by tangential scissor excision, tangential shave excision, curettage, or electrosurgery

- **External Genital Warts, Alternative Treatments (Provider administered)**

Intra-lesional interferon **OR**

Laser surgery

- **Cervical Warts**

For women who have exophytic cervical warts, high-grade squamous intraepithelial lesions (SIL) must be excluded before treatment is begun. Management of exophytic cervical warts should include consultation with an expert

- **Vaginal Warts, Recommended Treatment**

Cryotherapy with liquid nitrogen. The use of a cryoprobe in the vagina is not recommended because of the risk for vaginal perforation and fistula formation. **OR** TCA or BCA 80%-90% applied only to warts. Repeat weekly if necessary.

- **Urethral Meatus Warts, Recommended Treatment**

Cryotherapy with liquid nitrogen **OR**

Podophyllin 10%-25% in tincture of benzoin. The treatment area must be dry before contact with normal mucosa. Podophyllin may be applied weekly if necessary. *The safety of podophyllin during pregnancy has not been established.*

- **Anal Warts, Recommended Treatment**

Cryotherapy with liquid nitrogen **OR**

TCA or BCA 80%-90% applied to warts. Apply a small amount only to warts and allow to dry, at which time a white "frosting" develops; powder with talc or sodium bicarbonate (i.e., baking soda) to remove unreacted acid if an excess amount is applied. Repeat weekly if necessary. May place petroleum jelly around wart to reduce spread of medication to normal mucosa **OR**

Surgical removal

- Management of warts on rectal mucosa should be referred to an expert

Follow-up: After visible genital warts have cleared, a follow-up might be helpful

Management of Sex Partners: None. Examination of sex partners is not necessary for the management of genital warts because the role of reinfection is probably minimal and, in the absence of curative therapy, treatment to reduce transmission is not realistic

Special Considerations:

- **Pregnancy:** Imiquimod, podophyllin, and podofilox should not be used during pregnancy. Because genital warts can proliferate and become friable during pregnancy, many experts advocate their removal during pregnancy. HPV types 6 and 11 can cause laryngeal papillomatosis in infants and children. Vaginal delivery not contraindicated unless lesion size obstructive in labor (rare) or would result in excessive bleeding. The route of transmission (i.e., transplacental, perinatal, or postnatal) is not completely understood

VACCINE-PREVENTABLE STIs

One of the most effective means of preventing the transmission of STIs is preexposure immunization. Currently licensed vaccines for the prevention of STIs include those for hepatitis A and hepatitis B. Clinical development and trials are underway for vaccines against a number of other STIs, including HIV and HSV. As more vaccines become available, immunization possibly will become one of the most widespread methods used to prevent STIs. Quadrivalent HPV (6, 11, 16, 18) vaccine could prevent 90% of genital warts in young women who receive it prior to sexual exposure. ←

ECTOPARASITIC INFECTIONS

PEDICULOSIS PUBIS

Patients who have pediculosis pubis (i.e., pubic lice) usually seek medical attention because of pruritus. Such patients also usually notice lice or nits on their pubic hair. Usually sexually transmitted

Treatment:

- **Pediculosis Pubis, Recommended Regimens**

Permethrin.....1% creme rinse applied to affected areas and washed off after 10 minutes **OR**

Pyrethrins with piperonyl butoxide applied to the affected area and washed off after 10 minutes.

See 2006 guidelines for alternative regimens

Other Management Considerations:

- The recommended regimens should not be applied to the eyes. Pediculosis of the eyelashes should be treated by applying occlusive ophthalmic ointment to the eyelid margins twice a day for 10 days
- Bedding and clothing should be decontaminated (either machine-washed and machine-dried using the heat cycle or drycleaned) or removed from body contact for at least 72 hrs
- Fumigation of living areas is not necessary

Follow-up: Patients should be evaluated after 1 week if symptoms persist. Retreatment may be necessary if lice are found or if eggs are observed at the hair/skin junction. Patients who do not respond to one of the recommended regimens should be retreated with an alternative regimen

Management of Sex Partners: Sex partners within the last month should be treated

Special Considerations:

- **Pregnancy:** Pregnant and lactating women should be treated with either permethrin or pyrethrins with piperonyl butoxide

SCABIES

- Predominant symptoms is pruritus; sensitization takes several weeks to develop; pruritus might occur within 24 hours after a subsequent reinfestation
- Scabies in adults may be sexually transmitted, although scabies in children usually is not

• **Scabies, Recommended Regimen**

Permethrin cream.....(5%) applied to all areas of the body from the neck down and washed off after 8-14 hours. **OR**

Ivermectin.....200 mcg/kg orally, repeated in 2 weeks

• **Scabies, Alternative Regimens**

Lindane.....(1%) 1 oz. of lotion or 30 g of cream applied thinly to all areas of the body from the neck down and thoroughly washed off after 8 hours

- Lindane should not be used immediately after a bath, and it should not be used by
 - a) persons who have extensive dermatitis, b) pregnant or lactating women, and
 - c) children aged <2 years. Not first-line because of toxicity

Other Management Considerations: Bedding and clothing should be decontaminated (i.e., either machine-washed or machine-dried using the hot cycle or dry-cleaned) or removed from body contact for at least 72 hours. Fumigation of living areas is unnecessary

Follow-up: Pruritus may persist for several weeks. Some experts recommend retreatment after 1-2 weeks for patients who are still symptomatic; other experts recommend retreatment only if live mites are observed. Patients who do not respond should be retreated with an alternative regimen

Management of Sex Partners and Household Contacts: Both sexual and close personal or household contacts within the preceding month should be examined and treated

SEXUAL ASSAULT AND STIs: Adults and Adolescents

Evaluation for Sexually Transmitted Infections

- **Initial Examination** - (See inside back cover)
- **Follow-up Examination after Assault**
 - Examination for STIs should be repeated 2 weeks after assault (see inside back cover)
 - Serologic tests for syphilis and HIV infection should be repeated 6, 12, and 24 weeks after the assault if initial test results were negative
- **Prophylaxis:** Many experts recommend routine preventive therapy after a sexual assault. The prophylactic regimen suggested is on inside back cover
- An empiric antimicrobial regimen for chlamydia, gonorrhea, trichomonas, and BV should be administered (See inside back cover)

Other Management Considerations:

At the initial examination and, if indicated, at follow-up, patients should be counseled about:

- Risk for pregnancy and possible use of emergency contraception
- Symptoms of STIs and the need for immediate examination if symptoms occur
- Abstinence from sexual intercourse until STI prophylactic treatment is completed

Risk for Acquiring HIV Infection:

- Although HIV antibody seroconversion has been reported among persons whose only known risk factor was sexual assault or sexual abuse, the risk for acquiring HIV infection through sexual assault is low and depends on many factors
- These factors may include the type of sexual intercourse (i.e., oral, vaginal, or anal); presence of oral, vaginal or anal trauma; site of exposure to ejaculate; viral load in ejaculate; and presence of an STI

HIV INFECTION

OraQuick, a rapid test (40-60 minutes) was approved by the FDA in November, 2002.

For entire guidelines see www.aidsinfo.nih.gov

Proper management of HIV infection involves a complex array of behavioral, psychosocial, and medical services. This information should not be a substitute for referral to a health-care provider or facility experienced in caring for HIV-infected patients. Hotlines:

CDC AIDS Treatment Information Service.....1-800-HIV-0440 (1-800-448-0440)

e-mail to: atis@hivatis.org & www.hivatis.org

CDC AIDS Clinical Trials Information Service...1-800-TRIALS-A (1-800-874-2572)

e-mail to: actis@actis.org International....1-301-519-0459

For general information and referrals to local facilities:

CDC National AIDS Hotline.....1-800-342-AIDS (1-800-342-2437)

Spanish.....1-800-344-7432

CDC National AIDS Clearinghouse.....1-800-458-5231

CDC Division of HIV/AIDS Prevention.....www.cdc.gov/hiv

Post exposure prophylaxis PEP.....1-888-HIV-4911

Pregnancy: All pregnant women should be offered HIV testing as early in pregnancy as possible. Birthing facilities delivering women who may not have had prenatal HIV testing should make rapid HIV testing available 24/7. This recommendation is particularly important because of the available treatments for reducing the likelihood of perinatal transmission and maintaining the health of the woman. HIV-infected women should be informed specifically about the risk for perinatal infection. Current evidence indicates that 15%-25% of infants born to untreated HIV-infected mothers are infected with HIV; the virus also can be transmitted from an infected mother by breastfeeding. Zidovudine (ZDV) reduces the risk for HIV transmission to the infant from approximately 25% to <2% through use of antiretroviral regimens and obstetric intervention and by avoiding breastfeeding. Therefore, **ZDV TREATMENT SHOULD BE OFFERED TO ALL HIV-INFECTED PREGNANT WOMEN.** Most women in the U.S. now receive triple therapy during pregnancy not just ZDV. In the United States, HIV-infected women should be advised not to breast-feed their infants. In other countries, the reduced risk of death from malnutrition, diarrheal disease, or other infections may outweigh the risk of contracting HIV.

Insufficient information is available regarding the safety of ZDV or other antiretroviral drugs during early pregnancy; however, on the basis of the ACTG-076 protocol, ZDV is indicated for the prevention of maternal-fetal HIV transmission as part of a regimen that includes oral ZDV at 14-34 weeks of gestation, intravenous (IV) ZDV during labor, and ZDV syrup to the neonate after birth.

EVALUATION & MANAGEMENT OF SEXUAL ASSAULT

National Domestic Violence Hotline: 1-800-799-SAFE • www.ndvh.org

Engage Rape Crisis Services. Have trained provider do the examination whenever possible. See SANE (Sexual Assault Nurse Evaluation), www.sane-sart.com



Legal: Report to authorities if required by your state.
Contact child protective services if victim is a minor



Obtain informed consent before history, physical and treatment



History: circumstances of assault, whether victim had loss of consciousness (may want to test for rohypnol), date/time/location, use of weapons etc, specifics re: oral, vaginal or anal contact, penetration, ejaculation or condom use, areas of trauma, bleeding by victim or assailant, recent consensual sexual activity before or after assault including condom use, LMP, contraceptive use, use of drugs or alcohol, whether victim showered, changed clothing etc.



Physical exam: document any trauma with photographs (and patient's consent). Woods lamp (UV) may help identify semen or other debris.
Forensic exam done with a special "evidence collection kit" includes victim's clothing, swabs of buccal mucosa, vagina, rectum, combed (and pulled) specimens from scalp and pubic hair, fingernail scrapings and clippings, blood sample etc. Assure proper chain of evidence to legal authorities. PE may also include specimens for pregnancy, HIV, Hep B, syphilis, sperm, BV, Trich, GC/CT and Herpes.



Treatment: Offer emergency contraception. Empiric RX for STIs: ceftriaxone 125mg IM plus azithromycin 1g PO or doxycycline 100mg PO BID x 7 days. Metronidazole 2g PO x 1 dose. HEP B vaccine if not immune and consider anti-retrovirals to decrease risk of HIV infection. Advise to abstain from intercourse until prophylaxis therapy completed and consider condom use until follow-up serologic testing complete (6 months)



Follow-up: Medical visit in 2 weeks. Ongoing psychosocial support and advocate services should be assessed. Do pregnancy test. Test for GC, CT, Trich and BV if woman declined prophylaxis or developed new symptoms or requests it. Follow-up tests for HIV and RPR at 6 weeks, 3 and 6 months

APPENDIX

www.cdc.gov

U.S. MEDICAL ELIGIBILITY CRITERIA FOR CONTRACEPTIVE USE (2010)

The table on the following pages summarizes the latest CDC medical eligibility criteria for starting contraceptives. These criteria are also the basis for the checklists throughout *Managing Contraception*. These criteria are mostly evidence-based. Please visit the CDC website to view the full document. There you will find more information on the evidence supporting category assignment as well as references.

CDC categories for temporary methods:

- CDC 1** **Can use** the method. No restriction on use.
- CDC 2** **Can use the method.** Advantages generally outweigh theoretical or proven risks.
- CDC 3** **Should not use** the method unless clinician makes clinical judgment that the patient can safely use it. Theoretical or proven risks usually outweigh the advantages of method.
- CDC 4** **Should not use the method.** Condition represents an unacceptable health risk if method is used.

