

**MARYLAND STATE
FAMILY PLANNING PROGRAM
CLINICAL GUIDELINES**

**CENTER FOR MATERNAL AND CHILD HEALTH
FAMILY HEALTH ADMINISTRATION
MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

MARYLAND STATE FAMILY PLANNING PROGRAM
CLINICAL GUIDELINES
2005

The 2005 edition of the *Maryland State Family Planning Program Clinical Guidelines* has been prepared by the staff of the Center for Maternal and Child Health and supersedes all previous clinical guidelines and memoranda issued by this Office. These guidelines are primarily intended for use by clinic nurses, nurse clinicians, and physicians who care for family planning and reproductive health clients.

These guidelines reflect the current medical opinions of leaders in the field of obstetrics and gynecology as well as related specialty boards. Please note that the methods of clinical practice described are not intended to exclude other acceptable methods and may be modified in accordance with the clinical situation and the clinician's experience. These guidelines are not intended to be a comprehensive discussion of all clinical situations. Therefore, clinic nurses, nurse clinicians, and physicians rendering family planning and reproductive health care are encouraged to consult with appropriate specialists whenever questions arise regarding clinical management or treatment modalities.

Please note the inclusion of new topics and previous topics that have undergone major revisions. Future topics are being developed and will be forwarded as they are completed.

The Clinical Guidelines are to be utilized in conjunction with the *Maryland State Family Planning Program Administrative Guidelines* and should be kept in every clinic site in a clearly labeled loose-leaf binder. All staff who work in family planning clinics should be familiar with the contents of both volumes. Each staff member should sign and date the guidelines after reviewing them. The sign-off procedure by all family planning staff is a quality assurance activity and should be recorded in the clinic quality assurance notebook.

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COMPONENTS OF ROUTINE FAMILY PLANNING

History

- Reason for visit
- Age
- Allergies
- Current medications/vitamins/herbs
- Current method of contraception
- Previous method of contraception
- Current primary care clinician

Sexual History

- Age of onset
- Number of partners in lifetime
- Number of new partners
- Number of current partners
- Partner history
- Gender of partners
- Types of sex acts
- High-risk behavior
- Date of last vaginal intercourse

Obstetric History

- Gravity
- Parity
- Abortions (spontaneous or elective)
- Preterm births
- Living children
- Delivery type(s)
- Complications
- Date of last delivery (or date of last pregnancy termination)
- Breastfeeding

Gynecologic History

- Last menstrual period
- Menarche
- Length of cycle
- Length of flow
- Reproductive tract infection history, including abnormal Pap, HPV, HSV, gonorrhea, chlamydia, syphilis, bacterial vaginosis
- Surgery

Current or Past Medical History

- Medical problems
- Asthma
- Headaches
- Cardiovascular disease

- Liver disease
- Kidney disease
- GI disease
- Diabetes mellitus
- Thromboembolic disease
- Coagulopathies
- Mental health disorders

Infectious Disease History

- Sexually transmitted diseases
- Hepatitis
- HIV

Social History

- Alcohol
- Smoking
- Drug use
- Domestic violence
- Sexual abuse/assault
- Child abuse

Family History

- Heart disease
- Diabetes
- Addictions
- Cancer (ovary, breast, uterus)

Physical Examination

- Blood pressure
- Weight
- Height
- Thyroid
- Heart
- Lungs
- Breasts
- Abdomen
- Extremities
- Pelvis
- Skin

Laboratory Testing

- Hgb/Hct
- Rubella screen
- Hepatitis B screen
- HIV
- STS
- Urine dipstick
- Pap

- GC
- Chlamydia
- HPV
- Urine pregnancy test

Counseling

- Abstinence
Postponing sexual involvement
- Preventing unintended pregnancy
Contraceptive options
Emergency contraception
- Preconception
- Weight/diet/nutrition
- Vitamins
- Folic acid
- Calcium
- Exercise
- Sexually transmitted infections
Partner selection
Barrier protection
- Psychosocial
Personal goals
Behavior/learning disorder
Abuse/neglect
Interpersonal/peer/family relationships
Family involvement
Domestic violence
Depression/suicide
Lifestyle/stress
- Health/risk behaviors
Breast self-evaluation
Substance abuse (drugs, tobacco, alcohol)
Excess ultraviolet light
Tattoos/body piercing

The frequency and extent of investigation of the individual components are dependent on the type and frequency of each family planning visit, reason(s) for the visit, contraceptives in use and/or being considered for use, and findings from the physical examination and laboratory testing.

Primary References

ACOG. *Precis: Primary and Preventive Care*. 3rd Ed., 2004

Hatcher RA et al. *Contraceptive Technology*. 18th Revised Edition. Ardent Media, Inc., New York, 2004

COUNSELING ADOLESCENTS

Rationale

Providing services to adolescent clients is a priority of the Maryland State Family Planning Program. It is the hallmark of publicly funded family planning programs that clients receive counseling and education, along with medical services and supplies. For adolescents, the need for information and support and the opportunity for influencing health choices over a lifetime are clear.

Reproductive health services for youths must include age-appropriate counseling and education in the following areas:

- Encouraging family participation in sexuality discussions and in the decision of the young person to seek family planning services;
- Encouraging abstinence and the delay of sexual activities;
- Promoting the use of family planning and related preventive health services;
- Supporting the adolescent in resisting attempts to coerce him or her into engaging in sexual activities.

Additionally, all family planning clinics are required to offer HIV/AIDS education, counseling and testing either on-site or by referral. When any or all HIV/AIDS prevention services are offered on-site, prevention information should incorporate the “ABC” message for teens, as follows:

- “A” is for abstinence;
- “B” is for being faithful;
- “C” is for condom use, when a youth’s behaviors put him or her at risk for HIV/AIDS.

Plan of Action

1. When a teen comes to the clinic, with or without a parent, friend or other family member, issues of consent, confidentiality and its limits must be discussed at the earliest opportunity. It is important to explain that teens have a right to receive confidential services but that health care providers are mandated to report suspected instances of child abuse and neglect to the proper authorities. Similarly, young clients and family members must be made aware that confidentiality does not extend to information about suicide, homicide and certain life-threatening activities or serious medical conditions.
2. When a teen comes to the clinic alone or with someone other than a parent, he or she should be asked whether a parent is aware of the visit. Unless there is reason to believe that the teen would be in danger from the parent or that the parent would interfere with the teen’s access to care, clinic staff should encourage the teen to consider parental involvement. When a teen is unable or unwilling to involve a parent, he or she should be encouraged to involve some other supportive, adult family member. Encouragement of the family involvement should be documented in the youth’s record.

3. Whenever a provider discusses the client's sexual history, it is important to ask whether any sexual activity has been forced or coerced. All teens should be given the message that force and coercion have no place in sexual relationships and may be illegal. Informational materials and referrals to community resources that deal with domestic and sexual violence, including law enforcement, should be readily available. The Maryland Network Against Domestic Violence (MNADV) and the Maryland Coalition Against Sexual Assault (MCASA) can provide statewide information on laws as well as national and local resources. To contact MNADV, go to www.MNADV.org or call 1-800-MD HELPS. To contact MCASA, go to www.mcasa.org or call 1-800-983 RAPE.
4. It is important to support and reinforce positive choices for teens. Obtaining educational and medical services from a family planning clinic is a positive choice for sexually active teens and/or those who wish to be better prepared to make sexual choices. Other positive choices a teen may make involve delaying sexual activities and observing the ABC message in terms of preventing HIV/AIDS and other sexually transmitted diseases.
5. Document all counseling, reports, referrals and referral information in the adolescent's chart.

Follow-up

1. When a teen has disclosed child abuse or neglect, including child sexual abuse, the provider must make a report to the appropriate authorities according to legal requirements (see Mandated Reporting of Child Abuse and Neglect).
2. A minor may disclose violent or sexually exploitive behavior that does not meet the definition for child abuse such as dating violence, sexual assault or sexual activity with a partner who is significantly older and is neither a family or household member nor an individual with temporary or permanent, past or present responsibility for the care, custody or supervision of the minor (see Family and Intimate Partner Violence). When this occurs, the client should be advised that clinic staff are there to help any teen who requests assistance. The adolescent may need support in seeking the involvement of a parent or family member and/or in accessing community resources, including law enforcement or emergency medical facilities and shelters. Each clinic must maintain a list of resources and, when available, brochures and flyers issued by national and local programs. At a teen's request, a staff member may assist in making connections.
3. It is impossible to know what information from a family planning session may be retained, or when a client may be ready to act on information provided. Thus, it may be advisable to provide age-appropriate counseling repeatedly when visits occur more frequently than annually.

Primary References

Family Law Article, §5-704, Annotated Code of Maryland

Annotated Code of Maryland, Article 27, Sections 463, 464A, 464B and 464C

DOMESTIC VIOLENCE / INTIMATE PARTNER VIOLENCE

Rationale

Intimate partner violence (IPV) is the actual or threatened physical, sexual, psychological, or emotional abuse by a current or former spouse (including common-law spouse), dating partner, or boyfriend or girlfriend. Intimate partners can be of the same or opposite sex. Examples of IPV include physical assault (hit, slap, choke, bite, push, kick), sexual violence (rape, forced sex), stalking, harassment, psychological abuse, (intimidation, name-calling, not letting other person see family or friends) and threats (with or without weapons). These behaviors are used by the perpetrator to control the other person.

Violence occurs on all socioeconomic groups and to individuals among every culture, race, ethnicity, and religion. Nearly one-third of women in the United States reports experiencing violence by a current or former spouse or boyfriend at some point in her life. The cost of IPV is nearly \$6 billion annually in the U.S. Two-thirds of that amount is for direct medical and mental health services.

Plan of Action

1. Screening - Domestic violence screening is not an option; it is a standard of care. Studies show that women do not mind being asked about IPV. The family planning visit is an opportune time to screen for intimate partner violence. Screening should be done:
 - a. privately – Screening should be done in a private, confidential manner. Women may not disclose violence if the partner, family or friends are present.
 - b. for all women aged 14 and over (earlier if already dating)
 - 1) initial visit – ask about any prior history of abuse
 - 2) annually – ask about abuse during the previous year
 - 3) interim visit – screen for violence if injury or mental health conditions are present or if new intimate partner relationship has been disclosed
 - c. using a validated screening tool such as the 3-question tool recommended by ACOG - Introduce the topic by stating: “Because violence is so common in many women’s lives and because there is help available for women being abused, I now ask every patient about domestic violence.”
 - 1) Within the past year – or since you have been pregnant – have you been hit, slapped, kicked or otherwise physically hurt by someone?
 - 2) Are you in a relationship with a person who threatens or physically hurts you?
 - 3) Has anyone forced you to have sexual activities that made you feel uncomfortable?

Through the screening, try to convey that abuse is wrong; it is not the client's fault, and everyone has the right to feel safe at home.

d. Chart documentation if injury is present

- 1) full name of perpetrator and relationship to victim
- 2) exact time and location of injury occurrence
- 3) full names and relationship to witnesses of the trauma
- 4) description of injury using:
 - a) direct quotations from the client if possible
 - b) Polaroid camera photo
 - c) Diagram of body map to document nature and location of all injuries

e. Reporting requirements by Maryland law

Under Maryland law, **do not report suspected or confirmed domestic violence or sexual assault unless the adult victim consents.** Exceptions include children under age 18 who are abused by a parent or guardian, "vulnerable" (lacking mental or physical capacity to provide for daily needs) adults, or treatment of injury caused by gunshot or moving vehicle. To report abuse or children or vulnerable adults, call 1-800-MD-HELPS.

2. Refer

All positive screens should have a danger assessment and safety plan if appropriate. There are many local organizations that can help the client with her situation. The Maryland Network Against Domestic Violence has information on referrals by county, jurisdiction, and specific populations such as immigrants and military (Appendix). Its website (www.mnadv.org) also has excellent advice for helping the abused person including making a safety plan and applying for a protective order. Clients should be given the Maryland hotline number, 1-800-MD-HELPS.

3. Have information available for clients in bathroom, exam room, or waiting room.

References

ACOG. Intimate Partner Violence and Domestic Violence. Special Issues in Women's Health. 2005

Family Violence Prevention Fund (FVPPF). National Consensus Guidelines on Identifying and Responding to Domestic Victimization in Health Care Settings. San Francisco, 2004

Annotated Code of Maryland, Article 27, Sections 464A, 464B, and 464C

Maryland Network Against Domestic Violence
1-800-MD-HELPS
www.mnadv.org

APPENDIX

MARYLAND RESOURCES FOR DOMESTIC VIOLENCE

COUNTY	PROGRAM	HOTLINE
Allegany	Family Crisis Resource Center	301-759-9244
Anne Arundel	YWCA Domestic Violence Services	410-222-6800
Baltimore City	House of Ruth MD TurnAround, Inc.	410-889-7884 410-828-6390
Baltimore County	Family and Children's Services of Central MD Family Crisis Center of Baltimore County, Inc. TurnAround, Inc.	410-828-6390
Calvert	Crisis Intervention Center	410-535-1121
Carroll	Family and Children's Services of Central MD	410-857-0077
Caroline	Mid-Shore Council on Family Violence	800-927-4673
Cecil	Cecil Co. Domestic Violence/Rape Crisis Center	410-996-0333
Charles	Center for Abused Persons	301-645-3336
Dorchester	Mid-Shore Council on Family Violence	800-927-4673
Frederick	Heartly House	301-662-8800
Garrett	The Dove Center	301-334-9000
Harford	Sexual Assault/Spouse Abuse Resource Center	410-836-8430
Howard	Domestic Violence Center	410-997-2272
Kent	Mid-Shore Council on Family Violence	800-927-4673
Montgomery	Abused Persons Program	240-777-4195
Prince George's	Family Crisis Center, Inc. House of Ruth MD	301-731-1203 240-450-3270
Queen Anne's	Mid-Shore Council on Family Violence	800-927-4673
St. Mary's	Walden/Sierra, Inc.	301-863-6661
Somerset	Life Crisis Center	410-749-4357
Talbot	Mid-Shore Council on Family Violence	800-927-4673
Washington	CASA (Citizens Assisting and Sheltering the Abused)	301-739-8975
Wicomico	Life Crisis Center	410-749-4357
Worcester	Life Crisis Center	410-749-4357

Asian/Spanish Resources:

Asian/Pacific Islander Domestic Violence Resource Project
Adelante Familia/St. Vincent de Paul

202-464-4477
410-732-2176

MANDATED REPORTING OF CHILD ABUSE AND NEGLECT

Rationale

All health care workers acting in their professional capacity are mandated to report information that otherwise would be confidential when they suspect child abuse or neglect (Appendix A). In Maryland, reports are required even when a previously maltreated child is now an adult.

Workers are protected from civil liability and criminal penalty when making a report in good faith. Alternatively, they could be subject to sanctions from their professional licensing boards if they knowingly fail to report.

A child is defined as an individual under the age of 18. Child abuse includes physical injury or mental injury under circumstances indicating that a child's health or welfare is harmed or at substantial risk of harm and sexual abuse, with or without physical injury, perpetrated upon a child by a family or household member or someone with temporary or permanent, current or past care, custody or responsibility for supervision of the child.

Child neglect means the failure to provide proper care and attention to the child under circumstances that the child's health or welfare is harmed or placed at substantial risk of harm. It includes leaving the child unattended and mental injury or substantial risk of mental injury that is caused by failure to provide proper care and attention to the child.

When the perpetrator of a physical or sexual assault is an individual other than a family or household member or someone with temporary or permanent, current or past care, custody or responsibility for the supervision of the child, the mandated reporting requirement does not apply. In fact, a provider could risk licensing or criminal penalties or civil liability for violating the confidentiality of a client were the provider to make a report in a situation that falls outside the mandated reporting law. In Maryland, statutory rape is not reportable unless the perpetrator is a family or household member or someone with temporary or permanent, current or past care, custody or responsibility for the supervision of the minor. However, even when it is not reportable, a sexual relationship between an adolescent and an older adolescent or adult may raise concerns that sexual coercion is occurring. Family planning providers are required to counsel minors about ways to resist attempts to coerce them into engaging in sexual activities. In addition to counseling, referrals to sexual assault programs or other types of assistance may be offered.

Plan of Action

1. Under Maryland's mandated reporting law, after a health care provider has learned about a suspected incident or incidents of child maltreatment, a report to the appropriate authorities is required.
2. An oral report of child physical or sexual abuse must be made as soon as possible to Child Protective Services (CPS) or the appropriate law enforcement agency.
3. An oral report of neglect or mental injury must be made as soon as possible to CPS.

4. The head of the public health agency in which the provider is employed should be informed of an abuse or neglect report immediately.
5. Within 48 hours, a written report of abuse or neglect must be sent to CPS and, if the report concerns child abuse, a copy must also be sent to the State's Attorney. Reports may be made on the **DHR/SSA 180**. **DHR/SSA 180** reporting forms and statewide contact information about CPS may be found on-line at www.dhr.state.md.us/cps.
6. When the mandated reporting law does not apply in cases of statutory rape, dating violence or sexual assault, a young person may need assistance in accessing a variety of medical, including mental health, and community services. At a minimum, the client should be counseled about safety, parental involvement and ways to resist sexual coercion. The youth should be urged to take advantage of local victims' services programs. Referral to emergency medical facilities and/or local law enforcement authorities may also be appropriate.

Primary Reference

Family Law Article, §5-704, Annotated Code of Maryland

Annotated Code of Maryland, Article 27, Section 463, 464A, 464B, and 464C

APPENDIX A

Article - Family Law

§ 5-704.

(a) Notwithstanding any other provision of law, including any law on privileged communications, each health practitioner, police officer, educator, or human service worker, acting in a professional capacity in this State:

(1) (i) who has reason to believe that a child has been subjected to abuse, shall notify the local department or the appropriate law enforcement agency; or

(ii) who has reason to believe that a child has been subjected to neglect, shall notify the local department; and

(2) if acting as a staff member of a hospital, public health agency, child care institution, juvenile detention center, school, or similar institution, shall immediately notify and give all information required by this section to the head of the institution or the designee of the head.

(b) (1) An individual who notifies the appropriate authorities under subsection (a) of this section shall make:

(i) an oral report, by telephone or direct communication, as soon as possible:

1. to the local department or appropriate law enforcement agency if the person has reason to believe that the child has been subjected to abuse; or

2. to the local department if the person has reason to believe that the child has been subjected to neglect; and

(ii) a written report:

1. to the local department not later than 48 hours after the contact, examination, attention, or treatment that caused the individual to believe that the child had been subjected to abuse or neglect; and

2. with a copy to the local State's Attorney if the individual has reason to believe that the child has been subjected to abuse.

(2) (i) An agency to which an oral report of suspected abuse is made under paragraph (1) of this subsection shall immediately notify the other agency.

(ii) This paragraph does not prohibit a local department and an appropriate law enforcement agency from agreeing to cooperative arrangements.

(c) Insofar as is reasonably possible, an individual who makes a report under this section shall include in the report the following information:

- (1) the name, age, and home address of the child;
- (2) the name and home address of the child's parent or other person who is responsible for the child's care;
- (3) the whereabouts of the child;
- (4) the nature and extent of the abuse or neglect of the child, including any evidence or information available to the reporter concerning possible previous instances of abuse or neglect; and
- (5) any other information that would help to determine:
 - (i) the cause of the suspected abuse or neglect; and
 - (ii) the identity of any individual responsible for the abuse or neglect.

ABSTINENCE

Rationale

From a family planning perspective, abstinence is the absence of genital contact that could result in pregnancy, that is, penile penetration into the vagina.

The perfect use failure rate is 0%.

Abstinence requires commitment and self-control with an understanding partner. Abstinence can reduce cervical dysplasia and STIs, and is acceptable to many religions and cultures as a method of contraception. Abstinence may be continuous or periodic. Periodic abstinence may require another method of contraception during the period of non-abstinence.

Plan of Action

1. The client and her partner must be in agreement on the use of abstinence and to what extent other sexual expressions are practiced.
2. Counseling may include the discussion of alternative methods of expressing affection with the partner.
3. Counseling may include the discussion of alternative methods of contraception for the time when or if the client decides not to use abstinence as her primary method of contraception.
4. Offer condoms and advanced placement emergency contraception to be available if needed.

Follow-up

Inquire upon the success (or failure) of the client's practice of abstinence and offer appropriate counseling and/or alternate method(s) of contraception, including advanced placement emergency contraception.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Zieman M, Hatcher RA et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2007

AMENORRHEA

Rationale

Clinical problems arise in the management of family planning clients when amenorrhea interferes with or complicates the standard protocols for starting or changing birth control methods.

Any client fulfilling one of the following criteria should be considered as having primary amenorrhea:

1. No periods by age 13 in the absence of growth and development of secondary sexual characteristics.
2. No periods by age 15, regardless of the presence of normal growth and development with the appearance of secondary sexual characteristics.
3. No periods 5 years after the initiation of breast development or pubic or axillary hair development.

Any client who has been menstruating fulfilling one of the following criteria should be considered as having secondary amenorrhea:

1. The absence of periods for a length of time equivalent to a total of at least three of the previous cycle intervals.
2. Six months of no periods.

Plan of Action

1. In a client with amenorrhea the possibility of pregnancy should always be considered or ruled out.
2. Referral for endocrine evaluation is appropriate for anyone who has primary amenorrhea.
3. A historical review and appropriate physical examination should focus on medical conditions, surgical procedures and obstetrical events that might be causing amenorrhea (Appendix).
 - a. The current menstrual pattern should be compared to the client's usual pattern before pregnancy, hormonal contraception, any medication, significant weight change (15 or more pounds), or significant lifestyle changes.
 - b. All current and recent medication and hormonal contraception should be reviewed.
4. In some cases, with a negative history and physical examination, expectant management is appropriate. The client should be given reassurance and

encouraged to await her menstrual period, especially if the duration of amenorrhea is less than 6 months. After 6 months, consider laboratory testing, progestational challenge and/or referral.

5. When laboratory testing is indicated, a thyroid stimulating hormone level (TSH) and a serum prolactin should be ordered. A client with an abnormal test result should be referred for appropriate evaluation and management.
6. When appropriate, a progestational challenge may be given by prescribing medroxyprogesterone acetate (Provera®) 10 mg orally a day for 7 days to induce withdrawal bleeding. This bleeding would be useful for a client who wishes to start hormonal contraception or to have insertion of an IUD. A client who does not respond to a progestational challenge should have physician consultation.
7. If the resumption of hormonal contraception is desired after a brief lapse in hormonal contraception, pregnancy must be ruled out. This may be accomplished by getting a negative urine pregnancy test before and after a two-week interval of abstinence or the use of reliable contraception.
8. In clients with polycystic ovary syndrome, oral contraceptives, patches and vaginal rings with low androgenicity can decrease hirsutism and acne, prevent unopposed endometrial proliferation, and provide contraceptive protection. DMPA can prevent endometrial proliferation and reduce pregnancy risks.
9. An amenorrheic client with galactorrhea which is remote from pregnancy and not related to any current medication or hormonal contraception should be referred for physician consultation (Appendix).
10. Prompt referral for physician evaluation is indicated when amenorrhea is associated with other significant symptoms such as headache, nausea, vomiting, visual or auditory changes, and galactorrhea.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

ACOG. Precis: Reproductive Endocrinology. 3rd Ed., 2007

Curtis MG, Hopkins MP. Glass's Office Gynecology. 6th Ed., Lippincott Williams & Wilkins, Philadelphia, PA, 2006

APPENDIX

AMENORRHEA: DIFFERENTIAL DIAGNOSIS

HISTORICAL DATA	PHYSICAL FINDINGS	CONSIDERATIONS
Pulmonary tuberculosis, type 1 diabetes mellitus, renal disease, rheumatic heart disease, rheumatoid arthritis, abnormal hematocrit, hemoglobinopathies, cirrhosis, alcohol abuse, anorexia nervosa	Specific to each	Chronic medical conditions may cause amenorrhea
Client takes Dilantin, digitalis, reserpine, cytotoxic medications, some antibiotics	Specific to each	These medications may cause amenorrhea
Client takes phenothiazines, tricyclics, other tranquilizers, antihypertensives, or antidepressive agents	Leaking fluid from breasts	These medications may cause galactorrhea
Headache, nausea, vomiting	Changes in visual fields or acuity, changes in auditory acuity, galactorrhea	Space-occupying pituitary lesion
Prolonged postpartum lactation	Atrophy of uterus, galactorrhea	Chiari-Frommel syndrome
Necrotic process of adenohypophysis	Cachexia, loss of secondary sex characteristics, lowering of basal metabolic rate	Simmonds' disease
Severe postpartum hemorrhage causing collapse of blood supply to pituitary. Initial weight gain postpartum, then weight loss	Panhypopituitarism: loss of secondary sex characteristics, intolerance of cold, breast vulvar, and uterine atrophy	Sheehan's syndrome
Oral contraceptive pills discontinued with no menses for six months: irregular menses prior to oral contraceptives	Nonspecific	Hypothalamic oversuppression

APPENDIX – Continued

HISTORICAL DATA	PHYSICAL FINDINGS	CONSIDERATIONS
Appetite changes, strenuous regular exercise, high stress level	Cachexia, weight loss or weight gain, diminished body fat	Reversible hypogonadotropic functional amenorrhea
Toxic substance exposure, radiation exposure	Specific to each	Damage to ovaries, hypothalamus, endometrium
Oligomenorrhea, hypomenorrhea and subsequent amenorrhea, cold intolerance	Subnormal temperature, drowsy appearance, apathetic, slow speech, recent weight gain, sluggish or delayed reflexes, puffy facies, pretibial edema (myxedema), hair thinned, eyebrows thinned, dry skin, possible enlarged thyroid	Primary hypothyroidism
Oligomenorrhea, irregular cycles precede amenorrhea, weight loss, weakness, increased appetite, heat intolerance, nervousness	Exophthalmos, stare, lid lag, pretibial lesions and myxedema, palpitations, resting tachycardia, onycholysis, excessive sweating, warm moist skin, temporal alopecia, possible enlarged thyroid	Hyperthyroidism, Graves' disease
Amenorrhea	Obesity of trunk, "buffalo hump", moon facies, osteoporosis, hirsutism, acne, purple striae on trunk, hypertension, glucosuria, red cheeks	Cushing's disease
Amenorrhea	Uterine and breast tissue atrophy, clitorimegaly, deepening voice, temporal baldness, hirsutism, male habitus, acne, increased sebum secretion, male body and pubic hair distribution	Virilizing ovarian tumor

APPENDIX – Continued

HISTORICAL DATA	PHYSICAL FINDINGS	CONSIDERATIONS
Amenorrhea	All of the above associated with virilizing ovarian tumor, plus hypertension, and alterations in glucose metabolism and metabolites	Virilizing adrenal tumor
Irregular bleeding alternating with amenorrhea	Breast size increasing	Feminizing ovarian tumor
Irregular menses beginning with first few years after menarche	Hirsutism, obesity, subfertility	Polycystic ovary syndrome: Persistent anovulation, and hyperandrogenism
Recent or chronic pelvic infection or surgery on ovaries	Specific to each	Tubo-ovarian abscess
Mumps as an adult	Hypoestrogenic	Mumps oophoritis
Gradual cessation of menses, “hot flashes”	Age near 50, vagina, uterus, ovaries atrophic changes, dry vaginal mucosa, elevated serum gonadotropins (FSH, LH)	Menopause vs. ovarian pathology
No menstrual flow in adolescent, denies monthly discomfort in abdomen that could indicate menstruation	Secondary sex characteristics and reproductive structures seem present and patent	Hematocolpos, hematometra, congenital disorders, imperforate hymen, obstructed or deformed cervical os, transverse vaginal septum
No menses since vigorous D&C		Asherman’s syndrome

ANEMIA

Rationale

Anemia is defined as a reduction in either the percentage of red blood cells (hematocrit), or a reduction in the concentration of hemoglobin in a sample of venous blood when compared with reference values.

Iron deficiency is the most common anemia in the general population. The prevalence of iron deficiency is about 2% in males and 12% in women of reproductive age. Black and Hispanic women are at high risk for iron deficiency (~20%). This type of deficiency can result from blood loss or inadequate dietary intake of iron. Iron deficiency occurs when body iron stores become inadequate for red blood cell production. Women are particularly at risk due to iron losses during pregnancy and menstruation. Hormonal contraceptives that reduce menstrual bleeding are beneficial to women who have a tendency toward iron deficiency.

The first laboratory evidence of iron deficiency is a low serum ferritin. A value less than 30 micrograms per liter nearly always indicates absent iron stores and is a highly reliable indicator of iron deficiency. The serum iron binding capacity rises, and the serum iron values fall (Appendix A).

To make the diagnosis of iron deficiency anemia, one can either demonstrate an iron-deficient state or evaluate the response to a therapeutic trial of iron replacement. For women of reproductive age, a therapeutic trial of oral iron therapy is the recommended initial approach.

Plan of Action

1. Clients who attend family planning clinics should have hemoglobin and/or hematocrit studies done under the following circumstances:
 - a. at the initial comprehensive visit
 - b. when presenting with a history of, or signs or symptoms of anemia
 - c. if required for the provision of a contraceptive method
2. In general, a hemoglobin concentration less than 11 g/dL or a hematocrit less than 33% should prompt further evaluation (on-site or by referral), which includes a complete blood count (CBC), red blood cell indices and reticulocyte count.
3. Appropriate treatment for iron deficiency anemia is a daily dose of 60-180 mg of oral elemental iron (in the form of ferrous sulfate, ferrous gluconate, or ferrous fumarate).
4. Nutrition counseling and an iron-rich food list should be provided (Appendix B). Iron from meat, poultry or fish is absorbed more efficiently than iron from plant sources. Foods containing vitamin C (see Appendix B) also enhance iron absorption from plant sources when eaten at the same meal. Coffee, tea, colas, whole grains, legumes and dairy products (and calcium pills) decrease the amount of iron from plant sources absorbed at each meal.

5. A client with a hemoglobin concentration less than 10 g/dL or a hematocrit less than 30% should be referred to a physician for consultation. Additional testing might include serum ferritin, serum iron and total iron-binding capacity.
6. An unusually high hematocrit may be due to smoking, dehydration, or stress polycythemia. If the hematocrit is greater than 49%, polycythemia vera should be considered because combined hormonal contraceptives are contraindicated in this rare disease. Medical consultation should be obtained.
7. Any hormonal contraceptive may be used to decrease menstrual blood loss when excessive menstrual flow is a contributing factor for anemia.

Follow-up

1. An increase in the number of reticulocytes is the first sign of improvement after commencement of iron therapy. A reticulocyte value of 5-10% may be achieved within two to four weeks, but iron therapy should be continued for an additional three to six months to replenish iron stores.
2. Adequate response to supplementation is a return of the hematocrit level half way toward normal within three weeks, with full return to baseline after two months.
3. If the client shows no improvement with iron therapy, refer her for physician consultation.
4. If heavy menstruation appears to be the cause of persistent anemia, an appropriate change in contraceptive method should be considered and referral for gynecologic evaluation, if indicated.

Primary References

Hackley, B., Kriebs, J., and Rousseau, M. Primary Care of Women: A guide for midwives and women's health providers. Jones and Bartlett, Sudbury, 2007

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CDC, Iron Deficiency—United States, 1999-2000, MMWR October 11, 2002, 51 (40):897-899.

APPENDIX A

RELATIONSHIPS BETWEEN IRON STORES AND IRON STUDIES

Progression to Anemia	Iron Studies to Determine Progression
Iron store deficiency ↓	Normal erythropoiesis Decreased serum ferritin (<15 mcg/L)*
Absent stores with Iron-deficient erythropoiesis ↓	Decreased serum iron (<60 mcg/dL); increased TIBC (>360 mcg/dL) Decreased transferrin saturation (<15% typical) Microcytosis/hypochromia
Anemia	Decreased hematocrit/increased RDW Transferrin saturation of <10% Severe erythrocyte changes

Abbreviations: RDW indicates erythrocyte distribution width; TIBC, total iron-binding capacity.

*For postmenopausal women <20 mcg/L is diagnostic. In patients with chronic disease states, the ferritin concentration may rise, but a value of <50 mcg/L is still consistent with iron deficiency and a value of >100 mcg/L excludes it. Iron studies are normal in patients with thalassemia traits α and β .

APPENDIX B

IRON AND VITAMIN C FOOD LIST

Vitamin C-rich foods eaten in the same meal with an iron-rich food will help your body to use the iron.

IRON SOURCES

	Animal Sources	Plants Sources
Excellent	Oysters Liver Kidney	Iron fortified cereals
Very Good	Red meats Turkey Liverwurst	Dried beans Blackstrap molasses
Good	Chicken Crab	Canned plums Apricots,dried Greens (spinach, beets, chard) Enriched breads or pasta Peas
Fair	Egg yolk	Tomato juice, Nuts, Peanut Butter Raisins, Dates, Figs Brussels sprouts, Watermelon

VITAMIN C-RICH FOODS

Best Sources	Good Sources
Broccoli	Cabbage
Brussels sprouts	Cauliflower
Cantaloupe	Collard greens
Grapefruit	Greens, beet or turnip
Grapefruit juice	Potato
Orange	Rutabaga
Orange juice	Spinach
Peppers, red or green	Tangelo or tangerine
Strawberries	Tomato, raw or cooked
	Tomato juice
	V-8 juice

BACTERIAL VAGINOSIS

Rationale

Bacterial vaginosis (BV) is one of the most common causes of vaginitis. It results from the replacement of lactobacillus in the vagina with high concentrations of anerobic bacteria. About half of women with BV may be asymptomatic. Symptoms include a fish-like odor and/or a thin white or gray vaginal discharge. BV may also produce burning during urination or itching around the outside of the vagina.

The cause of the alteration of the vaginal flora is unclear. BV is associated with having a new sex partner, multiple sex partners, douching and the lack of lactobacilli. BV is a sexually associated condition, but it is not usually considered a sexually transmitted infection. BV may occur in females who have never been sexually active. BV occurs frequently in lesbians. Treatment of the male partner has not been found to be effective in preventing recurrences of BV.

Bacterial vaginosis has been associated with preterm labor, preterm birth, premature rupture of membranes, postabortion infection, chorioamnionitis, and postpartum endometritis. BV has been associated with endometritis, PID, and vaginal cuff cellulitis after invasive procedures. BV screening and/or prophylaxis treatment for BV prior to GYN procedures is a clinician's option.

Plan of Action

1. Diagnosis is made by use of 3 of 4 Amsel's criteria:
 - a. Homogenous, white, non-inflammatory discharge that smoothly coats the vaginal walls
 - b. "Clue cells" which are characterized by mature vaginal squamous cells coated with bacteria are seen on direct microscopic examination
 - c. Vaginal fluid pH is greater than 4.5
 - d. Positive "whiff" test is obtained when the vaginal discharge is mixed with 10% KOH and liberates an amine-like "fishy" odor
2. Vaginal culture and Pap smear have no role in making the diagnosis of BV.
3. All symptomatic clients need to be treated.
4. Recommended treatment options:
 - a. Metronidazole (Flagyl®) 500 mg orally twice a day for 7 days

OR

- b. Metronidazole gel (MetroGel-Vaginal®) 0.75%, one full applicator (5 g) intravaginally at bedtime for 5 days

OR

- c. Clindamycin cream (Cleocin®) 2%, one full applicator (5 g) intravaginally at bedtime for 7 days

NOTE: Intravaginal clindamycin preparations should not be used in the second half of pregnancy.

The recommended metronidazole regimens are equally efficacious. The vaginal clindamycin appears less efficacious.

The client should avoid alcoholic beverages during metronidazole therapy and for 24 hours after completing treatment because the combination may produce symptoms including abdominal cramps, nausea, vomiting, and headache.

Clindamycin cream and ovules are oil-based and might weaken latex condoms and diaphragms.

5. Alternate treatment options:

- a. Clindamycin (Cleocin®) 300 mg orally twice a day for 7 days

OR

- b. Clindamycin ovules (Cleocin®) 100 mg intravaginally at bedtime for 3 days

NOTE: Intravaginal clindamycin preparations should not be used in the second half of pregnancy.

6. Routine treatment of sex partners is not recommended.

Follow-up

Recurrences are not unusual; clients should return for additional therapy if symptoms persist or recur.

Primary References

CDC. Sexually Transmitted Diseases Treatment Guidelines. 2006

ACOG. Precip: Gynecology. 3rd Ed., 2006

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

BREAST DISEASE

Rationale

Fear of breast cancer motivates women with breast symptoms and concerns to consult their medical provider. It has been estimated that one of every four women in the United States will require medical attention for breast problems, most of which are benign. More than half of all women have some degree of symptomatic fibrocystic changes during their lifetimes. Other benign breast problems include mastodynia, nipple discharge and fibroadenoma.

Fibrocystic disease, the most common benign condition of the breast, occurs in 10% of women under age 21 and becomes more common in the premenopausal period. Common symptoms are bilateral pain and tenderness especially in the upper outer quadrants of the breasts, which increase during the premenstrual phase of the cycle. Examination reveals a generalized lumpiness or granular feeling especially in the upper outer quadrants and beneath the nipple-areola complex.

Nipple discharge may be spontaneous or provoked. Milky discharge in a non-lactating breast may be associated with hypothyroidism, a prolactin-secreting tumor or the administration of certain medications. Unilateral, spontaneous serous or serosanguinous discharge from a single duct is usually caused by intraductal papilloma, rarely cancer. In premenopausal women, spontaneous multiple duct discharge, unilateral or bilateral, is often due to fibrocystic change and may be green or brownish in color.

An American woman now has a 1 in 8 chance of developing breast cancer before she reaches the age of 85. A woman with a family history of a mother or sister having breast cancer is more likely to develop the disease. The risk is increased when the breast cancer occurred before menopause, was bilateral, or was present in 2 or more first-degree relatives. However, there is no history of breast cancer among female relatives in over 90% of the women with the disease.

After more than 50 studies over 50 years, most experts believe that estrogen/progestin contraceptives have little, if any, effect on the risk of developing breast cancer. There is no increased risk of breast cancer in progestin-only contraceptive users.

Plan of Action

1. Routine breast screening
 - a. CBE should be performed at each annual exam.
 - b. During the CBE, the client should be instructed in performing a BSE a few days after the cessation of each menstruation or on a monthly calendar day for women who are not menstruating. About 90% of breast masses are discovered by the woman.
 - c. Ask about nipple discharge.
 - d. Current ACOG guidelines recommend that women age 40-49 have mammography every 1-2 years and yearly beginning at age 50. Women age 35

- and older with a family history of premenopausally diagnosed breast cancer in a first-degree relative should have an annual mammogram.
2. A client who is premenstrual and has bilateral nodularity with tenderness should be scheduled for re-examination after menses.
 3. Evaluation of breast disease is based on risk factors, age history, and physical examination. History should include: the duration and onset of signs and symptoms, menstrual and reproductive history, hormone use and dietary habits. Factors that increase the risk of breast cancer should be considered (Appendix A).
 4. Management of fibrocystic disease may include:
 - a. Restriction of caffeine.
 - b. Avoidance of vigorous exercise during the times of most discomfort.
 - c. Wearing a bra with good support.
 - d. Taking Vitamin E, 400 IU p.o. bid.
 - e. Using a low-estrogen oral contraceptive or depot medroxyprogesterone acetate.
 - f. Using diuretic therapy or analgesics as necessary.
 5. Diagnostic evaluation for nipple discharge includes:
 - a. Cytology of the discharge and referral to a surgeon if abnormal.
 - b. A prolactin level done 24 or more hours after the breast examination and instruction of no further manipulation until blood is drawn. If the result is abnormal, refer the client to an endocrinologist.
 - c. A thyroid profile, and if abnormal, referral for medical evaluation.
 - d. A pregnancy test to rule out pregnancy.
 - e. History of certain medication use including hormonal contraceptives and chlorpromazine type drugs.
 6. Diagnostic evaluation of a breast mass that is not fibrocystic disease usually includes surgical consultation (Appendices B and C).
 7. For breast cancer prevention, all women should be encouraged to follow a healthy diet, control weight, exercise regularly and avoid overindulgence in alcoholic beverages.
 8. Do not provide any type of hormonal contraception to any client who currently has breast cancer or who has had breast cancer within the past 5 years.

Follow-up

1. Follow-up should be scheduled as appropriate to review client status, laboratory test results and treatment responses.
2. If a client expresses concern regarding nipple discharge and the diagnostic evaluation is negative, consider discontinuing hormonal contraception and offering alternative methods of birth control.

3. The referring clinic should follow up on all surgical consultations to insure that they have been carried out (Appendix C).

Primary References

ACOG. *Precis: Primary and Preventive Care*. 3rd Ed., 2004

ACOG. *Precis: Gynecology*. 3rd Ed., 2006

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APPENDIX A

FACTORS THAT INCREASE THE RISK OF BREAST CANCER

1. Increased age
2. Personal history of breast cancer
3. History of atypical ductal or lobular hyperplasia on past biopsies
4. Personal history of endometrial, ovarian, or colon cancer
5. Inherited genetic mutations
6. Jewish heritage
7. First-degree relatives with breast or ovarian cancer diagnosed at an early age
8. Early menarche (age <12 years)
9. Late menopause (age >55 years)
10. Nulliparity
11. No term pregnancies
12. Late age at first live birth (age >30 years)
13. Never breastfeed
14. Higher socioeconomic status
15. Obesity
16. Moderate to high alcohol intake (2 to 5 drinks per day)
17. Use of hormone therapy

APPENDIX B

INDICATIONS FOR REFERRAL

1. Dominant mass
2. Marked increase in size or firmness of one breast
3. Retraction of the nipple or the skin
4. Redness and edema over at least a third of the breast with underlying induration
5. Bloody nipple discharge
6. Changes in nipple epithelium, such as erosion
7. Mammographic evidence of breast disease
8. Genetic counseling and testing may be considered for clients with a strong family history

APPENDIX C

RECOMMENDED STEPS WHEN REFERRING FOR POSSIBLE BREAST LESION

1. Advise the client of the need for a surgical consultation and give her the name (or names) of a surgeon. Provide the full name, address, and telephone number of the surgeon.
2. Complete a clinic referral form for the client and attach a duplicate copy for the client's record.
3. Give the client the referral form to take to the surgeon, and request that the form be returned to the clinic after the surgeon has completed the evaluation and provided a note for the clinic record.
4. Give the client an appointment for a family planning visit within six weeks after the referral.

CERVICAL CANCER SCREENING

Rationale

Cervical cancer screening with cervical cytology, high-risk human papillomavirus (HPV) testing, and colposcopy can lead to the pathologic diagnosis of cervical intraepithelial neoplasia (CIN). The appropriate management of women with CIN is critical for the diagnosis and treatment of cervical cancer.

The 2001 Bethesda System Terminology for cytology (Pap) utilizes the terms low-grade squamous intraepithelial lesion (LSIL) and high-grade squamous intraepithelial lesion (HSIL) to refer to low-grade and high-grade cervical cancer precursors. The histologic (biopsy) classification of cervical intraepithelial neoplasia (CIN) applies the terms CIN 1 to low-grade lesions and CIN 2, 3 to high-grade precursors to cervical cancers. Cytological low-grade squamous intraepithelial lesion (LSIL) is not equivalent to histological CIN 1. Likewise, cytological high-grade squamous intraepithelial lesion (HSIL) is not equivalent to histological CIN 2, 3.

The 2006 Bethesda guidelines for the management of women with abnormal cervical cancer screening tests expand the clinical indications for HPV testing. Other notable changes include the cervical screening management for special populations.

The reliability of cervical cytology depends on the skill and experience of the person taking the sample, the area that is sampled, the collection technique, and the quality control system in the laboratory. False-negative results may be caused by laboratory errors and poor sampling techniques.

High-risk HPV DNA testing may be done directly from a liquid-based Pap test or as a separate stand-alone test when no Pap test is required. There are absolutely no indications for low-risk HPV DNA testing.

Therapies for biopsy-proven CIN are discussed in the Cervical Neoplasia Management guidelines in the Maryland State Family Planning Program Clinical Guidelines.

Adolescent women (age 20 and younger) have a high prevalence of HPV infection and more minor-grade cytological abnormalities (atypical squamous cells [ASC] and LSIL). However, there is a very low risk of invasive cervical cancer, compared with older women. The vast majority of HPV infections in this age group clear spontaneously within 2 years and have little long-term clinical significance. Colposcopy in adolescents with minor cytologic abnormalities should be discouraged.

Colposcopy in pregnant women at low risk for having cervical cancer should be deferred. Endocervical curettage is contraindicated in pregnant women.

Clinical judgment should always be used when applying a guideline to an individual client because it is impossible to develop guidelines that apply to all situations.

Plan of Action

Screening for Adolescent Women Age 20 and Under

1. Cervical cancer screening with cytology should begin approximately 3 years after the onset of vaginal intercourse or no later than age 21, whichever comes first.
2. Cervical cytology screening may be initiated sooner if there is any indication of childhood sexual abuse.
3. Once started, cervical cancer screening should be repeated annually until age 30.
4. HPV DNA testing should never be done in the adolescent age group, either as primary testing or as reflex testing.
5. The recommendations for cervical cytology screening for adolescents do not negate the need for the annual visit to obtain preventive health care, assessment of health risks, contraception, preventive counseling, pelvic examination, and screening for sexually transmitted infections. ACOG recommends that the first visit should take place around ages 13-15 years.

Screening for Women Age 21 through 29

Cervical cancer screening should be done annually using cervical cytology with reflex HPV testing.

Screening for Women Age 30 and Over

1. Cervical cytology plus HPV DNA testing should be done every 3 years. This option reduces the overall cost of screening if the screening interval is no less than 3 years. Using this option, clients receive results of both a Pap test and a HPV DNA test. If both tests are negative and the woman remains low-risk, she should be rescreened with both tests no more than every 3 years, due to the very high negative predictive value (approaching 100%) of the combination test.
2. Certain factors may put a woman at higher risk for cervical cancer and require annual cervical cancer screening. Women with the following risk factors should not go to extended screening intervals:
 - a. exposure to diethylstilbestrol (DES) in utero
 - b. previous diagnosis of cervical, endometrial, vulvar, or vaginal cancers
 - c. infection with human immunodeficiency virus (HIV)
 - d. history of including other immunocompromised states such as:
 - 1) organ transplant
 - 2) cancer chemotherapy
 - 3) chronic steroid use such as for chronic renal or bowel disease
 - 4) conditions such as lupus
 - 5) dialysis

3. Management of primary screening with Pap and HPV for women age 30 and over

If Pap (-)/HPV (-) → resume routine screen with Pap & HPV in 3 years

If Pap (-)/HPV (+) → repeat Pap & HPV in 12 months

If Pap (ASC-US)/HPV (-) → repeat Pap & HPV in 12 months

If Pap (ASC-US or greater)/HPV (+) → colposcopy

If Pap (greater than ASC-US)/HPV (+ or -) → colposcopy

If 12-month Pap (-)/HPV (-) → resume routine screen with Pap & HPV in 3 years

If 12-month Pap (-)/HPV (+) → colposcopy

If 12-month Pap (any abnormality)/HPV (+ or -) → colposcopy

4. If HPV DNA testing is not used, it is also appropriate and clinically sound to increase screening intervals using the Pap test alone. If a woman has 3 consecutive annual negative Pap test results and is not in a risk group who should be screened more frequently (see page 2, #2), the screening interval may be extended to 2-3 years.

Screening During Pregnancy

Cervical cancer screening may be done any time during pregnancy. The only indication for follow-up and/or treatment during pregnancy is to diagnose and treatment invasive cervical cancer.

Screening for Women Who Have Undergone Hysterectomy

1. Women who have had a hysterectomy with the removal of the cervix for any indications other than cervical or uterine carcinoma and who have no prior history of CIN 2 or CIN 3 or worse may discontinue routine cytology testing.
2. Women who have had a hysterectomy with the removal of the cervix for benign indications but who have had an unknown cervical cytology history or a history of CIN 2 or CIN 3 or worse should have annual screening until they have 3 consecutive negative vaginal cytology tests, at which point screening can be discontinued.
3. Women who have had a subtotal hysterectomy (the cervix remaining intact) should continue cervical cancer screening as per guidelines for the intact uterus.
4. Women who have had a hysterectomy with removal of the cervix for cervical or uterine carcinoma should continue annual screening.

Additional Screening Considerations

1. Women of all ages should be counseled that a pelvic exam is not the same as a Pap test, and a woman who may not need a cytology test still needs regular preventive health care visits, including gynecologic care and breast examination, family planning, risk assessments, and counseling.
2. In the presence of a visible suspicious cervical or vaginal lesion, physician consultation should be obtained and/or referral made to colposcopy.

3. The accuracy of the cytologic diagnosis can be directly related to the sampling technique. It is important to include the endocervix and exocervix as part of the specimen. The cervix must always be sampled at the squamocolumnar junction (Appendix A, B, and C).
4. At least 8 weeks should be allowed for regeneration of the epithelium when a Pap test is repeated for any reason.
5. At least 8 weeks should be allowed for the healing of the cervix following pregnancy delivery, abortion, cervicitis treatment.
6. According to ACOG, due to the limited studies in older post-menopausal women, it is difficult to establish a standard recommendation for an upper age limit for cervical cancer screening. Clinicians need to determine on an individual basis when an older woman may stop having cervical cancer screening.

Follow-up

Cytology laboratories have instituted “The 2001 Bethesda System” reporting format as noted below. The 2006 consensus guidelines, 2004 interim guidelines, and 2001 consensus guidelines are utilized as basis for the following recommendations:

1. SPECIMEN ADEQUACY or statement of specimen adequacy
 - a. SATISFACTORY FOR EVALUATION
 - Note the presence/absence of endocervical/transformation zone component
Management: When endocervical cells are absent and there is a history of abnormal Pap test or colposcopy, repeat Pap in 6 months. Otherwise, repeat in 1 year.
 - b. UNSATISFACTORY FOR EVALUATION
 - Specimen rejected/not processed. . . (specify reason)
 - Specimen processed and examined, but unsatisfactory for evaluation of epithelial abnormality because of. . . (specify reason)
Management: Repeat Pap test in 3-6 months depending on clinical history.
2. GENERAL CATEGORIZATION (optional)
 - a. NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY
Management: Pap test only, Pap test with reflex HPV DNA test, or Pap test and HPV DNA test according to age category.
 - b. EPITHELIAL CELL ABNORMALITY
Management: See INTERPRETATION/RESULT for management.
 - c. OTHER
Management: See INTERPRETATION/RESULT for management

3. INTERPRETATION/RESULT

a. NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY

Management: Pap test only, Pap test with reflex HPV DNA test, or Pap test and HPV DNA test according to age category.

1) Organisms

Management: Manage specific organism and/or infection based on treatment guidelines. Asymptomatic clients with clue or yeast are not always treated. Follow-up of Trichomoniasis on cytology may be either treatment or examination with wet mount to confirm diagnosis prior to treatment. No repeat Pap test is necessary.

2) Other non-neoplastic findings

(reactive cellular changes, glandular cells status post-hysterectomy, atrophy)

Management: Management is based on condition. No repeat Pap test is necessary.

b. EPITHELIAL CELL ABNORMALITIES

1) ATYPICAL SQUAMOUS CELLS OF UNDETERMINED SIGNIFICANCE (ASC-US)

Management:

a) Adolescents (Age 20 and under)

If 1st Pap (ASC-US) → repeat Pap at 12 months

If 12-month Pap (HSIL or greater) → colposcopy

If 12-month Pap (less than HSIL) → repeat Pap in 12 months

If 24-month Pap (ASC-US or greater) → colposcopy

b) Age 21-29

If Pap (ASC-US)/HPV (-) → repeat Pap in 12 months

If 12-month Pap (ASC-US or greater) → colposcopy within 3 months

If 12-month Pap (-) → resume routine Pap screening

If Pap (ASC-US)/HPV (+) → colposcopy within 3 months

(NOTE: HPV DNA testing is not to be done at intervals less than 12 months.)

OR

If HPV testing is not available, repeat cytology may be done at 6- and 12-month intervals.

If 2 consecutive Paps (-) → resume routine Pap screening

If either Pap (+) → colposcopy with 3 months

At colposcopy, endocervical sampling is preferred for women in whom no lesions were identified or those with an unsatisfactory colposcopy.

At colposcopy:

If CIN identified → Cervical Neoplasia Management

If no CIN identified → HPV at 12 months

(or Pap at 6 and 12 months)

If 12-month HPV (+) → repeat colposcopy

If 12-month HPV (-) → resume routine Pap screening

If either Pap (ASC-US or greater) → repeat colposcopy

If 2 consecutive Paps (-) → resume routine Pap screening

c) Age 30 and over

If Pap (ASC-US)/HPV (-) → repeat Pap & HPV in 12 months

If 12-month Pap (-)/HPV (-) → resume routine screen with
Pap & HPV in 3 years

If 12-month Pap (-)/HPV (+) → colposcopy

If 12-month Pap (any abnormality)/HPV (+ or -) →
colposcopy

If Pap (ASC-US)/HPV (+) → colposcopy

d) Pregnant Women

Management options for pregnant women over the age of 20 years with ASC-US are identical to those for nonpregnant women, with the exception that it is acceptable to defer colposcopy until at least 6 weeks postpartum. Endocervical curettage is unacceptable in pregnant women. HPV is not used for screening pregnant adolescents.

2) ATYPICAL SQUAMOUS CELLS, CANNOT EXCLUDE HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESION (ASC-H)

Management: Refer the client to colposcopy within 3 months, regardless of HPV status (All Ages).

At colposcopy

If CIN 2, 3 → Cervical Neoplasia Management

If no CIN 2, 3 → HPV at 12 months

(or Pap at 6 and 12 months)

If 12-month HPV (+) → repeat colposcopy

If 12-month HPV (-) → resume routine Pap screening

If either Pap (ASC-US or greater) → repeat colposcopy

If 2 consecutive Paps (-) → resume routine Pap screening

3) LOW-GRADE SQUAMOUS INTRAEPITHELIAL LESION (LSIL)

Management:

a) Adolescents (Age 20 and under)

If 1st Pap (LSIL) → repeat Pap at 12 months

If 12-month Pap (HSIL or greater) → colposcopy

If 12-month Pap (less than HSIL) → repeat Pap in 12 months

If 24-month Pap (ASC-US or greater) → colposcopy

b) Age 21 and over

Refer the client to colposcopy within 3 months.

At colposcopy, endocervical sampling is preferred for women in whom no lesions were identified or those with an unsatisfactory colposcopy.

At colposcopy

If CIN 2, 3 → Cervical Neoplasia Management

If no CIN 2, 3 → HPV at 12 months

(or Pap at 6 and 12 months)

If 12-month HPV (+) → repeat colposcopy

If 12-month HPV (-) → resume routine Pap screening

If either Pap (ASC-US or greater) → repeat colposcopy

If 2 consecutive Paps (-) → resume routine Pap screening

c) Pregnant Women

Colposcopy is preferred for pregnant nonadolescent women with LSIL. Endocervical curettage is unacceptable in pregnant women. Deferring initial colposcopy until 6 weeks postpartum is acceptable.

4) HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESION (HSIL)

Management:

a) Adolescents (age 20 and younger)

Colposcopy is recommended. Immediate loop electrosurgical excision (i.e. “see-and-treat”) is unacceptable.

If CIN 2, 3 → Cervical Neoplasia Management

If no CIN 2, 3 (colpo satisfactory, ECC (-) → Colposcopy and cytology at 6 mo intervals x 2 years

If during follow-up a high-grade colposcopic lesion is identified or HSIL cytology persists for 1 year, biopsy is recommended.

If HSIL persists for 24 months without identification of CIN 2, 3, a diagnostic excisional procedure is recommended.

After 2 consecutive Paps (-) and no high-grade colposcopy abnormality → resume routine Pap screening

If colposcopy is unsatisfactory or CIN of any grade is identified on endocervical assessment → diagnostic excision

b) Age 21 and over: Refer the client promptly to colposcopy.

At colposcopy, endocervical curettage is mandatory.

At colposcopy

If CIN 2, 3 → Cervical Neoplasia Management

If no CIN 2, 3 (colpo unsatisfactory) → diagnostic excision

If no CIN 2, 3 (colpo satisfactory) →

Colposcopy and cytology at 6 and 12 months

OR

Diagnostic excision

If repeat Pap (HSIL) → diagnostic excision

If 2 consecutive Paps (-) → resume routine Pap screening

Triage using only repeat cytology or HPV testing is unacceptable.

c) Pregnant Women

Colposcopy is recommended for Pap (HSIL). Endocervical curettage is unacceptable in pregnant women. Biopsy of the cervix to rule out invasive cancer should not be done in the local health department setting. Re-evaluation with cytology and colposcopy is recommended no sooner than 6 weeks postpartum for pregnant women with HSIL in whom CIN 2, 3 is not diagnosed.

5) SQUAMOUS CELL CARCINOMA

Management: Consult promptly with a GYN oncologist for referral (All Ages).

6) ATYPICAL GLANDULAR CELLS (AGC) (all subcategories)

Management:

a) Refer the client promptly to colposcopy (All Ages).

Endocervical sampling is mandatory.

Endometrial sampling is recommended in conjunction with colposcopy and endocervical sampling in women 35 year and older.

Endometrial sampling is recommended for women under age 35 years with clinical indications suggesting risk for neoplastic lesions.

Endometrial sampling is recommended for women with atypical endometrial cells

HPV DNA testing at the time of colposcopy is preferred in women with atypical endocervical, endometrial, or glandular cells not otherwise specified (NOS).

HPV DNA testing alone is unacceptable for the initial triage of all subcategories.

Repeat cervical cytology is unacceptable for the initial triage of all subcategories.

At colposcopy for a client with known HPV status with atypical endocervical, endometrial, or glandular cells (NOS) on Pap:

If no CIN or glandular neoplasia → repeat Pap and HPV in 6 months if HPV (+);
repeat Pap and HPV in 12 months if HPV (-)

If repeat HPV (+) → repeat colposcopy

If repeat Pap (ASC-US or greater) → repeat colposcopy

If Pap (-) and HPV (-) → resume routine Pap screening

At colposcopy for a client with unknown HPV status with atypical endocervical, endometrial, or glandular cells (NOS) on Pap:

If no CIN or glandular neoplasia → repeat Pap at 6-month intervals

If 4 consecutive Pap (-) → resume routine Pap screening

If CIN (+) but no glandular neoplasia → Cervical Neoplasia Management

At colposcopy no invasive disease is identified for a client with a Pap that states atypical endocervical or glandular cell “favors neoplasia” or endocervical adenocarcinoma in situ (AIS) → diagnostic excision

b) Pregnant Women

Evaluation should be the same as that of nonpregnant women. Endocervical and endometrial sampling are unacceptable.

c. OTHER

- 1) BENIGN ENDOMETRIAL CELLS - PREMENOPAUSE
(benign endometrial cell, endometrial stromal cells, or histiocytes)
Management: If asymptomatic, no further evaluation.
- 2) BENIGN ENDOMETRIAL CELLS – POSTMENOPAUSE
Management: Endometrial assessment regardless of symptoms.
- 3) BENIGN GLANDULAR CELL AFTER HYSTERECTOMY
Management: No further evaluation is recommended.

Primary References

Wright T et al. 2006 Consensus Guidelines for the Management of Women with Cervical Intraepithelial Neoplasia or Adenocarcinoma In Situ. AJOG, Vol. 197, Issue 4, 340-345, October 2007

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ACOG. Routine Pelvic Examination and Cervical Cytology Screening. Committee Opinion #431, May 2009

APPENDIX A

CERVICAL CYTOLOGY COLLECTION USING THE LIQUID-BASED MEDIUM SPATULA/ENDOCERVICAL BRUSH TECHNIQUE

1. Observe universal precautions for collecting and handling specimens.
2. Insert the speculum which may be slightly moistened with water or saline if necessary. A water-soluble lubricant may be used if the speculum cannot otherwise be inserted.
3. Visually inspect the cervix for abnormalities. Identify the transformation zone, if visible, and direct sampling efforts to encompass this area. (Comment: If an ulcerated, necrotic, or exudate-covered lesion is observed, a biopsy should be obtained after cytology sampling. Refer the client to colposcopy.)
4. Choose the contoured end of the plastic spatula that best conforms to the anatomy of the cervix and the location of the transformation zone. Rotate the spatula 360° about the circumference of the cervical os and ectocervix, while maintaining firm contact with the epithelial surface.

A clockwise rotation beginning and ending at 9 o'clock (or counter-clockwise rotation from 3 o'clock to 3 o'clock) will position the spatula so that the collected material is retained on the upper horizontal surface as the instrument is removed.

5. Rinse the spatula specimen into the preservative solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.
6. Insert the cervical brush into the os with gentle pressure and rotate only 90° to 180° to minimize bleeding. (Comment: Brushes have circumferential, radiating bristles that come in contact with the entire os surface upon insertion. This is in contrast to the edge of a spatula which is in contact with only a fraction of the epithelial surface at any one time. Therefore, the brush need only be rotated one quarter turn, 90°, while the spatula must be rotated a full turn, 360°.)
7. Rinse the brush in the preservative solution by rotating the brush in the solution 10 times while pushing against the vial wall. Swirl the brush vigorously to further release material. Discard the brush.
8. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
9. Record the client's name and other identification on the vial.

APPENDIX B

CERVICAL CYTOLOGY COLLECTION USING THE LIQUID-BASED MEDIUM BROOM-LIKE DEVICE TECHNIQUE

1. Obtain an adequate sampling from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction 5 times.
2. Rinse the broom specimen into the preservative solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release of material. Discard the broom.
3. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
4. Record the client's name and other identification on the vial.

APPENDIX C

HPV COLLECTION TECHNIQUE

This technique is for use in collecting a stand-alone HPV DNA test.

1. Collect the HPV specimen prior to application of acetic acid if a colposcopy will be performed immediately after the HPV specimen is collected.
2. Remove the excess mucus from the cervical os and surrounding ectocervix using a cotton or Dacron swab. Discard the swab.
3. Insert the brush 1-1.5 cm into the os of the cervix until the largest outer bristles touch the ectocervix. Rotate the brush 3 full turns in a counter-clockwise direction. Do not insert the brush completely into the cervical canal.
4. Remove the brush from the canal.
5. The specimen may be placed in one of two containers for shipment to the laboratory.
 - a. A liquid-based cytology vial may be used following the instructions in Appendix A, No. 6-9.

OR

- b. A vial specifically for the HPV test (provided by the laboratory) may be used for transport.
 - 1) Avoid touching the bristles to the outside of the tube or any other objects.
 - 2) Insert the brush to the bottom of the transport tube.
 - 3) Snap off the brush at the score line and cap the tube securely.
 - 4) Record the client's name and other identification on the vial.

CERVICAL NEOPLASIA MANAGEMENT

Rationale

Cervical cancer screening with cervical cytology, high-risk human papillomavirus (HPV) testing, and colposcopy can lead to the pathologic diagnosis of cervical intraepithelial neoplasia (CIN). The appropriate management of women with CIN is critical for the diagnosis and treatment of cervical cancer.

The 2001 Bethesda System terminology for cytology (Pap) utilizes the terms low-grade squamous intraepithelial lesion (LSIL) and high-grade squamous intraepithelial lesion (HSIL) to refer to low-grade and high-grade cervical cancer precursors. The histologic (biopsy) classification of cervical intraepithelial neoplasia (CIN) applies the terms CIN 1 to low-grade lesions and CIN 2, 3 to high-grade precursors to cervical cancers. Cytological low-grade squamous intraepithelial lesion (LSIL) is not equivalent to histological CIN 1. Likewise, cytological high-grade squamous intraepithelial lesion (HSIL) is not equivalent to histological CIN 2, 3.

CIN lesions may be treated using ablative or excisional modalities. Ablative methods that destroy the affected cervical tissue include cryotherapy, laser ablation, electrofulguration, and cold coagulation. Excisional methods that remove the affected cervical tissue and provide a tissue specimen for pathological examination include cold-knife conization, loop electrosurgical excision procedures (called LEEP or LLETZ), laser conization, and electrosurgical needle conization. All of the ablative and excisional methods listed have a similar efficacy in eliminating CIN and thus reducing a woman's risk of future invasive cervical cancer.

CIN treatment modalities can affect a woman's future pregnancy. The following excisional methods including cold-knife conization, loop excision, and laser conization increase a woman's risk of premature labor and delivery, premature rupture of membranes, a low birthweight infant, and cesarean section. Ablative methods may also have adverse effects on future pregnancies.

There are no proven medical treatments for CIN. Therapeutic HPV vaccines have not been proven effective.

Factors that determine which treatment option to use include age, parity, desire for future childbearing, prior cytology and treatment history, history of client's follow-up from prior treatment, clinician experience with treatment methods, and nonvisualization of the transformation zone.

The treatment failure rates for all treatment modalities approach 25%. Most failures occur within 2 years of treatment. Women who have been treated for CIN 2, 3 have still have a risk for developing invasive cervical cancer.

CIN lesions are common in adolescents (age 13 – 20 years) and young women but the risk of invasive cancer is very low. In adolescents CIN has a very high rate of spontaneous regression rarely requiring any treatment (Appendix A).

In pregnant women the risk of progression of CIN 2, 3 to invasive cancer is minimal. The rate of spontaneous regression of CIN postpartum is relatively high. Invasive cervical cancer is the only indication for therapy of cervical neoplasia in pregnant women (Appendix B).

Plan of Action

1. Refer to the Maryland State Family Planning Program “Cervical Cancer Screening” and “Colposcopy” Clinical Guidelines and the “2006 Consensus Guidelines for the management of Women with Cervical Intraepithelial Neoplasia or Adenocarcinoma In Situ” for discussion of determining appropriate candidates for CIN treatment.
2. Depending on the jurisdiction, the decision for CIN treatment may be made by the in-house colposcopist or the colposcopist to whom the client was referred. In both circumstances it is imperative to obtain the colposcopy examination records, all biopsy results, and recommendations for CIN treatment.
3. The CIN treatment record along with the treating clinician’s recommendation for follow-up must be obtained and reviewed with the client.
4. Follow-up protocols include cytology, colposcopy, HPV testing, combinations of all three with a variety of testing intervals. Randomized trials have not been done. HPV testing follow-up performance has exceeded cytology alone follow-up.
5. Adolescents and pregnant women constitute special populations for CIN treatment and follow-up (Appendix A and B, respectively).

1. CIN1

There is a very high rate of spontaneous regression CIN 1 in the absence of treatment. CIN 1 rarely progresses to CIN 2, 3 within the first 24 months.

The risk of having undetected CIN 2,3 or adenocarcinoma in situ (AIS) is expected to be greater in women with CIN 1 preceded by a HSIL or atypical glandular cells (AGC) cytology result than for women with CIN 1 preceded by an ASC or LSIL cytology result.

- a. CIN 1 PRECEDED BY ATYPICAL SQUAMOUS CELLS OF UNDETERMINED SIGNIFICANCE (ASC-US); ATYPICAL SQUAMOUS CELLS, CANNOT EXCLUDE HSIL, ASC-H, OR LSIL CYTOLOGY

Management: LSIL cytology – HPV DNA testing every 12 months

OR

Repeat cytology every 6 to 12 months

If HPV DNA test is positive or if repeat cytology is reported as ASC-US or greater, colposcopy is recommended.

If HPV DNA test at 12 months is negative or 2 consecutive repeat cytology test are negative, return to routine cytological screening.

If CIN 1 persists for at least 2 years, either follow-up or treatment is acceptable. If treatment is selected and the colposcopic examination is satisfactory, excision or ablation is acceptable. If the colposcopic examination is unsatisfactory, the endocervical sampling contains CIN or if the client has been previously treated, an excisional procedure is recommended.

Ablative procedures are unacceptable in clients with CIN 1 and an unsatisfactory colposcopic examination.

Podophyllin or podophyllin-related products are unacceptable for use in the vagina or on the cervix.

Hysterectomy as the primary or principal treatment for CIN 1 is unacceptable.

b. CIN 1 PRECEDED BY HSIL OR AGC-US CYTOLOGY

Management: Observation with colposcopy and cytology at 6 month intervals for 1 year

OR

Diagnostic excisional procedure

Colposcopic examination must be satisfactory and endocervical sampling negative. A diagnostic excisional procedure is recommended for women with a repeat HSIL or AGC-NOS at either the 6- or 12-month visit.

After 1 year of observation, women with 2 consecutive negative cytology tests can return to routine screening.

A diagnostic excisional procedure is recommended for women with CIN 1 preceded by a HSIL or AGC-NOS cytology in whom the colposcopic examination is unsatisfactory.

2. CIN 2,3

CIN 2, 3 includes lesions previously known as moderate dysplasia (CIN 2) and severe dysplasia/carcinoma in situ (CIN 3). CIN 2 lesions are more heterogeneous and more likely to regress during long-term follow-up than are CIN 3 lesions. CIN 2 is utilized as the threshold for treatment in the United States to provide an added measure of safety, and recommendations for the management of women with histologically diagnosed CIN 2 and CIN 3 are combined in the 2006 Consensus Guidelines.

Management: Both excision and ablation are acceptable treatment modalities for women with a histological diagnosis of CIN 2, 3 and satisfactory colposcopy.

A diagnostic excisional procedure is recommended for women with recurrent CIN 2, 3.

Ablation is unacceptable and a diagnostic excisional procedure is recommended for women with a histological diagnosis of CIN 2, 3 and unsatisfactory colposcopy.

Observation of CIN 2, 3 with sequential cytology and colposcopy is unacceptable, except with adolescents and pregnant women.

Hysterectomy is unacceptable as primary therapy for CIN 2, 3.