Simplified 2-category system for temporary methods

To make clinical judgment, the CDC 4-category classification system can be simplified into a 2-category system.

CDC Category	With Clinical Judgment	With Limited Clinical Judgment
1	Use the method in any circumstances	} Use the method
2	Generally use the method	
3	Use of the method not usually recommended unless other, more appropriate methods are not available or acceptable	} Do not use the method
4	Method not to be used	

NOTE: In the pages that follow, Category 3 and 4 conditions are shaded to indicate the method should not be provided where clinical judgment is limited.

To download most recent CDC Medical Eligibility Criteria go to: www.cdc.gov

Conditions that Expose a Woman to Increased Risk for Adverse Health Events as a Result of Unintended Pregnancy (§)

For women with conditions that may make unintended pregnancy an unacceptable health risk, long-acting, highly effective contraceptive methods may be the best choice. Women with these conditions should be advised that **sole use of barrier methods for contraception and behavior-based methods of contraception may not be the most appropriate choice** because of their relatively higher typical-use rates of failure. Conditions included in the U.S. MEC for which unintended pregnancy presents an unacceptable health risk are identified throughout the document with the symbol, section symbol (§) (See below for complete list).

CONDITION (§):
Breast cancer
Complicated valvular heart disease
Diabetes: <i>insulin-dependent; with nephropathy/retinopathy/neuropathy or other vascular disease; or of >20 years' duration</i>
Endometrial or ovarian cancer
Epilepsy
High blood pressure (systolic >160 mm Hg or diastolic >100 mm Hg)
History of bariatric surgery within the past 2 years
HIV/AIDS*
Ischemic heart disease
Malignant gestational trophoblastic disease
Malignant liver tumors (hepatoma) and hepatocellular carcinoma of the liver
Peripartum cardiomyopathy
Schistosomiasis with fibrosis of the liver
Severe (decompensated) cirrhosis
Sickle cell disease
Solid organ transplantation within the past 2 years
Sexually transmitted infections*
Stroke
Systemic lupus erythematosus
Thrombogenic mutations
Tuberculosis

**Dual protection is strongly recommended against HIV/AIDS and other STIs when a risk for STI/HIV transmission exists. This can be achieved through the simultaneous use of condoms with other methods or the consistent and correct use of condoms alone.*

CDC MEDICAL ELIGIBILITY CRITERIA FOR STARTING CONTRACEPTIVE METHODS (2010)

CONDITION	Combined Hormonal Contraceptives (CHCs) COCs, Patch (P), Ring (R)	Progestin-Only OCs	Depro-Provera NET EN	LNG/ETG Implants	LNG IUD	TCu-380A IUD
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PERSONAL CHARACTERISTICS & REPRODUCTIVE HISTORY

Pregnant	NA	NA	NA	NA	4	4	
Age	Menarche to < 40=1 ≥ 40=2	Menarche to < 18=1 18-45=1 > 45=1	Menarche to < 18=2 18-45=1 > 45=2	Menarche to < 18=1 18-45=1 > 45=1	Menarche < 20=2 ≥ 20=1	Menarche < 20=2 ≥ 20=1	← A
Parity a) nulliparous	1	1	1	1	2	2	
b) parous	1	1	1	1	1	1	
Breastfeeding* < 1 month PP	3	2	2	2			← B
1 month to ≤ 6 months PP	2	1	1	1			← C
≥ 6 months PP	2	1	1	1			
Non-breastfeeding* < 21 days	3	1	1	1			} May change soon
> 21 days	1	1	1	1			
Postpartum breastfeeding or non-breastfeeding							
<10 mins after placental delivery					2	1	
10 min to < 4 weeks					2	2	
≥ 4 weeks					1	1	
Puerperal Sepsis					4	4	
Post-abortion 1st trimester	1	1	1	1	1	1	
2nd trimester	1	1	1	1	2	2	← D
Immediate post septic AB	1	1	1	1	4	4	
Past ectopic pregnancy	1	2	1	1	1	1	
History of pelvic surgery	1	1	1	1	1	1	

To download most recent CDC Medical Eligibility Criteria go to: www.cdc.gov

A It is not known whether DMPA use among adolescents affects peak bone mass levels or whether adult women with long duration of DMPA use can regain BMD to baseline levels before entering menopause.

B Adverse outcomes in infants exposed to estrogen in breast milk have not been demonstrated. Theoretical concerns of CHC on milk production are greater early postpartum.

C Direct evidence demonstrates no negative effect of POCs on BF performance or health of infant.

D IUD expulsion risk greater when inserted immediately after second trimester abortion.

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

§ Condition exposes woman to increased risk with unintended pregnancy

CONDITION	CHCs	POPs	DMPA	LNG/ETG	LNGIUD	TCuIUD	
Smoking: Less than age 35	2	1	1	1	1	1	
Age ≥ 35 < 15 cigarettes/day	3	1	1	1	1	1	
Age ≥ 35 ≥ 15 cigarettes/day	4	1	1	1	1	1	
Obesity ≥ 30 kg/m ² BMI	2	1	1	1	1	1	
History of bariatric surgery §							
a) Restrictive procedures: decrease storage capacity of the stomach	1	1	1	1	1	1	← A
b) Malabsorptive procedures: decrease absorption of nutrients and calories by shortening small intestine	COCs: 3 P/R: 1	3	1	1	1	1	← B
CARDIOVASCULAR DISEASE							
Multiple risk factors for CAD (older age, smoking, diabetes, HBP)	3 or 4	2	3	2	2	1	← C
HBP - alone; no other CV risk factors							
HBP adequately controlled	3	1	2	1	1	1	
BP systolic 140-159 or Diastolic 90-99	3	1	2	1	1	1	
BP systolic ≥ 160 or Diastolic ≥ 100	4	2	3	2	2	1	
Vascular disease	4	2	3	2	2	1	
HBP during pregnancy, BP now normal	2	1	1	1	1	1	
Deep vein thrombosis/pulmonary embolism							
a) History of DVT/PE/not on AC/low risk/no risk factors	3	2	2	2	2	1	
b) History DVT/PE - not on AC/high risk	4	2	2	2	2	1	← D
c) Acute DVT/PE	4	2	2	2	2	2	
d) DVT/PE on AC at least 3 months							← E
low risk recurrence	3	2	2	2	2	2	
high risk recurrence	4	2	2	2	2	2	
e) Family History (first-degree relatives)	2	1	1	1	1	1	
f) Major surgery with prolonged immobilization	4	2	2	2	2	1	
g) Major surgery without prolonged immobilization	2	1	1	1	1	1	
h) Minor surgery without immobilization	1	1	1	1	1	1	
KNOWN THROMBOGENIC MUTATIONS § (e.g. Factor V Leiden, Prothrombin mutation, Protein S, Protein C and Antithrombin deficiencies)	4	2	2	2	2	1	← F
Superficial venous thrombosis							← G
a) varicose veins	1	1	1	1	1	1	
b) superficial thrombophlebitis	2	1	1	1	1	1	

A Vertical banded gastroplasty, laparoscopic adjustable gastric band, laparoscopic sleeve gastrectomy

B Roux-en-Y gastric bypass, biliopancreatic diversion (P= Patch; R= Ring)

C When multiple major risk factors exist, risk of CV disease may increase substantially. Some POCs may increase risk of thrombosis although this risk is substantially less than with COCs.

D High risk factors for recurrence: History of estrogen-associated DVT/PE, pregnancy-associated DVT/PE, idiopathic DVT/PE, known thrombophilia including antiphospholipid syndrome, active cancer (metastatic, on therapy, or within 6 mos after clinical remission) excluding non-melanoma skin cancer, history of recurrent DVT

E Limited evidence shows IM injections of DMPA in women on AC is not a significant risk for hematoma nor increased risk for heavy or irregular vaginal bleeding

F Routine screening not appropriate because of rarity of conditions and high-cost of screening

G Varicose Veins are not risk factors for DVT/PE

CDC MEDICAL ELIGIBILITY CRITERIA FOR STARTING CONTRACEPTIVE METHODS (2010) - CONTINUED

CONDITION	Combined Hormonal Contraceptives (CHCs) COCs, Patch (P), Ring (R)	Progestin-Only OCs	Depo-Provera NET EN	LNG/ETG Implants	LNG IUD	TCu-380A IUD	
Current & history of ischemic heart disease §	4	I-2/C-3	3	I-2/C-3	I-2/C-3	2	
Stroke (history of CVA)	4	I-2/C-3	3	I-2/C-3	2	1	
Known hyperlipidemia (screening NOT necessary)	2 or 3	2	2	2	2	1	← A, B
Valvular heart disease uncomplicated	2	1	1	1	1	1	← C
Valvular heart disease complicated	4	1	1	1	1	1	← D
Peripartum cardiomyopathy § a) Normal or mildly impaired cardiac function New York Heart Association Functional Class I or II							← E
< 6 months	4	1	1	1	2	2	
≥ 6 months	3	1	1	1	2	2	
b) Moderately or severely impaired cardiac function New York Heart Association Functional Class III or IV	4	2	2	2	2	2	← F
RHEUMATIC DISEASES							
Systemic lupus erythematosus (SLE) §							← G
a) Positive (or unknown) antiphospholipid antibodies	4	3	3	3	3	1	
b) Severe thrombocytopenia	2	2	I-3/C-2	2	2	I-3/C-2	
c) Immunosuppressive treatment	2	2	2	2	2	I-2/C-1	
d) None of the above	2	2	2	2	2	1	
Rheumatoid arthritis							
a) On immunosuppressive therapy	2	1	I-2/C-3	1	I-2/C-1	I-2/C-1	← H
b) Not on immunosuppressive therapy	2	1	2	1	1	1	
NEUROLOGIC CONDITIONS							
Headaches: assumes no other risk factors for stroke (age, HTN, smoking)							
a) non-migraine (mild or severe)	I-1/C-2	I-1/C-1	1	1	1	1	
b) migraine < 35; no aura	I-2/C-3	I-1/C-2	2	2	1	2	
c) migraine ≥ 35; no aura	I-3/C-4	I-1/C-2	2	2	1	2	
d) migraine with aura (any age)	4	I-2/C-3	I-2/C-3	I-2/C-3	I-2/C-3	1	← I
Epilepsy §	1	1	1	1	1	1	
Depressive Disorders	1	1	1	1	1	1	

A Routine screening not appropriate. Assess risk based on type, severity and presence of other CV risk factors.

B 2 or 3 based on the type, severity, and the presence of other CV risk factors.

C Not necessary to use prophylactic antibiotics to prevent endocarditis with IUD insertion or removal

D E.G. Pulmonary hypertension, risk for atrial fibrillation, history of subacute bacterial endocarditis (SBE)

E Patients with no limitation of activities or patients with slight, mild limitation of activity.

F Patients with marked limitation of activity or patients who should be at complete rest.

G Classifications based on no other CV risk factors. SLE increases risk for CVD and VTE/PE.

H DMPA use among women on long-term corticosteroid therapy with a history of, or risk factors for, nontraumatic fractures is classified as Category 3.

I Among women with migraines, women who also have focal neurologic symptoms have a higher risk of stroke than those without focal neurologic symptoms. In addition, among women with migraines, those who use COCs have a 2 to 4-fold increased risk of stroke compared with women who do not use COCs.

§ Condition exposes woman to increased risk with unintended pregnancy.