Acceptable post-treatment management options for women with CIN 2, 3

HPV DNA testing at 6 to 12 months

OR

Cytology alone at 6-month intervals

OR

Cytology and colposcopy at 6-month intervals

Colposcopy with endocervical sampling is recommended for women who are HPV DNA positive or have a repeat cytology result of ASC-US or greater.

If the HPV DNA test is negative or if 2 consecutive repeat cytology tests are negative, routine screening for 20 years commencing at 12 months is recommended.

Repeat treatment or hysterectomy based on a positive HPV DNA test is unacceptable.

If CIN 2, 3 is identified at the margins of a diagnostic excisional procedure or in an endocervical sample obtained immediately after the procedure, reassessment using cytology with endocervical sampling at 4-6 months after treatment is preferred. Performing a repeat diagnostic excisional procedure is acceptable. Hysterectomy is acceptable if a repeat diagnostic procedure is not feasible.

A repeat diagnostic excision or hysterectomy is acceptable for women with a histological diagnosis of recurrent or persistent CIN 2, 3.

3. AIS

Adenocarcinoma in situ (AIS) is much less commonly encountered than CIN 2, 3. Management is both challenging and controversial. Colposcopic changes associated with AIS can be minimal. AIS frequently extends for a considerable distance into the endocervical canal making complete excision difficult. AIS is frequently multifocal and frequently has “skip lesions”.

Management: An excisional biopsy is required in all women with AIS prior to making any subsequent management decision.

Hysterectomy is preferred for women who have completed child-bearing and have a histological diagnosis of AIS on a specimen from a diagnostic excisional procedure.

Conservative management is acceptable if future fertility is desired. If conservative management is planned and the margins of the specimen are involved or endocervical sampling obtained at the time of excision contains CIN or AIS, re-excision to increase the likelihood of complete excision is preferred. Reevaluation at 6 months using a combination of cervical cytology, HPV DNA testing, and colposcopy with endocervical sampling is acceptable. Long-term follow-up is recommended for women who do not undergo hysterectomy.

Primary References

Wright T et al. 2006 Consensus Guidelines for the Management of Women with Cervical Intraepithelial Neoplasia or Adenocarcinoma In Situ. *AJOG*, Vol. 197, Issue 4, 340-345, October 2007

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APPENDIX A

GUIDELINES FOR CERVICAL NEOPLASIA MANAGEMENT FOR ADOLESCENTS

CIN lesions are common in adolescents (age 13 -20 years) and young women but the risk of invasive cancer is very low. In adolescents CIN has a very high rate of spontaneous regression rarely requiring any treatment.

1. CIN 1

Management: Annual cytological assessment

At 12-month follow-up, only adolescents with HSIL or greater on the repeat cytology should be referred to colposcopy.

At 24-month follow-up, those adolescents with an ASC-US or greater on the repeat cytology should be referred to colposcopy.

Follow-up with HPV DNA testing is unacceptable.

2. CIN 2, 3

Management: Treatment or observation for up to 24 months using both colposcopy and cytology at 6-month intervals is acceptable, providing colposcopy is satisfactory.

For CIN 2, observation is preferred but treatment is acceptable.

For CIN 3 or unsatisfactory colposcopy, treatment is recommended.

If the colposcopic appearance of the lesion worsens or if HSIL cytology or a high-grade colposcopic lesion persists for 1 year, repeat biopsy is recommended.

After 2 consecutive negative cytology tests, adolescents and young women with normal colposcopy can return to routine cytological screening.

APPENDIX B

GUIDELINES FOR CERVICAL NEOPLASIA MANAGEMENT DURING PREGNANCY

In pregnant women the risk of progression of CIN 2, 3 to invasive cancer is minimal. The rate of spontaneous regression of CIN postpartum is relatively high. Invasive cervical cancer is the only indication for therapy of cervical neoplasia in pregnant women.

1. CIN 1

Management: Follow-up without treatment.

Treatment of pregnant women for CIN 1 is unacceptable.

2. CIN 2,3

Management: In the absence of invasive disease or advanced pregnancy, additional colposcopic or cytological examinations are acceptable at intervals no more frequent than every 12 weeks.

Repeat biopsy is recommended only if the appearance of the lesion worsens or if cytology suggests invasive cancer.

Deferring evaluation until at least 6 weeks postpartum is acceptable.

A diagnostic excisional procedure is recommended only if invasion is suspected.

Unless invasive cancer is identified, treatment is unacceptable.

Reevaluation with cytology and colposcopy is recommended no sooner than 6 weeks postpartum.

CHANCROID

Rationale

Chancroid is caused by the gram-negative bacillus, *Haemophilus ducreyi*. The incubation period is usually 4 to 7 days. The chancre begins as a tender papule surrounded by erythema. In 24 to 48 hours it becomes pustular, eroded, and ulcerated. The ulcer is usually very painful in males but less painful in females. The client may also present with tender inguinal adenopathy or suppurative inguinal adenopathy.

Chancroid appears to be spread only by sexual contact. It is endemic in many countries of the developing world but also found in selected areas of the United States, specifically where there is a high volume of exchange of sex for money and drugs. Female sex workers may be a reservoir of this disease in areas of endemic disease.

Ten percent of clients with chancroid are co-infected with *T. pallidum* or herpes simplex virus (HSV). High rates of HIV infection are reported in persons with chancroid. There is no test readily available for the diagnosis of chancroid.

Plan of Action

1. Probable diagnosis may be made if all of the following criteria are met:
 - a. The client has one or more painful genital ulcers.
 - b. There is no evidence of *T. pallidum* by a serologic test for syphilis performed at least 7 days after the onset of ulcers.
 - c. Clinical presentation of the ulcer(s) is not typical for HSV disease and a culture for HSV performed on the ulcer exudate is negative.
 - d. The combination of a painful ulcer(s) with tender inguinal adenopathy suggests a diagnosis of chancroid, and when accompanied by suppurative inguinal adenopathy is almost pathognomonic.
2. Recommended treatment options:
 - a. Azithromycin (Zithromax®) 1 gm orally in a single dose

OR
 - b. Ceftriaxone (Rocephin®) 250 mg intramuscularly in a single dose

OR
 - c. Ciprofloxacin (Cipro®) 500 mg orally twice a day for 3 days

NOTE: Ciprofloxacin is contraindicated for pregnant and lactating women and for persons aged less than 18 years.

OR

- d. Erythromycin base 500 mg orally three times a day for 7 days
3. Clients should be evaluated for chlamydia, gonorrhea, syphilis, hepatitis B infection, and HIV infection at the time chancroid is diagnosed.
4. Sexual contacts within 10 days prior to the onset of the patient's symptoms should be examined and treated even in the absence of symptoms.
5. The regular use of condoms is recommended to help reduce transmission.
6. Chancroid has no known adverse effects on pregnancy outcome or the fetus.

Follow-up

1. The client should be evaluated in 3 days for symptomatic improvement and examined in 7 days for objective improvement.
2. If there is no improvement, consider the following possibilities:
 - a. Incorrect diagnosis
 - b. Co-infection with another STD
 - c. Client infected with HIV
 - d. Non-compliance with treatment instructions
 - e. Resistant strain of *H. ducreyi*
3. Complete healing of large ulcers may require more than 2 weeks.
4. Healing is slower for some uncircumcised men who have ulcers under the foreskin.
5. Inadequate resolution of fluctuant lymphadenopathy may require needle aspiration.
6. Clients should be retested for syphilis and HIV 3 months after the diagnosis of chancroid, if the initial test results were negative.
7. HIV-infected clients should be monitored closely, because, as a group, they are more likely to experience treatment failure and to have ulcers that heal more slowly.

Primary References

CDC. Sexually Transmitted Diseases Treatment Guidelines. 2006

Red Book: 2006 Report of the Committee on Infectious Diseases. 27th Ed., American Academy of Pediatrics, Elk Grove Village, IL

CHLAMYDIA

Rationale

Chlamydia trachomatis is the most prevalent sexually transmitted infection in the United States today. The epidemiology of Chlamydia trachomatis and Neisseria gonorrhoeae are similar. Up to 40% of women with gonorrhea have concomitant chlamydia. However, the prevalence of chlamydia among asymptomatic women is higher than that of gonorrhea. Asymptomatic infection is common among both men and women. Most women are unlikely to be treated unless a male partner develops symptoms, or the diagnosis is made during routine screening.

Serious sequelae from chlamydia infection in women include PID, ectopic pregnancy, and infertility. The most common manifestation of chlamydia infection in women is mucopurulent cervicitis. Infection of the endocervix results in a hypertrophic appearance of the cervix and a mucopurulent discharge. A less common manifestation is acute urethral syndrome. This syndrome usually presents as the acute onset of dysuria, urgency and frequency in clients whose urine is sterile or contains less than 100,000 bacteria per mL.

Detection of chlamydia infections relies on screening tests. Annual screening of all sexually active women age 25 years or younger is recommended, as is screening of older women with risk factors. The benefits of chlamydia screening in women have been demonstrated in areas where screening programs have reduced both the prevalence of infection and rates of PID. Evidence is insufficient to recommend routine screening for chlamydia in sexually active young men. However, screening of sexually active young men should be considered in clinical settings with a high prevalence of chlamydia.

In women, chlamydia can be diagnosed by testing urine, or swabs from the endocervix or vagina. In men, chlamydia can be diagnosed by testing urine or urethral swab. Rectal chlamydia infection is diagnosed by rectal swab in both men and women who engage in receptive anal intercourse.

A variety of tests are currently available for diagnosing chlamydia. At the State of Maryland laboratory the EIA test, previously used for cervical and male urethral swabs, was replaced by the NAAT test. The NAAT is also used to test urine specimens. Chlamydia culture is used to test for rectal infection.

Plan of Action

1. Targeted chlamydia screening test – one of the following criteria should exist:
 - a. Female client, sexually active and age 25 years or younger, who attends a family planning clinic for a new or annual visit requiring a speculum examination may have an endocervical test for chlamydia. A concomitant endocervical gonorrhea culture test should be done.
 - b. Female client, sexually active and age 25 years or younger, who attends a family planning clinic only for pregnancy testing and/or for emergency contraception may have a urine test for chlamydia.

2. No targeted chlamydia screening required:
 - a. Females age 26 or older – no screening test, but testing only on a case-by-case basis
 - b. Symptoms or signs of chlamydia, including mucopurulent cervicitis, urethritis, and/or salpingitis – no screening test
 - 1) Presumptive treatment

OR
 - 2) Wet mount with white cells, then presumptive treatment
 - c. No screening test for a client named as a suspected chlamydia contact – presumptive treatment or referral to an STD clinic for evaluation
 - d. No screening test prior to IUD placement
 - e. No screening urine test when a pregnancy test is in conjunction with the dispensing of DMPA or other contraceptive
3. Recommended treatment options:
 - a. Azithromycin (Zithromax®) 1 g orally in a single dose

OR
 - b. Doxycycline 100 mg orally twice a day for 7 days (contraindicated during pregnancy)
4. Alternative treatment options:
 - a. Erythromycin base 500 mg orally four times a day for 7 days

OR
 - b. Erythromycin ethylsuccinate 800 mg orally four times a day for 7 days

OR
 - c. Ofloxacin (Floxin®) 300 mg orally twice a day for 7 days (contraindicated during pregnancy)

OR
 - d. Levofloxacin (Levaquin®) 500 mg orally once a day for 7 days (contraindicated during pregnancy)

5. Because of the high prevalence of co-infection with *Chlamydia trachomatis* among individuals with gonococcal infection, presumptive treatment for chlamydia in clients being treated for gonorrhea is appropriate.
6. Sex partners should be referred for STD evaluation if they had sexual contact with the client during the 60 days preceding onset of symptoms or diagnosis of chlamydia. The most recent partner should be evaluated and treated even if the last sexual contact was greater than 60 days from diagnosis or onset of symptoms.
7. Women exposed to nongonococcal urethritis through an infected partner should be treated for chlamydia.
8. Clients and their partners should be instructed to abstain from sexual intercourse for at least 7 days after the single-dose therapy or until completion of the 7-day regimen.

Follow-up

1. Clients with chlamydia infection should not be rescreened 3-4 months after treatment, but tested only if symptoms or signs persist or re-infection is suspected, because most post-treatment infections result from reinfection either because sex partners were not treated or clients resumed having sex among a network of persons with a high prevalence of infection.
2. All clients with chlamydia treatment should be offered a serologic test for syphilis and be offered testing for HIV infection.

Primary References

CDC. Sexually Transmitted Diseases Treatment Guidelines. 2006

ACOG. *Precis: Primary and Preventive Care*. 3rd Ed., 2004

Hatcher RA et al. *Contraceptive Technology*. 19th Revised Edition. Ardent Media, Inc., New York, 2007

ACOG. *Health Care for Adolescents*. 2003

ACOG. Sexually Transmitted Diseases in Adolescents. Committee Opinion #301, October 2004

ACOG. Primary and Preventive Care: Periodic Assessments. Committee Opinion #357, December 2006

COITUS INTERRUPTUS

Rationale

Coitus Interruptus is withdrawal of the penis from the vagina prior to ejaculation.

Perfect use failure rate in the first year: 4%

Typical use failure rate in the first year: 27%

Withdrawal is an important contraceptive choice for non-abstaining couples who have no other contraceptive method available at the time of intercourse. This method does not protect a couple against sexually transmitted infections.

Plan of Action

1. Prior to vaginal intercourse, the penis should be wiped clean of any pre-ejaculation fluid.
2. The coital position used must allow the male partner to withdraw his penis from the vagina quickly and easily at the appropriate time.
3. The male partner must have good self-control. Ejaculation, if and when it occurs, must take place away from the entrance to the vagina.
4. Reinsertion of the penis after ejaculation should probably not take place without cleansing the male genitalia (washcloth and warm water with or without soap) and urinating to flush the urethra.
5. Offer advanced placement emergency contraception for use if withdrawal does not occur with every act of vaginal intercourse.

Follow-up

1. Re-evaluate the success of the male partner to withdraw the penis from the vagina prior to ejaculation.
2. If ejaculation does not take place away from the vagina every time, have the client consider another method of contraception and offer advanced placement emergency contraception.

Primary References

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COLPOSCOPY

Rationale

The colposcope is a stereoscopic microscope designed to allow examination of the lower genital tract under increased illumination and magnification. Colposcopy has become a standard tool for evaluating women with abnormal cervical or vaginal cytology, since colposcopy may detect signs of cancer and other abnormalities not visible to the unaided eye.

The main value of colposcopy is in the evaluation of women with abnormal Pap test findings. Colposcopy assists in differentiating preinvasive cancerous lesions from invasive cancer of the cervix.

In the past, various classification systems for preinvasive lesions have been used:

CLASSIFICATION SYSTEMS FOR LESIONS OF THE CERVIX

DYSPLASIA	CIN: Cervical Intraepithelial Neoplasia	SIL: Squamous Intraepithelial Lesion
Mild Dysplasia	HPV (human papillomavirus)	Low Grade SIL (LSIL)
	CIN I	
Moderate Dysplasia	CIN II	High Grade SIL (HSIL)
Severe Dysplasia	CIN III	
Carcinoma in-situ		
Invasive Cancer	Invasive Cancer	Invasive Cancer

In addition to evaluating abnormal cervical cytology reports, other reasons for colposcopic referral include: (1) evaluation of visible lower genital tract lesions, (2) evaluation of women who were exposed in utero to diethylstilbestrol (DES), (3) as an aid to treatment modalities such as loop electrosurgical excision procedure (LEEP).

Colposcopy allows one to recognize the different types of mucous membrane which line the normal cervix. These tissue types include: (1) Squamous epithelium (which lines the exocervix and vagina), (2) columnar epithelium (which lines the endocervical canal), (3) the transformation zone (the area between the exocervix and the endocervix). The squamocolumnar junction is the line which distinctly separates squamous epithelium from columnar epithelium.

Colposcopy is based on study of the transformation zone. The transformation zone is that area of the cervix that was initially covered by columnar epithelium and, through a process referred to as metaplasia, has undergone replacement by squamous epithelium. Colposcopically, it has been shown that cervical neoplasia develops almost exclusively within the transformation zone as a result of atypical metaplasia.

The range and variation of colposcopic features found in the transformation zone make up the science of colposcopy:

1. Normal colposcopic findings include visualization of normal squamous epithelium, columnar epithelium, and the transformation zone. Cervical neoplasia is judged to be absent in clients with normal colposcopic findings and negative Pap tests.
2. Abnormal colposcopic findings include patterns suggestive of cervical neoplasia such as aceto-white epithelium, punctation, mosaic, and atypical vessels. In clients with abnormal colposcopic findings, biopsies should be taken from the most suspicious lesions for histopathologic diagnosis.
3. Unsatisfactory colposcopic findings are those cases in which the limits of the squamocolumnar junction cannot be visualized. Unsatisfactory colposcopy is present in less than 15% of clients under 45 years of age. In clients with unsatisfactory colposcopy findings, one cannot rely on colposcopy for a clinical diagnosis, since the pathologic changes may be high in the endocervical canal. In these cases other diagnostic methods, such as surgical conization of cervix, may be required.

With colposcopy it is possible to localize a lesion, evaluate its extent, and obtain a directed biopsy so that a histopathologic diagnosis can be made. The limitation of colposcopy lies in its inability to detect lesions deep in the endocervical canal in cases where the entire transformation zone is not visible. However, an important value of colposcopy is that in most instances a skilled colposcopist can differentiate invasive cancer from noninvasive cancer by direct biopsy and thus avoid the necessity of surgical conization of the cervix.

Management of abnormal cervical cytology in the pregnant woman is a challenge. Colposcopy has allowed for a more conservative diagnostic approach, based on serial colposcopic and cytological appraisal. The need for biopsy can be minimized and limited to highly significant lesions where invasion cannot be otherwise excluded (Appendix A).

Management of abnormal cervical cytology in the adolescent differs from that of the older reproductive aged woman allowing for a more conservative approach (Appendix B).

Plan of Action

1. Refer to the "Cervical Cancer Screening" clinical guidelines for determining appropriate candidates for colposcopic examination. Generally, colposcopy is indicated for clients with:

- a. Two Pap tests in sequence or within two years with a diagnosis of atypical squamous cells of undetermined significance (ASC-US) when the diagnosis is not qualified further or the cytopathology favors a reactive process (in clinics not using HPV DNA testing).
 - b. A cervical cytology report with any of the following diagnoses:
 - 1) Atypical squamous cells of undetermined significance (ASC-US) and positive for high-risk HPV
 - 2) Atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion (ASC-H)
 - 3) Low-grade squamous intraepithelial lesion (LSIL)
 - 4) High-grade squamous intraepithelial lesion (HSIL)
 - 5) Atypical glandular cells (AGC)
 - c. A visible, suspicious cervical or vaginal lesion, regardless of Pap test diagnosis.
 - d. See Appendices A and B for exceptions for pregnancy and adolescents.
2. Procedures are best performed during the week immediately after the menstrual period in order to avoid evaluating or treating a client with an early pregnancy and to permit healing of the cervix to take place before onset of the next menses.
 3. The standard colposcopic examination consists of the following:
 - a. Gross examination of the vulva, vagina, and cervix
 - b. Repeat Pap smear, at the discretion of the colposcopist
 - c. Cleaning the cervix with 3% to 5% acetic acid
 - d. Colposcopic examination
 - e. Endocervical curettage (ECC)(not performed on pregnant clients)
 - f. Colposcopically directed punch biopsies of suspicious lesions
 4. Bleeding from the cervical biopsy sites can be controlled with silver nitrate sticks, Monsel's solution (ferric subsulfate solution) or Monsel's paste.
 5. Medical records documentation of the colposcopic procedure should, at a minimum, include:
 - a. Identifying information
 - b. Client's last menstrual period
 - c. Pertinent gynecologic and medical history including previous history or CIN/carcinoma
 - d. Reason for colposcopic referral
 - e. Results of last Pap test(s) and prior colposcopy diagnosis(s) and/or biopsy(s)
 - f. Gross appearance of vulva, vagina, and cervix
 - g. Initial colposcopic appearance
 - h. Colposcopic findings after application of acetic acid or Shiller's solution including statement regarding the visualization or lack of visualization of the squamocolumnar junction and the transformation zone
 - i. Procedures performed including cytology, endocervical curettage, and biopsies
 - j. Illustration of colposcopic findings and biopsy sites

- k. Colposcopic impression
- l. Management and disposition

Follow-up

1. If the colposcopic examination is satisfactory (i.e., the entire limits of the lesion and squamocolumnar junction are visible), the ECC is negative (i.e., no evidence in the ECC specimen of squamous dysplasia, atypical glandular cells, or malignancy), the cytologic, colposcopic, and histologic findings correlate, and there is no evidence on colposcopy, directed biopsy, or the Pap smear of invasive or microinvasive carcinoma or glandular atypia, then the client is eligible for outpatient therapy for high-grade lesions by means of cryosurgery, loop excision, or laser ablation. Controversy persists regarding therapy for clients with low-grade cervical lesions (CIN 1, LSIL, changes consistent with HPV) with some studies showing high rates of regression to the nondysplastic state. Expectant management has been advocated to avoid overtreatment that could compromise future fertility of adolescent clients. Cervical stenosis is a possible by-product of aggressive treatment, thus making future evaluation with colposcopy more difficult.
2. If microinvasive or invasive cancer cannot be ruled out (e.g., the ECC is positive or the lesion extends into the endocervical canal such that it cannot be fully evaluated by colposcopy), outpatient ablative therapy is contraindicated and the client should be referred for further evaluation.
3. If the colposcopic examination is unsatisfactory (i.e., the full extent of the transformation zone is not visible), the client should be considered for referral for further evaluation.

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APPENDIX A

GUIDELINES FOR COLPOSCOPIC EXAMINATION DURING PREGNANCY

1. If, at any stage during pregnancy, there is cytological or colposcopic suspicion of microinvasive or invasive disease, a large biopsy (either a deep wedge or cone biopsy under general anesthesia) will be required for diagnosis. These clients should be referred to an appropriate center.
2. Endocervical curettage should not be performed in pregnant women. Eversion of the cervix during pregnancy often facilitates better visualization of the transformation zone.
3. During the first 16 weeks of gestation, the technique of colposcopy is basically the same as for the non-gravid woman (except for omitting the ECC during pregnancy).
4. During the remaining 24 weeks of gestation, punch biopsy is often accompanied by brisk bleeding, and therefore, should be undertaken only when absolutely necessary. If bleeding is encountered, pressure and Monsel's solution applied to the biopsy site are often helpful. In some cases, referral to an appropriate center for biopsy may be considered.
5. If cytology and/or colposcopic examination support a diagnosis of a low-grade lesion (e.g., CIN 1, LSIL, HPV), then a confirmatory biopsy during pregnancy may usually be omitted. Colposcopy and cytology may then be repeated in each of the remaining trimesters, and again at approximately 3 months after delivery. At any stage during this conservative management in pregnancy, a biopsy might be indicated if progression is suspected.
6. If cytology and/or colposcopic examination support a diagnosis of a high-grade SIL (e.g., CIN 2 or CIN 3), then closer surveillance is necessary. Re-examination by colposcopy and cytology may be more frequent, approximately every 6 weeks. If there are no signs of microinvasion, then management may be the same as those with low-grade SIL; however, if there is any concern about the possibility of microinvasion or invasion, the client should be referred to an appropriate center for consideration of large biopsy.
7. If cytology and/or colposcopic examination support a diagnosis of invasive carcinoma, then the client should immediately be referred to a gynecologic oncologist at a high-risk center in consultation with the client's obstetrician.

APPENDIX B

GUIDELINES FOR MANAGEMENT OF ABNORMAL CERVICAL CYTOLOGY AND HISTOLOGY IN THE ADOLESCENT (UNDER AGE 20)

ASC-US/HPV(+) and LSIL Pap tests are very common in this sexually active age group. However, the clearance of HPV is high and the risk of invasive cancer approaches zero. The following management option for abnormal cervical cytology in the adolescent is recommended:

- Adolescents with the first abnormal Pap of ASC-US/HPV(+) or LSIL may be monitored with Pap tests at 6 and 12 months or a single HPV test at 12 months, with colposcopy for any abnormal cytology result or positive HPV test result.

Most cases of CIN 1 will resolve spontaneously over time. For an adolescent with CIN 1, excision or ablative treatment is not recommended.

- Biopsy-proven CIN 1 may be monitored with Pap tests at 6 and 12 months or a single HPV test at 12 months, with colposcopy for any abnormal cytology result or positive HPV test result.

Although CIN 2, a recognized cancer precursor, generally requires ablation or excision, CIN 2 in the adolescent has a high spontaneous regression rate.

- Biopsy-proven CIN 2 may be monitored with Pap tests at 6 and 12 months or a single HPV test at 12 months, with colposcopy for any abnormal cytology result or positive HPV test result.

CIN 3, a recognized cancer precursor, requires ablation or excision.

- An adolescent with biopsy-proven CIN 3 should be promptly referred for ablation or excision.

CONDOM – FEMALE

Rationale

The female condom is a soft, polyurethane vaginal sheath. It is pre-lubricated on the inside with a silicone-based lubricant. Lubricant for the outside is also provided. The lubricant does not contain spermicide.

The female condom acts as a mechanical barrier by preventing the sperm from penetrating the upper female reproductive tract.

Perfect use failure rate in the first year of use: 5%
Typical use failure rate in the first year of use: 21%

The female condom must be used with every act of intercourse. It may be inserted up to 20 minutes before intercourse. It is intended for one-time use only; re-use is not recommended. The female condom can be used with a spermicidal lubricant, water-based lubricant or oil-based lubricant (polyurethane does not disintegrate with an oil-based lubricant as latex does). Male and female condoms should not be used together; they can adhere to each other and cause slippage or dislodgement.

The female condom reduces the risk of acquiring sexually transmitted infections including HIV.

The female condom is an option for women who are felt to be at significant risk of acquiring sexually transmitted infections and whose partners refuse to use male condoms. It is an excellent choice for barrier contraception when the client or her male partner has a latex allergy or sensitivity.

Disadvantages include: difficulty of use compared to the male condom, client and/or partner dissatisfaction with the method, noise caused by the female condom during intercourse, high failure rate, and relatively high cost.

Plan of Action

1. As part of client education, appropriate family planning clients should be shown the female condom and have its use explained (Appendix).
2. Clients should practice using the female condom before relying on it.
3. If a spermicide is used with the female condom, it is recommended that the spermicide be inserted into the vagina prior to the insertion of the female condom.
4. Offer advanced placement emergency contraception to be used if condom breakage or slippage occurs.

Follow-up

1. Re-evaluate the client's success in using the female condom.
2. Provide advanced placement emergency contraception if indicated.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

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APPENDIX

SUMMARY OF INSTRUCTION FOR USE OF THE FEMALE CONDOM

1. Use the female condom for every act of sexual intercourse.
2. The female condom can be inserted between 2 to 20 minutes prior to intercourse.
3. Find a comfortable position for inserting the female condom (this may be the same position you use for inserting a tampon).
4. Be sure the inner ring is at the closed-end of the pouch.
5. If you wish, add a drop of extra lubricant to the closed-end outside of pouch or to the outside ring for extra comfort before you insert the female condom. Extra lubricant decreases noise from the female condom during intercourse.
6. Hold the female condom with the open end hanging down. While holding the outside of the pouch, squeeze the ring with your thumb and middle finger.
7. Place your index finger between the thumb and middle finger and squeeze the inner ring of the female condom.
8. Still squeezing the female condom with your three fingers, with your other hand, spread the lips of the vagina and insert the female condom into the vagina.
9. Push the inner ring and the pouch the rest of the way into the vagina with your index finger (check to be sure the inner ring is up just past the pubic bone).
10. When properly inserted, the outer ring will hang down slightly outside the vagina. The pouch should not be twisted. During intercourse, when the penis enters the vagina, the slack will lessen.
11. Use your hand to guide the penis into the female condom.
12. The female condom should be removed immediately after intercourse, before standing up. Squeeze and twist the outer ring, then pull out the female condom gently.
13. If the female condom had become dislodged or compromised in any manner, emergency contraception use is recommended.
14. The female condom should be discarded in the trash, not in the toilet.
15. A new female condom should be used for the next sexual intercourse.

CONDOM – MALE

Rationale

The male condom is a thin sheath that is placed over the erect penis prior to any sexual act and worn until after ejaculation. Unlike more effective non-barrier contraceptives, a condom, if used consistently and correctly, prevents both unintended pregnancy and sexually transmitted infections (STIs).

The male condom acts as a mechanical barrier by preventing the sperm from penetrating the upper female reproductive tract and can prevent contact with genital lesions and infectious secretions.

Perfect use failure rate in the first year of use: 2%
Typical use failure rate in the first year of use: 15%

There are three types of condoms: (1) those made from latex (rubber), (2) those made from intestinal caecum of lambs (natural membrane), and (3) those made from polyurethane (plastic). Both synthetic condoms and natural membrane condoms prevent pregnancy by blocking the passage of sperm through their surfaces. Natural membrane condoms have small pores that may permit the passage of viruses and are not recommended for STI protection. Polyurethane condoms are recommended for all couples when either the man or the woman has a latex allergy. Non-latex condoms have a slightly higher breakage and slippage rate than latex condoms.

The male condom must be used with every act of vaginal intercourse to prevent pregnancy. It is intended for one-time use only; re-use is not recommended. Synthetic condom use during oral or anal sex is recommended for STI protection.

Condom use is appropriate for anyone at risk for STIs, especially non-monogamous couples and adolescents. Condoms can be used as primary contraception or as a back-up method.

Condoms with spermicide are not recommended as they do not provide any additional protection against pregnancy and STIs. Spermicides do not protect against HIV and frequent spermicide use may cause tissue irritation that theoretically could increase susceptibility to HIV.

Plan of Action

1. Discuss condom indications and precautions with the client.
2. Clients should receive instructions on proper use of the condom (Appendix A).
3. Oil-based lubricants or medications may cause degeneration of latex strength and permeability. These substances should not be used with latex condoms. Appendix B lists lubricants and products that are safe or unsafe to use with latex condoms.

4. Recommend the use of condoms to protect against STIs for clients using non-barrier contraceptives.
5. Give the client an initial supply of condoms and discuss the options of obtaining more condoms including over-the-counter purchase.
6. Offer advanced placement emergency contraception to be used if condom breakage or slippage occurs.

Follow-up

1. Re-evaluate the client's success in using the male condom
2. Provide advanced placement emergency contraception if indicated.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Zieman M, Hatcher RA et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2007

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APPENDIX A

INSTRUCTIONS FOR USE OF THE MALE CONDOM

1. Use the condom for every act of sexual intercourse.
2. Practice using the condom before it is needed.
3. Open the package carefully without tearing the condom.
4. Put the condom on when the penis is hard and before any foreplay in which the penis touches any genital area.
5. Unroll the condom down all the way to the base of the erect penis, avoiding an air pocket.
6. Leave $\frac{1}{4}$ inch to $\frac{1}{2}$ inch of space at the tip of the condom to hold semen (this will be unnecessary if a nipple-ended condom is used).
7. If the condom is used for oral or rectal intercourse, replace it with a new condom prior to any vaginal entry.
8. After ejaculation, but before the penis gets soft, firmly grasp the rim of the condom at the base of the penis and withdraw the condom and penis together from the vagina being careful not to spill semen on the hands or partner's body.
9. The condom should be checked for breaks.
10. If the condom breaks, slips, tears, or falls off, the client should take emergency contraception as soon as possible.
11. The condom should be discarded and not re-used.
12. A new condom should be used for the next sexual intercourse.

APPENDIX B

LUBRICANT AND PRODUCTS THAT ARE SAFE OR UNSAFE TO USE WITH LATEX CONDOMS*

SAFE	UNSAFE
Water and saliva	Baby Oil
H-R Lubricating Jelly	Cold creams
AquaLube	Edible oils (olive, peanut, corn, sunflower)
Glycerin	Massage oils
K-Y Jelly	Mineral oil
Astroglide	Petroleum jelly
Prepair	Rubbing alcohol
ForPlay	Head and body lotions
Aloe-9	Shortening
Probe	Suntan oil and lotions
All I-D Lubricants	Whipped cream
Gynol II	Aldara cream
Silicone Lubricant	Vaginal infection medications in cream or suppository form:
deLube	<ul style="list-style-type: none">• Clindamycin 2% vaginal cream
Wet	<ul style="list-style-type: none">• Butoconazole cream
Cornhuskers Lotion	<ul style="list-style-type: none">• Clotrimazole cream
Spermicides	<ul style="list-style-type: none">• Clotrimazole vaginal tablet
Slippery Stuff	<ul style="list-style-type: none">• Miconazole vaginal suppository• Terconazole ointment• Terconazole cream or vaginal suppository
	Vegetable oil and cooking oils

*All of the above are safe to use with polyurethane condoms.

Spermicides do not damage latex, but are not recommended for lubrication.

CONDYLOMATA ACUMINATA

Rationale

Condylomata acuminata or genital warts usually are caused by human papillomavirus (HPV) type 6 or 11. HPV infections of the genital tract are the most common sexually transmitted viral infections in the United States.

The primary goal of treatment is the removal of symptomatic warts. Treatment can induce wart-free periods in most clients. Secondary infections should be treated as they facilitate the growth or spread of genital warts. The persistence or recurrence of HPV disease is common following completion of all treatment modalities. Removing the wart does not remove the virus. Spontaneous regression of genital warts often occurs. Expression varies but the virus remains. An important part of the clinical management is helping the client understand that the disease is a lifelong infection that may recur at any time and at any anatomic site.

Plan of Action

1. Clients with genital warts should be made aware that they are infectious to sexual partners.
2. Examination of sex partners is not necessary; however they may be referred for examination for possible genital warts and other STIs. There is no evidence to indicate that reinfection causes recurrences.
3. The regular use of condoms is recommended to help reduce transmission.
4. If appropriate, treatment of vaginitis is advised to avoid stimulating the growth or spread of condylomatous lesions.
5. Washing of the external genitalia followed by thorough drying, performed at least once daily, may inhibit proliferation of warts and minimize discomfort.
6. Recommended treatment options:
 - a. External genital and/or perianal warts
 - 1) Trichloroacetic acid (80-90%). The acid should be applied carefully to warts while avoiding contact with the normal skin. Sodium bicarbonate paste or powder may be applied to relieve client discomfort resulting from treatment. Treatment application may be repeated weekly. If warts persist after 6 applications, other therapy should be considered. Obtain physician consultation prior to initiating therapy if warts are extensive.

OR

- 2) Podofilox (Condylox®) 0.5% solution or gel. The client should 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 treatment may be repeated for a total of 4 cycles.

NOTE: The safety of podofilox during pregnancy has not been established.

OR

- 3) Imiquimod (Aldara®) 5% cream. The client should apply imiquimod cream at bedtime, 3 times a week for up to 16 weeks. The treatment area should be washed with soap and water 6-10 hours after the application.

NOTE: The safety of imiquimod during pregnancy has not been established.