I=Initiation/C=Continuation

CONDITION	CHCs	POPs	DMPA	LNG/ETG	LNGIUD	TCuIUD
REPRODUCTIVE TRACT INFECTIONS & DISORDERS						
Irregular without heavy bleeding	1	2	2	2	1	1
Heavy or prolonged vaginal bleeding (regular or irregular)	1	2	2	2	I-1/C-2	2
Unexplained vaginal bleeding. Suspicious for serious underlying condition. Before evaluation	2	2	3	3	I-4/C-2	I-4/C-2
Endometriosis	1	1	1	1	1	2
Benign ovarian tumors (including cysts)	1	1	1	1	1	1
Severe dysmenorrhea	1	1	1	1	1	2
Benign gestational trophoblastic disease	1	1	1	1	3	3
Malignant gestational trophoblastic disease §	1	1	1	1	4	4
Cervical ectropion	1	1	1	1	1	1
Cervical intraepithelial neoplasia (CIN)	2	1	2	2	2	1
Cervical cancer (awaiting treatment)	2	1	2	2	I-4/C-2	I-4/C-2
Undiagnosed breast mass	2	2	2	2	2	1
Benign breast disease	1	1	1	1	1	1
Family history of breast cancer	1	1	1	1	1	1
Breast cancer (current) §	4	4	4	4	4	1
Past breast cancer; No current disease for 5 years §	3	3	3	3	3	1
Endometrial hyperplasia	1	1	1	1	1	1
Endometrial cancer §	1	1	1	1	I-4/C-2	I-4/C-2
Ovarian cancer §	1	1	1	1	1	1
Uterine fibroids	1	1	1	1	2	2
Anatomical abnormalities						
distorted uterine cavity					4	4
no distorted uterine cavity					2	2
Past history PID (no current STI risk factors) with subsequent pregnancy	1	1	1	1	1	1
Past history PID (no current STI risk factors) without subsequent pregnancy	1	1	1	1	2	2
Current PID (or within last 3 months)	1	1	1	1	I-4/C-2	I-4/C-2
STIs						
a) Current purulent cervicitis or chlamydial infection or gonorrhea	1	1	1	1	I-4/C-2	I-4/C-2
b) Other STIs (excluding HIV & hepatitis)	1	1	1	1	2	2
c) Vaginitis (including trichomonas vaginalis & bacterial vaginosis)	1	1	1	1	2	2
d) Increased risk of STIs	1	1	1	1	I-2/3 C-2	I-2/3 C-2

A There is some concern that COCs and DMPA increase risk of CIN to invasive disease with long-term use (≥ 5 years)

B Breast cancer is hormonally sensitive, and the prognosis of women may worsen with hormonal methods

C In women at low risk of STIs, IUD insertion poses little risk of PID.

D Treat the PID using appropriate antibiotics. IUD usually need not be removed. Continued use depends on woman's informed choice and current risk factors for STIs and PID. Evidence shows clinical course did not differ whether IUD pulled or left in place.

E If a woman has a very high risk of exposure to infection (Category 3)

* Initiation: 2 and Continuation: 3 expressed as I-2/C-3

** If distinction is made between levels of severity of a condition it is expressed as 2 or 3

§ Condition exposes woman to increased risk with unintended pregnancy

CDC MEDICAL ELIGIBILITY CRITERIA FOR STARTING CONTRACEPTIVE METHODS (2010) - CONTINUED

CONDITION	Combined Hormonal Contraceptives (CHCs) COCs, Patch (P), Ring (R)	Progestin-Only OCs	Depo-Provera NET EN	LNG/ETG Implants	LNG IUD	TCu-380A IUD
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HIV/AIDS

High risk of HIV	1	1	1	1	2	2
HIV-positive §	1	1	1	1	2	2
AIDS §	1	1	1	1	I-3/C-2	I-3/C-2
Clinically well on ARV therapy	if on treatment see drug interactions below				2	2

← A

DRUG INTERACTIONS: ANTIRETROVIRAL THERAPY (for information on specific drugs go to www.cdc.gov)

a) Nucleoside reverse transcriptase inhibitors (NRTIs)	1	1	1	1	I-2 or 3 C-2	I-2 or 3 C-2
b) Non-nucleoside reverse transcriptase inhibitors (NNRTIs)	2	2	1	2	I-2 or 3 C-2	I-2 or 3 C-2
c) Ritonavir-boosted protease inhibitors	3	3	1	2	I-2 or 3/C-2	I-2 or 3/C-2

ENDOCRINE CONDITIONS

History gestational diabetes	1	1	1	1	1	1
Non-insulin dependent diabetes (non-vascular disease)	2	2	2	2	2	1
Insulin dependent diabetes § (non-vascular disease)	2	2	2	2	2	1
Diabetic nephropathy/retinopathy/neuropathy §	I-3/C-4	2	3	2	2	1
Other vascular disease; diabetes of > 20 years §	I-3/C-4	2	3	2	2	1
Thyroid: simple goiter	1	1	1	1	1	1
Hyperthyroid	1	1	1	1	1	1
Hypothyroid	1	1	1	1	1	1

← B

← C

To download most recent CDC Medical Eligibility Criteria go to: www.cdc.gov

A Women at high risk of HIV are also at high risk of other STIs

B Limited evidence inconsistent about development of NIDDM among users of POCs with history of gestational diabetes.

C There is concern about the possible negative effect of DMPA on lipid metabolism, possibly affecting the progression of nephropathy, retinopathy or other vascular disease. Categories should be assessed according to severity of condition.

§ Condition exposes woman to increased risk with unintended pregnancy

I=Initiation/C=Continuation

CONDITION	CHCs	POPs	DMPA	LNG/ETG	LNGIUD	TCuIUD	
GASTROINTESTINAL CONDITIONS							
Inflammatory bowel disease (IBD) (ulcerative colitis, Crohn disease)	I-2/C-3 §	2	2	1	1	1	← A
Symptomatic gall bladder disease post cholecystectomy	2	2	2	2	2	1	
Symptomatic gall bladder disease medically treated	3	2	2	2	2	1	
Symptomatic gall bladder disease - current	3	2	2	2	2	1	← B
Asymptomatic gall bladder disease	2	2	2	2	2	1	
History of pregnancy-related cholestasis	2	1	1	1	2	1	
Past COC-related cholestasis	3	2	2	2	2	1	
Viral hepatitis active	I-3/4 C-2	1	1	1	1	1	
Viral hepatitis carrier or chronic	1	1	1	1	1	1	
Cirrhosis: mild compensated	1	1	1	1	1	1	
Cirrhosis: severe (decompensated) §	4	3	3	3	3	1	← C
Benign hepatic adenoma §	4	3	3	3	3	1	
Malignant liver tumor (hepatoma) §	4	3	3	3	3	1	
ANEMIAS							
Thalassemia	1	1	1	1	1	2	
Sickle cell disease §	2	1	1	1	1	2	
Iron deficiency anemia	1	1	1	1	1	2	
SOLID ORGAN TRANSPLANTATION §							
a) Complicated: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy	4	2	2	2	I-3/C-2	I-3/C-2	
b) Uncomplicated	2	2	2	2	2	2	← D
DRUG INTERACTIONS							
Griseofulvin	2	2	1	2	1	1	
ANTICONSULSANT THERAPY							
a) Certain anticonvulsants: Phenytoin, barbiturates, carbamazepine, primidone, topiramate, oxycarbazepine	3	3	2	3	1	1	← E
b) Lamotrigine	3	1	1	1	1	1	← F
ANTIMICROBIAL THERAPY							
a) Broad spectrum antibiotics, anti-fungals, anti-parasitics	1	1	1	1	1	1	
b) Rifampicin or Rifabutin	3	3	1	2	1	1	

A For women with mild IBD, with no other risk factors for VTE, the benefits of COC/P/R use generally outweigh the risks. However, for women with IBD with increased risk for VTE (e.g. those with active or extensive disease, surgery, immobilization, corticosteroid use, vitamin deficiencies, fluid depletion), the risks for COC/P/R use generally outweigh the benefits.

B COCs may cause small increased risk of gall bladder disease. There is also concern that COCs may worsen existing gallbladder disease.

C COCs are metabolized by liver and use may adversely affect women whose liver function is already compromised. There is concern about the hormonal load associated with POC use, but it is less than for COCs.

D Women with Budd-Chiari syndrome should not use COC/P/R because of the increased risk for thrombosis.

E Although the interaction between commonly used liver enzyme inducers and COCs is not harmful to women, it is likely to reduce the efficacy of COCs. Use of other contraceptives should be encouraged for women who are long-term users of any of these drugs. Whether increasing the hormone dose of COCs is of benefit remains unclear.

F Lamotrigine levels decrease significantly with COC use. In women using lamotrigine and another anti-convulsant okay to use COCs.

I=Initiation/C=Continuation

§ Condition exposes woman to increased risk with unintended pregnancy

HISTORY OF CONTRACEPTION AND POPULATION GROWTH

"We have not inherited the earth from our grandparents, we have borrowed it from our grandchildren."

—PROFESSOR JOHN GUILLERAUD-ATTRIBUTED TO THE ANCIENT CHINESE

2009	World population 6.7 billion	
2005	Subcutaneous Depo-Provera and Implanon approved	
2003	Seasonale, first extended-use pill (0.15 mg LNG, 0.03 mg EE), approved and marketed	
2001	Ortho Evra Patch and NuvaRing approved	1999 - 6 billion (10/12/99!!)
2000	RU486 (mifepristone), Lunelle and Mirena approved by FDA	
1999	World population hits 6 billion (this billion took 12 years)	
1997	FDA approves Emergency Contraceptive Pills	
1994	Plastic (polyurethane) condom for men (Avanti)	
1993	FDA approves polyurethane (plastic) female condom (Reality)	
1992	FDA approves Depo-Provera (DMPA) injections	
1988	Copper T 380-A IUD marketing begins, 5 years after FDA approval	
1987	World population reaches 5 billion (this billion took 12 years)	1987 - 5 billion
1983	FDA approves Copper T 380-A and the Today sponge	
1982	Baulieu describes medical abortion using mifepristone	
1981	First documented case of HIV/AIDS	
1981	Garret Hardin writes "nobody ever dies of overpopulation" after 500,000 die from flooding of an overcrowded East Bengal River delta	
1975	World population reaches 4 billion (this billion took 15 years)	
1974	Al Yuzpe describes emergency contraception using Ovral pills	
1973	FDA approved progestin-only pills (minipills)	1975 - 4 billion
1973	U.S. Supreme Court abortion decision (Roe v Wade & Doe v Bolton)	
1965	U.S. Supreme Court overturns anti-birth control laws in most states (Griswold v. CT)	
1965	U.S. Agency of International Development initiates Population Program	
1960	Food and Drug Administration approves combined oral contraceptives	
1960	World population reaches 3 billion (this billion took 30 years)	
1942	American Birth Control League renamed Planned Parenthood	
1937	AMA ends longstanding opposition to contraception	
1936	German gynecologist Friedrich Wilde describes first cervical cap (fitted from a wax impression)	
1930-31	Knaus (Austria) and Ogino (Japan) develop rhythm method	
1930	World population now 2 billion (this billion took 100 years)	1960 - 3 billion
1930	Pope Pius XI virulently attacks both contraception and abortion	
1927	Novak (Hopkins) describes suction as means of performing an abortion	
1918	N.Y. court approves condoms to prevent disease only	
1916	Margaret Sanger opens first American birth control clinic in Brooklyn, NY	
1914	Margaret Sanger coins word "birth control"	
1912	Sadie Sachs post-abortion death affects Margaret Sanger profoundly	
1909	German surgeon Richard Richter reports success with silkworm-gut shaped into a ring	
1893	First vasectomy by Harrison in London	1930 - 2 billion
1882	First contraceptive clinic established in Amsterdam	
1880	First tubal ligation	
1873	Comstock Act: classifies birth control devices and information as obscene	
1839	Charles Goodyear discovers vulcanization technology; quickly leads to rubber condoms	
1830	World population reaches 1 billion (this billion took 100,000 to 6 million years)	
1798	Thomas Robert Malthus proposes dismal theory that population growth eventually will exceed the ability of the earth to provide food	1800 - 1 billion
Late 1770s	Casanova popularizes condoms for infection control and contraception	
1 AD	World population reaches 250 million, abstinence (particularly postpartum), withdrawal, lactation, stones in camels, lemons for mechanical and spermicidal effect, abortion using molokeeia (same stem used today), homosexuality and polygamy	

1 AD - 250 million

Special thanks to Andrea Tone at Georgia Tech

INDEX

A

Abbreviations, xii–xiii

Abortion

- Adolescents, 19, 20
- CDC eligibility criteria for contraceptives, A3
- Contact information, xi
- Elective, 31–36
- Emergency contraception, 73
- Perimenopause, 23
- Websites, A18

Abstinence

- Contraceptive method, 44–46
- HSV, 149
- Method comparison, 40
- Periodic, 52–55
- Postpartum contraception, 29
- Sex education, 20, 45–46
- Sexual assault, 164
- Urethritis symptoms, 152