OR

- 4) Refer the client for physician consultation and management to include cryotherapy, electrocautery, surgical excision, and laser therapy.

- b. Cervical, vaginal, anal and/or large vulvar warts

The client should be referred for physician consultation and management.

Follow-up

Recurrent lesions following apparent complete removal and spontaneous remission are common; subsequent treatment may be necessary.

Primary References

CDC. Sexually Transmitted Diseases Treatment Guidelines. 2006

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ACOG. Human Papillomavirus. Practice Bulletin #61, April 2005

CONTRACEPTION AFTER AGE 35

Rationale

The years from age 35 to menopause can be referred to as the transition years. About 75% of pregnancies in women over age 40 are unintended. Perimenopausal women have the highest abortion rate of any group except women under age 15. An increasing importance of contraception in this age group is the result of the recent trend toward delayed childbearing and the recent emphasis on the potential benefits of the use of combined oral contraceptives (Appendix). Except for women who smoke, there is no age limitation of contraceptive choices.

Pregnancy in this age group is associated with an increased rate of spontaneous abortion, chromosomal anomalies, and maternal morbidity and mortality. Gynecologic problems, such as irregular bleeding, menorrhagia, dysmenorrhea, and premenstrual syndrome, are also more common.

Certain medical conditions are more common in this age group and appropriate screening should be considered. Among these conditions are thyroid disease, diabetes mellitus, breast cancer and cardiovascular disease. Regular medical evaluations should be encouraged as appropriate in addition to the general gynecological evaluation.

The median age of menopause is 51.3 years, as confirmed by amenorrhea for 1 year in symptomatic women. During the years leading up to the menopause fertility decreases, but it is unpredictable. There are no tests to diagnose menopause early and reliably enough to guarantee a woman that she is no longer at risk for pregnancy. Due to the variability of follicle stimulating hormone (FSH) blood levels in relation to symptoms and bleeding pattern, the use of FSH testing is no longer routinely recommended.

Plan of Action

1. Complete the history and physical examination, and order laboratory testing as appropriate for age and identified risk factors.
2. A woman age 35 or older with a plan for future childbearing is a candidate for preconception and genetics counseling.
3. A couple who have completed their family may be candidates for tubal ligation or vasectomy. Appropriate information and/or referral should be provided.
4. Appropriate periodic medical evaluations should be encouraged. The woman should be encouraged to communicate with her primary care provider regarding her contraceptive use.
5. Combined estrogen/progestin contraceptives may be prescribed for women over 35 years of age who do not smoke and have no cardiovascular risks. Unless otherwise indicated, low-dose combined oral contraceptives may be used up to age 55.

6. Combined estrogen/progestin contraceptives should not be prescribed for women age 35 and over who suffer from migraine headaches.
7. Progestin-only contraception should be considered when estrogen-related risks are a concern.
8. Both copper and progestin IUDs are appropriate for use in respective clients until menopause.
9. Barrier methods of contraception are more effective in the perimenopause since fertility is decreased.

Follow-up

1. For clients using hormonal contraception during the perimenopause, evaluation of menopausal symptoms including bleeding patterns will usually dictate the timing of discontinuation of hormonal contraceptives and possible use of hormone replacement therapy (HRT).
2. Use of nonhormonal contraception is advised until the diagnosis of menopause is secure.

Primary References

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APPENDIX

POTENTIAL BENEFITS OF COMBINED ESTROGEN-PROGESTIN CONTRACEPTIVE USE IN HEALTHY, NONSMOKING WOMEN AFTER AGE 35

1. Adequate contraception with reduced need for abortion.
2. Control of irregular bleeding secondary to erratic ovarian functioning.
3. Prevention of vasomotor symptoms associated with episodic declining estrogen levels.
4. Reduction in ovarian and endometrial cancers.
5. Reduction in rheumatoid arthritis.
6. Possible bone sparing effect resulting in potentially less osteoporosis and associated fractures.
7. Reduced menorrhagia and associated anemia.
8. Reduced dysmenorrhea and mid-cycle pain of ovulation.
9. Reduced leiomyomata uteri.
10. Reduced ovarian cysts.
11. Reduced surgical procedures, including:
 - a. sterilization
 - b. endometrial biopsy
 - c. dilatation and curettage
 - d. laparoscopy (diagnostic and operative)
 - e. hysterectomy
12. Reduced fibrocystic breasts and fibroadenomas.
13. Reduced premenstrual syndrome.
14. Probable decreased incidence of endometriosis.
15. Possible protection against atherosclerosis.

CONTRACEPTIVE EFFICACY

Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception and the percentage continuing use at the end of the first year.

Method (1)	% of Women Experiencing an Unintended Pregnancy with the First Year of Use		% of Women Continuing Use At One year ³ (4)
	Typical Use ¹ (2)	Perfect Use ² (3)	
No method ⁴	85	85	
Spermicides ⁵	29	18	42
Withdrawal	27	4	43
Fertility Awareness-Based methods	25		51
Standard Days method ⁶	12	5	
TwoDay method ⁶	14	4	
Ovulation method ⁶	25	3	
Sponge			
Parous women	32	20	46
Nulliparous women	16	9	57
Diaphragm ⁷	16	6	57
Condom ⁸			
Female (Reality)	21	5	49
Male	15	2	53
Combined pill and progestin-only pill	8	0.3	68
Evra patch	8	0.3	68
NuvaRing	8	0.3	68
Depo-Provera	3	0.3	56
IUD			
ParaGard (copper T)	0.8	0.6	78
Mirena (LNG-IUS)	0.2	0.2	80
Implanon	0.05	0.05	84
Female sterilization	0.5	0.5	100
Male sterilization	0.15	0.10	100
Emergency Contraceptive Pills: Treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%. ⁹			
Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception. ¹⁰			

FOOTNOTES:

¹Among 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. Estimates of the probability of pregnancy during the first year of typical use for spermicides, withdrawal, fertility awareness-based methods, the diaphragm, the male condom, the pill, and Depo-Provera are taken from the 1995 National Survey of Family Growth corrected for the underreporting of abortions; see the text for the derivation of estimates for the other methods.

²Among 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. See the text for derivation of the estimate for each method.

³Among couples attempting to avoid pregnancy, the percentage who continue to use a method for one year.

⁴The 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 percentage who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether.

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

⁶The Ovulation and TwoDay methods are based on evaluation of cervical mucus. The Standard Days method avoids intercourse on cycle days 8 through 19.

⁷With spermicidal cream or jelly.

⁸Without spermicides.

⁹The treatment schedule is one dose within 120 hours after unprotected intercourse, and a second dose 12 hours after the first dose. Both doses of Plan B can be taken at the same time. Plan B (1 dose is 1 white pill) is the only dedicated product specifically marketed for emergency contraception. The Food and Drug Administration has in addition declared the following 22 brands of oral contraceptives to be safe and effective for emergency contraception: Ogestrel or Ovral (1 dose is 2 white pills), Levlen or Nordette (1 dose is 4 light-orange pills), Cryselle, Levora, Low-Ogestrel, Lo/Ovral, or Quasence (1 dose is 4 white pills), Tri-Levlen or Triphasil (1 dose is 4 yellow pills), Jolessa, Portia, Seasonale, or Trivora (1 dose is 4 pink pills), Seasonique (1 dose is 4 light-blue-green pills), Empresse (1 dose is 4 orange pills), Alesse, Lessina, or Levlite (1 dose is 5 pink pills), Aviane (1 dose is 5 orange pills), and Lutera (1 dose is 5 white pills).

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

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Zieman M, Hatcher RA et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2007

DEPOT MEDROXYPROGESTERONE ACETATE (DMPA)

Rationale

Depot medroxyprogesterone acetate (DMPA), Depo-Provera® Contraceptive Injection or generic DMPA, is a long-acting injectable progestin-only contraceptive which, when given intramuscularly within a 13-week interval, is a reliable method of birth control.

DMPA suppresses ovulation by inhibiting FSH and LH surge. Other mechanisms of action are thickening of the cervical mucus to block the passage of sperm, creation of a thin atrophic endometrium, and slowing of tubal and endometrial motility.

Perfect use failure rate in the first year of use: 0.3%

Typical use failure rate in the first year of use: 3%

DMPA is administered in a 150 mg dose by deep intramuscular injection in the deltoid (upper arm) or gluteus (buttock). DMPA is effective immediately after the first injection.

DMPA may well be the ideal contraceptive for women who have difficulty remembering to take pills every day, who dislike using methods associated with coitus, who are not suitable candidates for IUDs or not ready to make a long-term commitment to an implant or sterilization. DMPA is an excellent contraceptive option for women who cannot take estrogen. Breastfeeding women can use DMPA since it does not interfere with lactation once milk flow has been established, nor does it have any observable effects on the infant. Milk flow may actually increase. DMPA should be considered in clients with seizure disorders. An improvement in seizure control can be achieved probably because of the sedative properties of progestins.

Possible side effects of DMPA include irregular bleeding, breast tenderness, weight gain, depression or mood changes, headache, acne, hirsutism, fatigue, hot flashes, alopecia and decreased libido. Regular clinic visits are required for injections. There is no STD or HIV protection. There is no method for rapid discontinuation of DMPA and it may take 6-8 months to clear from the body. After discontinuing DMPA, some women have a 6 to 12 month delay in return to fertility.

On November 17, 2004, the FDA announced that a “black box” warning was added to the labeling of Depo-Provera Contraceptive Injection indicating that its prolonged use may result in loss of bone density. The warning states: “Women who use Depo-Provera Contraceptive Injection may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible. It is unknown if use of Depo-Provera Contraceptive Injection during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk of osteoporotic fracture in later life. Depo-Provera Contraceptive Injection should be used as a long-term birth control method (e.g., longer than 2 years) only if other birth control methods are inadequate.” This labeling is applicable to the recently released generic version of Depo-Provera.

Plan of Action

1. Clients expressing an interest in this contraceptive method should be counseled regarding the advantages, benefits (Appendix A), side effects, disadvantages, and risks (Appendix B) and be given a patient information pamphlet. The DMPA consent should be signed.
2. Structured counseling must include a discussion of the potential for menstrual changes (including heavy flow, irregular spotting or bleeding, and/or amenorrhea), weight gain, depression, and headaches. This discussion beforehand will increase product usage compliance.
3. All clients requesting and/or continuing DMPA must be counseled on the FDA “black box” warning concerning the long-term use of DMPA and bone loss. The counseling must compare the risk of long-term DMPA use to the compliance issues the client might have or has had with other methods of contraception. No client should be categorically denied Depo-Provera just because she has passed the 2-year mark.
4. All clients requesting DMPA should be advised on the ways to maintain bone health. These include eating a healthy diet, smoking cessation, limitation of alcohol, and getting regular weight bearing exercise such as walking, running, and weight lifting. Adolescents require 1,200 mg of calcium and 400-800 IU of vitamin D every day. Calcium-rich foods include milk, cheese, yogurt, ice cream, leafy green vegetables, and calcium-fortified juices. Recommended daily supplements to augment the diet include calcium carbonate, calcium citrate, or TUMS®.
5. Reasons for not using DMPA include:
 - a. Confirmed or suspected pregnancy
 - b. Undiagnosed vaginal bleeding
 - c. Confirmed or suspected breast cancer
 - d. Acute liver disease or tumors
 - e. Acute thrombophlebitis or thromboembolic disease including stroke
 - f. Ischemic heart disease
 - g. Known sensitivity to DMPA
 - h. Uncontrolled hypertension, systolic >160 or diastolic >100
 - i. Diabetic vascular disease or diabetes >20 years duration
 - j. Current use of aminoglutethimide (used in cancer chemotherapy and Cushing Syndrome)

6. Special conditions for which physician consultation is recommended before starting DMPA:
 - a. History of thromboembolic disease
 - b. Severe migraine headaches
 - c. Chronic liver disease
7. DMPA is available in 150 mg vials (1 cc) and in prefilled syringes. The needle should be 1½ inches long and 21-23 gauge. The vial should be shaken before administration to insure uniform mixing of the suspension. Deep intramuscular injection may be made into the deltoid or gluteus maximus muscles. The area of the injection should not be massaged because this may lower the effectiveness of Depo-Provera.
8. Product labeling emphasizes the need to determine that the client is not pregnant before injection, if the interval extended beyond 13 weeks. The order for DMPA should read: DMPA (or Depo-Provera) 150 mg IM q12 weeks or (q 11-13 weeks) x 5.
9. Controversy persists concerning how long the contraceptive level is maintained if the interval extends beyond 13 weeks.
9. DMPA may be given earlier than 13 weeks, for circumstances such as the injection being due while the client is away on vacation or before a college student returns from school. An earlier injection at 11, 10, or even 9 weeks is acceptable; however, the goal is within the 13-week interval.
10. The initial DMPA injection options include:
 - a. During the first 5 days of a normal menstrual period and with a negative urine pregnancy test.
 - b. Recommend use of a back-up method of contraception for 7 days after the first injection if it is not administered within the first 5 days of the menstrual cycle.
 - c. Within 5 days after childbirth for women who are not breastfeeding.
 - d. Within 5 days after a first- or second-trimester abortion or miscarriage.
 - e. Anytime after childbirth (usually 4 to 6 weeks postpartum) after the milk flow has been established for breastfeeding women who have not resumed sexual intercourse.
 - f. All other circumstances necessitate that the client is confirmed not to be pregnant. This may be accomplished by getting a negative urine pregnancy test before and after a 2-week interval of abstinence or use of reliable contraception.
 - g. When switching from combined oral contraceptives or contraceptive patch to DMPA, the first injection should be given during the 5 days of the withdrawal menstrual period or, if necessary due to scheduling problems, anytime during the last pack of pills or the last patch.

- h. When switching from IUD to DMPA, the first injection may be given anytime while the IUD is in place. If this is done during the first 5 days of menses, the IUD may be removed and the DMPA is effective immediately. If the DMPA is started after removal of the IUD, follow the usual guidelines for DMPA.
- i. The first DMPA injection may be given anytime prior to the removal of Norplant®.
- j. In unusual situations, which may require more complex clinical judgment, consideration should be given to a review of the client's recent sexual activity, current method of contraception, menstrual history, pelvic examination, and urine pregnancy test. Physician consultation may be necessary.

Follow-up

1. A reminder card may be prepared at the time of injection, which lists the scheduled date for the next injection. The client can carry a copy of this card and a copy put in a tickler file to be mailed to the client as a reminder 2 weeks before the expected date.
2. When a client is late for her next DMPA injection (more than 13 weeks since the last injection), pregnancy must be ruled out before the next dose is given. This may be accomplished by getting a negative urine pregnancy test before and after a 2-week interval of abstinence or use of reliable contraception.
3. Management of side effects:
 - a. Menstrual Changes – Almost all women experience spotting, irregular or prolonged bleeding during the first few months of DMPA use. Amenorrhea occurs in about half of the women by the end of the first year and increasingly thereafter. The client should be reassured and may be given 1 or 2 cycles of a low-dosed oral contraceptive to control bleeding. Another option is Ibuprofen 200-400 mg qid x 5 days. Prolonged or excessive bleeding requires physician consultation.
 - b. Weight Gain - There is a tendency for some women to gain weight while on DMPA (average of 5.4 lbs. in the first year and 16.5 lbs. after 5 years). Discussion of weight gain with DMPA is an opportunity to discuss the importance of diet and exercise.
 - c. Amenorrhea – Cessation of menses is expected over time in most women on DMPA. However, if the onset is immediate, pregnancy must be ruled out. There is no need to induce menses. Likewise, anytime the client has symptoms that could suggest pregnancy, a urine pregnancy test should be done.
 - d. Other possible side effects include headaches, breast tenderness, acne, hirsutism, alopecia, hot flashes, loss of libido, depression, nervousness, and fatigue. These symptoms may lead the client to discontinue this method of contraception.
4. If the client wishes to discontinue DMPA and does not want to become pregnant, a new contraceptive method should be started before 13 weeks after the last injection.

5. If the client wishes to discontinue DMPA and become pregnant, remind the client that the contraceptive effect may persist for a number of months, and fertility usually returns in 6 to 12 months.

Primary References

Hatcher RA et al. Contraceptive Technology. 18th Revised Edition. Ardent Media, Inc., New York, 2004

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Medical Eligibility Criteria For Contraceptive Use. 3rd Ed., Reproductive Health and Research, World Health Organization, Geneva, Switzerland, 2004

Selected Practice Recommendations For Contraceptive Use. 2nd Ed., Reproductive Health and Research, World Health Organization, Geneva, Switzerland, 2004

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U.S. Food and Drug Administration. Black Box Warning Added Concerning Long-Term Use of Depo-Provera Contraceptive Injection. FDA Talk Paper. T04-50, November 17, 2004

Depo-Provera Contraceptive Injection package insert. Revised November 2004

APPENDIX A

POSSIBLE HEALTH BENEFITS OF DMPA

1. Decreases menstrual bleeding
2. Less dysmenorrhea
3. Decreases risk for endometrial cancer
4. Decreases risk for ovarian cancer
5. Decrease in endometriosis
6. Decreases risk of PID
7. Decreases risk of sickle cell crisis
8. Best method for women taking anticonvulsant medications
9. Decreases frequency of grand mal seizures
10. Assists in the treatment of anemia
11. Decreases risk of ectopic pregnancy

APPENDIX B

POSSIBLE HEALTH RISKS OF DMPA

1. Hypoestrogenism (rare, reversible)
2. Bone loss
3. Severe depression
4. Significant weight gain
5. Metabolic impact (slight increase in blood glucose)
6. Allergic reaction

DEPRESSION

Rationale

Depression is one of the most debilitating and financially burdensome disorders facing our society today. Depression leads to a threefold increase in health care visits, often placing the patient at risk for unnecessary, risky surgical procedures. Morbidity includes loss of self-esteem and disruption of family, job and social function. Worldwide, depression is the second most important cause of life years lost to disability and is a major risk factor for suicide.

Depression is associated with unintended pregnancy, unhealthy behaviors and adverse pregnancy outcomes. Eighty percent of depressed patients are undiagnosed and only 20% of those afflicted receive treatment. Depression is especially common in women of reproductive age, when peak incidences of depression occur. The most valuable time periods for women to suffer from a depressive episode are during the premenstrual (up to 2 weeks before onset of period), postpartum (up to a year after delivery, or pregnancy, and peri-menopausal (up to five years before and after menopause) time periods.

Some hormonal contraceptive options may be not as suitable for women who are depressed or who have had a history of depression.

Plan of Action

1. Screening – The family planning annual visit, or other primary care visits, is an opportune time to screen for depression and it is often the client's only source of care.
 - a. General Depression – The U.S. Public Health Service recommends the following two questions as a screen for general depression.

During the last TWO WEEKS or more have you:

- 1) felt sad, blue, or “down in the dumps”?
- 2) lost interest in things you used to enjoy?

If answer is “no” to both questions, do not proceed.

If answer is “yes” to either question, ask the following set of questions:

Have you been experiencing:

- 1) feelings of worthlessness, hopelessness, or guilt?
- 2) unexplained change in weight or appetite?
- 3) trouble sleeping or sleeping too much?
- 4) fatigue, loss of energy?
- 5) agitation or restlessness?
- 6) problems concentrating or making decisions?
- 7) thoughts of death or suicide or suicide attempts?

If the client answers “yes” to five or more questions, the provider should refer the client for a clinical assessment for depression. If the client answers “yes” to #7, a seamless client referral to a mental health care professional should be considered.

b. Perinatal depression

Approximately 5%-25% of women experience depression during pregnancy or within a year of delivery (postpartum depression). Children of depressed mothers are more likely to develop learning and behavior problems. Too often, women are not diagnosed and do not receive counseling or treatment that can benefit themselves and their children.

The Edinburgh Postnatal Depression Scale (EPDS) is a questionnaire that has been validated for the assessment of signs of depression during pregnancy and postpartum depression. Many women take this simple 10-question test to see if they need further evaluation for depression by a health care provider. (Refer to the Appendix in Maryland State Family Planning Program Clinical Guidelines, "Post partum Evaluation and Contraception" for EPDS)

The website, www.healthynewmoms.org at the Mental Health Association of Maryland has good information about perinatal depression for mothers and providers. They also operate a 24-hour help-line at 1-800-572-6426.

c. Premenstrual Syndrome (PMS) and Premenstrual Dysphoric Disorder (PMDD)

Refer to the Maryland State Family Planning Program Clinical Guidelines, "Premenstrual Syndrome".

2. Treatment of depression

Treatment may include counseling and/or medication. Refer to mental health professionals should be made at the discretion of the provider. If comfortable with basic treatment of depression, therapy may be initiated for mild cases. Any complications or lack of improvement should be referred to mental health services. The SSRIs (selective serotonin reuptake inhibitors) are very effective antidepressant medications. Therapy is usually continued for 6-12 months.

3. Contraception and current depression or history of depression

Although current depression or a history of depression is not a contraindication to Depo-Provera, some studies have shown an increase in the likelihood of depression among women using Depo-Provera. With combined estrogen/progestin contraceptives (pills, patches, vaginal rings), there is little evidence that the incidence of depression is increased. However, some women report "moodiness" and "depression" on the pill.

Usually the benefits of effective contraception will outweigh the risks of depression but this decision must be made in collaboration with the client on an individual basis.

- a. If depression occurs or worsens among women using combined estrogen/progestin contraception or progestin-only contraception, consider switching to a low-estrogen pill or a non-hormonal method.
- b. If depression occurs during the pre-menstrual phase of oral contraceptives, consider extended or continuous use of active pills.

- c. Women with a history of depression during pregnancy or postpartum depression may not want to take a chance with hormonal contraception within 6 weeks after delivery since this may precipitate postpartum depression.
- d. Make sure that the client is aware that if depression occurs or worsens on Depo-Provera, there is no way to mitigate this effect. Mental health follow-up is especially important for these women.

References

ACOG. Clinical Updates in Women's Health Care, Mood and Anxiety Disorders. November 2008

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DIABETES MELLITUS

Rationale

Glucose screening should be offered to clients with historical or clinical risk factors for diabetes mellitus. Diabetes mellitus is not a contraindication to any available form of contraception. Contraceptive choices may be affected by severity and complications of diabetes mellitus.

Risk factors for diabetes mellitus include family history, age 30 or older, history of gestational diabetes, macrosomia, fetal anomalies or fetal death, obesity, hypertension, hyperlipidemia, persistent glucosuria, persistent proteinuria, and recurrent candidiasis.

Diabetes mellitus occurs in two general forms in nonpregnant adults. Type 1 diabetes (insulin-dependent diabetes; IDDM) is an autoimmune disorder directed at the pancreatic B cells. The disease generally occurs in children and young adults, and the autoimmune B cell destruction leads to a complete lack of endogenous insulin production. Thus, these individuals are dependent on exogenous insulin for survival; they will develop ketoacidosis if they are not treated with insulin.

Type 2 diabetes (non-insulin-dependent diabetes; NIDDM) encompasses all other forms of chronic hyperglycemia severe enough to meet current diagnostic criteria for diabetes. Individuals with NIDDM have some degree of endogenous insulin production, so that they rarely develop ketoacidosis. They develop hyperglycemia because of an imbalance between the amount of insulin that the pancreas can produce and the amount of insulin that is required to keep blood glucose levels normal.

Plan of Action

1. A client who has a first degree relative (parent, sibling or child) with diabetes mellitus should be advised that she is potentially at risk to develop this condition. Weight control and exercise should be advised, and a fasting plasma glucose test (FPG) or a 75-g 2-hour oral glucose tolerance test (75-g 2 hr OGTT) should be considered.
2. A client with one or more risk factors for diabetes mellitus should have an FPG or 75-g 2 hr OGTT every three years.
3. A client with gestational diabetes mellitus should have a 75-g 2 hr OGTT 6-12 weeks postpartum. Approximately half of people with gestational diabetes will ultimately develop overt diabetes. Repeat testing should be done every three years.
4. Screening values
 - a. Either an FPG or 75-g 2 hr OGTT are appropriate for diagnosing diabetes.
 - b. Although the FPG is easier to perform, it lacks sensitivity detecting other forms of abnormal glucose metabolism.

- c. Results of the 75-g 2 hr OGTT can confirm an impaired fasting glucose level and impaired glucose tolerance (Appendix).
 - d. FPG concentrations of <100 mg/dL are normal and warrant nothing more than repeated measurements at 3-year intervals.
 - e. FPG concentrations of ≥ 126 mg/dL are consistent with diabetes and should be repeated once to confirm the diagnosis.
 - f. FPG concentrations of 100-125 mg/dL are abnormal but not diagnostic of diabetes. These individuals are at higher risk for diabetes and cardiovascular disease than are people with normal glucose levels and are considered to have impaired fasting glucose.
 - g. Referral for medical evaluation should be considered when a client's FPG is greater than 100 mg/dL.
5. Diabetes mellitus is not a contraindication to any available form of contraception.
- a. Combined hormonal contraceptives can be prescribed for clients with diabetes mellitus:
 - 1) If other forms of contraception are not acceptable.
 - 2) If only low-dose contraceptives are used, preferably with a progestin other than norgestrel.
 - 3) If the client is under age 35 and has no known vascular complications or other risk factors, such as a strong family history or ischemic heart disease. Women with advanced diabetes complicated by nephropathy (proteinuria), retinopathy, neuropathy, or diabetes of more than 20-year duration are not candidates for estrogen-containing methods of contraception.
 - b. Changes in blood levels of insulin and glucose with low-dose oral contraceptives are so slight that they are of minimal clinical significance. The observed changes in carbohydrate metabolism with oral contraceptives are in the non-diabetic range.
 - c. Progestin-only oral contraceptives, so-called "mini-pills (Micronor®), have minimal effects on carbohydrate metabolism and are less likely to increase the risk of cardiovascular disease than combined oral contraceptives. By comparison, they have a much higher incidence of irregular bleeding and a higher pregnancy rate.
 - d. The injectable contraceptive (Depo-Provera®) may be ideal for contraception in women with diabetes. The contraceptive effectiveness is comparable to combined oral contraceptives, there is less likelihood of an increase in the risk of cardiovascular disease, and there is only a slight modification in glucose metabolism with long-term usage.

- e. If a client with diabetes elects to use a diaphragm or other barrier method, she should be educated as to the symptoms and methodology for prompt diagnosis and treatment of a urinary infection. This problem is twice as common among diaphragm users as among women using oral contraceptives. Spermicide use can also increase the risk of bacteriuria with E. Coli perhaps due to an alteration in the vaginal flora.
 - f. IUD usage is appropriate and may be the ideal choice of contraception especially if vascular disease is present.
 - g. A client who has completed her family is a candidate for tubal ligation.
6. A client with diabetes is a candidate for preconception counseling.

Follow-up

Clients with diabetes may be followed on the same schedule as other family planning clients provided they are under ongoing medical supervision. They should be encouraged to discuss contraceptive choices with their medical health care providers.

Primary References

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APPENDIX

DIAGNOSIS OF DIABETES MELLITUS IN NONPREGNANT ADULTS

Test	Normal (mg/dL)	Impaired Fasting Glucose (IFG)	Impaired Glucose Tolerance (IGT) (mg/dL)	Diabetes*
Fasting plasma glucose ^o (FPG)	<100	100-125	N/A	≥126
75-g 2-hour glucose tolerance test (75-g 2 hr OGTT)	<140	100-125	2-hr PG 140-199	FPG≥126 or 2-hr PG≥200

*Confirm diagnosis with a second fasting plasma glucose level of ≥126 mg/dL

^oMeasured in plasma in a certified clinical laboratory

DIAPHRAGM

Rationale

The diaphragm is a latex rubber dome-shaped device that is filled with a spermicidal cream or jelly and placed in the vagina to cover the cervix prior to intercourse. The diaphragm acts as a barrier preventing the sperm from being deposited directly onto the cervix and gives the spermicidal agent time to act. Proper fit is essential for comfort and neither partner should be aware of its presence.

Perfect use failure in the first year: 6%

Typical use failure in the first year: 16%

Advantages include an absence of systemic side effects or other sequelae of hormonal contraception. It is female-controlled and may be placed into the vagina up to 6 hours prior to intercourse and may be used for multiple acts of intercourse up to 24 hours. The diaphragm may reduce the risk of cervical infections including gonorrhea and chlamydia.

Disadvantages include the potential for a local allergic reaction to the latex or the spermicide, vaginal erosions, an increased risk of urinary tract infection, and a potential risk of toxic shock syndrome if left in place for prolonged periods during menses. There is no protection against HIV.

The optimal candidate for use must be highly motivated to use this method, be comfortable with vaginal manipulation of the diaphragm, and have the dexterity to properly insert and remove the diaphragm. The woman must not be at high risk for HIV.

Plan of Action

1. The diaphragm must be fitted properly by a health care provider who is trained in diaphragm fitting (Appendix A).
2. All clients fitted for a diaphragm must receive detailed instruction on usage and side effects (Appendix B).
3. The client should be encouraged to practice insertion and removal of the diaphragm prior to using the diaphragm for contraception.
4. Emergency contraception should be made available.

Follow-up

1. Schedule a follow-up clinic visit within 2-4 weeks to evaluate appropriate fitting, usage and provide further client education if indicated.
2. The diaphragm should be replaced if there is evidence of holes, cracks, stiffness, or other defects.

3. Reevaluate the fitting if a 20% weight change has occurred, after pregnancy, if there are recurrent symptoms of a urinary tract infection, or if the client is concerned in any other way with the condition or fitting of the diaphragm.
4. It is advisable to offer the client a replacement diaphragm every two years.
5. If the client's use of the diaphragm has not been satisfactory or consistent, have the client consider another method of contraception and offer emergency contraception to be available.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Zieman M, Hatcher RA et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2007

Speroff L, Darney P. A Clinical Guide For Contraception. 4th Ed., Lippincott Williams & Wilkins, Philadelphia, PA, 2005

APPENDIX A

DIAPHRAGM FITTING

1. Perform the fittings with diaphragms of different sizes and types. These fitting diaphragms must be carefully disinfected after each use. *
2. Avoid the use of open rings for fittings if possible. They are more flexible than the diaphragm and an accurate estimation of the appropriate size may prove difficult.
3. The diaphragm must fit snugly behind the symphysis pubis and deep into the posterior fornix so that the entire cervix is covered. (For more details, see Contraceptive Technology)
4. Use the largest diaphragm that meets the above noted criteria. Sizes available generally range in 5 mm increments from 50 mm to 95 mm.
5. Allow the client to practice insertion and removal to insure her ability to determine correct placement.

***Instructions for Cleaning and Disinfecting Diaphragm Fitting Devices**

1. Clean the fitting diaphragms or fitting rings thoroughly by scrubbing with a liquid detergent and water. Rinse well with water.
2. Then disinfect the fitting diaphragms or fitting rings using one of the three following options:
 - a. Autoclave at 121 degrees Centigrade, 15 pounds per square inch (psi) for 20 minutes unwrapped or 30 minutes wrapped.
 - b. Soak in a solution of one part Clorox to nine parts water (results in a solution of sodium hypochlorite of 5,000ppm) at 30 minutes at room temperature; rise with tap water; then soak in 70% ethyl or isopropyl alcohol for 15 minutes. Discard all solutions.
 - c. Immerse in Cidex (2% glutaraldehyde) for 20 minutes at room temperature; then rinse and place in boiling water for 30 minutes. Follow the manufacturer's instructions concerning preparation and disposal or reuse of Cidex solution.

Note: Some experts believe that autoclave sterilization is the only safe option.

3. After disinfection, allow the diaphragms or rings to air dry, then store them in a disinfected container until later use.

Units which demonstrate scaling, peeling, flaking or other signs of wear should be replaced.

APPENDIX B

INSTRUCTIONS FOR USE OF THE DIAPHRAGM

1. Prior to insertion, check the diaphragm for defects. Fill with water to test for perforations if needed, or hold the diaphragm up to a bright light to check for holes.
2. Place the spermicide in the center of the diaphragm and along the rim.
3. The diaphragm may be inserted up to 6 hours or less before vaginal intercourse.
4. 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.
5. Insert with the dome side down as far into the vagina as possible. Push the diaphragm over the cervix so that it covers the cervix completely.
6. Check for proper placement of the diaphragm after insertion to make sure the entire cervix is covered.
7. DO NOT remove or reposition the diaphragm to add additional spermicide.
8. For a second and each subsequent act of intercourse, do not remove the diaphragm but use a condom for additional protection.
9. The diaphragm must be left in place for a minimum of 6 hours after intercourse but not longer than 24 hours.
10. To remove the diaphragm, put the index finger behind the front rim and pull the diaphragm down and out.
11. After removal, the diaphragm should be washed with soap and water, rinsed, dried, and stored in the case in a cool, dark location.
12. Oil-based lubricants or medications such as Terazol®, Monistat®, and Vagisil® can have a rapid deleterious effect on the diaphragm strength and permeability. Such preparations should not be used with the diaphragm. (See Condom-Male guideline for a list of safe and unsafe products that affect latex.)

DYSLIPIDEMIA

Rationale

Coronary heart disease (CHD) is the single leading cause of death of women in the United States. Dyslipidemia is a major risk factor for CHD in women. For women at increased risk, elevated low-density lipoprotein (LDL) cholesterol is considered to be the major cause of atherosclerosis and CHD. Research has conclusively demonstrated that lowering cholesterol, especially LDL cholesterol, reduces the risk for CHD.

The cholesterol level in blood plasma is determined partly by genetic make-up and partly by the fat and cholesterol content of the diet. Other factors such as obesity and physical inactivity all contribute to an undesirable elevation of cholesterol. Because LDL cholesterol is the primary atherogenic lipoprotein, LDL cholesterol levels are closely correlated with CHD risk over a broad range from low to very high. A low high-density lipoprotein (HDL) cholesterol level (<40 mg/dL) is also a risk factor. In contrast, a high HDL cholesterol level (≥60 mg/dL) is considered to be a negative risk factor and to be protective against CHD. Elevated triglycerides also are associated with increased CHD risk.

Along with cholesterol testing, adults should be evaluated for the presence of other CHD risk factors including hypertension, cigarette smoking, severe obesity, diabetes mellitus, sedentary lifestyle, and a history in CHD in the client or premature CHD in family members. Intervention is based on the client's cholesterol levels and CHD risk factors.

Management of major risk factors for CHD, such as hypertension and hypercholesterolemia, starts with lifestyle changes that emphasize a healthier diet (high in fiber and low in saturated fat), weight control, smoking cessation, and increased physical activity. If the response is inadequate, drug therapy is required.

Estrogens are known to have a desirable effect on lipids by increasing HDL and decreasing LDL. Progestins tend to have the opposite effect. The adverse changes produced by progestins are related to the specific progestin and its dose. A prudent choice, if lipoproteins are a concern, would be to use a low dose of norethindrone or possibly a norgestimate-containing oral contraceptive.