Abuse, xi. See also sexual assault/rape

Accutane, 39

Acetaminophen, 33

ACHES COC danger signals, 105

Actinomycosis, 89

Activella®, 24

Acyclovir, 149

Adolescents

- Abortion, 19, 20
- Abstinence, 45, 46
- Chlamydia, 153
- COCs, 98
- DMPA, 123
- Emergency contraception, 76
- Female sterilization, 137
- Female-controlled barrier methods, 64
- Issues concerning, 18–20
- Male condoms, 58
- Ortho Evra patch, 113
- Paragard® IUDs, 84
- Risk assessment for contraception, 5–6
- STI issues, 147
- Websites, A18
- Withdrawal method, 72

Adoption

Age, and CDC eligibility criteria for contraceptives, A3

AIDS, See Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS)

Alcohol

- Metronidazole, 155, 157
- Tinidazole, 157

Allesse®

- Emergency contraception, 80, A20
- Photo, A23

Alora®, 24

Amenorrhea

- See also lactational amenorrhea method (LAM)
- Contraceptives, due to, 4, 13
- DMPA, 121, 122, 126, 127
- Implanon, 130, 131
- Menopause, 23–24
- Mirena® IUDs, 90

Aminoglutethimide, 124

Amoxicillin

- Chlamydia, 153
- Gonococcal infections, 154

Ampicillin/sulbactam, 160

Anal warts, 162

Analgesia, and abortion, 31

Androgens

- COCs, 103
- Menstrual cycle, 1, 3

Anemias, A8

Anesthesia

- Elective abortion, 31, 32
- Female sterilization, 137, 138
- Mirena® IUDs, 92
- Paragard® IUDs, 85

Anorgasmia, 16, 17

Anovulation, 1

Anti-fungals, A8

Anti-parasitics, A8

Antibiotics

- CDC eligibility criteria for contraceptives, A8
- COCs, 99, 104
- Paragard® IUDs, 85
- POPs, 119

Antinausea medication, 77, 80, A20

Antiretroviral medications

- CDC eligibility criteria for contraceptives, A8
- COCs, 99, 104
- ParaGard® IUDs, 85
- POPs, 119

Anticonvulsants, A8

Antinausea medication, 77, 80, A20

Antiretroviral medications

- CDC eligibility criteria for contraceptives, A7
- COCs, 96
- Pregnancy, 165
- Sexual assault, 166

Apri®, A26

Aranelle™, A29

ARCH Foundation, 90

Aromatase, 1

Asherman's syndrome, 33

Aviane®,

Emergency contraception, A20

Photo, A23

Aygestin®, 24

Azithromycin

Chancroid, 148

Chlamydia, 153

Gonococcal infections, 153, 154

Granuloma inguinale, 150

Sexual assault, 166

Urethritis, 152

B

Bacterial vaginosis

CDC eligibility criteria for contraceptives, A6

Diagnosis and treatment, 155–156

Elective abortion, 32

Paragard® IUDs, 84, 85, 89

Pregnancy, 147

Sexual assault, 164

Balziva™ 1/35, A27

Barbiturates, A8

Bariatric surgery

CDC eligibility criteria for contraceptives, A4

Unintended pregnancy, A2

Basal Body Temperature

Fertility awareness methods, 53

Menstrual cycle, 2

Bichloroacetic acid (BCA), 162

Bipolar tubal cautery, 134, 135

Birth rates, adolescent, 20

Bleeding, vaginal

Abortion, 33, 34, 35

CDC eligibility criteria for contraceptives, A6

COCs, 94, 96, 106, 109

DMPA, 121, 122, 126, 127

Implanon, 130, 131

Mirena® IUDs, 90

NuvaRing, 115, 116

Paragard® IUDs, 83, 84, 87, 88

POPs, 117, 118, 120

Bone mineral density

As high-risk factor, 10

DMPA, 19, 123, 125

BCA 1 gene mutations

COCs, 95

Female sterilization, 137

Breast disorders

Benign disease, 95, A6

Cancer, 11, 23, 95, 99, 118, A2, A6

CDC eligibility criteria for contraceptives, A6

Unintended pregnancy, A2

Breastfeeding

Azithromycin, 148

CDC eligibility criteria for contraceptives, A3

Ciprofloxacin, 148

COCs, 51, 99, 103, 107

Contact information, xi

Contraceptive decisions, 51

DMPA, 51, 123

HIV/AIDS, 165

Implanon, 51, 131

Importance of, 50

LAM, 29, 30, 38, 40, 47–50

Lindane, 164

POPs, 51, 117, 118

Postpartum contraception, 29, 30

Problems, 49–50

Rings, vaginal, 51

Tips for success, 50

Breicon®, A28

Butoconazole, 158

C

Calcium intake, 10, 123, 125

Calendar Method, 40, 52, 53

Calymmatobacterium granulomatis, 150

Camilla®

HRT, 24

Photo, A22

Cancer

Anovulation, 1

BRCA mutations, 95, 137

Breast, 11, 23, 95, 99, 118, A2, A6

Cervical, 85, 96, 97, 145, 161, 162, A6

COCs, 95, 96, 97, 99

Colorectal, 10, 95

DMPA, 121

Endometrial, 1, 90, 95, 99, 121, A2, A6

Female sterilization, 137

Hepatic, 96, 97, 99, A2, A8

Ovarian, 95, 121, 137, A2, A6

POPs, 118

Prostate, 22, 23

Skin, 11

Testicular, 22

Unintended pregnancy, A2

Candida albicans, 155, 157

Candidiasis, See vulvovaginal candidiasis

Carbamazepine, A8

Cardiomyopathy

CDC eligibility criteria for contraceptives, A5

Unintended pregnancy, A2

Cardiovascular disease

CDC eligibility criteria for

contraceptives, A4–A5

Unintended pregnancy, A2



Cefixime, 153, 154

Cefotaxime

Gonococcal infections, 154
PID, 160

Cefotetan, 159

Cefoxitin

Gonococcal infection, 154
PID, 159, 160

Ceftizoxime

Gonococcal infection, 154
PID, 160

Ceftriaxone

Chancroid, 148
Gonococcal infections, 153, 154
PID, 160
Sexual assault, 166
Syphilis, 151

Cenestin®, 24

Centers for Disease Control and Prevention (CDC) medical eligibility criteria for contraceptive use, A1–A8

Cervarix, 20, 145

Cervical caps

Breastfeeding, 51
Female-controlled barrier methods, 63, 64, 65
Method comparison, 40, 41
Postpartum contraception, 30
Spermicides, 68

Cervical disorders

Cancer, 85, 96, 97, 145, 161, 162, A5
CDC eligibility criteria for contraceptives, A6
Cervicitis, 152
Dysplasia, 63
Genital warts, 162
Gonococcal infection, 153–154
HPV vaccine, 20, 145, 147, 161, 163

Cervical mucus

DMPA, 121
Implanon, 130
Menstrual cycle, 2
POPs, 117

Cervical mucus ovulation detection method, 52–53, 54

Cesia™, A29

Chancroid, 148

Chlamydia

Diagnosis and treatment, 152–153
Diaphragms, 147
Elective abortion, 32
Gonorrhea, concurrent, 152, 153, 154
Paragard® IUDs, 84
Reinfection, 153
Sexual assault, 164

Chlamydia trachomatis

Chlamydia, 152, 153, 154

LGV, 150

PID, 159

Pregnancy, 147

Vaginal discharge, 155

Cholelithiasis, 98

Ciprofloxacin

Chancroid, 148
Granuloma inguinale, 150

Cirrhosis

CDC eligibility criteria for contraceptives, A8
Unintended pregnancy, A2

Climara Pro®, 24

Climara®, 24

Clindamycin

Bacterial vaginosis, 155, 156
PID, 159, 160

Clotrimazole, 158

Clue cells, 155

COCs, See combined oral contraceptives (COCs)

Coitus interruptus, See withdrawal

Colorectal cancer, 10, 95

Combined contraceptives, non-oral

See patches, contraceptive; rings, vaginal

Combined oral contraceptives (COCs)

About, 94–111
Advantages, 94–96
Breastfeeding, 51, 99, 103, 107
Cancer, 95, 96, 97, 99
CDC medical eligibility criteria, A3–A8
Complications, 97–98
Danger signals, 105
Disadvantages, 96
Emergency contraception, 73, 74, 75, 76, 77, 78, 79, 80
Extended use, 100, 106
Medical eligibility checklist, 101–102
Medications taken with, 108
Method comparison, 38, 40, 41
Missed pills, 106
Photo section, A22–A33
Postpartum contraception, 30
Prescribing precautions, 99
Selecting a pill, 108
Transition from, to other contraception, at menopause, 111
Transitioning from, to POPs, 120

CombiPatch™, 24

Condoms

Antiretrovirals and COCs, 96
Breastfeeding, 51
COCs, transitioning from, 111
Female, 63, 64, 67
HSV, 149



- Latex vs. polyurethane, 56
- Male, 56–62
- Male reproductive health, 21
- Male, instructions for use, 61
- Male, problems with, 59–60, 62
- Male, with female barrier methods, 66
- Method comparison, 38, 40, 41
- Postpartum contraception, 29, 30
- Spermicidal, 68, 146
- STI prevention, 146, 147
- Vaginal medications weakening, 155, 158
- Confidentiality**
 - Adolescents, 18
 - Sexual histories, 14
- Consent, legal**
 - Adolescents, 19, 147
 - Sexual assault management, 166
 - STI diagnosis and treatment, 19, 147
- Contact information**, xi, 165, A18
- Contraception**
 - CDC criteria, A1–A8
 - Contact information, xi, A18
 - Historical events, A9
 - Incorrect or inconsistent use, 30
 - Methods, choosing, 37–43
 - Noncontraceptive benefits, 41
 - Starting use of after ECPs, 77–78
- Copper IUDs**, See Paragard® T380A copper IUDs
- Cost**
 - COCs, 94
 - DMPA, 121
 - Emergency contraception, 75, 79
 - Implanon, 130, 144
 - Mirena® IUDs, 90, 144
 - NuvaRing, 114
 - Ortho Evra patch, 112
 - Paragard® IUDs, 79, 83, 144
 - POPs, 117
- Counseling**
 - Abstinence, 45
 - Adolescents, 18
 - Contact information, xi, A18
 - Contraceptive methods, 37
 - Female sterilization, 137, 139, 140
 - GATHER method, 12
 - Genetic, 10, 26
 - Guidelines for, 12–13
 - HSV, 149
 - Pregnancy tests, 28
 - Prepregnancy planning, 25–26
 - Structured, 13, 126
- Creams, contraceptive**, 68, 70
- Crinone®**, 24
- Cryotherapy**, 162

- Cryselle®**
 - Emergency contraception, A20
 - Photo, A25
- Cyclebeads™**, 52, 55
- Cyclessa**, A29
- Cytomegalovirus**
 - PID, 159
 - Pregnancy, 147
- D**
- Deep vein thrombosis**
 - CDC eligibility criteria for contraceptives, A4
 - COCs, 97, 99, 104
- Demulen® 1/35**, A27
- Demulen® 1/50**, A33
- Depo-Provera (DMPA)**
 - About, 121–129
 - Advantages, 121–122
 - Breastfeeding, 51, 123
 - Cancer, 121
 - CDC medical eligibility criteria, A3–A8
 - COCs, transition from, 111
 - Disadvantages, 122
 - Drug interactions, 124
 - Initiating, 42–43, 125, 128
 - Menopause, transitioning to, 129
 - Menstrual cycle changes, 4
 - Method comparison, 38, 40, 41
 - Ortho Evra patch, transitioning to, 113
 - POPs, transitioning to, 120
 - Postpartum contraception, 29, 30
 - Prescribing precautions, 124
 - STIs, 147
 - Structured counseling, 13, 126
 - Subcutaneous, 121
 - Unintended pregnancy, 40
- Depression**
 - CDC eligibility criteria for contraceptives, A5
 - DMPA, 127
- Desogen®**, A26
- Diabetes**
 - CDC eligibility criteria for contraceptives, A7
 - DMPA, 122
 - POPs, 118
 - Testing for, 10
 - Unintended pregnancy, A2
- Diaphragms**
 - Breastfeeding, 51
 - Female-controlled barrier methods, 63, 64, 66
 - Medication forms weakening, 155, 158
 - Method comparison, 38, 40, 41
 - Postpartum contraception, 30