Plan of Action

1. Family planning clients with two or more CHD risk factors (Appendix A) or age 45 or older should be referred for serum cholesterol screening. This test can be performed any time of the day in the nonfasting state. A lipid profile specimen should be obtained in the fasting state.
2. Appropriate clients should receive information regarding risk factors for CHD (Appendix A). Advise clients of health benefits attained from instituting lifestyle changes such as quitting smoking, reducing obesity, and initiating an exercise program. Encourage dietary interventions such a diet high in fiber and low in saturated fat.

3. Clients with no CHD risk factors should be advised that their normal serum cholesterol values (<200 mg/dL) should be periodically reevaluated. Every 5 years is a reasonable interval.
4. Classifications based on total cholesterol levels are included in Appendix B.
5. Dyslipidemia should be managed by the client's primary care provider.
6. Management of clients on combined estrogen/progestin contraceptives:
 - a. Women over the age of 35 who are starting or continuing combined estrogen/progestin contraceptives should be considered for serum cholesterol, and a follow-up determination at least every 5 years, if the initial level is in the normal range.
 - b. Women with a known borderline serum cholesterol (200-239 mg/dL) should be referred for a fasting lipoprotein analysis and receive dietary education and advice on exercise. These clients should have annual cholesterol determinations with follow-up fasting lipoprotein analyses, if still elevated.

However, if two or more CHD risk factors are present in such clients, these clients should be referred to a private provider of their choice for medical management. They may not be good candidates for some hormonal contraceptives. Physician consultation is advised.
 - c. Women with a known serum cholesterol \geq 240 mg/dL should be referred for a fasting lipoprotein analysis and be referred to a private provider of their choice for medical management and advice while continuing their current contraceptive.
7. Recent changes in combined oral contraceptives have involved efforts to lower the progestins and to find new formulations capable of producing a more favorable lipoprotein pattern. The latest generation of "new progestin" pills that lead to a positive lipid pattern include Ortho-Cyclen®, Ortho Tri-Cyclen®, and Ortho Tri-Cyclen® Lo.
8. HDL cholesterol levels fall significantly in women using depot medroxyprogesterone acetate (Depo-Provera®) injections.

Follow-up

Clients with marked elevated cholesterol levels or hyperlipidemia must be under the care of a private provider familiar with the medical management, and treatment modalities available.

Primary References

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APPENDIX A

RISK FACTORS AND LIFESTYLE CHANGES IN CORONARY HEART DISEASE

POSITIVE PREDICTORS

- Female: Age more than 55 years
- Premature menopause
- Cigarette smoking
- Hypertension (blood pressure >140/90 mm Hg)
- Diabetes mellitus
- High-density lipoprotein cholesterol less than 35 mg/dL
- Family history of myocardial infarction or sudden death before age 50 years in a first-degree male relative, or age 60 years in a first-degree female relative

NEGATIVE RISK FACTOR

- High-density lipoprotein cholesterol of more than 60 mg/dL (also allows subtraction of one risk factor)

MODIFIABLE CHANGES TO REDUCE CORONARY ARTERY DISEASE

- Lose weight if obese
- Discontinue cigarette smoking if present
- Control diabetes mellitus if present
- Initiate exercise program
- Control hypertension
- Follow a low-fat and high-fiber diet
- Moderate alcohol use (two or fewer drinks per day)

APPENDIX B

**NATIONAL CHOLESTEROL EDUCATION PROGRAM
CLASSIFICATION OF CHOLESTEROL AND TRIGLYCERIDE LEVELS**

Cholesterol Level (mg/dL)	Classification
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Total Cholesterol	
<200	Desirable
200-239	Borderline High
≥240	High

Low-Density Lipoprotein Cholesterol	
<100	Optimal
100-129	Near or Above Optimal
130-159	Borderline High
160-189	High
≥190	Very High

High-Density Lipoprotein Cholesterol	
<40 (1.05)	Low
≥60 (1.55)	High

Triglycerides	
<150	Normal
150-199	Borderline High
200-499	High
≥500	Very High

Modified from National Cholesterol Education Program, National Heart, lung, and Blood Institute, National Institutes of Health. Third report of the Nation Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III): executive summary. Bethesda (MD): NHLBI; 2001. NIH Publication No: 01-3670.

DYSMENORRHEA

Rationale

Dysmenorrhea, painful menstruation, is one of the most common gynecologic disorders. It is the greatest single cause of lost work and school days among young women. Dysmenorrhea may be primary, with no associated organic pathology, or secondary, with demonstrable pathology.

Primary dysmenorrhea is caused by prostaglandin-induced uterine contractions. Primary dysmenorrhea tends to occur with the onset of ovulatory cycles and usually improves with time, coincides with the onset of menstrual bleeding, and frequently is associated with other prostaglandin-mediated symptoms such as nausea, vomiting, diarrhea, and dizziness. The pain is sharp and crampy, and is located in the lower midline. The pelvic examination in a nonmenstruating client with primary dysmenorrhea should not demonstrate tenderness or other pathological changes.

Secondary dysmenorrhea means pelvic pain caused by (secondary to) a disorder or disease. Secondary dysmenorrhea most commonly begins in women who are in their late teens or early twenties and progressively worsens. The pain may begin long before menses and continues during and even after menses. Dyspareunia is also common. Gynecological problems that can cause secondary dysmenorrhea include pelvic inflammatory disease, leiomyomata, endometriosis, adenomyosis, and intrauterine device use. Menorrhagia is not uncommon. The pain of secondary dysmenorrhea often occurs in both lower quadrants. When evaluating a client with crampy pelvic pain, one must be sure to consider the possibility of infection or early pregnancy with associated sequelae. Pelvic examination will demonstrate uterine and/or adnexal tenderness and possibly other findings such as pelvic mass, uterosacral nodularity, or fixation of the uterus with poor mobility.

Plan of Action

1. History
 - a. Take a detailed gynecological history include age, parity, first day of last menstrual period, age of menses onset, length and regularity of cycles, and duration of flow.
 - b. Take a pain history to include severity, duration, character, location, radiation and the relationship of pain to menarche, menses, Mittelschmerz, coitus, bowel movements, voiding and any other associated symptoms.
 - c. Document previous known or suspected pelvic problems.
 - d. Review the past obstetric history, including first trimester losses.
 - e. Review the past history for other organ system problems that can present with pelvic pain.

- f. Review the pelvic infection history, with special attention to recent or past STIs including the history of STIs among current or former partners.
 - g. Review the contraceptive history with special attention to past or present IUD use and oral contraception. Document any changes in symptoms with the particular contraceptive use.
 - h. Review the surgical history, including surgical procedures involving the cervix, Cesarean delivery, gynecological procedures, and other abdominal procedures.
2. A complete gynecologic examination with cervical testing, including abdominal and rectal examination, should be performed with special attention directed toward reproducing the pain and detecting other diseases.
 3. If secondary dysmenorrhea is suspected by history and examination, an appropriate evaluation for disease identification and treatment should be undertaken with physician consultation as indicated.
 4. If primary dysmenorrhea is suspected by history and examination, medical treatment with prostaglandin inhibitors should be prescribed before proceeding with other diagnostic procedures.
 5. Oral contraceptives should be considered for treatment of dysmenorrhea in women who desire contraception in addition to pain control. The combined oral contraceptives yield the best results with progestin-only contraceptives being less effective. Depo-Provera may be used to decrease prostaglandin levels.
 6. Over-the-counter prostaglandin inhibitors:

Drug name Tablet strength	Recommended dose	Maximum dosage in 24 hours
Aspirin 325 mg	325-650 mg q 4 h	3,900 mg
Ibuprofen (Motrin®, Advil®) 200 mg	200-400 mg q 4-6 h	1,200 mg
Naproxen Sodium (Aleve®) 200 mg	400 mg then 200 mg q 8-12 h	800 mg

7. Severe dysmenorrhea may require prescription prostaglandin inhibitors (nonsteroidal anti-inflammatory drugs – NSAIDs). Contraindications to their use are a history of allergy to aspirin or a history of allergy to any NSAID. Caution is also needed for clients who have ulcer disease, kidney disease, or asthma.

8. Prescription prostaglandin inhibitors:

Drug name Tablet strength	Recommended dose	Maximum dosage in 24 hours
Ibuprofen (Motrin®) 400, 600, 800 mg	400 mg q 4-6 h 600 mg q 6 h 800 mg q 8 h	3,200 mg
Mefenamic acid (Ponstel ®) 250 mg	500 mg then 250 mg q 6-8 h	1,250 mg
Naproxen (Naprosyn®) 250, 375, 500 mg	500mg then 250 mg q 6-8 h	1,250 mg
Naproxen Sodium (Anaprox®) 275 mg (Anaprox® DS 550 mg	550 mg then 275 mg q 6-8 h	1,375 mg

Follow-up

If the client fails a trial of either or both oral contraception and prostaglandin inhibitor therapies, further diagnostic studies including laparoscopy may be indicated and an appropriate physician referral initiated.

Primary References

Hatcher Ra et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

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ECTOPIC PREGNANCY

Rationale

An ectopic pregnancy is defined as implantation of the fetus in a site other than the uterine cavity. During the past thirty-five years there has been a marked increase in both the absolute number and rate of ectopic pregnancies in this country. Although the death rate from ectopic pregnancy has decreased dramatically over this same time period due to better diagnosis and treatment, ectopic pregnancy complications cause up to 15% of all maternal deaths. It, therefore, behooves reproductive health professionals to always keep the possibility of ectopic pregnancy in mind.

There are many reasons for this increased incidence of ectopic pregnancy. Chief among them is scarring of the fallopian tubes from pelvic infection with chlamydia and gonorrhea. A list of risk factors for ectopic pregnancy is given in the Appendix.

All types of contraception reduce the risk of both intrauterine and ectopic pregnancy. The risk of a pregnancy being ectopic is increased when it occurs in association with progestin-only contraceptives, IUDs, and tubal ligation.

The principal symptoms of ectopic pregnancy are pain, amenorrhea, and bleeding. The combination of either abdominal pain and abnormal vaginal bleeding or abdominal pain and amenorrhea (or a sequence of these combinations) should alert the clinician to the possibility of ectopic pregnancy.

Plan of Action

1. Keep ectopic pregnancy in mind at all times and particularly when dealing with combinations of amenorrhea, abdominal pain, and/or unusual vaginal bleeding.
2. Look for pregnancy symptoms and physical findings compatible with ectopic pregnancy.
3. Obtain urine pregnancy test, and a hemoglobin and/or hematocrit.
4. Obtain urgent gynecologic consultation if ectopic pregnancy is suspected.

Primary References

Berek JS. Berek & Novak's Gynecology. 14th Ed., Lippincott Williams & Wilkins, Philadelphia, PA, 2007

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Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

APPENDIX

HISTORICAL RISK FACTORS FOR ECTOPIC PREGNANCY

1. Pelvic infection or STDs that affect the fallopian tubes
2. Tubal surgery
3. Tubal ligation
4. Prior ectopic pregnancy
5. Prior abdominal surgery
6. Prior infertility
7. Present IUD use
8. Endometriosis
9. Advanced maternal age
10. Pregnancy occurring on Depo-Provera, or Micronor
11. DES exposure in utero
12. Tumors that distort the fallopian tubes
13. Developmental abnormalities of the fallopian tube
14. Present use of ovulation-inducing drugs
15. Following in vitro fertilization and ovum or embryo transfer
16. Smoking

EMERGENCY CONTRACEPTION

Rationale

Emergency contraception (EC) is contraception used after sexual intercourse but before a woman becomes pregnant. It may be appropriate for women to use emergency contraception when condoms break, diaphragms or cervical caps becomes dislodged, hormonal contraception is not used properly, IUDs are expelled, teratogens are taken, no contraception is used, or sexual assault occurs. It is an important contraceptive option for women who have had unprotected intercourse within the last 120 hours. Emergency contraception may be accomplished using oral contraceptive pills in certain dosages or by placing intrauterine contraception (See intrauterine contraception guidelines).

There are two categories of emergency contraceptive pills (ECPs): high-dose progestin-only contraceptive pills and combined oral contraceptive pills. The progestin-only ECPs are more effective than the combined oral contraceptive ECPs and cause fewer side effects.

The progestin-only ECPs available are Plan B®, Plan B® One-Step, and New Choice, a generic version of Plan B®. All three drugs may be obtained in pharmacies by prescription for those women younger than age 17 and are available over-the-counter for those 17 years and older.

Emergency contraceptive pills (ECPs) do not cause abortion. An implanted pregnancy cannot be disrupted by emergency contraception. Before ovulation, ECPs can disrupt normal follicular development and maturation and inhibit ovulation. ECPs may create a deficient luteal phase or have a contraceptive effect by thickening the cervical mucus. After ovulation, ECPs have little effect on ovarian hormone production and limited effect on endometrial maturation. Tubal transport of sperm or ova may be affected.

The efficacy of ECPs is dependent on the time interval from unprotected intercourse to taking the ECPs. The progestin-only ECP failure rate is 0.4%-2.7%. ECPs are effective up to 120 hours (5 days).

There are only 3 contraindications to taking progestin-only ECPs:

- a. Proven pregnancy
- b. Unexplained vaginal bleeding
- c. Hypersensitivity to any ingredient in the ECP.

ECPs are not intended for use as routine contraception since the failure rate is higher than that of other hormonal contraception. ECPs afford no STD protection. There is no risk to the fetus if the ECPs fail to prevent pregnancy or if pregnancy has already occurred. Possible side effects include nausea, vomiting, abdominal pain, breast tenderness, headache, spotting, and changes in the next menses.

Plan of Action

1. It is imperative that a client requesting emergency contraception be seen as soon as possible after having unprotected intercourse (walk-in or same-day basis when the client calls).
2. The client need not be an established family planning client and a family planning clinic need not be in progress when the client requests emergency contraception.
3. Do a focused evaluation using the Family Planning Emergency Contraceptive Pills Record (DHMH 4522). This form can be used for both new and established clients.
4. All women of reproductive age who have had unprotected intercourse in the last 120 hours are eligible for ECPs. If there have been any other episodes of unprotected intercourse since the last menstrual period, ECPs may not be effective since the client may already be pregnant. Reviewing the cycle time at which exposure occurred may enable the clinician to estimate whether pregnancy risk is high or low, but what determines whether emergency contraception is warranted is how the woman feels about reducing the risk of pregnancy, no matter whether the risk is high or low.
5. Explore the client's feelings about continuing the pregnancy in the event that emergency contraception does not prevent pregnancy. There is no evidence that ECPs would be harmful to a fetus but an attempt should be made to avoid any unnecessary medication during pregnancy.
6. Routine urine pregnancy testing is not required. The performance of a urine pregnancy test is dependent on the presenting clinical situation.
7. The client should read, understand, and sign the Consent for Emergency Contraceptive Pills (DHMH 4523).
8. Put both the Family Planning Emergency Contraceptive Pills Record and the Consent for Emergency Contraceptive Pills in either a new record or the established record, whichever is applicable.
9. If there is no clinician available when a client seeks emergency contraception, the following options are available after the clinic nurse has completed the client intake:
 - a. Call a clinician for a telephone order for ECPs.
 - b. Fax the order for ECPs to a clinician for a signature.
 - c. Utilize "standing orders" for ECPs according to each jurisdiction's protocol.

No woman who is a candidate for ECPs should ever be turned away because of a clinic's inability to obtain an order for ECPs.

10. Recommended emergency contraception treatment options:

Plan B, 2 tablets orally as a single dose immediately in the clinic

Plan B One-Step, 1 tablet orally immediately in the clinic

Next Choice, 2 tablets orally as a single dose immediately in the clinic

11. Alternate emergency contraception treatment:

Any combined oral contraceptive containing the progestin levonorgestrel or norgestrel may be used as emergency contraception but the emergency contraceptive effectiveness is less and there are more side effects and more potential restrictions for use of these products. Details may be found in Hatcher's Contraceptive Technology.

12. Remind the client that ECPs will not protect her from pregnancy if she has unprotected intercourse in the days or weeks following the treatment. Contraceptive counseling should be done and a method should be initiated (Appendix A).
13. Tell the client to expect her menses within 3 weeks. Her period may be a little earlier or later than usual. If there are any symptoms of pregnancy, she should see her clinician at once.
14. Remind the client that unprotected intercourse can lead to the acquisition of a sexually transmitted infection.
15. Schedule the client for a follow-up appointment based on her ongoing method of contraception, the need for STD testing, and her last annual visit.
16. Offer advanced placement ECPs (Appendix B) and condoms, if indicated.

Follow-up

1. Do a urine pregnancy test if the client has not had a period 3 weeks after taking ECPs.
2. Do STD testing, if indicated.
3. If she is not pregnant, discuss with the client her present and future contraceptive options.
4. If she is pregnant, inform the client that although no long-term studies have been done specifically to evaluate the risk to the fetus, there is no evidence of any increase in congenital defects. Remind the client that there is about a 2% incidence of congenital anomalies in all pregnancies.
5. Offer advanced placement ECPs (Appendix B) and condoms, if indicated.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

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Gold MA et al. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. J Pediatr Adolesc Gynecol 2004 Apr; 17:87-96

APPENDIX A

INITIATING ONGOING CONTRACEPTION AFTER ECP USE

Because ECPs can delay ovulation, a client could be at risk of pregnancy in the few days after treatment. A client should use a back-up method of contraception for the remainder of the treatment cycle and thereafter.

METHOD	WHEN TO INITIATE
Condom	Immediately
Diaphragm	Immediately
Spermicide	Immediately
Combined Oral Contraceptives (COC)	Initiate a new pack, either according to manufacturer's instructions after beginning the next menstrual cycle, or begin taking one COC tablet daily the day after ECP treatment is completed. Clients using levonorgestrel-containing COC as EC can continue taking one pill per day from the same pack. Client using other brands can begin a new pack the day after ECP treatment is completed, abstain from intercourse or use backup protection for first 7 days of the pill pack.
Progestin-only Oral Contraceptives (POP)	Initiate a new pack, either according to manufacturer's instructions after beginning the next menstrual cycle, or begin taking one POP tablet daily the day after ECP treatment is completed. If starting immediately after ECP use, abstain from intercourse or use backup protection in addition to the POPs for the first 2 days of the POP pack.
Three-Month Injectable	Initiate the day ECP treatment is completed or the day after ECP treatment is completed or within 7 days of beginning the next menstrual period. If starting immediately after ECP use, abstain from intercourse or use backup protection for the first 7 days.
Contraceptive Patch	Initiate the day after ECP treatment is completed or within 5 days of beginning the next menstrual period. If starting immediately after ECP use, abstain from intercourse or use backup protection in addition to the patch for the first 7 days.
Vaginal Ring Contraception	Initiate the day after ECP treatment is completed or within 5 days of beginning the next menstrual period. If starting immediately after ECP use, abstain from intercourse or use backup protection in addition to the ring for the first 7 days.
Implants	Initiate within 7 days of beginning the next menstrual period.
IUD	Initiate during the next menstrual period. If the client intends to use an IUD for ongoing contraception, consider inserting a copper-releasing IUD for emergency contraception treatment.
Fertility Awareness	Initiate after the onset of the next normal menstrual period and after the client has been trained in using the method
Sterilization	Perform the operation any time after beginning the next menstrual period.

Adapted from Hatcher et al. Contraceptive Technology. 2007

APPENDIX B

ADVANCED PLACEMENT EMERGENCY CONTRACEPTION

Rationale

The provision of advanced placement emergency contraception is encouraged for clients at risk for unprotected intercourse and/or contraceptive failure.

Studies have demonstrated that:

1. using advanced placement ECPs did not increase the incidence of unprotected intercourse.
2. after unprotected intercourse those women with advanced placement ECPs were more likely to use them than women who had a prescription or had to go to a health care facility or provider in order to get ECPs.

Plan of Action

1. The client should read, understand, and sign the Consent for Emergency Contraceptive Pills (DHMH 4523).
2. If sufficient supplies are available, one package of ECPs should be offered to every family planning client especially teens, clients using barrier methods of contraception, and clients using contraceptive pills, patches or rings.
3. Offer condoms if the potential for STD acquisition is a consideration.
4. When unprotected intercourse does occur, the clients should follow the instructions in the ECPs package.
5. The client should call the clinic as soon as possible to discuss contraception usage, to make an appointment, and/or get more ECPs.

FERTILITY AWARENESS-BASED METHODS

Rationale

Fertility Awareness-Based methods (FAB) are a couple's understanding, acceptance and use of their phases of fertility and infertility for the purpose of achieving or avoiding pregnancy. Couples are taught to recognize the time during a woman's fertility cycle when pregnancy is possible thereby permitting them to regulate conception by the timing of intercourse.

FAB methods which may be used are:

1. The Calendar Rhythm Method is based on documentation of multiple menstrual cycles and the calculation of probable ovulation generally occurring 14 days prior to menses assuming sperm viability of 3-5 days and ovum viability of 24 hours.
2. The Standard Days Method (SDM) can be used by women who usually have cycles between 26 and 32 days and use a barrier method or avoid intercourse on days 8-19 of the cycle.
3. The Basal Body Temperature (BBT) method is based on the woman taking her temperature each morning before rising, charting it on a graph and observing that ovulation has probably occurred when there is a rise in the BBT.
4. The Ovulation Method (Cervical Mucus Method/Billings Method) is based on the detection of daily changes in the cervical mucus described as dry days, wet mucus days, peak mucus days, and thick or dry mucus days.
5. The Symptothermal Method combines the use of the BBT and Ovulation Methods as well as noting other possible signs of ovulation.
6. The Lactation Amenorrhea Method (LAM) may be used by postpartum women. It is based on a high frequency of anovulation in women who are doing full breastfeeding and who are not having menstrual periods. It is most reliable during the first six months postpartum.
7. Two-Day Method is a simple method which involves consideration of cervical secretions other than menstrual bleeding. A woman considers herself fertile on a given day if she notices cervical secretions and/or remembers that she had cervical secretions on the day before.

FAB methods involve instruction, motivation, commitment, and periods of abstinence.

FAB methods may be desirable for:

1. Couples who are opposed to artificial contraception, drugs, or devices for cultural or religious reasons.
2. Couples who prefer not to use artificial methods to avoid conception.

3. Couples who desire a pregnancy and want to plan when it may occur.
4. Women who have a medical contraindication to or are unable to tolerate any artificial method of contraception.

Advantages: FAB methods are safe, natural methods with no side effects. They are inexpensive, acceptable to any religious belief, and promote fertility awareness, freedom of choice and partner sharing.

Disadvantages: FAB methods require periodic abstinence and offer no STD protection. The calendar method relies on past menstrual cycles to predict ovulation in future cycles. The BBT method does not give couples enough advance notice of ovulation. FAB methodology is complicated by irregular menses which may be based on a woman's age, usual menstrual pattern, recent pregnancy or recent hormonal contraception. Vaginitis and fever may interfere with use of some methods. The typical use failure rates for FAB methods are as high as 25%.

Plan of Action

1. Offer FAB methods information (from the below-noted references) to clients who are not interested in or are not candidates for artificial methods of birth control.
2. Refer clients to instructors of FAB methods, if available.
3. Offer advanced placement emergency contraception, and education for emergency contraception, condoms, and spermicides.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Zieman M, Hatcher RA et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2007

GONORRHEA

Rationale

Neisseria gonorrhoeae infection is the second most commonly reported bacterial sexually transmitted disease. In women, the primary infection usually occurs in the cervix, although sites such as the urethra, rectum, and pharynx can be involved. Many infections among women do not produce recognizable symptoms until complications such as PID have occurred. PID, whether symptomatic or asymptomatic, can cause tubal scarring leading to infertility and/or ectopic pregnancy.

The majority of urethral infections caused by gonorrhea among men produce symptoms that cause them to seek curative treatment soon enough to prevent transmission to others.

Detection of gonorrhea infections in women rely on screening tests. Annual screening of all sexually active women age 25 years or younger is recommended as is screening of older women with risk factors. The benefits of gonorrhea screening in women have been demonstrated in areas where screening programs have reduced both the prevalence of infection and rates of PID.

A Gram stain of a male urethral specimen that demonstrates polymorphonuclear leukocytes with intracellular Gram-negative diplococci can be considered diagnostic for gonorrhea in symptomatic men. A Gram stain should not be considered sufficient for ruling out gonorrhea in asymptomatic men. Gram stain for endocervical specimens, pharyngeal, or rectal specimens also are not sufficient to detect gonorrhea and, therefore, not recommended.

Culture, nucleic acid hybridization tests, and NAAT are available for detection of genitourinary gonorrhea. Culture and nucleic acid hybridization tests require female endocervical or male urethral swab specimens. NAAT can be used for endocervical swabs, vaginal swabs, male urethral swabs, and female and male urine. In general, culture is the most widely available option for the diagnosis of gonorrhea in nongenital sites (rectum and pharynx).

Clients infected with gonorrhea are frequently coinfecting with chlamydia. The recommendation is that clients treated for gonorrhea also be treated routinely with a regimen that is effective against uncomplicated genital chlamydia if a chlamydia infection has not been ruled out.

Plan of Action

1. Screening and testing
 - a. Women who attend the family planning clinics should have endocervical screening for gonorrhea annually if they meet any one of the following criteria:
 - 1) All sexually active women age 25 years or younger

- 2) New sexual partner within the last 3 months
 - 3) New sexual partner since the last gonorrhea test
 - 4) Two or more sexual partners within the last year
 - 5) History of a sexually transmitted disease within the last year
 - 6) Sexual partner with a history of a sexually transmitted disease or other high-risk behavior
 - 7) Symptoms or signs of gonorrhea, including mucopurulent cervicitis, urethritis, proctitis, pharyngitis, and/or salpingitis
 - 8) Exchanging sex for drugs or money
 - 9) Other high-risk sexual behavior
- b. Chlamydia screening should be done according to chlamydia guidelines in this manual.
2. Recommended treatment options:
- a. For uncomplicated gonococcal infections of the cervix, urethra, and rectum
 - 1) Ceftriaxone (Rocephin®) 125 mg in single intramuscular dose

OR

 - 2) Cefixime 400 mg orally in a single dose

PLUS
 - b. Recommended chlamydia treatment options if chlamydia is not ruled out::
 - 1) Azithromycin (Zithromax®) 1 g orally in a single dose

OR

 - 2) Doxycycline 100 mg orally twice a day for 7 days
(contraindicated during pregnancy)
 - c. Alternative treatment options are discussed in the CDC 2006 Sexually Transmitted Diseases Treatment Guidelines.
 - d. For uncomplicated gonococcal infections of the pharynx
 - 1) Ceftriaxone (Rocephin®) 125 mg in a single intramuscular dose

PLUS

- e. Chlamydia treatment options as noted above

3. SPECIAL NOTES ON TREATMENT:

- a. Because of developing resistance of gonorrhea to fluoroquinolones (ciprofloxacin, ofloxacin, or levofloxacin), the CDC no longer recommends the use of fluoroquinolones for the treatment of gonococcal infections and associated conditions such as PID.
 - b. Azithromycin (Zithromax®) 2g oral dose is effective against uncomplicated gonococcal infections but CDC does not recommend widespread use of azithromycin because of concerns regarding rapid emergence of resistance. Azithromycin might be an option for treatment of uncomplicated gonococcal infections from any site in persons with documented severe allergic reactions to penicillins or cephalosporins.
- 4. Treatment of disseminated gonococcal infections is outside the scope of the family planning clinic.
 - 5. Clients exposed to gonorrhea through an infected partner should be tested for gonorrhea and treated, regardless of the test result.
 - 6. Sex partners should be referred for STD evaluation, testing and treatment if they had sexual contact with the client during the 60 days preceding onset of symptoms or diagnosis of gonorrhea. The most recent partner should be evaluated and treated even if the last sexual contact was greater than 60 days from diagnosis or onset of symptoms.
 - 7. Clients and their partners should be instructed to abstain from sexual intercourse until therapy is completed and they have no symptoms.
 - 8. Clients with other than uncomplicated cervical gonorrhea should be given an STD referral.

Follow-up

- 1. Clients with uncomplicated gonorrhea treated with any of the recommended regimens do not require a post-treatment test-of-cure.
- 2. Infections identified after treatment with one of the recommended regimens usually result from reinfection rather than treatment failure indicating a need for improved client education and STD referral for partner(s).
- 3. All clients with gonorrhea treatment should be offered a serologic test for syphilis and be offered testing for HIV infection.

Primary Reference

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CDC. Update to CDC's Sexually Transmitted Diseases Treatment Guidelines, 2006: Fluoroquinolones No Longer Recommended for Treatment for Gonococcal Infections. MMWR 2007; 56:332-336

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ACOG. Health Care for Adolescents. 2003

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ACOG. Primary and Preventive Care: Periodic Assessments. Committee Opinion #357, December 2006

HEMOGLOBINOPATHY

Rationale

Hemoglobinopathies, while relatively uncommon among obstetric patients, can be associated with a variety of effects on the mother, fetus or newborn. The effects range from absence of clinical disease to severe morbidity and death.

Since most hemoglobinopathies are inherited as autosomal recessive conditions, screening, counseling, and preconception diagnosis are important components of reproductive health care for these women.

The purpose of preconception screening is to allow relevant counseling before pregnancy.

The normal adult hemoglobins are A, A², and F. Hemoglobin A accounts for 95% or more of hemoglobin in adults. Hemoglobin A² accounts for 2-3.5% of adult hemoglobin, and the remainder is hemoglobin F.

Abnormal hemoglobin patterns which may be found on hemoglobin electrophoresis screening include the categories listed below:

1. Hemoglobin S (more common in blacks) may present as sickle cell disease (SS) or sickle cell trait (AS). An individual with a trait is usually asymptomatic and a pregnant woman is not at increased risk for poor perinatal outcome but is twice as likely to develop a urinary tract infection during a pregnancy.

Sickle cell disease affects all organ systems and is serious in pregnancy. Anemia is more intense and "crises" more frequent, with an increase in infectious and pulmonary complications. Maternal morbidity is great and perinatal outcomes poor. These patients would need high-risk care if pregnant.

2. Hemoglobin C may present as a trait (AC) which is not pathological. Hemoglobin C disease (CC) causes severe anemia. These patients would need high-risk care if pregnant.
3. Hemoglobin E is predominant in Southeast Asians. It is not pathological as a trait (AE) and the homozygous state (EE) causes mild anemia but does not appear to increase risk in pregnancy.
4. Combinations of S, C, and E vary in severity and risk. The morbidity of SC disease is less than sickle cell disease but does increase the incidence of early spontaneous abortion and hypertension in pregnancy. These patients may go into crises if pregnant and would need the same high-risk care as patients with SS disease. The risk of SE disease in pregnancy is not clear.
5. Alpha thalassemia has two major phenotypes: hemoglobin Bart which is incompatible with life, and hemoglobin H which causes severe hemolytic anemia. Alpha-thalassemia minor causes a hypochromic, microcytic anemia.

6. Beta thalassemia major or Cooley's anemia (homozygous) causes severe anemia with hemolysis, infections and cardiovascular complications. These individuals often die before reaching childbearing. Those who do become pregnant are treated as high risk. Beta thalassemia minor is characterized by an increase of greater than 3.5% of A², and F may be increased more than 2%. It is associated with a hypochromic, microcytic anemia and usually a satisfactory outcome of pregnancy. Sickle beta thalassemia is similar to sickle cell-C in perinatal mortality and morbidity and would be treated as high risk. C-beta thalassemia appears to be benign. E-beta thalassemia may cause severe anemia.

Plan of Action

1. Clients should have a hemoglobin electrophoresis test if indicated.
2. Any client found to have a trait should be referred for counseling and encouraged to bring her partner for testing, in relation to preconception counseling.
3. If both partners have a trait, they should be referred to one of the following centers for counseling.

Johns Hopkins Hospital – 410-955-6132
University of Maryland – 410-328-2808
Sinai Hospital – 410-601-5864

4. Newly diagnosed clients with SS, CC, SC, S-beta thalassemia, and Beta thalassemia major warrant immediate referral to medical care.

Common hemoglobin electrophoresis patterns are found in the Appendix. Assistance in interpreting patterns may be obtained by calling the Office of Genetics and Children with Special Health Care Needs, DHMH, at 410-767-6730.

5. Clients who have traits or combined hemoglobinopathies with an associated anemia should be referred for a work-up to include a CBC, serum ferritin, red blood cell indices and reticulocyte determination to allow for appropriate management.
6. Combination estrogen/progestin contraceptives and progestin-only contraceptives are safe to use for clients with sickle cell disease, thalassemia, or traits. Both method types tend to reduce the frequency and severity of sickle cell crises. Hormone and nonhormone users appear to have no differences with regard to coagulation studies and blood viscosity measurements. In addition, hormone use may decrease menstrual blood loss.
7. IUD use is not contraindicated as long as there is not excess menstrual blood loss and the client does not have signs or symptoms of anemia. Mirena may actually decrease the menstrual blood loss.

Follow-up

1. Contraception follow-up for clients with a hemoglobinopathy is based on the standard contraception guidelines and management of the hemoglobinopathy. The client should be monitored for changes in cardiovascular status including anemia.

2. The hemoglobinopathy health care provider should be notified of the client's contraceptive use.

Primary References

Cunningham FG et al. Williams Obstetrics. 22nd Ed., McGraw-Hill, New York, 2005

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Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Speroff L, Darney P. A Clinical Guide For Contraception. 4th Ed., Lippincott Williams & Wilkins, Philadelphia, PA, 2005

ACOG. Hemoglobinopathies in Pregnancy. Practice Bulletin #64, July 2005

Interpretation of Adult Hemoglobin Patterns. Maryland State Department of Health and Mental Hygiene Laboratories Administration, June 25, 2009

APPENDIX

MARYLAND STATE DEPARTMENT OF HEALTH AND MENTAL HYGIENE
LABORATORIES ADMINISTRATION

INTERPRETATION OF ADULT HEMOGLOBIN PATTERNS

DISEASE PATTERNS	
SS	Designates the presence of sickle hemoglobin without detectable adult normal hemoglobin A. This is consistent with homozygous sickle cell anemia.
CC	Designates the presence of hemoglobin C without detectable adult normal hemoglobin A. This is consistent with homozygous hemoglobin C disease, characterized by anemia.
SC	Indicates the presence of both hemoglobins S and C. This doubly heterozygous condition, sickle C disease, is similar, although often milder, than sickle cell anemia.
SAA ²	Designates the doubly heterozygous condition S ^{Beta+} thalassemia which is a clinically significant sickling disorder.
AA ₂	May designate Beta thalassemia trait or Beta ⁺ thalassemia, which is a clinically significant hematologic disorder.

TRAIT PATTERNS	
AS	Indicates the presence of adult normal hemoglobin A and hemoglobin S. This preliminary finding is consistent with the benign sickle cell trait.
AC	Indicates the presence of adult normal hemoglobin A and hemoglobin C. This finding is consistent with the benign hemoglobin C trait.
AV	Indicates the presence of normal adult hemoglobin A and an anomalous variant hemoglobin "V" which does not appear to be any of the common variants.

NORMAL PATTERNS	
AA	Designation for adult normal hemoglobin.
F	Designates the presence of hemoglobin F, fetal hemoglobin. When specifically mentioned in an adult, there is usually an abnormally large amount of hemoglobin F present. Adults normally have trace amounts of hemoglobin F. Additional testing including CBC with indices and a quantitative hemoglobin electrophoresis will be necessary to determine whether the condition is clinically significant.

HEPATITIS B

Rationale

Hepatitis B is the most serious form of hepatitis. There are about one million chronically infected carriers in the United States, and they represent about 10% of those that were acutely infected. Most cases of acute viral hepatitis are asymptomatic. Some experience a flu-like illness, and a few are jaundiced.

The hepatitis B virus (HBV) is usually spread by transfer of blood or body fluids. Chronic carriers are at risk of infecting their offspring and household and sexual contacts. Infectious persons test positive for hepatitis B surface Antigen (HBsAg).

Preventing HBV transmission during early childhood is important because of the high likelihood of chronic HBV infection and chronic liver disease that occurs when children less than five years of age become infected. Testing to identify pregnant women who are hepatitis B surface antigen (HBsAg) positive and providing their infants with immunoprophylaxis effectively prevents HBV transmission during the perinatal period.

Pregnancy is not a contraindication to hepatitis B vaccination or hepatitis B immunoglobulin administration.

With the implementation of routine infant hepatitis B vaccination and the wide-scale implementation of vaccination programs for adolescents, vaccination of adults at high risk for HBV has become a priority in the strategy to eliminate HBV transmission in the United States.

Plan of Action

1. Clients at risk for HBV infection should be offered screening for the presence of HBsAg (Appendix A).
2. Clients who test positive (presence of HBsAg) should be referred for a medical evaluation which includes liver function profile and complete hepatitis work-up. They may be candidates for treatment.
3. Clients who test positive should receive education and counseling on the implications of the chronic carrier state, and on the means to prevent transmission to sexual contacts and household members.
4. Clients who are at risk for HBV infection (Appendix A) and who test negative are candidates for the vaccine series. Vaccination may be received during pregnancy.

For more information regarding HBV prophylaxis and vaccination, direct inquiries to the Maryland Perinatal Hepatitis B Prevention Program, DHMH – Immunization Division at 410-767-6679 or 410-767-5716.

5. Blood, sera, saliva, semen, and vaginal fluids have been shown to be infectious. Clinic staff should follow DHMH Infection Control Guidelines and standard precautions for handling blood, specimens, and instruments.
6. Clients who have had sexual contact with acutely infected persons should receive HBV immunoglobulin followed by the vaccine series.
7. Hormonal contraception should not be given to clients with active viral hepatitis or to women who remain positive for HBsAg and have abnormal liver function studies.
8. Hormonal contraception may be considered for clients with a history of HBV infection when recommended by a medical doctor who agrees to monitor the client for evidence of complications of her chronic disease.

Follow-up

1. Sexual contacts and household members of the woman with chronic HBV infection should be tested, and susceptible persons should receive the vaccine series.
2. Persons in high-risk occupations should receive immunization in connection with their employment (Appendix A, Nos. 6, 7, and 8).

Primary References

CDC. Sexually Transmitted Diseases Treatment Guidelines. 2002

Hatcher RA et al. Contraceptive Technology. 18th Revised Edition. Ardent Media, Inc., New York, 2004

CDC. National Center for Infectious Diseases. Interpretation of the Hepatitis B Panel. 2004

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Cunningham FG et al. Williams Obstetrics. 21st Ed., McGraw-Hill, New York, 2001

APPENDIX A

RISK FACTORS FOR HEPATITIS B

1. History of illicit drug use
2. History of sexually transmitted diseases
3. Household contact with an HBV carrier
4. Multiple sexual partners
5. Sexual partners including bisexual men and intravenous drug users
6. Work in a health care or public safety field
7. Work or residence in an institution for the developmentally disabled
8. Work or residence in a detention facility
9. Receipt of blood components for medical indications
10. History of a tattoo
11. Immigrants/refugees from areas of high HBV endemicity

APPENDIX B

INTERPRETATION OF THE HEPATITIS B PANEL

TESTS	RESULTS	INTERPRETATION
HBsAg anti-HBc anti-HBs	negative negative negative	susceptible
HBsAg anti-HBc anti-HBs	negative positive positive	immune due to natural infection
HBsAg anti-HBc anti-HBs	negative negative positive	immune due to hepatitis B vaccination
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	acutely infected
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	chronically infected
HBsAg anti-HBc anti-HBs	negative positive negative	four interpretations possible*
<p>*</p> <ol style="list-style-type: none"> 1. May be recovering from acute HBV infection. 2. May be distantly immune and test not sensitive enough to detect very low level of anti-HBs in serum. 3. May be susceptible with a false positive anti-HBc. 4. May be undetectable level of HBsAg present in the serum and the person is actually a carrier. 		

HEPATITIS C

Rationale

Hepatitis has many causes including chemical and infectious agents. The viral agents are now listed from hepatitis A to hepatitis G.

The hepatitis C virus (HCV) was first identified as a distinct virus in 1988. It is the most prevalent of all the bloodborne viruses, used to be the primary causative agent of post-transfusion hepatitis, and is the most frequent cause of endstage liver disease requiring transplant.

Since 1992, blood and blood products have been screened for HCV, and transfusion associated transmission is very rare. Currently, intravenous drug abuse accounts for the greatest risk. Since the transmission routes for HCV are bloodborne, sexual and perinatal, other risk groups for HCV include hemodialysis patients, sexual contacts of infected persons, persons with multiple sex partners, infants born to infected mothers and health care workers.

The incubation period is six to seven weeks. About one third of newly infected people are asymptomatic. When present, symptoms include fatigue, jaundice, nausea and vomiting and abdominal pain. More than eighty five percent of those infected develop chronic hepatitis C which is often a subclinical disease leading to cirrhosis and hepatocellular carcinoma after decades of recurrent attacks on the liver. More than seventy percent of infected people develop chronic liver disease.

HCV infection occurs among people of all ages, but the greatest incidence of new infection occurs in those in their twenties and thirties. Alcohol worsens the outcome, possibly by increasing viral replication or by increasing the susceptibility of liver cells to further injury from HCV.

The diagnosis of hepatitis C is based on the presence of serum antibody (anti-HCV). Currently available tests require clinical interpretation, as they do not distinguish between new infection, chronic infection, severe infection, or resolved infection. Individuals should be evaluated for the severity of liver damage because this virus is known to have irregular pulses of activity and inactivity.

Alpha interferon is the treatment most widely used for HCV. Ribavirin is often added for individuals who have relapsed after interferon alone.

Current guidelines to reduce the risk of health care workers becoming infected with bloodborne diseases are especially important for the prevention of occupationally transmitted HCV because: it is the most prevalent of bloodborne viruses in the United States; it remains asymptomatic in most infected persons for long periods of time, decreasing the likelihood of clinical recognition; it can be transmitted by needle-stick; and there is no vaccine or postexposure prophylaxis for HCV. The strategy is to treat all clients as though they have bloodborne disease that can be infectious to others. The principles of Standard Precautions serve to protect the client as well.

Plan of Action

1. Clients at high risk should be offered screening for HCV (Appendix).
2. Clients found to test positive for serum antibody (anti-HCV) should be referred for medical evaluation and possible treatment.
3. To protect their liver from further harm, HCV-positive individuals should be advised to avoid using alcohol and taking new medication (including over-the-counter and herbal supplements) until they have consulted their physician.
4. HCV-positive individuals should be vaccinated against hepatitis A and hepatitis B if they are not immune.
5. To reduce transmission to others, these HCV-positive individuals should be advised not to share any personal items that may have blood on them (e.g., toothbrushes and razors).
6. Hormonal contraception may be appropriate according to the current WHO criteria.
7. Hormonal contraception may be considered when recommended by a medical doctor who agrees to monitor the client for evidence of complications of her chronic disease.

Primary References

CDC. Sexually Transmitted Diseases Treatment Guidelines. 2002

ACOG. Precip: Primary and Preventive Care. 3rd Ed., 2004

CDC. Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. MMWR, Vol.47, RR-19, October 16,1998.

Tierney LM Jr. et al. Current Medical Diagnosis and Treatment. 44th Ed., McGraw-Hill, New York, 2005

APPENDIX

GUIDELINES FOR HCV SCREENING

Routine testing for HCV infection should be performed on the following individuals based on their risk for infection:

- Persons who have injected illegal drugs, including those who injected one or a few times many years ago and do not consider themselves as drug users
- Persons with selected medical conditions, including
 - Persons who received clotting factor concentrates produced before 1987
 - Persons who were ever on chronic (long-term) hemodialysis
 - Persons with persistently abnormal alanine aminotransferase levels
- Prior recipients of transfusions or organ transplants, including
 - Persons who were notified that they received blood from a donor who later tested positive for HCV infection
 - Persons who received a transfusion or blood or blood components before July 1992
 - Persons who received an organ transplant before July 1992

Routine testing for HCV infection should be performed on the following individuals based on a recognized exposure:

- Health care, emergency medical, and public safety workers after needlesticks, sharps, or mucosal exposures to HCV-positive blood
- Children born to HCV-positive women

Persons for whom routine HCV testing is not recommended unless they have risk factors for infection:

- Health care, emergency medical, and public safety workers
- Pregnant women
- Household (nonsexual) contacts of HCV-persons
- The general population

Persons for whom routine HCV testing is of uncertain need:

- Recipients of transplanted tissue (e.g., corneal, musculoskeletal, skin, ova, sperm)
- Intranasal cocaine and other noninjecting illegal drug users
- Persons with a history of tattooing or body piercing
- Persons with a history of multiple sex partners or sexually transmitted diseases
- Long-term steady sex partners of HCV-positive persons

CDC. Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. MMWR, Vol. 47, RR-19, October 16, 1998

HERPES GENITALIS

Rationale

Herpes genitalis is a sexually transmitted disease caused by the herpes simplex virus (HSV), a DNA virus that has two serotypes: HSV-1 and HSV-2. HSV-1 is responsible for virtually all cases of oral herpes and for approximately 50% of the first episode of genital infections. HSV-2 is the principle serotype that causes recurrent or subclinical genital infection. Genital herpes infections may be classified as primary, nonprimary, and recurrent.

Primary infection represents the individual's first exposure to HSV and is characterized by constitutional symptoms and multiple painful vesicles on the vulva, vagina, and/or cervix. Lesions may occur between 2 and 14 days following exposure to infectious virus. These lesions tend to resolve within 3 weeks. Shedding of the virus from the lower genital tract of women occurs during the first 3 months after primary genital lesions have healed.

A nonprimary herpes first episode can be identified as a first clinically recognized genital HSV infection that does not behave clinically like a symptomatic primary infection. There are fewer systemic manifestations, less pain, a briefer duration of viral shedding and a more rapid resolution than primary herpes. These episodes may be the result of an initial HSV-2 infection in the presence of partially protective HSV-1 antibodies.

Recurrent herpes infections typically produce minimal constitutional symptoms, fewer lesions, and more rapid resolution. Recurrent herpes is caused by reactivation of latent viral infection and is manifested by a characteristic prodrome followed by a limited vesicular eruption. Shedding of the virus from the genital tract without symptoms or signs of clinical lesions (subclinical shedding) is episodic and last on the average of 1.5 days. Subclinical shedding makes this viral STD difficult to control and prevent.

Most neonatal HSV infection is the consequence of delivery of a neonate through an infected birth canal. The virus either invades the uterus following membrane rupture or contacts the fetus at delivery. Neonatal infection may be localized to the skin, eye, and mouth; involve the central nervous system; be disseminated; or be symptomatic. Studies indicate a 30-50% risk of neonatal infection with a primary maternal infection near the time of delivery, but low risk (<1%) among women with recurrent maternal infection at term or who acquire genital herpes during the first half of pregnancy. Neonatal mortality is 30% with disseminated disease and 4% with CNS disease. Approximately 20% of survivors of neonatal herpes have long-term neurologic sequelae.

Systemic antiviral drugs partially control the symptoms and signs of herpes episodes when used to treat first clinical episodes and recurrent episodes or when used as daily suppressive therapy. However, these drugs neither eradicate latent virus nor affect the risk, frequency, or severity of recurrences after the drug is discontinued.

Plan of Action

1. A clinical diagnosis of HSV infection may be confirmed by viral culture from skin lesions. However, there is a false-negative rate of 25%.
2. Advise the client to abstain from sexual contact during the prodromal period and while lesions are present.
3. Advise the client to use latex condoms during asymptomatic periods to avoid transmission of the virus.
4. Recommended treatment options:
 - a. First clinical episode
 - 1) Acyclovir (Zovirax®) 400 mg orally 3 times a day for 7-10 days
OR
 - 2) Acyclovir (Zovirax®) 200 mg orally 5 times a day for 7-10 days
OR
 - 3) Famciclovir (Famvir®) 250 mg orally 3 times a day for 7-10 days
OR
 - 4) Valacyclovir (Valtrex®) 1 g orally twice a day for 7-10 days
 - b. Recurrent episodes – episodic treatment
 - 1) Acyclovir (Zovirax®) 400 mg orally 3 times a day 5 days
OR
 - 2) Acyclovir (Zovirax®) 800 mg orally twice a day for 5 days
OR
 - 3) Acyclovir (Zovirax®) 800 mg orally 3 times a day for 2 days
OR
 - 4) Famciclovir (Famvir®) 125 mg orally twice a day for 5 days
OR
 - 5) Famciclovir (Famvir®) 1000 mg orally twice a day for 1 day
OR

6) Valacyclovir (Valtrex®) 500 mg orally twice a day for 3 days

OR

7) Valacyclovir (Valtrex®) 1 g orally once a day for 5 days

c. Daily suppressive therapy

1) Acyclovir (Zovirax®) 400 mg orally twice a day (up to 6 years)

OR

2) Famciclovir (Famvir®) 250 mg orally twice a day (up to 1 year)

OR

3) Valacyclovir (Valtrex®) 500 mg orally once a day (up to 1 year)

OR

4) Valacyclovir (Valtrex®) 1 g orally once a day (up to 1 year)

5. The decision to use suppressive therapy depends on the frequency and severity of recurrent episodes. Therapy management must be individualized.
6. Once-daily valacyclovir suppressive therapy significantly reduces the risk of transmission of genital HSV among heterosexual HSV-2 discordant couples.
7. Clients with HSV should inform their current partners that they have HSV and inform future partners before initiating a sexual relationship.
8. Sex partners of HSV-infected persons should be advised that they might be infected even if they have no symptoms.

Follow-up

The client should be educated that if she becomes pregnant she should inform her obstetric health care provider of her past history of HSV.

Primary References

CDC. Sexually Transmitted Diseases Treatment Guidelines. 2006

ACOG. Health Care for Adolescents. 2003

ACOG. Precip: Obstetrics. 3rd Ed., 2005

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ACOG. Management of Herpes in Pregnancy. Practice Bulletin #82, June 2007

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Corey L, Wald A, Patel R et al. Once-Daily Valacyclovir to Reduce the Risk of Transmission of Genital Herpes. N Engl J Med. 2004;350: 11-20

HUMAN IMMUNODEFICIENCY VIRUS (AIDS/HIV TESTING)

Rationale

The Acquired Immunodeficiency Syndrome (AIDS) is one of the leading causes of death in women of reproductive age. In addition, AIDS is also a contributor to childhood mortality, and is one of the leading causes of childhood mortality in many inner city communities.

The etiologic agent of AIDS is the human immunodeficiency virus (HIV), an RNA-retrovirus capable of inducing severe immunological dysfunction in T-4 helper lymphocytes. HIV may infect a number of different cell types; however, cells which possess the CD4 antigen complex on the cell membrane are primary target for HIV. As each infected cells becomes altered, dies, or ceases to function, it contributes to the malfunction of the immune system. This diminution of the immune system allows opportunistic infections and malignancies to develop, leading to death of the host.

At the time of initial infection, an individual may be asymptomatic or may develop an acute mononucleosis-like syndrome. Antibodies can be detected in most individuals 6-12 weeks after exposure, but this latent period can be longer. After seroconversion has occurred, an asymptomatic period usually follows. In some persons, the time frame from infection to development of AIDS may be over 10 years. Many individuals are infectious and remain asymptomatic for prolonged periods of time, but the long-term prognosis remains poor. Evidence of immune dysfunction may be followed by clinical conditions ranging from fever, weight loss, malaise, lymphadenopathy, and central nervous system dysfunction. Infections such as herpes simplex or oral candidiasis become prevalent and resistant to treatment.

The transmission of HIV is by three primary routes: intimate contact with bodily secretions of infected individuals, exposure to blood or blood products infected with HIV, and perinatally from an infected mother to her fetus or infant. Heterosexual activity is an important mode of transmission. Most women contract HIV by use of intravenous drugs or by sexual relations with intravenous drug users. Eighty percent of women and children with AIDS are African American or Hispanic.

During 1985-1995, approximately 6,000-7,000 HIV-infected women gave birth in the United States each year. An estimated 1,000-2,000 infants were born with HIV infection annually. During 2000-2001, perinatal transmission rates $\leq 2\%$ have been achieved, and the CDC estimates that 280-370 infants are born currently with HIV infection each year in the United States. The dramatic improvement may be due to treatment of the gravida with zidovudine (AZT or ZDV) alone or in combination with other drugs antepartum and intrapartum, elective cesarean delivery at about 38 weeks gestation before labor and before rupture of membranes, and treatment of the baby for the first six weeks of life with zidovudine.

All clients will be offered and encouraged to take the HIV screening test. Specific information will be shared with the client before and after testing. In addition to discussions of lowering the risk of sexual transmission, pretest counseling should

include a description of AIDS and HIV infection, risk behaviors associated with infection, and a description of the testing procedure.

Standard testing procedures include an initial screening test (enzyme immunoassay or EIA) followed by a confirmatory Western blot or an immunofluorescent assay. No antibody test should be considered positive unless a confirmatory assay has been performed. These tests measure levels of antibody to the virus, not the virus itself. An individual who has tested positive to HIV antibody must be considered infectious. Individuals who test negative for HIV antibody should be provided with the information that false-negative (virus-positive, antibody-negative) results can occur. The false-negative status is important due to the prolonged latent phase, during which the exposed individual may test negative for HIV antibody while remaining infectious.

Strategies available for dealing with HIV infection are primary prevention through education that leads to changes in behavior, and secondary prevention through the identification of infected individuals and selected drug therapy to retard/prevent progression of the HIV infection.

Plan of Action

1. At the initial family planning visit, all clients should receive specific education about the risk factors for acquiring HIV infection (Appendix A).
2. Clients requesting or receiving testing should not be identified in a way that makes them unique in the clinic setting (i.e., charts flagged or clients referred to a single interviewer or location).

Information regarding counseling and testing may be obtained from the AIDS Administration, Maryland State Department of Health and Mental Hygiene at 410-767-5013.

3. The test is voluntary and confidential after appropriate counseling and consent.
4. All clients should be offered and encouraged to have the HIV screening test, because a substantial percentage of infected women (up to 40% in one study) acknowledge no risk behavior.
5. If the screening test (EIA) is positive, it must be followed by a confirmatory Western blot or an immunofluorescent assay.
6. Clients who are HIV-infected should be provided with counseling that includes a discussion of the risks of perinatal transmission and allows the clients to make informed reproductive choices. Inform the clients that treatment is available to reduce the risk of perinatal transmission of HIV.
7. Refer HIV-positive clients to those providers who are skilled in the management and care of HIV-infected individual.
8. In HIV-positive individuals, the family planning goal is high contraceptive efficacy, low risk of woman-to-partner HIV transmission, and low risk of partner-to-woman STI transmission. This goal is met by choices such as hormonal contraceptives or IUD plus male condoms.

9. Anti-HIV protease inhibitors can increase or decrease serum levels of estrogen and progestins. Specific anti-HIV protease inhibitor labeling must be reviewed to see if additional back-up methods of contraception or different methods of contraception need to be considered. Because of the potential for the interaction between anti-HIV protease inhibitors and combined estrogen/progestin contraceptives, use of condoms in addition to the hormonal contraceptives must be mandatory.

Follow-up

1. Women who test positive for HIV antibody should be provided with detailed education and counseling.
2. Although a negative antibody test usually means a person is not infected, antibody tests cannot rule out infection from a recent exposure. The test should be repeated 3 and 6 months after the most recent exposure.
3. HIV-infected women should be advised not to breastfeed their infants, since breast milk can transmit infection to the baby.
4. A mother should be advised to avoid contact between her body fluids and an open area on the skin or mucous membranes of her baby.

Primary References

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ACOG. Scheduled Cesarean Delivery and the Prevention of Vertical Transmission of HIV Infection. Committee Opinion #234, May 2000

CDC. Revised Recommendations for HIV Screening of Pregnant Women. MMWR, Vol. 50, RR-19, November 9, 2001

APPENDIX A

RISK FACTORS FOR ACQUIRING HIV INFECTION

1. Illicit drug use (especially intravenous drug use)
2. Current or previous multiple sexual partners or prostitution
3. Transfusion of blood or blood products before adequate screening began in the U.S. (between 1975-1985-)
4. Bisexual activity
5. Origin of countries where the incidence of HIV is high
6. Symptoms suggestive of HIV infection (e.g., fever or illness of unknown origin)
7. History of or current sexually transmitted diseases, hepatitis, or tuberculosis
8. Known sexual or needle-sharing exposure to an HIV-infected person

APPENDIX B

COUNSELING FOR HIV-POSITIVE INDIVIDUALS SHOULD INCLUDE THE FOLLOWING POINTS

1. A description of the early clinical manifestations of HIV infection, with advice to seek immediate medical attention in order to institute appropriate care.
2. Current understanding of the prognosis of HIV infection.
3. Emphasis of the need for responsible sexual behavior and avoidance of sharing intravenous needles.
4. A prohibition from donating blood products, body organs, etc.
5. Recommendation not to share toothbrushes, razors, and other implements that could be contaminated with blood.
6. The suggestion that sexual and needle-sharing partners be notified and advised of counseling and testing.
7. The importance for the client to notify her health care workers of her HIV antibody results.
8. The client should be informed of the risks of perinatal transmission.

HYPERTENSION

Rationale

Blood pressure (BP) must be <120 mm Hg systolic and <80 mm Hg diastolic to be considered normal. Prehypertension is defined as a systolic BP of 120-139 mm Hg or a diastolic BP of 80-89 mm Hg. High blood pressure is defined as a systolic BP \geq 140 mm Hg or diastolic BP \geq 90 mm Hg (Appendix A).

Once a patient is diagnosed with hypertension, the goal of therapy is to reduce cardiovascular morbidity and mortality. The goal should be to lower diastolic blood pressure to levels <80 mmHg and lower systolic blood pressure to levels <120 mm Hg. The objective is to achieve the designated blood pressure and maintain long-term management. The severity of blood pressure elevation and the presence of other complications determine the antihypertensive treatment.

A client's hypertension status, whether present or past, treated or untreated, will determine the use of hormonal contraception.

Plan of Action

1. Blood pressure should be measured and the client should be informed of her blood pressure reading at each visit.
2. Blood pressure measurements must be accurate and reproducible. Proper technique is important (Appendix B).
3. Recommended management of elevated blood pressure:
 - a. Those clients with a diastolic BP 90-100 mm Hg or systolic BP 140-199 mm Hg should have a repeat evaluation within 4 weeks. If the BP is still elevated, refer the client to a health care provider of her choice for medical management.
 - b. Refer all clients with a diastolic BP \geq 100 mm Hg or systolic BP \geq 200 mm Hg for immediate medical management.
4. Counsel smokers about the health benefits of tobacco cessation.
5. There is a strong correlation between body weight and blood pressure. Weight reduction to control obesity can result in decreases in BP. Obese patients should be referred to weight reduction programs.
6. Exercise programs should be encouraged.
7. Ingestion of more than 2 ounces of alcohol per day is associated with an increased prevalence of hypertension. Those who drink should moderate their alcohol consumption to no more than 1 ounce of ethanol daily. One ounce of ethanol is contained in 2 ounces of 100 proof whiskey, 8 ounces of wine, or 24 ounces of beer.

8. Some clients with hypertension may achieve BP control through moderate dietary sodium restriction. Advise clients to avoid adding salt to food during preparation or at the table, and to avoid processed foods to which salt is added as a preservative. Restrict sodium to 1.5-2.5 grams (or 4-6 grams of salt) daily.
9. Calcium intake should be maintained.
10. Contraception for the hypertensive client
 - a. Clients with pregnancy-induced hypertension can use estrogen/progestin contraception as soon as the blood pressure is normal in the postpartum period.
 - b. Low-dose estrogen/progestin contraception can be used in clients less than 35 years old with hypertension controlled by medication, and who are otherwise healthy and do not smoke. Consultation should be provided by the client's health care provider who is managing the client's hypertension. Within the clinic setting, physician consultation is appropriate, and the client should be seen at three-month intervals.
 - c. Combined estrogen/progestin contraceptives should be discontinued in a client who becomes hypertensive while using this method. The physiologic changes take 3 to 6 months to disappear after stopping estrogen/progestin contraception.
 - d. Progestin-only contraceptives, the "mini-pills" (Micronor®) and the injection (Depo-Provera®) are less likely to increase blood pressure than combined estrogen/progestin products.
 - e. Non-hormonal contraception should be considered for clients with uncontrolled hypertension and those with recurrent blood pressure elevations under the influence of combined estrogen/progestin contraceptives and/or progestin-only contraceptives.

Follow-up

Long-term monitoring of blood pressure is important in clients with hypertension; therefore, interval medical assessments with a private health care provider are essential for appropriate management.

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APPENDIX A

CLASSIFICATION AND MANAGEMENT OF BLOOD PRESSURE FOR ADULTS AGED 18 YEARS OR OLDER

BP Classification	Systolic BP (mm Hg)	Diastolic BP (mm Hg)	Lifestyle Modification	Management*	
				Initial Drug Therapy	
				Without Compelling Indication	With Compelling Indications δ
Normal	<120	<80	Encourage		
Prehypertension	120-139	Or 80-89	Yes	No antihypertensive drug indicated	Drug(s) for the compelling indications ϕ
Stage 1 hypertension	140-159	Or 90-99	Yes	Thiazide-type diuretics for most; may consider ACE Inhibitor, ARB, β -blocker, CCB, or combination	Drug(s) for the compelling indications; other antihypertensive drugs, (diuretics, ACE inhibitor, ARB, β -blocker, CCB) as needed
Stage 2 hypertension	\geq 160	Or \geq 100	Yes	Two-drug combination for most (usually thiazide-type diuretic and ACE Inhibitor or ARB or β -blocker or CCB π)	Drugs(s) for the compelling indications; other antihypertensive drugs; (diuretics, ACE inhibitor, ARB, β -blocker, CCB) as needed

Abbreviations: BP indicates blood pressure; ACE, angiotensin-converting enzyme; ARB, angiotensin II receptor blocker; CCB, calcium channel blocker.

*Treatment determined by highest blood pressure category.

δ Heart failure, postmyocardial infarction, high coronary disease risk, diabetes, chronic kidney disease, recurrent stroke prevention.

ϕ Treat patients with chronic kidney disease or diabetes to achieve blood pressure goal less than 130/80 mm Hg.

π Initial combination therapy should be used cautiously in those a risk for orthostatic hypotension.

Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL Jr, et al. The seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC Report [published erratum appears in JAMA 2003; 290: 197]. JAMA 2003;289:2560-72.

APPENDIX B

MEASURING BLOOD PRESSURE

1. The client should avoid cigarettes and caffeine for 30 minutes before the blood pressure measurement is taken.
2. The client should sit quietly for at least 5 minutes and remain seated during measurement, with the arm parallel to the floor and at the level of the heart.
3. The sphygmomanometer cuff size should be adequate for the arm circumference and should not be too tight or too loose.
4. The sphygmomanometer bladder length should encircle approximately 80% of the arm circumference.
 - a. Inflate the bladder to 30 mm Hg above the level where the radial pulse is occluded. The systolic blood pressure level is the appearance of the first sound and the diastolic blood pressure level is the disappearance of sound.
 - b. Repeat the measurement after 2 minutes and average the readings.

IMPLANON™ - SUBDERMAL CONTRACEPTIVE IMPLANT

Rationale

Implanon is a long-acting, reversible, progestin-only, subdermal contraceptive implant which is effective for up to 3 years.

The primary mechanism of action is inhibition of ovulation. Within 24 hours of insertion thick cervical mucus prevents normal sperm transport. An atrophic endometrium is also produced.

Perfect use failure rate in the first year of use: 0.01%

Implanon is an off-white, non-biodegradable single sterile rod subdermal implant. It is 4 cm in length with a diameter of 2 mm. Each rod is composed of a solid core of ethylene vinylacetate (EVA) containing 68 mg of the synthetic progestin etonogestrel (ENG) surrounded by an EVA skin that controls the rate of etonogestrel release. The release rate is 60 mcg to 70 mcg/day initially then decreasing to 25 mcg to 30 mcg/day by the end of the third year. Implanon is a progestin-only contraceptive and does not contain estrogen. It does not contain latex and is not radio-opaque and therefore can not be seen by X-ray or CT scan. However, it is detectable by ultrasound using a high-frequency linear-array transducer or by MRI.

Implanon's contraceptive effect is established within 24 hours of insertion and is effective for up to 3 years. Implanon must be removed by the end of 3 years and may be replaced by a new Implanon at the time of removal if continued contraception is desired. Over 90% of women resumed ovulation within 3 months post-removal. Serum concentrations of etonogestrel were undetectable within 1 week of removal. There have been pregnancies reported that have occurred as early as the first week after Implanon removal. Another contraceptive must be initiated immediately if the client does not wish to become pregnant.

Implanon should be considered for women who:

1. Want to delay the next pregnancy for at least 3 years
2. Desire a highly effective, long-term method of contraception
3. Experience serious estrogen-related side effects with estrogen-progestin contraception
4. Have medical conditions that may preclude the use of an estrogen-progestin contraceptive such as thrombosis, hypertension, coronary artery disease, cerebrovascular disease, migraines with aura
5. Are smokers over the age of 35
6. Have difficulty remembering to take pills every day
7. Have contraindications or difficulty using IUDs
8. Desire a non coitus-related method of contraception
9. Have completed their childbearing but are not yet ready to undergo permanent sterilization
10. Have a history of anemia with heavy menstrual bleeding

11. Intend to breastfeed for 1 or 2 years
12. Have chronic illnesses, in which health is threatened by pregnancy

Based on limited data, Implanon may be used during lactation after the 4th postpartum week. No significant effects and no differences were observed in the physical and psychomotor development of the infants. No differences in the production and quality of breast milk were detected.

Implanon does not protect against HIV or other sexually transmitted diseases.

The effectiveness of Implanon in overweight women has not been defined because women who weighed more than 130% of their ideal body weight were not studied. However, serum concentrations of etonogestrel are inversely related to body weight and decrease with time after insertion. It is therefore possible that with time Implanon may be less effective in overweight women, especially in the presence of other factors that decrease etonogestrel concentrations such as concomitant use of hepatic enzyme inducing drugs.

Understanding the bleeding patterns that can occur with Implanon is crucial for client continuation with this method of contraception. All hormone contraceptive bleeding patterns are categorized by frequency and duration of bleeding. Some women may have a more favorable pattern while others may not and it is usually impossible to predict ahead of time who will have the more favorable pattern. Implanon bleeding patterns are similar to other progestin-only methods; however, there are differences:

1. Bleeding can be light or heavy.
2. Bleeding can be for a few days or many days in a row.
3. There can be many consecutive days or weeks of no bleeding.
4. Clients must be ready to experience any of these patterns.
5. Bleeding patterns can vary throughout the duration of use.
6. On the average, the total amount of bleeding/spotting is similar to or slightly better than a normal menstruating woman.
7. The key difference is the irregularity and unpredictability of the bleeding.
8. Some women may have a slight trend towards lighter and infrequent bleeding or no bleeding at all.

The most common reason for the discontinuation of Implanon will be the bleeding pattern, in spite of comprehensive counseling.

Plan of Action

1. A complete family planning medical evaluation, including history, physical examination, and relevant laboratory tests, should be performed prior to Implanon insertion.
2. The client should be counseled regarding the advantages, benefits, disadvantages, and risks associated subdermal contraceptive implant use and be given "Patent Labeling" an information pamphlet containing method use and warning signs (Appendix A and B). In essence, the client who is eligible for other progestin-only contraceptive methods is a candidate for Implanon. The Implanon insertion consent should be signed.

3. Consider the precautions prior to inserting the subdermal contraceptive implant (Appendix C). Refrain from providing the subdermal contraceptive implant to those clients with major risk factors and use caution when considering those with relative risk factors. Many clients in this second category should not receive estrogen and therefore are prime candidates for Implanon.
 - a. Although Implanon contains no estrogen, the client should be reminded of potential hormone side effects that may occur with any hormonal contraceptive product. The “A.C.H.E.S.” should be reviewed.
 - b. Carbohydrate metabolism – Implanon may induce mild insulin resistance and small changes in glucose concentrations of unknown clinical significance. Women with diabetes or impaired glucose tolerance should be carefully observed while using Implanon.
 - c. Lipid metabolism – Women who are being treated for hyperlipidemias should be followed closely if they elect to use hormonal contraception. Some progestins elevate LDL levels and may render the control of hyperlipidemias more difficult.
 - d. Liver function – The hormone in Implanon may be poorly metabolized in women with impaired liver function.
 - e. Contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D).
4. TIMING OF IMPLANON INSERTION
 - a. If no preceding hormonal contraceptive use in the past month, counting the first day of menstruation as Day 1, Implanon must be inserted Days 1 – 5, even if the woman is still bleeding.
 - b. If switching from a combined hormonal contraceptive, Implanon may be inserted
 - 1) Anytime while taking the active oral contraceptive tablets or within 7 days after the last active oral contraceptive tablet.
 - 2) Anytime while the NuvaRing is in place or during the 7-day ring-free period of NuvaRing.
 - 3) Anytime while the Ortho Evra patch is in place or during the 7-day patch-free period of Ortho Evra.
 - c. If switching from a progestin-only method, Implanon may be inserted
 - 1) Any day of the month when switching from a progestin-only pill, do not skip any days between the last pill and insertion of Implanon.
 - 2) On the same day as contraceptive implant removal.