- Spermicides, 68
- STI prevention, 147
- Diet and nutrition**
 - Pregnancy, 27, 28
 - Prepregnancy, 25, 26
- Divigel®**, 24
- DMPA**. See Depo-Provera (DMPA)
- Donovanosis (granuloma inguinale)**, 150
- Douching**, 116
- Doxycycline**
 - Chlamydia, 153
 - Gonococcal infections, 153, 154
 - Granuloma inguinale, 150
 - LGV, 151
 - PID, 159, 160
 - Sexual assault, 166
 - Syphilis, 151
 - Urethritis, 152
- Drospirenone**, 108
- Drug interactions**, A8
- Dysmenorrhea**, A6
- Dyspareunia**, 15, 126

E

- Ectoparasitic infections**, 163–164
- Ectopic pregnancy**
 - CDC eligibility criteria for contraceptives, A3
 - Elective abortion, 32, 35
 - Female sterilization, 137
 - Mirena® IUDs, 90
 - Paragard® IUDs, 83

Education

- Contact information, A18
- Sex education, 20, 45–46

Effectiveness

- Abstinence, 40, 44
- All methods, 37, 38, 40
- Cervical caps, 40, 63
- COCs, 40, 94
- Condoms, 40, 56, 63, 68
- Diaphragms, 40, 63
- DMPA, 40, 121
- Emergency contraception, 75, 79
- Female sterilization, 40, 134
- Fertility awareness methods, 40, 53
- Implanon, 40, 130
- Lactational amenorrhea method, 47
- Lunelle, 40
- Male sterilization, 40, 141
- Mirena® IUDs, 40, 90
- NuvaRing, 40, 114
- Ortho Evra patch, 40, 112
- ParaGard® IUDs, 40, 83
- POPs, 40, 117
- Spermicides, 40, 68
- Withdrawal, 40, 71

Ejaculation

- Sexual dysfunction, 16–17
- Withdrawal method, 71–72

Elestrin®, 24

ELISA test, 27

Emergency contraception

- See also Next Choice; Plan B
- About, 73–81
- COCs, 104, 107, A20
- Contact information, xi
- Elective abortion, 33
- Female-controlled barrier methods, 63, 64, 67
- LAM, 47
- Male condoms, 56, 59, 61, 62
- Negative pregnancy tests, 28
- NuvaRing, 115
- Paragard® IUDs, 83
- POPs, A20
- Postpartum period, 29, 30
- Sexual assault, 164
- Spermicides, 69, 70
- Unintended pregnancies, 40
- Websites, A18
- Withdrawal method, 72

Endocrine disorders, A7

Endometriosis

- CDC eligibility criteria for contraceptives, A6
- COCs, 103
- DMPA, 121

Endometrium

- Cancer, 1, 90, 95, 99, 121, A2, A6
- Menstrual cycle, 2

Enjuvia, 24

Enpresse®

- Emergency contraceptives, A20
- Photo, A30

Environment

- Pediculosis pubis, 163
- Pregnancy planning, 26
- Scabies, 164

Enzyme-linked immunosorbent assay (ELISA) test, 27

Epilepsy

- CDC eligibility criteria for contraceptives, A5
- Unintended pregnancy, A2

Erectile dysfunction

- Prostate surgery, 22
- Sexual dysfunction, 17

Ergotamine (methergine), 33

Errin®

- HRT, 24
- Photo, A22

Erythromycin

- Chancroid, 148

Chlamydia, 153
 Granuloma inguinale, 150
 LGV, 151
 Pregnancy, 153
 Urethritis, 152

Esclim, 24

Essure method of sterilization, 134, 138, 139, 140

Estrace®, 24

Estraderm®, 24

Estradiol (E₂)
 HRT, 24
 Menstrual cycle, 1, 3

Estrasorb®, 24

Estratest®, 24

Estratest® H.S., 24

Estring®, 24

Estrogel®, 24

Estrogen
 COCs, 94
 HRT, 23–24
 Menstrual cycle, 1–3
 Postpartum contraception, 29

Estropipate, 24

Estrostep® Fe, A30

Etonorgestrel implant, See Implanon

Evamist®, 24

Exercise, 23

F

Fallope ring, 134, 135

FAM, See fertility awareness methods (FAM)

Famciclovir, 149

FC female condoms, 63, 67

Female athletic triad, 19

Female-controlled barrier methods, 63–67
 See also specific methods

FemCap, 63, 65

Femcon Fe™, A27

Femhrt®, 24

FemPatch®, 24

Femring®, 24

Femtrace, 24

Fertility
 Abstinence, 45
 Male reproductive health, 22
 PID, 39

Fertility after contraceptive use
 COCs, 107
 DMPA, 122, 127
 Emergency contraception, 79
 Female sterilization, 139
 Fertility awareness methods, 55
 Implanon, 131
 Lactational amenorrhea method, 50
 Male condoms, 60

Mirena® IUDs, 91
 NuvaRings, 116
 Ortho Evra patch, 114
 Paragard® IUDs, 89
 POPs, 120
 Spermicides, 70
 Vasectomy, 142
 Withdrawal method, 72

Fertility awareness methods (FAM)
 About, 52–55
 Method comparison, 38, 40
 Postpartum contraception, 30
 Websites, A18

Film, contraceptive, 68, 70

Filshie clip, 134, 135

Fimbriectomy, 136

Five “R’s” of fertility awareness methods, 55

Fluconazole, 158

Fluoride supplements, 10

Foams, contraceptive, 68, 70

Folic acid, 25, 26, 27, 28

Follicle stimulating hormone (FSH), 1–3

Follicular phase of menstrual cycle, 2

Forensic exam for sexual assault, 166

G

Gall bladder disease, A8

Gardasil, 20, 145

Gardnerella vaginalis, 155, 159

Gastrointestinal disorders, A8

GATHER method of counseling, 12

Gels, contraceptive, 68, 70

Genetic testing and counseling, 10, 26

Genital herpes simplex virus (HSV) infection, 147, 148–150

Genital ulcers, diseases characterized by, 148–152

Genital warts, 147. See also human papillomavirus (HPV)

Gentamicin
 Granuloma inguinale, 150
 PID, 160

Gestational trophoblastic disease
 CDC eligibility criteria for contraceptives, A6
 Unintended pregnancy, A2

Gonococcal infection
 Chlamydia, concurrent, 152, 153, 154
 Diagnosis and treatment, 152, 153–154
 Diaphragms, 147
 Paragard® IUDs, 84
 Sexual assault, 164
 Unprotected intercourse, 39

Granuloma inguinale (Donovanosis), 150

Granulosa cells, 1, 3

Griseofulvin, 104, A8



Group B streptococcal infections, 147

H

Haemophilis ducreyi, 148

Haemophilus influenzae, 159

HCG, See human chorionic gonadotropin (HCG)

Headache

CDC eligibility criteria for contraceptives, A5

COCs, 99, 105, 110

HEADSS interview technique, 19

Health assessment

Adolescents, 19, 20

Males, 21–22

Prepregnancy, 25, 26

Screening, by age, 5–11

Hepatic disorders

Cancer, 96, 97, 99, A2, A8

CDC eligibility criteria for contraceptives, A8

Hepatitis

CDC eligibility criteria for contraceptives, A8

Vaccinations, 10, 147, 163, 166

Hepatitis A, 163

Hepatitis B

Pregnancy, 147

Sexual assault, 166

Vaccine, 147, 163, 166

Hepatitis C, 147

Herpes simplex virus (HSV) infection,

147, 148–150

Histories

Prepregnancy, 25

Risk factors, 5–11, 14

Sexual assault, 166

Sexual, taking, 14

HIV/AIDS. See human immunodeficiency

virus/acquired immunodeficiency

syndrome (HIV/AIDS)

Home pregnancy tests, 27

Hormone replacement therapy (HRT)

COCs, 111

DMPA, 129

Menopause, 23–24

Hospitalization for PID, 159, 160

Hot flashes

COCs, 106

Menopause, 23

HPV. See human papillomavirus (HPV)

HRT. See hormone replacement therapy (HRT)

Hulka-Clemens clip, 134, 135

Human chorionic gonadotropin (HCG)

Menstrual cycle, 2

Pregnancy tests, 27

Human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS)

CDC eligibility criteria for contraceptives, A7

COCs, 96

Contact information, xi, 165

Counseling, 12

Diagnosis and treatment overview, 165

Female-controlled barrier methods, 64

Genital ulcers, 148

Lactational amenorrhea method, 48

Male condoms, 56, 57, 62

Pregnancy, 147

Prevention measures, 146, 147

Risk factors for, 10

Sexual assault, 164, 165

Spermicides, 68, 69, 146

Syphilis, 151

Trichomoniasis infections, 157

Unintended pregnancy, A2

Vulvovaginal candidiasis, 159

Websites, A18

Human papillomavirus (HPV)

Diagnosis and treatment, 161–163

Vaccine for, 145, 147, 161, 163

Hyperlipidemia,

CDC eligibility criteria for contraceptives, A5

Hypertension

CDC eligibility criteria for contraceptives, A4

COCs, 97, 99

Unintended pregnancy, A2

Hysterectomies, 147

Hysteroscopic tubal occlusion, 134, 138,

139, 140

I

Imiquimod, 161, 163

Implanon

About, 130–133

Advantages, 130

Breastfeeding, 51, 131

Candidates for use, 131

Cost, 130

Disadvantages, 130–131

Effectiveness, 40, 130

Insertion, 132–133

Menstrual cycle changes, 4

Ordering and stocking, 144

Removal, 133

Structured counseling, 13

Implants, contraceptive. See also Implanon

About, 130–133

CDC medical eligibility criteria, A3–A8

Method comparison, 38, 40, 41

Infection

See also sexually transmissible infections (STIs)

Elective abortion, 32, 33, 34, 35

Implanon, 131

Paragard® IUDs, 89

Inflammatory bowel disease, A8
Influenza vaccinations, 11
Inhibin A and B, 1, 3
Injectable contraceptives, See Depo-Provera (DMPA)
Interactive lecture, using, v
Interactive questions, vi–viii
Interferon, intra-lesional, 162
Interval mini-laparotomy, 136–137, 139–140
Intrauterine devices (IUDs)
 See also Mirena® levonorgestrel-releasing intrauterine system (LNG-IUS); Paragard® T380A copper IUDs
 About, 82–93
 Breastfeeding, 51
 DMPA, transitioning from, 129
 Elective abortion, after, 36
 Emergency contraceptive, 73, 74, 79, 81
 Male condoms, 62
 Method comparison, 38, 40, 41
 POPs, transitioning to, 120
 Postpartum contraception, 29, 30
Irving method of sterilization, 136
Ischemic heart disease
 CDC eligibility criteria for contraceptives, A5
 Unintended pregnancy, A2
Ivermectin, 164
J
Jarisch-Herxheimer reaction, 151
Jaundice, 99, 105
Jenest, A30
Jolessa™, A20, A25
Jolivet®, A22
Junel™, A24, A26
Junel™ Fe, A24, A26
K
Kariva®, A24
Kelnor™, A27
Klebsiella granulomatis, 150
L
Laboratory tests, 5, 6, 7, 8, 10–11
Lactational amenorrhea method (LAM)
 Breastfeeding, 47–50
 Method comparison, 38, 40
 Postpartum contraception, 29, 30
Lactobacillus sp., 155
Lamotrigine, A8
Laparoscopic sterilization, transabdominal, 134–135, 137, 139–140
Laser surgery, 162
Latex allergies, 57, 58, 59
Lea's Shield, 63, 65
Leena®, A29
Legal issues