- 3) On the same day as removal of a progestin-containing IUD.
 - 4) On the day when the next contraceptive injection would be due.
 - d. Following a first trimester abortion or miscarriage
 - 1) Implanon may be inserted immediately following a complete first trimester abortion.
 - 2) If Implanon is not inserted within 5 days following a first trimester abortion, follow the instructions under “No preceding hormonal contraceptive use in the past month”.
 - e. Following delivery or second trimester abortion
 - 1) Implanon may be inserted between 21 – 28 days postpartum if not exclusively breastfeeding or between 21 – 28 days following second trimester abortion.
 - 2) If more than 4 weeks have elapsed, pregnancy should be excluded and the client should use a non-hormonal method of birth control during the first 7 days after the insertion.
 - 3) If the client is exclusively breastfeeding, Implanon may be inserted after the fourth postpartum week.
 - f. If Implanon is inserted as recommended above, backup contraception is not necessary.
 - g. If the client has abstained from sexual intercourse for 2 or more weeks, pregnancy must be ruled out and a backup non-hormonal contraceptive must be used for 7 days after Implanon insertion.
 - h. If deviating from the recommended timing of insertion, pregnancy must be ruled out and a backup non-hormonal contraceptive must be used for 7 days after Implanon insertion.
5. **IMPLANON INSERTION - Implanon must be inserted only by clinicians completing the Organon training program.**
- a. A sensitive urine pregnancy test must be done on the day of insertion.
 - b. Implanon insertion and removal equipment and supplies are listed in Appendix E.
 - c. The instructions for Implanon insertion are listed in Appendix F.
 - d. After Implanon insertion, apply a pressure bandage with sterile gauze to minimize bruising. The client may remove the pressure bandage in 24 hours and the small bandage over the insertion site in 3-5 days.

- e. Complete the USER CARD and give it to the client to keep.
- f. Complete the Patient Chart Label and affix it to the client's medical record.

Follow-up

1. The client should return in 1 week for an incision check by a clinician or nurse.
2. Serious side effects of all hormonal contraceptives that may warrant immediate consultation and discontinuation of Implanon include:
 - a. Sharp chest pain, coughing up blood, or sudden shortness of breath
 - b. Pain in calf or leg
 - c. Crushing chest pain or tightness in chest
 - d. Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg
 - e. Sudden partial or complete loss of vision
 - f. Breast lumps
 - g. Severe abdominal pain or tenderness
 - h. Severe problems with sleeping, weakness, lack of energy, fatigue, or a change in mood
 - i. Jaundice
 - j. Swelling of the fingers or ankles
3. BLEEDING PATTERN CHANGES
 - a. The changes in timing and amount of vaginal bleeding are not predictable.
 - b. The bleeding is generally considered to be more bothersome than dangerous. Anemia rarely develops.
 - c. A personal calendar (bleeding diary) may be used to track a client's bleeding pattern.
 - d. Amenorrhea may result from Implanon use. A urine pregnancy test can rule out pregnancy.
 - e. Spotting and bleeding may be treated with 2 cycles of a low-dose combined oral contraceptive or any one of the NSAIDs.

4. Other side effects may occur but do not necessarily require discontinuation of Implanon:
 - a. Weight change
 - b. Breast pain
 - c. Galactorrhea
 - d. Acne
 - e. Ovarian cysts
 - f. Headache
 - g. Depression
 - h. Emotional lability

5. ARM PAIN
 - a. Rule out nerve damage or infection.
 - b. Apply ice for 24 hours.
 - c. If pain is due to bruising, make sure the bandage is not too tight.
 - d. Take acetaminophen or NSAID

6. INFECTION IN THE INSERTION AREA
 - a. No abscess, cellulitis only
 - 1) Do not remove Implanon.
 - 2) Clean the infected area with antiseptic.
 - 3) Treat with oral antibiotic for 7 days.
 - 4) Recheck in 24-48 hours and at the end of therapy.

 - b. Abscess
 - 1) Preload with antibiotics.
 - 2) Prepare the infected area with antiseptic.
 - 3) Make incision.
 - 4) Drain pus.
 - 5) Remove implant.
 - 6) Continue antibiotic and wound care.

7. IMPLANON REMOVAL – **Implanon must be removed only by clinicians completing the Organon training program.**
 - a. The indications for Implanon removal are:
 - 1) Client request
 - 2) Medical indication
 - 3) Desired pregnancy
 - 4) At the end of 3 years of use

 - b. The instructions for Implanon removal are listed in Appendix G.

 - c. After Implanon removal, close the incision with a butterfly closure and apply an adhesive bandage.

- d. Apply a pressure bandage with sterile gauze to minimize bruising.
- e. The client should return in 1 week for an incision check by a clinician or nurse.

Primary References

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APPENDIX A

POSSIBLE HEALTH BENEFITS AND/OR ADVANTAGES OF IMPLANON

1. Safe, highly effective continuous method of contraception
2. Safe for breastfeeding
3. Requires little user effort
4. High contraceptive continuation rate
5. Decreased menstrual bleeding possible
6. Decreased menstrual pain
7. Less anemia
8. Less follicular ovarian cysts
9. Decreased cyclic headaches
10. Return to fertility after removal is prompt
11. No associated changes in carbohydrate or lipid metabolism, coagulation, liver or kidney function, or immunoglobulin levels
12. No decrease in bone mineral density

APPENDIX B

POSSIBLE HEALTH RISKS AND/OR DISADVANTAGES OF IMPLANON

1. Disruption of bleeding patterns, especially during the first year of use
2. Insertion and removal of Implanon must be done by a trained healthcare professional
3. Client anxiety and apprehension on insertion and removal of Implanon
4. Discoloration or scarring of the skin over the implant
5. Pain at insertion site
6. Weight gain
7. Sore breasts
8. Headaches
9. Acne
10. Depression
11. Dizziness
12. Emotional lability
13. No STD protection
14. Cultural factors can influence the acceptability of menstrual changes

APPENDIX C

PRECAUTIONS IN PROVIDING IMPLANON

Refrain from providing Implanon for women with:

1. Known or suspected pregnancy
2. Current or past history of thrombosis or thromboembolic disorders
3. Hepatic tumors (benign or malignant), active liver disease
4. Undiagnosed abnormal genital bleeding
5. Known or suspected carcinoma of the breast or personal history of breast cancer
6. Hypersensitivity to any of the components of Implanon

Special consideration with further client evaluation may be necessary when providing Implanon for women with:

1. Heavy cigarette smoking (15 or more daily) in women older than 35 years
2. History of ectopic pregnancy
3. Diabetes Mellitus – Client should be good candidate if diabetes is well-controlled
4. Hypercholesterolemia
5. Hypertension
6. History of cardiovascular disease, including myocardial infarction, cerebral vascular accident, coronary artery disease, angina or clients with artificial heart valves
7. Gall bladder disease
8. Chronic disease, such as immunocompromised clients
9. Severe depression
10. Anemia
11. Severe acne

APPENDIX D

DRUG INTERACTIONS

Implanon is not recommended for women who require chronic use of drugs that are potent inducers of hepatic enzymes because Implanon is likely to be less effective for these women. Contraceptive effectiveness may be reduced when hormonal contraceptives are co-administered with some antibiotics, antifungals, anticonvulsants, and other drugs that increase the metabolism of contraceptive steroids. This could result in an unintended pregnancy or breakthrough bleeding. Examples include:

1. barbiturates (Phenobarbital)
2. griseofulvin
3. rifampin
4. phenylbutazone (Butazolidin®)
5. phenytoin (Dilantin®)
6. carbamazepine (Tegretol®)
7. felbamate (Felbatol®)
8. oxcarbazepine (Trileptal®)
9. topiramate (Topamax®)
10. modafinil
11. nevirapine
12. primidone (Mysoline®)

Clients should use an additional non-hormonal contraceptive method when taking medications that may decrease the efficacy of hormonal contraceptives.

Anti-HIV Protease Inhibitors – It is unknown whether the risks of the combination of anti-HIV protease inhibitors and Implanon are the same as with the use of combined oral contraceptives. Healthcare providers should refer to the labeling of the individual anti-HIV protease inhibitors for further drug-drug interaction information.

Herbal Products – Herbal products containing St. John's Wort (*Hypericum perforatum*) may induce hepatic enzymes and p-glycoprotein transporter and may reduce the effectiveness of contraceptive steroids.

Increase in Plasma Hormone Levels Associated with Co-Administered Drugs – Inhibitors of hepatic enzymes such as itraconazole or ketoconazole may increase plasma hormone levels.

APPENDIX E

EQUIPMENT AND SUPPLIES FOR IMPLANON INSERTION AND REMOVAL

For Implanon insertion and removal

- Examination table
- Sterile drapes
- Talc-free sterile gloves
- Sterile marker
- Antiseptic solution – iodine or alcohol based
- Local anesthetic – 1% Lidocaine
- Needles – 25 gauge, 1-1½ inch
- Syringe – 2 cc
- Biohazard container for disposal of insertion tool and Implanon post-removal
- Adhesive bandage, pressure bandage and/or sterile gauze squares for post-procedure dressing

For Implanon insertion

- Implanon in blister pack – for insertion
- Implanon user card – to give to the client following insertion
- Bleeding diary – to give to client if desired
- Client chart label – to be placed in client's record post-insertion

For Implanon removal

- Sterile scalpel
- Sterile forceps (straight and curved mosquito)
- Butterfly closure

APPENDIX F

INSTRUCTIONS FOR IMPLANON INSERTION

1. Confirm that the client does not have allergies to Implanon, the antiseptic, or anesthetic being used.
2. Have the client lie on her back on the examination table with her non-dominant arm flexed at the elbow and externally rotated so that her wrist is parallel to her ear or her hand is positioned next to her head.
3. Identify the insertion site, which is 6-8 cm (2½-3 inches) above the elbow crease at the inner side of the upper arm overlying the groove between the biceps and the triceps of her non-dominant arm.
4. Mark the insertion site with a sterile marker. Make 2 marks: first, mark the spot where the Implanon rod will be inserted, and second, mark a spot about 6-8 cm (2½-3 inches) proximal to the first mark. This second mark will later serve as a direction guide during Implanon insertion.
5. Clean the insertion site with an antiseptic solution.
6. Anesthetize the insertion area (for example, with anesthetic spray or by injecting 2 cc of 1% Lidocaine just under the skin along the planned insertion tunnel).
7. Carefully remove the Implanon applicator from its blister. Keep the shield on the needle and look for the Implanon rod, seen as a white cylinder inside the needle tip.
8. If you don't see the Implanon rod, tap the top of the needle shield against a firm surface to bring the implant into the needle tip.
9. Following visual conformation, lower the Implanon rod back into the needle by tapping it against the needle tip. Then remove the needle shield, while holding the applicator upright.
10. Note that Implanon can fall out of the needle. Therefore, after you remove the needle shield, keep the applicator in the upright position until the moment of insertion.
11. Keep the Implanon needle and rod sterile. If contamination occurs, use a new package of Implanon with a new sterile applicator.
12. Apply counter-traction to the skin around the proposed insertion.
13. At a slight angle (not greater than 20°), insert only the tip of the needle with the beveled side up into the insertion site.
14. Lower the applicator to a horizontal position. Lift the skin up with the tip of the needle, but keep the needle in the subdermal connective tissue.

15. While “tenting” (lifting) the skin, gently insert the needle to its full length. Keep the needle parallel to the surface of the skin during insertion.
16. If Implanon is placed too deeply, the removal process can be difficult or impossible. If the needle is not inserted to its full length, the Implanon may protrude from the insertion site and fall out.
17. Break the seal of the applicator by pressing the obturator support.
18. Turn the obturator 90° in either direction with respect to the needle.
19. While holding the obturator fixed in place on the arm, fully retract the cannula. Note: This procedure is opposite from an injection. Do not push the obturator. By holding the obturator fixed in place on the arm and fully retracting the cannula, Implanon will be left in its subdermal position. Do not simultaneously retract the obturator and cannula from the client’s arm.
20. Confirm that Implanon has been inserted by checking the tip of the needle for the absence of Implanon. After Implanon insertion, the grooved tip of the obturator will be visible inside the needle.
21. Always verify the presence of Implanon in the client’s arm immediately after insertion by palpation. By palpating both ends of the implant, you should be able to confirm the presence of the 4 cm rod.
22. Place a small adhesive bandage over the insertion site. Request that the client palpate Implanon.
23. If you cannot feel Implanon as 4 cm long rod, confirm its presence using other methods. Suitable methods to locate Implanon are: ultrasound (US) with a high-frequency linear array transducer (10MHz or greater) or magnetic resonance imaging (MRI). Please note that the Implanon rod is not radio-opaque and cannot be seen by X-ray or CT scan. If ultrasound and MRI fail, call 1-877-IMPLANON (1-877-467-5266) for information on the procedure for measuring ENG blood levels. Until you confirm proper Implanon insertion, your client must use a non-hormonal contraceptive method.
24. Apply a pressure bandage with sterile gauze to minimize bruising. The client may remove the pressure bandage in 24 hours and the small bandage over the insertion site in 3-5 days.
25. Complete the USER CARD and give it to the client to keep. Also, complete the Patient Chart Label and affix it to the client’s medical record.
26. The applicator is for single use only. Dispose of the applicator in accordance with the Center for Disease Control and Prevention guidelines for handling of hazardous waste.

APPENDIX G

INSTRUCTIONS FOR IMPLANON REMOVAL

Before initiating the removal procedure, the healthcare provider may consult the USER CARD that is kept by the client and/or the Patient Chart Label. The arm in which Implanon is located should be indicated on the USER CARD and the Patient Chart Label. Implanon should have been inserted in the medial aspect of the upper non-dominant arm. Prior to removing Implanon, carefully read the instruction for removal. Find Implanon by palpation. If Implanon cannot be palpated, use either ultrasound with a high-frequency linear array transducer (10 MHz or greater) or magnetic resonance imaging to localize the implant. Consider conducting difficult removals with ultrasound guidance. Only remove a non-palpable implant once the location of Implanon has been established. If these imaging methods fail, call 1-877-IMPLANON (1-877-467-5266) for further information.

1. Implanon must only be removed by a healthcare provider who has been instructed and trained in the Implanon removal technique.
2. The arm in which Implanon is located should be indicated on the USER CARD and the Patient Chart Label. Implanon should be in the medial aspect of the upper non-dominant arm.
3. After confirming that the client does not have any allergies to the antiseptic, wash the client's arm and apply an antiseptic. Locate Implanon by palpation and mark the end closest to the elbow, for example, with a sterile marker.
4. After determining the absence of allergies to the anesthetic agent or related drugs, anesthetize the arm, for example, with 0.5-1 cc 1% Lidocaine at the site where the incision will be made (near the tip of the Implanon that is closest to the elbow). Be sure to inject the local anesthetic under Implanon to keep the implant close to the skin surface.
5. Make a 2-3 mm incision in the longitudinal direction of the arm at the tip of the implant closest to the elbow.
6. Gently push the Implanon toward the incision until the tip is visible. Grasp the implant with forceps (preferably curved mosquito forceps) and pull it out gently.
7. If Implanon is encapsulated, make an incision into the tissue sheath and then remove Implanon with the forceps.
8. If the tip of the implant is still not visible after gently pushing it towards the incision, gently insert a forceps into the incision and grasp the implant. Turn the forceps around.
9. With a second forceps carefully dissect the tissue around Implanon and then remove Implanon. Be sure to remove the Implanon rod entirely. Confirm that the entire rod, which is 4 cm long, has been removed by measuring its length. If the client would like to continue using Implanon, insert a new Implanon rod immediately after the old Implanon rod is removed. The new Implanon can be inserted in the same arm, and

through the same incision, or a new Implanon can be inserted in the other arm. If the client does not wish to continue using Implanon and does not want to become pregnant, recommend another contraceptive method.

10. After removing Implanon, close the incision with a butterfly closure and apply an adhesive bandage.
11. Apply a pressure bandage with sterile gauze to minimize bruising.

INFERTILITY

Rationale

Infertility is defined as a couple's inability to conceive after one year of regular, unprotected sexual intercourse. Approximately 15% of American couples of reproductive age are unable to conceive within a year.

Infertility is perceived as a life crisis by many couples. They experience a range of emotions and require a significant amount of social and emotional support.

During the infertility investigation, one must consider both partners because there may be multiple contributory factors. Evaluations of the male and female should begin concurrently in order to emphasize the responsibility shared by both parties. The infertility evaluation requires investigating a number of factors important to reproduction. Among couples with identifiable causes of infertility, 40% are male factors, 40% female factors, and 20% both male and female factors. Approximately 20% of couples will have no identifiable cause of infertility.

The workup requires multiple diagnostics tests and may last for 12 to 18 months. The complexity of an infertility workup requires an infertility specialist with the capacity to perform appropriate surgical procedures.

Plan of Action

1. Obtain a complete medical, obstetrical, menstrual, contraceptive, and sexual history.
2. Do a complete physical and pelvic examination and counsel the client regarding any problems identified in the history or physical findings.
3. Counsel the client on maximizing conception chances through an understanding of the menstrual cycle and timing of intercourse.
4. Review Preconception Counseling guidelines in this manual with the client and be sure the client is taking a daily multivitamin containing 0.4 mg of folic acid.
5. Refer the client to a physician with training and experience in infertility.
6. Refer the client to appropriate support organizations.

Primary References

ACOG. *Precis: Reproductive Endocrinology*. 3rd Ed., 2007

Hatcher RA et al. *Contraceptive Technology*. 19th Revised Edition. Ardent Media, Inc., New York, 2007

The National Fertility Association website at <http://www.resolve.org>

INTRAUTERINE CONTRACEPTION - PARAGARD® IUD

Rationale

The two options for intrauterine contraception (IUC) are the ParaGard® T 380A copper Intrauterine Device (IUD) and the Mirena® levonorgestrel Intrauterine System (LNG-IUS or IUS), discussed in another guideline.

ParaGard IUD is a T-shaped intrauterine contraceptive made of radiopaque polyethylene, with 2 flexible arms that bend down for insertion but open in the uterus to hold the solid sleeves of copper against the fundus. Fine copper wire is wrapped around the stem of the IUD. The surface area of copper = 380 mm². This IUD has 2 monofilament strings attached that protrude into the vagina.

The primary mechanism of action is 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 IUDs do not routinely work after fertilization. IUDs are not abortifacients. IUDs primarily prevent pregnancy by killing sperm. The IUD's approved duration of use is 10 years; however, studies indicate effectiveness up to 12 years.

Perfect use failure rate in the first year: 0.6%

Typical use failure rate in the first year: 0.8%

Cumulative 10-year failure rate: 2.1-2.8%

Benefits include a high level of reliability, lack of systemic metabolic effects, high client satisfaction, absence of compliance problems, and rapid return to fertility.

The IUD is now approved for nulliparous women in stable relationships from age 16 through menopause. The IUD is no longer contraindicated for women with a history of STDs or PID unless the woman currently has acute PID or engages in sexual behavior suggesting a high risk for PID. Mutual monogamy no longer is a user requirement, although a stable relationship is encouraged. ParaGard is now indicated for women in all stages of reproductive life whether young and nulliparous, between pregnancies, or finished with childbearing. There is no protection against any STDs including HIV/AIDS.

Disadvantages are the increased menstrual blood loss, increased dysmenorrhea, increased risk of pelvic infection in the first 20 days after insertion, possibility of uterine or cervical perforation, and pregnancy-related complications.

Plan of Action

1. Screen the client for any known precautions and risk factors prior to IUD consideration (Appendix A).
2. Clients who desire an IUD should be thoroughly counseled regarding the advantages and disadvantages as well as risks and benefits of this method. In general, clients

are good candidates for the IUD if they are low risk for sexually transmitted infections and desire contraception for at least 2 years.

3. The client must read and appear to understand the ParaGard “Information for Patients” pamphlet packaged with each IUD before consenting to IUD insertion.
4. The clinician must review the Consent for Intrauterine Contraception – ParaGard with the client and a signature must be obtained where indicated.
5. All potential minor and major complications should be discussed with the client (Appendix B).
6. Certain precautions must be followed during IUD insertion (Appendix C).
7. During the first month after insertion, the client should use a barrier method of contraception along with the IUD.
8. Advise the client to check for the string on a monthly basis.
9. Ideally the IUD should be inserted during the menses to help ensure that the client is not pregnant.
10. The IUD may be inserted anytime during the menstrual cycle if a woman has been consistently and reliably using another method of contraception or if in the clinician’s evaluation and judgment, pregnancy has been ruled out.
11. In a postpartum woman wait for at least 4-6 weeks for uterine involution before doing IUD insertion.

Follow-up

1. Do a speculum and bimanual pelvic examination after the first post-insertion menstrual period.
2. All clients must have a periodic pelvic exam, Pap test, and gonorrhea and chlamydia testing as per guidelines.
3. Ideally the IUD should be removed during menstruation; however, the IUD may be removed at any time electively or as indicated.
4. Remove the IUD because of symptoms such as abnormal bleeding, pelvic pain, pregnancy, infection, or required replacement (Appendix B).
5. The ParaGard IUD should be kept in place no longer than 10 years.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Zieman M, Hatcher RA et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2007

ACOG. Intrauterine Device. Practice Bulletin #59, January 2005

ACOG. Benefits and Risks of Sterilization. Practice Bulletin #46, September 2003

ACOG. Precip: Primary and Preventive Care. 3rd Ed., 2004

ParaGard Prescribing Information. November 2004

APPENDIX A

PRECAUTIONS AND RISK FACTORS FOR INTRAUTERINE CONTRACEPTION

The following criteria should be considered prior to making the decision to insert intrauterine contraception:

- Confirmed or suspected pregnancy
- Known or suspected cervical or uterine malignancy
- Acute cervicitis, especially purulent (current or within the past 3 months)
- Pelvic inflammatory disease (current or within the past 3 months)
- Postpartum endometritis (current or within the past 3 months)
- Postabortion endometritis (current or within the past 3 months)
- Sexually transmitted infection (current or within the past 3 months)
- Multiple sexual partners
- Undiagnosed abnormal vaginal bleeding
- Severe anemia
- Hypermenorrhea
- Severe dysmenorrhea
- Allergy or hypersensitivity to copper or history of Wilson's Disease
- Allergy or hypersensitivity to iodine
- Abnormalities of the uterus which may result in severe distortion of the uterine cavity
- History of Cesarean delivery(s)
- History of cervix treatment (cone, cryo, LEEP)
- Uterine fibroids that may interfere with IUC placement
- Current thromboembolic disease or history thereof
- Known or suspected breast cancer or history thereof
- Cerebrovascular or coronary disease or history thereof
- Hepatic disease (tumors, hepatitis, cirrhosis)

APPENDIX B

COMPLICATIONS OF IUD

1. Vasovagal reaction or fainting with insertion – This problem may be anticipated by prior history of vasovagal reaction.
2. Uterine Perforation – Perforation is a known risk factor with IUD insertion. Any device that has perforated the uterine wall or cervix must be promptly removed. Refer the client for appropriate care immediately.
3. Bleeding - The IUD may increase menstrual blood loss, cramping, intermenstrual spotting, and vaginal discharge. Excessive bleeding may be treated with non-steroidal anti-inflammatory drugs.
4. Expulsion – Between 2 to 10% of IUD users spontaneously expel their IUD within the first year. A woman who has expelled one IUD has a 30% chance of subsequent expulsion.
5. Pelvic Infection – Pelvic inflammatory disease is potentially the most serious complication associated with the use of IUDs. Most cases occur in the first 20 days after insertion. Minor infections of the vulva or vagina can be treated with the IUD in place. If symptoms of a more severe pelvic infection develop, appropriate studies and treatment should be instituted, and consideration given to possible IUD removal.
6. Actinomyces – An asymptomatic IUD user who has “Actinomyces-like organisms” reported on a Pap test should be informed about this finding, which represents colonization, not infection. If she is asymptomatic, nothing more need be done. If she develops evidence of infection, the device should be removed and appropriate studies and treatment instituted.
7. Missing IUD Strings
 - a. If the IUD tail string cannot be felt by the client or seen by the clinician, it is necessary to rule out pregnancy, expulsion, or perforation.
 - b. When pregnancy is ruled out, consider one of the following methods:
 - 1) Probing of the endocervical canal with an alligator forcep, a uterine sound, cytobrush, or a cotton swab
 - 2) Pelvic ultrasonography
 - 3) Refer for hysteroscopic or colposcopic visualization
8. IUD in Pregnancy – If pregnancy results while using the IUD, the client should be advised to have the IUD promptly removed because of the increased risks of spontaneous abortion and septic abortion possibly resulting in death.
 - a. If the client desires to continue the pregnancy and the IUD tail string is accessible, refer the client to a maternity facility for removal of the IUD and appropriate follow-up. Advise the client that removal of the IUD may lead to a spontaneous abortion.

- b. If the IUD string is not accessible and the client decides to continue the pregnancy, refer the client to a hospital maternity facility. There appears to be no increased risk of congenital abnormalities, but close monitoring during the entire pregnancy is indicated for infection and/or preterm labor.
9. IUD Removal Difficulty – If the IUD cannot be delivered by the usual traction on the strings, physician consultation should be obtained.
10. IUD removal should be considered if there is an increase in the length of the strings extending from the cervix or any other indication of partial expulsion.

APPENDIX C

TECHNIQUE OF IUD INSERTION

1. Prophylactic antibiotics are not required before IUD insertion. Because many of these clients do not get pre-insertion chlamydia or gonorrhea testing, these clients may be treated at the discretion of the clinician.
2. Clients at high risk for bacterial endocarditis should have medication prescribed by their treating cardiac physicians.
3. Perform a bimanual exam to define the position of the uterus and to exclude uterine or adnexal enlargement.
4. Insert a speculum into the vagina and inspect the cervix and vagina.
5. Cleanse the cervix with an appropriate antiseptic solution. All instruments used in this procedure must be sterile.
6. Grasp the cervix with a tenaculum; apply traction to correct the uterine angle and to stabilize the cervix.
7. Sound the cervical canal and the uterine cavity. If the length of the uterine cavity is less than 6 cm or greater than 9 cm, an IUD should probably not be inserted.
8. Follow the package instructions for insertion. The IUD should be placed high in the fundal portion of the uterus.
9. After withdrawal of the inserter, the IUD tail string is cut approximately 3 to 5 cm from the external os. The length of the string should be recorded on the client's chart.
10. Instruct the client to check for the string of the IUD after each menstrual period.
11. Give the client the name of the device and its recommended length of use.
12. Advise the client to return for examination after the first post-insertion menstrual period; and at any time for symptoms of pregnancy or for symptoms of infection such as fever, pain, unusual bleeding or heavy vaginal discharge.

LACTATIONAL AMENORRHEA METHOD (LAM)

Rationale

Lactational Amenorrhea Method (LAM) of contraception is dependent on the natural contraceptive effects of breastfeeding.

Breastfeeding causes a surge in maternal prolactin, which inhibits estrogen production and ovulation. Milk expression, by hand or pump, is not a substitute for breastfeeding in terms of its fertility inhibiting effect.

Perfect use failure in the first 6 months: 0.5%

Typical use failure in the first 6 months: 2%

There are 3 criteria for LAM to be effective:

- (1) used only for the first 6 months postpartum
- (2) fully or nearly fully breastfeeding
- (3) amenorrhea since delivery

There is no protection against STIs or HIV. Breastfeeding is not recommended for HIV+ mothers.

Plan of Action

1. Breastfeeding must start immediately or as soon as possible after delivery, with intervals not exceeding 4 hours during the day or 6 hours at night.
2. Supplementation feeding must be minimal (<10% of baby's feedings).
3. Encourage the client to consider an alternate method of contraception as back-up if the client has issues with her ability to meet the breastfeeding requirement of LAM.
4. Advanced placement emergency contraceptive pills should be offered to be used if any of the three LAM criteria cannot be met.
5. Discuss with the client her contraceptive options to be considered after 6 months postpartum.

Follow-up

1. The client must notify a family planning health care provider if breastfeeding is stopped or significantly decreased and/or if a menstrual period occurs within the first 6 months.
2. The client must make a family planning appointment prior to 6 months postpartum to discuss contraceptive options.
3. Provide additional emergency contraception as indicated.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Zieman M, Hatcher RA et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2007

Medical Eligibility Criteria For Contraceptive Use. 3rd Ed., Reproductive Health and Research, World Health Organization, Geneva, Switzerland, 2004

LYMPHOGRANULOMA VENEREUM

Rationale

Lymphogranuloma venereum (LGV) is a sexually transmitted disease caused by one of three serotypes of *Chlamydia trachomatis*. It is a sporadic disease in North America but endemic in Asia and Africa. Although LGV is rare, cases have been reported in men who have sex with men. This infection is often asymptomatic in women.

LGV is primarily a disease of pelvic lymphatic tissue. Clinical manifestations of the disease may be in one of three stages. There may be a primary lesion manifesting itself as a papule, a shallow ulcer or erosion, a small herpetiform lesion (the most common form) or non-specific urethritis. The secondary stage is characterized by acute lymphadenitis with bubo formation (the inguinal syndrome) and/or acute proctitis (the anogenitoretal syndrome). The third is a chronic inflammatory response in the anogenital tissue and the development of genital ulcers, fistulas, rectal strictures and genital elephantiasis.

Plan of Action

1. Diagnosis is made by:
 - a. Exclusion of other causes of inguinal lymphadenopathy or genital ulcers.
 - b. An ELISA IgG antibody test that measures the chlamydia IgG antibody. A negative test is less than 0.9 ISR. A positive test is greater than 1.10 ISR. The positive range is 1.10-2.79. A positive test may be caused by other chlamydia infections. This test can remain positive for years after treatment. This test is the primary LGV test used by the State laboratory (use a miscellaneous lab slip). For more details, call 410-767-6167.
 - c. A complement-fixation test (CF) test. The CF test may result in cross-reactions in infections caused by other chlamydia infections, and the antibody may persist in high or low titers for many years. In general, active LGV infections have CF titers of 1:64 or greater, but high CF titers occasionally are found in asymptomatic individuals and those with other chlamydia infections. Titers below 1:64 in an individual suspected of LGV on clinical grounds should be interpreted with caution. Although a rise in CF titer of two dilutions or more may occur in early LGV, most individuals with documented LGV initially have high CF titers that show little difference between serum specimens obtained during acute infection and at 6 weeks into convalescence.
 - d. A positive chlamydia culture from aspiration of fluctuant nodes.
2. Cervical chlamydia testing must be done.
3. Treatment in the primary and secondary stages cures infection and prevents ongoing tissue damage, although tissue reaction can result in scarring.

4. Fluctuant buboes may require needle aspiration to prevent rupture.
5. Open lesions may require cultures because of co-infection with other organisms.
6. Recommended treatment:

Doxycycline 100 mg orally twice a day for 21 days
(contraindicated during pregnancy and during lactation)
7. Alternate treatment:

Erythromycin base 500 mg orally four times a day for 21 days
8. Clients should avoid sexual activity until the disease is resolved. Condom use should be encouraged.
9. Sexual contacts within 60 days before the onset of the client's symptoms should be referred for examination, tested for urethral or cervical chlamydia infection and treated with a standard chlamydia regimen.
10. Clients with fluctuant or ruptured buboes, or in the third clinical stage should be referred for physician consultation.

Follow-up

Clients should be followed clinically until signs and symptoms are resolved.

Primary References

CDC. Sexually Transmitted Diseases Treatment Guidelines. 2006

Red Book: 2006 Report of the Committee on Infectious Diseases. 27th Ed., American Academy of Pediatrics, Elk Grove Village, IL

Wampole Laboratories Chlamydia IgG ELISA Test Instructions

MOLLUSCUM CONTAGIOSUM

Rationale

Molluscum contagiosum is a benign, usually asymptomatic viral disease of the skin. This virus is transmitted by sexual and non-sexual routes. The incubation period varies from 2 to 7 weeks but may extend to 6 months. Lesions are usually flesh-colored, dome-shaped papules with central umbilication and are commonly found on the lower abdomen, thighs, buttocks, inguinal, genital and perianal areas.

Plan of Action

1. Diagnosis is usually made on the basis of the characteristic, pearly, umbilicated papule.
2. The infection is self-limiting and the average duration of untreated molluscum is 2 years. Individual lesions are transient and usually resolve within 2 months.
3. Advise that spread can be reduced by restricting direct body contact and sharing of potentially contaminated fomites (e.g., towels and wash cloths).
4. Treatment options to prevent autoinoculation and spread to others:
 - a. Although lesions can regress spontaneously, treatment may prevent autoinoculation and spread to other people.
 - b. Topical application with podophyllin, silver nitrate, or trichloroacetic acid to each lesion.

NOTE: The safety of podophyllin during pregnancy has not been established.

OR

- c. Curettage or expression of the core of the lesion by direct pressure, which may be followed by cauterization with a chemical agent such as silver nitrate or trichloroacetic acid.

OR

- d. Cryotherapy

Follow-up

1. Topical applications may require more than one treatment at 1 to 2 week intervals.
2. Sex partner(s) should be examined.

Primary References

Red Book: 2006 Report on the Committee on Infectious Diseases. 27th Ed., American Academy of Pediatrics, Elk Grove Village, IL

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

NORPLANT®

Rationale

Norplant® is no longer available on the U.S. market. However, because the implants are effective for 5 years of use, some women still have the implants in place and continue to rely on them for contraceptive protection.

Norplant's main mode of action is to produce an endometrium that is not receptive to ovum implantation, and cervical mucus that is thick and hostile to sperm. Norplant may or may not inhibit ovulation via suppression of the gonadotropin surge.

6 silicone rubber capsules are surgically placed subdermally in the client's upper arm. Each capsule contains 36 mg of dry crystalline levonorgestrel for a total of 216 mg in the 6 capsules. This progestin diffuses through the wall of the capsule into the surrounding tissues where it is absorbed by the circulatory system. This occurs on a continuous basis over a 5-year period.

Perfect use failure rate in the first year: 0.05%

Typical use failure rate in the first year: 0.05%

Cumulative 7-year failure rate: 1.9%

There are a number of benefits to using Norplant. It is a safe, highly effective continuous method of contraception that requires little user compliance. Effectiveness begins 24 hours after insertion; and pre-Norplant fertility is restored 24 hours after removal. Norplant can be utilized by women who have contraindications for the use of estrogen-containing contraceptives. The sustained release of low doses of progestin avoids the high initial dose delivered by injectables and the daily hormone surge associated with oral contraceptives. Norplant is an excellent choice for a breastfeeding woman and can be inserted postpartum (Appendix A).

Norplant disadvantages include a number of possible side effects (i.e., irregular bleeding, depression, weight gain, acne, amenorrhea, and headaches). This method does not protect the client against sexually transmitted diseases.