Adolescents, 18, 19
 Emergency contraception, 73
 Sexual assault, 166
 Sexual histories, 14
Lessina®
 Emergency contraception, A20
 Photo, A23
Levlen®
 Emergency contraception, 80, A20
 Photo, A25
Levlite™
 Emergency contraception, 80, A20
 Photo, A23
Levofloxacin
 Chlamydia, 153
 PID, 160
 Urethritis, 152
Levonorgestrel IUDs. See Mirena® levonorgestrel-releasing intrauterine system (LNG-IUS)
Levora
 Emergency contraception, 80, A20
 Photo, A25
LGV (lymphogranuloma venereum), 150–151
LH (luteinizing hormone), 1–3
Libido, 15-16
Lindane, 164
Liver, See cirrhosis; hepatic disorders; hepatitis
LNG-IUS. See Mirena® levonorgestrel-releasing intrauterine system (LNG-IUS)
Lo/Ovral®
 Emergency contraception, 80, A20
 Photo, A25
Loestrin-24, 94
Loestrin® 1.5/30, A26
Loestrin® Fe 1/20, A24
LoSeasonique™, A22
Low-Ogestrel
 Emergency contraception, 80, A20
 Photo, A25
Lubricants
 Condoms, 61
 NuvaRing, 116
Lunelle, 40
Luteal phase of menstrual cycle, 1, 2
Luteal pregnancy, 138
Luteinizing hormone (LH), 1–3
Lutera™
 Emergency contraception, A20
 Photo, A23
Lybrel™
 Formulation, 94, 103, 106
 Photo, A23
Lymphogranuloma venereum (LGV), 150–151

M

Males

- Adolescent issues, 18–20
- Condoms, 56–62
- HPV vaccine, 145
- Reproductive health, 21–22
- Sexual dysfunction, 16–17
- Sterilization, 151–153

Measles, mumps, and rubella vaccine, 11

Meclizine, 77, 80

Medical abortion, 31, 34–36

Medical eligibility for contraceptives

- CDC criteria, A1–A8
- Combined contraceptives, 101–102, A3–A8
- DMPA, 124, A3–A8
- Fertility awareness methods, 54–55
- Implants, A3–A8
- IUDs, A3–A8
- Lactational amenorrhea method, 48–49
- POPs, 119, A3–A8
- Reverse fertility awareness methods, 54–55
- Withdrawal method, 72

Medroxyprogesterone acetate, 24

Megace®, 24

Megestrol acetate, 24

Menest®, 24

Meningococcal vaccine, 11

Menopause

- Condoms, 111
- Contraception, changing, 111
- DMPA, 111, 129
- Mirena® IUDs, 91, 111
- Physiology and HRT, 23–24
- Websites, A18

Menostar, 24

Menstrual cycle

- Changes due to contraceptives, 4, 13
- Fertility awareness methods, 52
- Menopause, 23–24
- Physiology of, 1–3

Mercilon®, A24

Methergine (ergotamine), 33

Methotrexate (MTX), 34, 35, 36

Methyl testosterone, 24

Metronidazole

- Bacterial vaginosis, 155, 156
- PID, 159, 160
- Sexual assault, 166
- Trichomoniasis, 157
- Urethritis, 152

Miconazole, 158

Microbicides, spermicides as, 68

Microgestin Fe®, A24

Microgestin Fe® 1.5/30, A26

Microgestin®, A24

Microgestin® 1.5/30, A26

Micronor®

Menopause, 24

Photo, A22

Mifepristone (RU-486), 34–35, 36

Mini-pills, See progestin-only pills (POPs)

Mircette, A24

Mirena® levonorgestrel-releasing intrauterine system (LNG-IUS)

- Breastfeeding, 51
- CDC medical eligibility criteria, A3–A8
- COCs, transition from, 111
- Emergency contraception, 79, 81
- Female sterilization, alternative to, 140
- Insertion, 92–93
- Insertion, timing of, 43
- Intrauterine contraceptives, 82, 90–93
- Menopause, 24
- Menstrual cycle changes, 4
- Method comparison, 40, 41
- Ordering and stocking, 144
- Postpartum period, 30
- Structured counseling, 13

Misoprostol (MIS), 32, 34–36

Mobiluncus sp., 155

Modicon®, A28

Modified Parkland procedure, 136

Modified Pomeroy procedure, 136

Mononesessa, A27

Monophasic oral contraceptives, 94

Morbidity

- Causes by age groups, 6, 7, 8, 9
- Elective abortion, 31

Mortality

- Causes by age groups, 5, 7, 8, 9
- Elective abortion, 31, 33

MTX (methotrexate), 34, 35, 36

Multiphasic oral contraceptives, 94

Mycoplasma hominis, 155, 159

Myocardial infarction, 97

N

Natural family planning (NFP)

- Postpartum contraception, 30
- Websites, A18

Necon® 0.5/35, A28

Necon 1/35, A28

Necon 1/50, A32

Necon® 10/11, A29

Necon® 7/7/7, A31

Neisseria gonorrhoeae

- Gonococcal infection, 153, 154
- PID, 159
- Pregnancy, 147
- Vaginal discharge, 155

Next Choice, 73, 74, 75, 77, 78, 80. See also emergency contraception

NFP, See Natural family planning (NFP)

Nitrogen, liquid, 162

Non-steroidal anti-inflammatory drugs

(NSAIDs)

COCs, 108

Elective abortion, 33

Mirena® IUDs, 92

Paragard® IUDs, 83, 88

Nonoxyl-9. See also spermicides

Spermicide, 68, 69

STIs, 146, 147

Nor-QD®

Menopause, 24

Photo, A22

Nora-Be®, A22

Nordette®

Emergency contraception, 80, A20

Photo, A25

Norethin 1/35E, A28

Norethindrone

Emergency contraception, 80

HRT, 24

Norgestimate, 24

Norinyl® 1+35, A28

Norinyl® 1/50, A32

Norplant, 130, 147. See also implants, contraceptive

Nortrel®, A28

Nortrel® 7/7/7, A31

NSAIDs, See non-steroidal anti-inflammatory drugs (NSAIDs)

NuvaRings, 40, 114–116.

See also rings, vaginal

Nystatin, 158

O

Obesity

CDC eligibility criteria for contraceptives, A4

COCs, 104

Essure sterilization, 138

Ortho Evra patch, 113

Ocella™, A26

Odor, and vaginal infections, 155

Ofloxacin

Chlamydia, 153

PID, 160

Urethritis, 152

Ogen®, 24

Ogestrel

Emergency contraception, 80, A20

Photo, A32

Organ transplantation

CDC eligibility criteria for contraceptives, A8

Unintended pregnancy, A2

Ortho Evra patches, 40, 112–114. See also patches, contraceptive

Ortho Tri-Cyclen®

COCs, 96

Photo, A31

Ortho Tri-Cyclen® Lo, A29

Ortho-cept®, A26

Ortho-Cyclen®, A27

Ortho-est®, 24

Ortho-Novum® 1/35, A28

Ortho-Novum® 1/50, A32

Ortho-Novum® 10/11, A29

Ortho-Novum® 7/7/7, A31

Outercourse, 45, 46

Ovarian disorders

Cancer, 95, 121, 137, A2, A6

CDC eligibility criteria for contraceptives, A6

Cysts, 103

Follicles, 118

Ovcon® 35

COCs, 98

Photo, A27

Ovcon® 50, A33

Over-the-counter medications

Plan B, 73

Vulvovaginal candidiasis, 158

Ovral

Emergency contraception, 80, A20

Photo, A32

Ovrette, 73

Ovulation

Lactational amenorrhea, 47

Menstrual cycle, 1–4

Ovulation method, 40

Oxycarbazepine, A8

P

Pain

DMPA, 121

Menstrual cycle, 2, 4

Paragard® IUDs, 88

Vasectomy, 142

PAINS IUD warning signs, 87

Papanicolaou smears, 147

Paragard® T380A copper IUDs

Breastfeeding, 51

CDC medical eligibility criteria, A3–A8

Emergency contraception, 73, 74, 79, 81, 83

Female sterilization, alternative to, 140

Insertion, 85–87

Insertion, postpartum, 29

Insertion, timing of, 43

Intrauterine contraceptives, 82–89

Male condoms, 62

Menopause, 111

Method comparison, 40, 41

Ordering and stocking, 144
Removal, 89
Parity, and CDC eligibility criteria for contraceptives, A3
Partners, treating
BV, 156
Gonococcal infection, 154
Pediculosis pubis, 163
Scabies, 164
Trichomoniasis infections, 157
Vulvovaginal candidiasis, 158
Patches, contraceptive
About, 112–114
Breastfeeding, 51
CDC medical eligibility criteria, A3–A8
Method comparison, 38, 40, 41
Postpartum contraception, 30
Pediculosis pubis, 163
Pelvic exams, 19
Pelvic inflammatory disease (PID)
BV, 156
CDC eligibility criteria for contraceptives, A6
Diagnosis and treatment, 159–160
Mirena® IUDs, 91
Paragard® IUDs, 84, 89
Unprotected intercourse, 39
Penicillin G, 151
Perimenopause, 23, 111
Perinatal infection, 150
Permethrin
Pediculosis pubis, 163
Scabies, 164
Pharynx, gonococcal infection of, 154
Phenytoin, A8
Physical exam, Recommended, by age, 5, 6, 7, 8
Sexual assault, 16
PID, See pelvic inflammatory disease (PID)
Piperonyl butoxide, 163
Plan B. See also emergency contraception
COCs, 98, 104
Contraception, starting, 43
Emergency contraception, 73, 74, 75, 76, 77, 78, 80, A20
Male condoms, 56, 59, 62
OTC med, 73, 75, 77
POPs, 120, A20
Spermicides, 70
Withdrawal method, 72
Pneumococcal vaccine, 11
Podofilox, 161, 163
Podophyllin, 162, 163
POPs. See progestin-only pills (POPs)
Population organizations, A18
Portia®
Emergency contraception, A20

Photo, A25
Post-ovulation Method, 53
Postpartum contraception, 29–30
Postpartum insertion of Paragard® IUDs, 87
Postpartum mini-laparotomy, 136–137, 139–140
Postplacental insertion of Paragard® IUDs, 87
Pre-ejaculate fluid, 71
Prefest®, 24
Pregnancy
Bacterial vaginosis, 155, 156
Chancroid, 148
Chlamydia, 152, 153
Contact information, xi
Contraception, starting, 42, 43
Counseling, 12–13
Erythromycin, 153
Gonococcal infections, 154
Health conditions affected by, A2
HIV, 165
HPV, 161, 162, 163
HPV vaccine, 145
HSV, 149
Lindane, 164
Luteal pregnancies, 138
Myths about, 20
Paragard® IUDs, 84, 89
Pediculosis pubis, 163
PID, 159, 160
Planning and preparation, 25–26
Reverse fertility awareness methods, 54
Scabies, 164
Sexual assault, 164
STIs, 147
Syphilis, 151
Testing, 27–28
Trichomonas infections, 157
Unintended, 39, 40, A2
Vulvovaginal candidiasis, 159
Premarin®, 24
Premphase®, 24
Prempro®, 24
Preterm birth, 25
Preven, A20
Previfem™, A27
Prevotella sp., 155
Primadone, A8
Probenecid
Gonococcal infection, 154
PID, 160
ProChoice America, 31
Progesterone, 1–3
Progestin

COCs, 94
HRT, 24
Progestin-only contraceptives
See also Depo-Provera (DMPA);
Implanon; Implants, contraceptive
Breastfeeding, 51
Method comparison, 41
Postpartum contraception, 29, 30
Progestin-only pills (POPs)
About, 117–120
Advantages, 117
Breastfeeding, 51, 117, 118
CDC medical eligibility criteria, A3–A8
Disadvantages, 118
Emergency contraception, 73, 74, 75, 76,
77, 78, 79, 80, A20
Initiating, 120
Method comparison, 38, 40, 41
Photos, A22
Prescribing precautions, 118
Prolactin, 47
Proliferative phase of menstrual cycle, 2
Prometrium®, 24
Prophylaxis, for sexual assault, 164
Prostate cancer, 22, 23
Provera®, 24
Pruritis
Pediculosis pubis, 163
Scabies, 164
Vaginal infections, 155
Pulmonary embolism, A4
Pyrethrins, 163
Q
Quasense™, A20, A25
Quick Start method
COCs, 102
NuvaRing, 116
Timing initiation of contraceptives, 42
Quinolone, 154
R
Rape, See sexual assault/rape
Reality condoms, 40, 58
Rectum
Anal warts, 162
Gonococcal infections, 153, 154
Reproductive health research, A18
Rh factor, 32
Rheumatic diseases, A5
Rheumatoid arthritis, A5
Rifampicin, A8
Rifampin, 104
Rings, vaginal
About, 114–116
Breastfeeding, 51

CDC medical eligibility criteria, A3–A8
Elective abortion, after, 36
Method comparison, 38, 40, 41
Postpartum contraception, 30
Risabutin, A8
Risk assessment
Adolescents, 19
Contraception, 5–11
Hormone replacement therapy, 23–24
Pregnancy planning, 25–26
Sexual histories, 14
Unprotected intercourse, 39
RU-486 (mifepristone), 34–35, 36

S

Safety of contraceptives, 41
Salpingectomy, partial, 134
Scabies, 164
Schistosomiasis, A2
Seasonale
COCs, 94, 103
Emergency contraception, A20
Photo, A25
Seasonique
COCs, 103, 106
Emergency contraceptives, A20
Photo, A25

Secretory phase of menstrual cycle, 2

Seizures, 121

Sex education

Abstinence only, 20, 45–46
Adolescents, 20

Sexual assault/rape

Contact information, xi
Evaluation and management, 166
STI, 164–165

Sexual dysfunction, 15–17

Sexually transmissible infections (STIs)

See also specific infections
Adolescents, 19, 20
CDC eligibility criteria for contraceptives, A6
CDC treatment guidelines, 146–165
Clinical prevention guidelines, 146–147
Contact information, xi
Counseling, 12
Female-controlled barrier methods, 64
Fertility awareness methods, 54, 55
High-risk factors, 11
Lactational amenorrhea method, 48
Male condoms, 56, 57
Male reproductive health, 22
Ortho Evra patch, 112
Pregnancy planning, 25, 26
Sexual assault, 164–165, 166
Special populations, 147
Spermicides, 68, 69

- Unintended pregnancy, A2
- Websites, A18
- Withdrawal method, 72
- Sickle cell disease**
 - CDC eligibility criteria for contraceptives, A8
 - Unintended pregnancy, A2
- Side effects of contraceptive methods, 41**
- Silastic bands, 134, 135**
- Skin**
 - Cancer, 11
 - Ortho Evra patch, 113
- Smoking**
 - CDC eligibility criteria for contraceptives, A4
 - COCs, 99
 - Implanon, 131
 - POPs, 117
- Spanish/English translations, A19**
- Spectinomycin, 154**
- Sperm**
 - Vasectomy, 141, 142
 - Withdrawal, 71
- Spermicides**
 - About, 68–70
 - Female-controlled barrier methods, 63, 64, 65, 66, 68
 - Method comparison, 38, 40
 - Paragard® IUDs as, 83
 - Spermicidal condoms, 56, 61, 146
 - STIs, 146, 147
- Spinnbarkeit test, 2**
- Sponges, contraceptive**
 - Breastfeeding, 51
 - Female-controlled barrier method, 63, 64, 67
 - Spermicides, 68
- Spring clip application, tubal, 134**
- Sprintec®, A27**
- Sronyx®, A23**
- Standard Days Method, 52, 53**
- Sterilization**
 - Breastfeeding, 51
 - Female, 134–140
 - Male, 141–143
 - Method comparison, 38, 40, 41
 - Postpartum contraception, 29, 30
 - STIs, 147
- STIs, See Sexually transmissible infections (STIs)**
- Streptococcus agalactiae, 159**
- Streptococcus infections, 147, 159**
- Stroke**
 - CDC eligibility criteria for contraceptives, A5
 - COCs, 97
 - Unintended pregnancy, A2
- Structured counseling, 13, 126**

- Suppositories, contraceptive, 68, 70**
- Surgery**
 - Abortion, 31–34
 - Female sterilization, 134–140
 - HPV, 162
 - Male sterilization, 141–143
 - Prostate, 22
- Symptothermal Method, 40, 53**
- Syphilis**
 - Diagnosis and treatment, 151–152
 - Pregnancy, 147, 151
 - Sexual assault, 164
- Systemic lupus erythematosus (SLE)**
 - CDC eligibility criteria for contraceptives, A5
 - Progestin-only contraceptives, 118
 - Unintended pregnancy, A2
- T**
- Tablets, contraceptive, 68, 70**
- TCA (trichloroacetic acid), 162**
- Terconazole, 158**
- Testicular cancer, 22**
- Tetracycline, 151, 154**
- Thalassemia, A8**
- Theca cells, 1, 3**
- Thrombogenic mutations, A3**
 - CDC eligibility criteria for contraceptives, A4
 - Unintended pregnancy, A2
- Thrombosis**
 - Implanon, 131
 - POPs, 118
- Thyroid disorders**
 - CDC eligibility criteria for contraceptives, A7
 - Screening for, 11
- Timing of contraceptive use**
 - COCs, 102, 107
 - DMPA, 125, 128
 - Emergency contraceptives, 74–81
 - NuvaRings, 115
 - POPs, 118, 120
 - Routine, starting, 42–43, 77–78
- Tinidazole**
 - Trichomonas infections, 157
 - Urethritis, 152
- Tioconazole, 158**
- Today™ sponges, 63, 67**
 - See also sponges, contraceptive
- Topiramate, A8**
- Treponema pallidum, 148, 151**
- Tri-Legest® Fe, A30**
- Tri-Leven®**
 - Emergency contraception, 80, A20
 - Photo, A30
- Tri-Norinyl®, A29**
- Tri-Previfem™, A31**

Tri-Sprintec®, A31
Trichloroacetic acid (TCA), 162
Trichomonas infections
 CDC eligibility criteria for
 contraceptives, A6
 Diaphragms, 147
 Paragard® IUDs, 84, 85, 89
 Sexual assault, 164
 Trichomoniasis, 155, 157
Trichomonas vaginalis, 155, 157
Trimethoprim-sulfamethoxazole, 150
Trinessa, A31
Triphasil®
 Emergency contraception, 80, A20
 Photo, A30
Trivora®
 Emergency contraception, 80, A20
 Photo, A30
Tubal ligation or occlusion
 Advantages, 137
 Counseling about, 137, 139, 140
 Disadvantages, 137
 Effectiveness, 40, 134
 Female sterilization, 134–140
 Laparoscopic method, 134–135
 Postpartum contraception, 29, 30
 Postpartum or interval methods, 136
Tuberculosis, 11, A2
Tuboovarian abscesses, 159, 160
Two-cell two gonadotropin theory, 1, 3
TwoDay Method, 53
U
Uchida method of sterilization, 136
U. urealyticum, 159
Urethral disorders
 Genital warts, 162
 Gonococcal infections, 153, 154
Urethritis, 152
Urinary tract infections, 10
Uterine anomalies
 CDC eligibility criteria for
 contraceptives, A6
 Paragard® IUDs, 85
Uterine perforation
 Mirena® IUDs, 91
 Paragard® IUDs, 84, 88
V
Vaccines
 Hepatitis A and B, 147, 163
 HPV, 145, 147, 161, 163
 Influenza, 11
 Measles, mumps, and rubella, 11
 Meningococcal, 11

Pneumococcal, 11
 Varicella, 11
Vagifem®, 24
Vaginal discharge, diseases characterized by, 155–159
Vaginal warts, 162
Vaginismus, 15
Valacyclovir, 149
Valvular heart disease
 CDC eligibility criteria for contraceptives, A5
 Unintended pregnancy, A2
Varicella vaccine, 11
Vasectomy
 Advantages, 141
 Disadvantages, 141
 Effectiveness, 40, 141
 Male reproductive health, 21
 Male sterilization, 141–143
 Method comparison, 38, 40, 41
 Problem management, 142
 Procedure for, 143
 Timing of, 29, 30
Velivet®, A29
Venous thromboembolism
 COCs, 97, 99
 Ortho Evra patch, 113
Venous thrombosis, superficial, A4
Visual changes, 98, 105
Vivelle™, 24
Vulvovaginal candidiasis
 Diagnosis and treatment, 155, 157–159
 Paragard® IUDs, 89
W
Weight gain, with DMPA, 122, 125, 126, 127
Wilson's disease, 85
Withdrawal
 Contraceptive method, 71–72
 Method comparison, 38, 40
Y
Yasmin
 COCs, 108
 Photo, A26
Yaz
 COCs, 94, 108
 Photo, A23
Yoon band, 134
Yuzpe method, 73, 74, 75
Z
Zenchant®, A27
Zidovudine, 165
Zovia® 1/35E, A27
Zovia® 1/50, A33



PROGESTIN - ONLY PILLS



MICRONOR[®] TABLETS
28-DAY REGIMEN
 (0.35 mg norethindrone)
 (active pills lime green)
 Ortho-McNeil



NOR-QD[®] TABLETS
 (0.35 mg norethindrone)
 (active pills yellow)
 Watson



CAMILLA[®]
 (norethindrone tablets, USP 0.35 mg)
 (active pills light pink)
 Barr Laboratories



ERRIN[®]
 (norethindrone tablets, USP 0.35 mg)
 (active pills yellow)
 Barr Laboratories

JOLIVETTE[®]
 (0.35 mg norethindrone)
 Watson

NORA-BE[®]
 (0.35 mg norethindrone)
 Watson

COMBINED PILLS - 20 microgram PILLS

LoSEASONIQUE[™]
 (levonorgestrel/ethinyl estradiol/0.10mg/
 0.2mg and ethinyl estradiol 0.01 mg)
 Duramed

COMBINED PILLS - 20 microgram PILLS



LYBREL™
(90 mcg levonorgestrel/20 mg ethinyl estradiol)
(active pills pink)
Wyeth



YAZ® 28 TABLETS
(3.0 mg drospirenone/02 mg ethinyl estradiol)
(active pills pink)
Berlex



ALESSE® - 28 TABLETS
(0.1 mg levonorgestrel/20 mcg ethinyl estradiol)
(active pills pink)
Wyeth



LEVLITE™ - 28 TABLETS
(0.1 mg levonorgestrel/20 mcg ethinyl estradiol)
(active pills pink)
Berlex



AVIANE®
(levonorgestrel/ethinyl estradiol tablets, USP 0.10 mg/0.02 mg)
(active pills orange)
Barr Laboratories



LUTERA™
(0.1 mg levonorgestrel/20 mcg ethinyl estradiol)
(active pills white)
Watson

SRONYX®
(0.1 mg levonorgestrel/
20mcg ethinyl estradiol)
Watson



LESSINA®
(levonorgestrel/ethinyl estradiol tablets,
USP 0.1 mg/0.02 mg)
(active pills pink)
Barr Laboratories



LOESTRIN® FE 1/20
(1 mg norethindrone acetate/20 mcg ethinyl estradiol/
75 mg ferrous fumarate [7d])
(active pills white)
Barr Laboratories



JUNEL TM
(norethindrone acetate and ethinyl estradiol tablets,
USP 1 mg/20 mcg)
(active pills light yellow)
Barr Laboratories



JUNEL TM Fe
(norethindrone acetate and ethinyl estradiol tablets,
USP and ferrous fumarate tablets 1 mg/20 mcg)
(active pills light yellow)
Barr Laboratories

**MICROGESTIN® &
MICROGESTIN FE®**

(1mg norethindrone acetate/
20 mcg ethinyl estradiol FE also contains
/75 mg ferrous fumarate
Watson



KARIVA®
(desogestrel/estradiol tablets 0.15 mg/0.02
mg and ethinyl estradiol tablets 0.01 mg)
(active pills white and light blue)
Barr Laboratories



MIRCETTE® - 28 TABLETS
(0.15 mg desogestrel/ 20 mcg ethinyl estradiol X
21 (white)/placebo X 2 (green)/
10 mcg ethinyl estradiol X 5 (yellow)
Barr Laboratories

MERCILON®
(0.15 mg desogestrel/20mcg ethinyl
estradiol/10mcg ethinyl estradiol)
Organon Laboratories

COMBINED PILLS - 30 microgram PILLS



SEASONALE[®]
(0.15 mg levonorgestrel/
30 mcg ethinyl estradiol)
84 active pink pills
followed by 7 placebo pills
Barr Laboratories



SEASONIQUE
(0.15 mg levonorgestrel/
30 mcg ethinyl estradiol)
84 active pink pills followed by
7 pills with 10 mcg ethinyl estradiol
Barr Laboratories

JOLESSA[™]
(0.15 mg levonorgestrel/
30 mcg ethinyl estradiol)
91 day regimen
Barr

QUASENSE[™]
(0.15 mg levonorgestrel/
30 mcg ethinyl estradiol)
Watson Laboratories



NORDETTE[®] -28 TABLETS
(0.15 mg levonorgestrel/30 mcg ethinyl estradiol)
(active pills light orange)
Wyeth



LEVORA TABLETS
(0.15 mg levonorgestrel/
30 mcg ethinyl estradiol)
(active pills white)
Watson



PORTIA[®]
(levonorgestrel and ethinyl estradiol
tablets, USP 0.15 mg/0.03 mg)
(active pills pink)
Barr Laboratories



LEVLEN[®] 28 TABLETS
(0.15 mg levonorgestrel/
30 mcg ethinyl estradiol)
(active pills light orange)
Berlex



LO/OVRAL[®]-28 TABLETS
(0.3 mg norgestrel/
30 mcg ethinyl estradiol)
(active pills white)
Wyeth



LOW-OGESTREL[®] - 28
(0.3 mg norgestrel/
30 mcg ethinyl estradiol)
(active pills white)
Watson



CRYSELLE[®]
(norgestrel and
ethinyl estradiol tablets,
USP 0.3 mg/0.03 mg)
(active pills white)
Barr Laboratories



YASMIN® 28 TABLETS
(3.0 mg drospirenone/30 mcg ethinyl estradiol)
(active pills yellow)
Berlex

OCELLA™ 28 TABLETS
(3.0 mg drospirenone/30 mcg ethinyl estradiol)
(active pills yellow)
Berlex



DESOGEN® 28 TABLETS
(0.15 mg desogestrel/
30 mcg ethinyl estradiol)
(active pills white)
Organon

SOLIA™
(0.15 mg desogestrel/30 mcg ethinyl estradiol)
Organon



ORTHO-CEPT® TABLETS
28-DAY REGIMEN
(0.15 mg desogestrel/
30 mcg ethinyl estradiol)
(active pills orange)
Ortho-McNeil



APRI®
(desogestrel/
ethinyl estradiol 0.15 mg/
0.03 mg tablets)
(active pills rose)
Barr Laboratories



LOESTRIN® 21 1.5/30
(1.5 mg norethindrone acetate/30 mcg ethinyl estradiol)
(active pills green)
Barr Laboratories



MICROGESTIN® 1.5/30 with or without Fe
(1.5 mg norethindrone acetate/
30 mcg ethinyl estradiol)
Watson



JUNEL™
(norethindrone acetate and ethinyl estradiol
tablets, USP 1.5 mg./30 mcg.)
(active pills pink)
Barr Laboratories



JUNEL™ Fe
(norethindrone acetate and ethinyl estradiol tablets,
USP and ferrous fumarate tablets 1.5 mg./30 mcg.)
(active pills pink)
Barr Laboratories

COMBINED PILLS - 35 microgram PILLS



ORTHO-CYCLEN® 28 TABLETS
(0.25 mg norgestimate/
35 mcg ethinyl estradiol)
(active pills blue)
Ortho-McNeil



SPRINTEC®
(norgestimate and ethinyl estradiol tablets,
0.250 mg/0.035 mg)
(active pills blue)
Barr Laboratories



MONONESSA®
(norgestimate and
ethinyl estradiol tablets,
0.250 mg/0.035 mg)
Watson

PREVIFEM™
(norgestimate and ethinyl estradiol tablets, 0.250 mg/0.035 mg)
Teva



OVCON® 35 28-DAY
(0.4 mg norethindrone/
35 mcg ethinyl estradiol)
(active pills peach)
Warner-Chilcott
Now there is a chewable
Ovcon-35 pill!

ZENCHENT®
(0.4 mg norethindrone/
35 mcg ethinyl estradiol)
Watson

FEMCON FE™
(0.4 mg norethindrone/
35 mcg ethinyl estradiol)
Warner-Chilcott

**BALZIVA™ 1/35
21 OR 28 TABLETS**
(0.4 mg norethindrone/
35 mcg ethinyl estradiol)
Barr Laboratories



DEMULEN® 1/35-28
(1 mg ethynodiol diacetate/
35 mcg ethinyl estradiol)
(active pills white)
Pharmacia - A Division of Pfizer



KELNOR™
(ethynodiol diacetate 1 mg. and
ethinyl estradiol 35 mcg, USP)
(active pills light yellow)
Barr Laboratories



ZOVIA® 1/35E-28
(1 mg ethynodiol diacetate/
35 mcg ethinyl estradiol)
(active pills light pink)
Watson



NORETHIN 1/35E-28
(1 mg norethindrone/35 mcg ethinyl estradiol)
(active pills white)
Shire



NORINYL® 1+35 28-DAY TABLETS
(1 mg norethindrone/35 mcg ethinyl estradiol)
(active pills yellow-green)
Watson



ORTHO-NOVUM® 1/35 28 TABLETS
(1 mg norethindrone/35 mcg ethinyl estradiol)
(active pills peach)
Ortho-McNeil



NECON® 1/35-28
(1 mg norethindrone/35 mcg ethinyl estradiol)
(active pills dark yellow)
Watson



NORTREL®
(norethindrone and ethinyl estradiol tablets,
USP 1.0/0.035 mg)
(active pills yellow)
Barr Laboratories



NORTREL®
(norethindrone and ethinyl estradiol tablets,
USP 1.0 mg/0.035 mg 28-day regimen)
(active pills yellow)
Barr Laboratories



BREVICEON® 28-DAY TABLETS
(0.5 mg norethindrone/35 mcg ethinyl estradiol)
(active pills blue)
Watson



MODICON® TABLETS
28-DAY REGIMEN
(0.5 mg norethindrone/
35 mcg ethinyl estradiol)
(active pills white)
Ortho-McNeil



NECON 0.5/35®
(0.5 mg norethindrone/35 mcg ethinyl estradiol)
Watson

NORTREL®
(norethindrone and ethinyl estradiol
tablets, USP 0.5/0.035 mg)
(active pills light yellow)
Barr Laboratories

COMBINED PILLS - PHASIC PILLS



ORTHO TRI-CYCLEN[®] LO - 28 TABLETS

(norgestimate/ethinyl estradiol)
 0.18 mg/25 mcg (7d) (white),
 0.215 mg/25 mcg (7d) (light blue),
 0.25 mg/25 mcg (7d) (dark blue)
 remaining 7 placebo pills are green
 Ortho-McNeil



CYCLESSA[®]

(desogestrel/ethinyl estradiol - triphasic regimen)
 0.1 mg/25 mcg (7d) (light yellow)
 0.125 mg/25 mcg (7d) (orange)
 0.150 mg/25 mcg (7d) (red)
 Organon



VELIVET[™]

(desogestrel/ethinyl estradiol tablets - triphasic regimen)
 (active pills beige, orange and pink)
 Barr Laboratories

CESIA[™]

(desogestrel/ethinyl estradiol tablets - triphasic regimen)
 Prasco



ORTHO-NOVUM[®] 10/11 - 28 TABLETS

(norethindrone/ethinyl estradiol)
 0.5 mg/35 mcg (10d) (white),
 1 mg/35 mcg (11d) (peach)
 Ortho-McNeil



NECON[®] 10/11 - 28 TABLETS

(norethindrone/ethinyl estradiol)
 0.5 mg/35 mcg (10d) (white),
 1 mg/35 mcg (11d) (peach)
 Watson

LEENA[®]

(norethindrone/ethinyl estradiol) 0.5mg/0.035mg
 (light blue), 1 mg/0.035 mg (yellow-green)
 Watson

ARANELLE[™]

(norethindrone/ethinyl estradiol)
 0.5mg/0.035mg (blue), 1 mg/0.035 mg
 Barr Laboratories

TRI-NORINYL[®]

(norethindrone/ethinyl estradiol) 0.5mg/0.035mg
 (blue), 1 mg/0.035 mg (yellow-green)
 Watson



ESTROSTEP® FE - 28 TABLETS
(norethindrone acetate/ethinyl estradiol)
1 mg/20 mcg (5d) (white triangular),
1 mg/30 mcg (7d) (white square),
1 mg/35 mcg (9d), 75 mg ferrous
fumarate (7d) (white round)
Pfizer

TRI-LEGEST® FE
(norethindrone acetate/ethinyl estradiol)
1 mg/20 mcg (5d), 1 mg/30 mcg (7d)
1 mg/35 mcg (9d), 75 mg ferrous fumarate (7d)
Barr



JENEST® 28 TABLETS
(norethindrone/ethinyl estradiol)
0.5 mg/35 mcg (7d) (white),
1 mg/35 mcg (14d) (peach)
Organon



TRIPHASIL® - 28 TABLETS
(levonorgestrel/ethinyl estradiol-triphasic regimen)
0.050 mg/30 mcg (6d) (brown),
0.075 mg/40 mcg (5d) (white),
0.125 mg/30 mcg (10d) (light yellow)
Wyeth



TRIVORA®
(levonorgestrel/ethinyl estradiol-triphasic regimen)
0.050 mg/30 mcg (6d), 0.075 mg/
40 mcg (5d), 0.125 mg/30 mcg (10d) (pink)
Watson



TRI-LEVEN® 28 TABLETS
(levonorgestrel/ethinyl estradiol-triphasic regimen)
0.050 mg/30 mcg (6d) (brown),
0.075 mg/40 mcg (5d) (white),
0.125 mg/30 mcg (10d) (light yellow)
Berlex



ENPRESSE®
(levonorgestrel and ethinyl estradiol tablets,
USP - triphasic regimen)
(active pills pink, white and orange)
Barr Laboratories



ORTHO TRI-CYCLEN® - 28 TABLETS

(norgestimate/ethinyl estradiol)
0.18 mg/35 mcg (7d) (white),
0.215 mg/35 mcg (7d) (light blue),
0.25 mg/35 mcg (7d) (blue)
Ortho-McNeil



TRI-SPRINTEC®

(norgestimate and ethinyl estradiol tablets -
triphasic regimen)
(active pills gray, light blue and blue)
Barr Laboratories



TRINESSA®

(norgestimate/ethinyl estradiol)
0.18 mg/35 mcg (7d) (white),
0.215 mg/35 mcg (7d) (light blue),
0.25 mg/35 mcg (7d) (dark blue)
remaining 7 placebo pills are green
Watson

TRI-PREVIFEM™ - 28 TABLETS

(norgestimate and
ethinyl estradiol tablets -
triphasic regimen)
Teva



ORTHO-NOVUM® 7/7/7 - 28 TABLETS

(norethindrone/ethinyl estradiol)
0.5 mg/35 mcg (7d) (white),
0.75 mg/35 mcg (7d) (light peach),
1 mg/35 mcg (7d) (peach)
Ortho-McNeil



NORTREL® 7/7/7

(norethindrone and ethinyl estradiol tablets,
USP - triphasic regimen)
(active pills light yellow,
blue and peach)
Barr Laboratories



NECON® 7/7/7

0.5 mg/35 mcg (7d) (yellow),
0.75 mg/35 mcg (7d) (blue),
1 mg/35 mcg (7d) (peach)
Watson

COMBINED PILLS - 50 microgram PILLS



OVRAL® - 21 TABLETS
(0.5 mg norgestrel/50 mcg ethinyl estradiol)
(active pills white)
Wyeth



OGESTREL®
(0.5 mg norgestrel/50 mcg ethinyl estradiol)
(active pills white)
Watson



ORTHO-NOVUM® 1/50 - 28 TABLETS
(1 mg norethindrone/50 mcg mestranol)
(active pills yellow)
Ortho-McNeil



NECON® 1/50 - 28 TABLETS
(1 mg norethindrone/50 mcg mestranol)
Watson



NORINYL® 1/50
(1 mg norethindrone/50 mcg mestranol)
Watson

COMBINED PILLS - 50 microgram PILLS (continued)



OYCON[®] 50 28-DAY
(1 mg norethindrone/50 mcg ethinyl estradiol)
(active pills yellow)
Warner-Chilcott



DEMULEN[®] 1/50-28
(1 mg ethynodiol diacetate/50 mcg ethinyl estradiol)
(active pills white)
Pharmacia - A Division of Pfizer



ZOVIA[®] 1/50
(1 mg ethynodiol diacetate/50 mcg ethinyl estradiol)
Watson