Plan of Action

1. Norplant Management

a. Working guidelines for handling incisions complications include:

- 1) Client should be seen as soon as possible in clinic.
- 2) If infection (not an abscess) is diagnosed, then:
 - a) Give p.o. a broad spectrum antibiotic such as Augmentin®, Keflex®, or Erythromycin.
 - b) Instruct the client to apply moist warm compresses 4 times per day.
 - c) RTC in 1 week or PRN.
 - d) If no improvement in 1 week, remove Norplant.
- 3) If abscess is diagnosed, refer for physician management.

b. Irregular menstrual bleeding

- 1) If bleeding is prolonged, heavy or causes the client to be symptomatic (e.g., light headedness), then the client should return to the clinic.
- 2) For all clients the following should be considered:
 - a) Pregnancy test.
 - b) Hemoglobin/hematocrit.
 - c) Pelvic examination (speculum and bimanual).
- 3) If work-up is negative, reassure the client and offer one of the following:
 - a) Ibuprofen 800 mg tid x 5 days.
 - b) 1 or 2 cycles of a low-dose combined oral contraceptive.
 - c) Exogenous estrogen, such as conjugated estrogen (Premarin®) 0.625 mg or 1.25 mg qd x 7 to 25 days.
- 4) If above measures fail, then schedule Norplant removal or physician consultation.

c. Amenorrhea

- 1) If amenorrhea lasts for 8 weeks or more, especially after a pattern of regular menses, the client should return to the clinic.
- 2) A pregnancy test and pelvic examination should be done to rule out pregnancy.
- 3) If negative, reassure the client and advise her to return if amenorrhea remains a concern.
- 4) Do not induce bleeding.

d. Headache/blurred vision

- 1) Determine the pre-insertion versus post-insertion characteristics and frequency.
- 2) After appropriate evaluation, consider referral to family physician, optometrist, ophthalmologist, or neurologist.
- 3) Consider trial of non-steroidal anti-inflammatory agents and reevaluate in one month.
- 4) If headaches are severe, recurrent, or blood pressure is elevated since starting Norplant, remove Norplant.

e. Implant expulsion

If capsule has been expelled, then schedule for the removal of remaining Norplant capsules.

2. Norplant Removal

- a. Norplant should be removed after 5 years.
- b. Removal should be done after a client's request for any reason.
- c. Removal should be done for complications which have not responded to conservative management.

- d. Post-removal wound care and complications are the same as those following insertion (Appendix B).
- e. Plan a post-removal visit for 1 to 2 weeks after removal.
- f. When appropriate, alternate contraception should be coordinated with Norplant removal.

Primary References

Hatcher RA et al. Contraceptive Technology. 18th Revised Edition. Ardent Media, Inc., New York, 2004

Hatcher RA, Ziemann M et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2004

ACOG. Precip: Primary and Preventive Care. 3rd Ed., 2004

Norplant Management Guidelines. 1992

APPENDIX A

INFORMATION FOR CLIENTS WITH NORPLANT IN PLACE

Benefits:

1. Norplant is the most effective reversible method of birth control, except for abstinence.
2. Norplant is a very low-dose contraceptive with low progestin and no estrogen.
3. It is easily reversible. After removal most women can get pregnant right away.
4. It lasts 5 years or until removed.
5. It is convenient to use.

Risks:

1. Four out of five women experience some menstrual irregularity, spotting, breakthrough bleeding, or missed periods.
2. Both insertion and removal require a minor surgical procedure.
3. Removal may be difficult and occasionally requires 2 visits.
4. In rare cases, infection may develop at site of insertion.
5. Norplant provides no protection against HIV or other sexually transmitted infections. Condoms should be used if there is risk for sexually transmitted infections.

Explanation of the procedures:

1. Six (6) matchstick sized capsules are placed in the skin of the upper arm, about four fingerbreadths above the bend of the elbow.
2. Clients should continue to come to the clinic for the periodic examination and Pap test.
3. Norplant should be removed in 5 years.

APPENDIX B

PROCEDURE FOR NORPLANT REMOVAL

1. Have the client read and sign the informed consent.
2. Position the client on table with her arm flexed and externally rotated as for the insertion.
3. Identify position of all 6 capsules; the skin may be marked with a marking pencil.
4. Prep the skin with Hibiclens and Betadine.
5. Put on sterile gloves and position sterile drapes.
6. Draw up 6.5 cc 1% Lidocaine.
7. Anesthetize the site of incision and under the implant tips.
8. Remove the capsules.
9. Apply pressure to incision (1-2 minutes).
10. Apply steri strips over incision.
11. Cleanse area with alcohol and apply pressure bandage.
12. Show all 6 capsules to the client.
13. Advise the client to avoid heavy lifting and keep the dressing dry for 3 days. After 24 hours, the bandage may be removed and a band-aid should be applied over the steri strips. Signs of bruising may be seen for 3-10 days, and during this time acetaminophen or ibuprofen may be used prn for discomfort.
14. The client should return in 1-2 weeks for arm check.
15. If any capsule cannot be removed, a second attempt at removal should be done in 4-6 weeks.
16. Any "lost" implant may be located with a high frequency (7-10) megahertz, short focus ultrasound.

NUVARING® - VAGINAL CONTRACEPTIVE RING

Rationale

Oral contraceptive pills are very popular and effective, but poor compliance results in a significant rate of pregnancy. The vaginal contraceptive ring was developed to provide a similar reversible contraceptive with a more convenient dosing schedule that would enhance patient compliance and achieve high contraceptive efficacy.

The primary mechanism of action is inhibition of ovulation. In addition, the vaginal contraceptive ring produces an endometrium which is not receptive to ovum implantation, and cervical mucus which becomes thick and hostile to sperm transport. Tubal and endometrial motility are slowed.

Perfect use failure rate in the first year of use: 0.3%
Typical use failure rate in the first year of use: 8%

NuvaRing® is a soft, flexible, transparent ring measuring 54 mm diameter and cross-sectional diameter of 4 mm. It is made of ethylene vinyl acetate copolymers and releases 15 mcg ethinyl estradiol and 120 mcg etonogestrel per day in a steady low rate while in place and releases less estrogen daily than contraceptive pills or patches. In the unlikely event of damage to the ring, leakage or higher release of hormones does not occur, because the progestin and estrogen are mixed in the ethylene vinyl acetate core.

The vaginal contraceptive ring is inserted by the client and worn for 3 weeks out of every 4 weeks. Routine use of the vaginal contraceptive ring requires the insertion of a new ring every 4 weeks to allow for withdrawal bleeding. Extended regimen use of the ring is optional (off-label use).

Removal of the ring for sexual intercourse is not recommended, but efficacy is maintained if the ring is replaced within 3 hours.

Tampon use is acceptable.

Oil-based vaginal medications do not affect the effectiveness of the ring. Water-based spermicides such as nonoxynol-9 do not affect the hormone levels of the ring.

Evidence among healthy women suggests the vaginal contraceptive ring does not alter vaginal flora or cervical cytology. Limited evidence on women with low-grade squamous intraepithelial lesions found use of the ring did not worsen the condition. The vaginal contraceptive ring may not be suitable for clients with conditions that make the vagina more susceptible to infection or ulceration. The ring may not be suitable for women with significant pelvic relaxation, who are unable or unwilling to touch their genitalia, or who have vaginal obstruction.

Plan of Action

1. The client should be counseled regarding the benefits, disadvantages, and risks associated with vaginal contraceptive ring use and be given an information pamphlet containing method use and warning signs (Appendix A and B). In essence, the client who is eligible for oral contraception is a candidate for the vaginal contraceptive ring.
2. Consider the precautions prior to prescribing the vaginal contraceptive ring (Appendix C). Refrain from providing the vaginal contraceptive ring to those with major risk factors and use caution in prescribing for those with relative risk factors.
 - a. In healthy clients over age 35 or those with a family history of premature death from cardiovascular disease, it is desirable to obtain a fasting lipid profile and fasting blood sugar prior to prescribing the vaginal contraceptive ring. If that is not feasible, those tests can be obtained at the time the next ring supply is given.
 - b. Be cautious in prescribing the vaginal contraceptive ring for clients with oligomenorrhea or amenorrhea. They may be infertile. Unless such a client's diagnosis is already known, she should be advised that an endocrine evaluation might be appropriate.
 - c. Clients with first-degree relatives (parent, sibling, or child) who have diabetes mellitus should have a fasting blood sugar ordered around the time of the initial visit and every 2-3 years.
 - d. Postpartum clients with a history of gestational diabetes should have a fasting blood sugar ordered around the time of the initial visit and every 2-3 years.
 - e. The vaginal contraceptive ring may interfere with lactation. Once lactation is well established, progestin-only contraceptives are preferable for those clients requesting to use a hormone contraceptive while breastfeeding. For non-breastfeeding clients the vaginal contraceptive ring may be initiated at 4 weeks postpartum or with the first menstrual period.
 - f. Contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D)
3. **NUVARING CANDIDATE**
 - a. Any client who meets criteria for any of the estrogen/progestin contraceptives.
 - b. Any client who cannot remember to take the pill, deal with the patch, does not like shots or does not use local contraception at the time of intercourse.
4. **NUVARING SCHEDULE**
 - a. Standard
 - 1) Each ring is to remain in the vagina for 3 weeks.

- 2) A new ring must be inserted 1 week after the prior ring was removed in order to have pregnancy protection.
- b. Extended Regimen (Off-Label Use)
- 1) The continuous use of the contraceptive ring is effective for contraception.
 - 2) The ring must be changed every 3 weeks; a new ring is immediately inserted after the old ring is removed.
 - 3) Any ring-free interval cannot exceed 7 days.
 - 4) Clients must be counseled that the more periods they skip, the more spotting they will have.
 - 5) Extended regimen requires dispensing an extra ring for every 3 months of use.

5. METHOD INITIATION

- a. If no hormonal contraceptive use in the past month,
- 1) A new ring may be inserted any time during the first 5 days of a normal menstrual cycle.
 - 2) A back-up method of contraception is recommended for 7 days.
- b. If switching from a combination oral contraceptive,
- 1) A new ring may be inserted any time within 7 days after the last combined oral contraceptive tablet and no later than the day a new cycle of pills would have been started.
 - 2) No back-up contraception is needed.
- c. If switching from a progestin-only oral contraceptive,
- 1) A new ring may be inserted any day of the month, but not skipping any days between the last pill and the first day of ring use.
 - 2) A back-up method of contraception is recommended for 7 days.
- d. If switching from a progestin-only contraceptive injection,
- 1) A new ring may be inserted on the same day when the next contraceptive injection is due.
 - 2) A back-up method of contraception is recommended for 7 days.
- e. If switching from a progestin-only contraceptive implant,

- 1) A new ring may be inserted on the same day as the implant removal.
 - 2) A back-up method of contraception is recommended for 7 days.
- f. If switching from a progestin-containing IUD,
- 1) A new ring may be inserted on the same day as the IUD removal.
 - 2) A back-up method of contraception is recommended for 7 days.
- g. Following a complete first trimester abortion or miscarriage,
- 1) A new ring may be inserted within 5 days and no back-up contraception is needed.
 - 2) If not inserted within 5 days, a new ring should be inserted during the first 5 days of the next menstrual period. A back-up method of contraception is recommended for the first 7 days of ring use.
- h. Following a second trimester abortion,
- 1) A new ring may be inserted 4 weeks after the second trimester abortion.
 - 2) A back-up method of contraception is recommended for 7 days.
- i. Following a delivery,
- 1) Women who breastfeed should not use NuvaRing.
 - 2) Women who do not breastfeed must wait 4 weeks postpartum before initiating NuvaRing. A back-up method of contraception is recommended for 7 days.

6. METHOD INITIATION (OFF-LABEL USE)

- a. Any time during the cycle,
- 1) The clinician must be reasonably certain the client is not pregnant.
 - 2) The client may be a candidate for emergency contraception if vaginal intercourse has occurred within the past 5 days.
 - 3) A back-up method of contraception is recommended for 7 days.

7. NUVARING INSERTION

- a. The client washes and dries her hands.
- b. The ring is removed from its reclosable foil pouch. The pouch is kept for proper disposal of the ring after use.

- c. Client position for ring placement are lying down, squatting, or standing with one leg up.
- d. The ring is held between the thumb and index finger and the opposite sides of the ring are pressed together.
- e. The folded ring is gently placed into the vagina. The exact position of the ring is not important for it to work.
 - 1) Most women do not feel the ring in place.
 - 2) If the ring is causing discomfort, it should be gently pushed farther into the vagina.
- f. The ring is to remain in place for 3 weeks in a row.

8. NUVARING REMOVAL

- a. The ring should be removed 3 weeks after the insertion on the same day of the week as it was inserted.
- b. The ring is removed by hooking in index finger under the forward rim or by holding the rim between the index finger and middle finger and pulling it out.
- c. Put the used ring in the foil pouch and properly dispose of it in a waste receptacle out of the reach of children and pets. Do not discard it in the toilet.
- d. The menstrual period will start in 2-3 days and may not be finished before the next ring is inserted.

9. PROLONGED USE

- a. If the ring has been left in the vagina for an extra week or less (4 weeks or less),
 - 1) Remove the ring and insert a new ring after a 1-week ring-free break.
 - 2) No back-up contraception is needed.
- b. If the ring has been left in the vagina for 4 or more weeks,
 - 1) Remove the ring and insert a new ring.
 - 2) Pregnancy should be ruled out.
 - 3) A back-up method of contraception must be used until a new ring has been in place for 7 days.

10. PROLONGED RING-FREE INTERVAL

- a. If the ring-free interval has extended beyond 1 week,

- 1) The possibility of pregnancy should be considered.
- 2) A new ring may be inserted immediately.
- 3) A back-up method of contraception must be used until a new ring has been in place for 7 days.

11. INADVERTENT RING REMOVAL OR EXPULSION

- a. If the ring has slipped out or been removed from the vagina for less than 3 hours,
 - 1) The client is still protected from pregnancy.
 - 2) The ring can be rinsed with cool to lukewarm (not hot) water and re-inserted as soon as possible, and at the latest within 3 hours.
 - 3) No back-up method of contraception is needed.
- b. If the ring has been out of the vagina for more than 3 hours,
 - 1) The client may not be adequately protected from pregnancy.
 - 2) The ring can be rinsed with cool to lukewarm (not hot) water and re-inserted as soon as possible.
 - 3) A back-up method of contraception must be used until the ring has been place for 7 days in a row.

12. NUVARING STORAGE

- a. Prior to dispensing to the client, NuvaRing should be refrigerated at 36-46°F.
- b. The client should store NuvaRing at room temperature, range 59-86°F for up to 4 months. Avoid direct sunlight or storing above 86°F.
- c. A client may refrigerate the ring if so desired, but it is not recommended unless the client's refrigerator has a working thermometer.

13. DISPENSING NUVARING

- a. Give the new NuvaRing client a 1- or 2-month supply (1 or 2 rings).
- b. Dispense no more than a 3-month supply (3 rings) at any one time. This method ensures product effectiveness with no more than 4 months of no refrigeration.
- c. Dispensing more than 3 rings at a time may be necessary in certain occasions and will require review on a case-by-case basis.
- d. The routine use of condoms is recommended when a back-up method of contraception is warranted.

- e. The routine use of condoms is recommended to decrease the risk of acquiring sexually transmitted diseases.

Follow-up

1. The client should return in 1-2 months for evaluation of ring continuation. The client should have a blood pressure check and be evaluated for side effects. The 3-month dispensing schedule of NuvaRing is then begun.
2. Serious side effects of all estrogen/progestin contraceptives including the contraceptive ring that may warrant immediate consultation and discontinuation of the contraceptive ring include:
 - a. Sharp chest pain, coughing up blood, or sudden shortness of breath.
 - b. Pain in calf or leg.
 - c. Crushing chest pain or tightness in chest.
 - d. Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg.
 - e. Sudden partial or complete loss of vision.
 - f. Breast lumps.
 - g. Severe abdominal pain or tenderness.
 - h. Severe problems with sleeping, weakness, lack of energy, fatigue, or a change in mood.
 - i. Jaundice
 - j. Swelling of the fingers or ankles
3. Minor side effects specific to the contraceptive ring are vaginal leukorrhea, vaginal infection and irritation. A wet mount and STD testing may be required for ruling out other causes of these symptoms.
4. Other common side effects of all estrogen/progestin contraceptives including the contraceptive ring include nausea and vomiting, breast tenderness, headache, menstrual cramps, abdominal cramps and bloating, changes in appetite, nervousness, depression, weight changes, rash, irregular vaginal bleeding, and intolerance to contact lens.
5. Since there is only one formulation of the contraceptive ring, the client must decide whether to tolerate a minor side effect or switch to another contraceptive.

6. Other reasons for stopping the contraceptive ring:
 - a. If major surgery or immobilization for an extended period of time is contemplated, the client should discuss discontinuing the use of the contraceptive ring with her surgeon.
 - b. An elevated blood pressure (BP) with a systolic of 140-160 or a diastolic of 90-100 on 3 separate visits or any BP >160-100 are reasons to discontinue the contraceptive ring and refer the client for medical evaluation.
 - c. With evidence of severe clinical depression, stop the contraceptive ring and refer the client for psychiatric evaluation. For mild mood changes a different estrogen/progestin contraceptive may be offered.
7. Any client with post-ring amenorrhea of more than 6 months should be referred for evaluation.
8. With 28-day cycling one missed period with a negative pregnancy test may be managed by reassurance or a change in estrogen/progestin contraceptive. After 2 or more missed periods the client should be examined. Consideration may be given to additional evaluation and/or a change in contraception.
9. Any client desiring to become pregnant may be advised to use a barrier method of contraception for several months after discontinuing the contraceptive ring in order to establish regular menstrual cycles for more accurate pregnancy dating. The client should receive preconception counseling and be instructed in the importance of taking a daily multivitamin preparation containing 0.4 mg of folic acid.

Primary References

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APPENDIX A

POSSIBLE HEALTH BENEFITS OF THE VAGINAL CONTRACEPTIVE RING

The possible health benefits of the vaginal contraceptive ring are considered to be the same as those of combined oral contraceptives.

1. Decreased menstrual bleeding
2. Less dysmenorrhea
3. Less pelvic inflammatory disease
4. Less risk for functional ovarian cyst
5. Less risk of ovarian and endometrial cancer
6. Less risk for benign breast disease
7. Decrease in frequency of ectopic pregnancy
8. Possible improvement of acne and hirsutism
9. Decrease in endometriosis
10. A protective effect against osteoporosis

APPENDIX B

POSSIBLE HEALTH RISKS OF THE VAGINAL CONTRACEPTIVE RING

The possible health risks of the vaginal contraceptive ring are considered to be the same as those of combined oral contraceptives.

1. Blood pressure elevation
2. Thrombophlebitis and venous thrombosis with or without embolism
3. Arterial thromboembolism
4. Pulmonary embolism
5. Myocardial infarction
6. Cerebral hemorrhage
7. Cerebral thrombosis
8. Gall bladder disease
9. Hepatic adenoma

Cigarette smoking increases the risk of serious cardiovascular side effects from hormonal contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use the vaginal contraceptive ring should be strongly advised not to smoke.

APPENDIX C

PRECAUTIONS IN PROVIDING THE VAGINAL CONTRACEPTIVE RING

The precautions in providing the vaginal contraceptive ring are considered to be the same as those of combined oral contraceptives.

Refrain from providing the vaginal contraceptive ring for women with:

1. Thrombophlebitis, thromboembolic disorders
2. A past history of deep vein thrombophlebitis or thromboembolic disorders
3. Cerebrovascular or coronary artery disease (current or past history)
4. Vascular heart disease with complications
5. Severe hypertension (>160/100 mm Hg)
6. Diabetes mellitus complicated by vascular disease or of more than 20 years' duration
7. Headaches with focal neurological symptoms and/or aura
8. Major surgery with prolonged immobilization
9. Known or suspected carcinoma of the breast or personal history of breast cancer
10. Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
11. Cholestatic jaundice of pregnancy or jaundice with prior hormonal contraceptive use
12. Acute or chronic hepatocellular disease with abnormal liver function
13. Hepatic adenomas or carcinomas
14. Known or suspected pregnancy
15. Hypersensitivity to any component of the vaginal contraceptive ring
16. Smoking and over age 35

Exercise caution in providing the vaginal contraceptive ring for women with:

1. Severe headache without aura
2. Hypertension
3. Chronic liver disease, congenital hyperbilirubinemia or active gall bladder disease
4. During the first 3-4 weeks postpartum
5. Surgery or injury requiring immobilization
6. Sickle cell disease or Sickle C disease (not sickle trait)
7. Hyperlipidemia or history thereof
8. Lactation
9. Diabetes mellitus, history of gestational diabetes or other high-risk factors for diabetes
10. Amenorrhea or oligomenorrhea
11. Difficulty in compliance, e.g., mental illness, drug abuse, etc.
12. Undiagnosed vaginal/uterine bleeding
13. Cardiac or renal disease or history thereof
14. Over 50 years of age
15. Family history of the death of a parent or sibling due to myocardial infarction before age 50

APPENDIX D

DRUG INTERACTIONS

Contraceptive effectiveness may be reduced when hormonal contraceptives are co-administered with some antibiotics, antifungals, anticonvulsants, and other drugs that increase metabolism of contraceptive steroids. This could result in unintended pregnancy or breakthrough bleeding. Examples include:

1. barbiturates (Phenobarbital)
2. griseofulvin
3. rifampin
4. phenylbutazone (Butazolidin®)
5. primidone (Mysoline®)
6. phenytoin (Dilantin®)
7. carbamazepine (Tegretol®)
8. felbamate (Felbatol®)
9. oxcarbazepine (Trileptal®)
10. topiramate (Topamax®)
11. St. John's Wort
12. anti-HIV protease inhibitors

ORAL CONTRACEPTION

Rationale

Oral contraceptives (OCs), also known as “the pill”, are the most popular method of contraception among female adolescents. There are two types of oral contraceptives: (1) combined oral contraceptives (COCs) which contain an estrogen and a progestin, and progestin-only contraceptives (POPs) which contain a progestin but no estrogen.

The primary mechanism of action is inhibition of ovulation. In addition, oral contraceptives produce an endometrium which is not receptive to ovum implantation and cervical mucus which becomes thick and hostile to sperm transport. Tubal and endometrial motility are slowed.

Perfect use failure rate in the first year: 0.3%

Typical use failure rate in the first year: 8%

Combined oral contraceptives are available in 2 basic formulations. The monophasic formulation has each active pill containing the same doses of estrogen and progestin. The multiphasic formulations can have varying amounts of estrogen and/or progestin in the active pills. Most pill packs have 21 active hormone pills and 7 inactive (placebo) pills.

Combined oral contraceptives have many benefits including their effectiveness, safety in years of consecutive use without risk of complications, ease of reversibility, and positive menstrual effects such as decreased cramps, decreased blood loss, and reduction of premenstrual symptoms. Health benefits are listed in Appendix A.

Combined oral contraceptives also have some disadvantages. They must be taken daily, are expensive, and provide no protection against sexually transmitted infections including HIV. Possible side effects include missed periods, breakthrough bleeding, nausea, vomiting, headaches, depression, and decreased libido. Health risks are listed in Appendix B.

The progestin-only pill (the minipill) is less effective than combined oral contraceptives in preventing pregnancy. This pill, which is taken every day without interruption, is free of estrogen, and is, therefore, useful for clients unable to tolerate the estrogen effects of combined oral contraceptives or who have contraindications against taking an estrogen-containing contraceptive. Minipills can be taken during lactation and appear to have no harmful effect on blood pressure or on coagulation. The disadvantages of the minipill are irregular menstruation and a requirement for more exact timing of daily dosage than with the combined pills. If the minipill is taken 3 or more hours later than the usual time, a back-up method should be used for at least 48 hours.

Plan of Action

1. The client should be counseled regarding the benefits, disadvantages, and risks associated with combined oral contraceptive use and be given an information pamphlet containing method use and warning signs (Appendix A and B).

2. Consider the precautions prior to prescribing combined oral contraceptives (Appendix C). Refrain from providing combined oral contraceptives to those with major risk factors and use caution in prescribing for those with relative risk factors.
 - a. In healthy clients over age 35 or those with a family history or premature death from cardiovascular disease, it is desirable to obtain a lipid profile and fasting blood sugar prior to prescribing combined oral contraceptives. If that is not feasible, those tests can be obtained at the time the next pill supply is given.
 - b. Be cautious in prescribing combined oral contraceptives for clients with oligomenorrhea or amenorrhea. They may be infertile. Unless such a client's diagnosis is already known, she should be advised that an endocrine evaluation might be appropriate.
 - c. Clients with first-degree relatives (parent, sibling, or child) who have diabetes mellitus should have a fasting blood sugar ordered around the time of the initial visit and every 2-3 years.
 - d. Postpartum clients with a history of gestational diabetes should have a fasting blood sugar ordered around the time of the initial visit and every 2-3 years.
 - e. Combined oral contraceptives may interfere with lactation. Once lactation is well established, progestin-only contraceptives are preferable for those clients requesting to use a hormonal contraceptive while breastfeeding. For non-breastfeeding clients combined oral contraceptives may be initiated at 3-4 weeks postpartum or with the first menstrual period.
 - f. Contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D).
3. PILL CHOICE
 - a. Use the lowest dose of oral contraceptives that will provide pregnancy protection, provide non-contraceptive benefits, and minimize side effects.
 - b. Monophasic formulations should be ordered if cycle lengths are to be extended with elimination of some pill-free intervals.
 - c. Triphasic formulations may be preferable to reduce certain pill side effects when it is not desirable to increase hormone levels throughout the entire cycle or when it is desirable to reduce total cycle progestin levels.
4. METHOD INITIATION – A pelvic examination is not necessary to start OCs.
 - a. FIRST DAY START
 - 1) Take the first pill of the pack on the first day of the menses.
 - 2) No back-up contraception is needed.
 - b. SUNDAY START

- 1) Take the first pill of the pack on the Sunday after the first day of the menses.
- 2) A back-up method of contraception is recommended for 7 days.
- 3) Sunday starts usually result in no periods on the weekends.

c. QUICK START

- 1) Take the first pill of the pack on the day of the visit.
- 2) A back-up method of contraception is recommended for 7 days.
- 3) If the client is in need of emergency contraception, she should take both tablets of Plan B® at once on the visit day and start her pills no later than the next day.
- 4) Her next menses may be delayed until she completes her first cycle of pills.
- 5) Quick start does not increase irregular spotting or bleeding.

5. PATTERN OF PILL USE

- a. 28-DAY CYCLING – 21 active pills followed by 7 placebo pills
- b. SHORTENED PILL-FREE INTERVAL – Starting the new pack of pills on the first day of menstruation usually decreases the pill-free interval thus allowing less time for a new follicle to develop. Pill-free interval should not be more than 7 days.
- c. EXTENDED REGIMEN – There is no biological reason to have monthly withdrawal bleeding on oral contraception. Monophasic combined oral contraceptives must be used in any extended regimen. Extended regimens in one form or another provide options for women who need to control the timing of their bleeding or have severe symptoms when bleeding.
 - 1) BICYCLING – Skipping the placebo pills at the end of every other pack of pills yields one period after 6 weeks of active pills.
 - 2) TRICYCLING – Skipping the placebo pills at the end of 2 out of every 3 packs of pills yields one period after 9 weeks of active pills.
 - 3) SEASONALE® - This pack has 84 active pills followed by 7 inactive pills. The progestin and estrogen are the same as Nordette®.
 - 4) CONTINUOUS – The client takes only active pills daily continuously. Breakthrough bleeding will occur.
 - 5) All clients using extended regimens have the potential for breakthrough bleeding and must be counseled as such.

6. MISSED PILLS – American manufacturers of combined oral contraceptives now have standardized instructions to users on what to do when one or more contraceptive pills are missed (Appendix E). Instruct the client to follow these recommendations. Additionally, for some situations the use of emergency contraceptive pills may be considered.
7. Recommend the routine use of condoms to decrease the risk of acquiring sexually transmitted diseases.
8. The typical use failure rate is very high among adolescents due to poor compliance. Education with each visit is important in this age group.
9. For new COC starts, dispensing or prescribing no more than a 3-month supply of a combined oral contraceptives is recommended in order that the client may be evaluated for compliance and side effects after the first several cycles.

Follow-up

1. The client should return in 3 months for evaluation for oral contraception continuation. The client should have a blood pressure check and be evaluated for side effects. If there are no problems and the client wishes to continue oral contraceptives, she may be given the remainder of her year's supply (10 packs).
2. Serious side effects that may warrant immediate consultation and discontinuation of combined oral contraceptives include:
 - a. Sharp chest pain, coughing up blood, or sudden shortness of breath.
 - b. Pain in calf or leg.
 - c. Crushing chest pain or tightness in the chest.
 - d. Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg.
 - e. Sudden partial or complete loss of vision.
 - f. Breast lumps.
 - g. Severe abdominal pain or tenderness.
 - h. Severe problems with sleeping, weakness, lack of energy, fatigue, or change in mood.
 - i. Jaundice.
3. Minor side effects or oral contraceptives may occur.
 - a. Symptoms such as headache, nausea, vomiting, mastalgia, weight gain, irritability, fatigue, and mood changes are usually transient and often respond to changes in pill formulation.

- b. Breakthrough bleeding in the first few months should be managed by encouragement and reassurance. If it occurs after many months of use, a short course of exogenous estrogen or changing to another oral contraceptive may be offered after appropriate evaluation.
 - c. With 28-day cycling one missed period with a negative pregnancy test may be managed by reassurance or a change to another oral contraceptive. After 2 or more missed periods the client should be examined. Consideration may be given to additional evaluation and/or a change in contraception.
 - d. Weight gain on combined oral contraceptives, although not typical, can occur in certain individuals. A change in oral contraceptive formulation with less estrogen and progestin may be helpful.
4. Other reasons for stopping combined oral contraceptives.
- a. If major surgery or immobilization for an extended period of time is contemplated, the client should discuss the elimination of oral contraception with her surgeon.
 - b. An elevated blood pressure (BP) with a systolic of 140-160 or a diastolic of 90-100 on 3 separate visits or any BP >160/100 are reasons to discontinue oral contraception and refer the client for medical evaluation.
 - c. With evidence of severe clinical depression, stop the oral contraceptives and refer the client for psychiatric evaluation. For mild mood changes a different formulation may be offered.
5. Any client desiring to become pregnant may be advised to use a barrier method of contraception for several months after discontinuing oral contraceptives in order to establish regular menstrual cycles for more accurate pregnancy dating. The client should receive preconception counseling and be instructed in the importance of taking a daily multivitamin preparation containing 0.4 mg of folic acid.
6. Any client with post-pill amenorrhea of more than 6 months should be referred for evaluation.

Primary References

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APPENDIX A

POSSIBLE HEALTH BENEFITS OF COMBINED ORAL CONTRACEPTIVES

1. Decreased menstrual bleeding
2. Less dysmenorrhea
3. Less pelvic inflammatory disease
4. Less risk for functional ovarian cyst
5. Less risk of ovarian and endometrial cancer
6. Less risk for benign breast disease
7. Decrease in frequency of ectopic pregnancy
8. Possible improvement of acne and hirsutism
9. Decrease in endometriosis
10. A protective effect against osteoporosis

APPENDIX B

POSSIBLE HEALTH RISKS OF COMBINED ORAL CONTRACEPTIVES

1. Blood pressure elevation
2. Thrombophlebitis and venous thrombosis with or without embolism
3. Arterial thromboembolism
4. Pulmonary embolism
5. Myocardial infarction
6. Cerebral hemorrhage
7. Cerebral thrombosis
8. Gall bladder disease
9. Hepatic adenoma

Cigarette smoking increases the risk of serious cardiovascular side effects from hormonal contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use combined oral contraceptives should be strongly advised not to smoke.

APPENDIX C

PRECAUTIONS IN PROVIDING COMBINED ORAL CONTRACEPTIVES

Refrain from providing combined oral contraceptives for women with:

1. Thrombophlebitis, thromboembolic disorders
2. A past history of deep vein thrombophlebitis or thromboembolic disorders
3. Cerebrovascular or coronary artery disease (current or past history)
4. Valvular heart disease with complications
5. Severe hypertension (>160/100 mm Hg)
6. Diabetes mellitus complicated by vascular disease or of more than 20 years' duration
7. Headaches with focal neurological symptoms and/or aura
8. Major surgery with prolonged immobilization
9. Known or suspected carcinoma of the breast or personal history of breast cancer
10. Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
11. Cholestatic jaundice of pregnancy or jaundice with prior hormonal contraceptive use
12. Acute or chronic hepatocellular disease with abnormal liver function
13. Hepatic adenomas or carcinomas
14. Known or suspected pregnancy
15. Hypersensitivity to any component of combined oral contraceptives
16. Smoking and over age 35

Exercise caution in providing combined oral contraceptives for women with:

1. Severe migraine
2. Hypertension (<160/100 mm Hg)
3. Chronic liver disease, congenital hyperbilirubinemia or active gall bladder disease
4. During the first 3-4 weeks postpartum
5. Surgery or injury requiring immobilization
6. Sickle cell disease or Sickle C disease (not sickle trait)
7. Hyperlipidemia or history thereof
8. Lactation
9. Diabetes mellitus, history of gestational diabetes or other high-risk factors for diabetes
10. Amenorrhea or oligomenorrhea
11. Difficulty in compliance, e.g., mental illness, drug abuse, etc.
12. Undiagnosed vaginal/uterine bleeding
13. Cardiac or renal disease or history thereof
14. Over 50 years of age
15. Family history of the death of a parent or sibling due to myocardial infarction before age 50

APPENDIX D

DRUG INTERACTIONS

Contraceptive effectiveness may be reduced when hormonal contraceptives are co-administered with some antibiotics, antifungals, anticonvulsants, and other drugs that increase metabolism of contraceptive steroids. This could result in unintended pregnancy or breakthrough bleeding. Examples include:

1. barbiturates (Phenobarbital)
2. griseofulvin
3. rifampin
4. phenylbutazone (Butazolidin®)
5. primidone (Mysoline®)
6. phenytoin (Dilantin®)
7. carbamazepine (Tegretol®)
8. felbamate (Felbatol®)
9. oxcarbazepine (Trileptal®)
10. topiramate (Topamax®)
11. St. John's Wort
12. anti-HIV protease inhibitors

APPENDIX E

WHAT TO DO IF YOU MISS PILLS

If you miss 1 “active” pill:

1. Take it as soon as you remember. Take the next pill at your regular time. This means you may take 2 pills in 1 day.
2. You do not need to use a back-up birth control method if you have sex.
3. The clinician should offer emergency contraception if the missed pill is at the beginning of the pack.

If you miss 2 “active “ pills in a row in week 1 or week 2 of your pack:

1. Take 2 pills on the day you remember and 2 pills the next day.
2. Then take 1 pill a day until you finish the pack.
3. You could become pregnant if you have sex in the 7 days after you miss pills. You must use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you miss 2 “active” pills in a row in week 3:

1. If you are a Sunday starter:
Keep taking 1 pill every day until Sunday. On Sunday, throw out the rest of the pack and start a new pack of pills that same day.

If you are a Day 1 starter:
Throw out the rest of the pill pack and start a new pack that same day.
2. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your health care professional because you might be pregnant.
3. You could become pregnant if you have sex in the 7 days after you miss pills. You must use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you miss 3 or more “active” pills in a row (during the first 3 weeks):

1. If you are a Sunday starter:
Keep taking 1 pill every day until Sunday. On Sunday, throw out the rest of the pack and start a new pack of pills that same day.

If you are a Day 1 starter:
Throw out the rest of the pill pack and start a new pack that same day.

2. You may not have your period this month but this is expected. However, if you miss your period 2 months in a row, call your health care professional because you might be pregnant.
3. You could become pregnant if you have sex in the 7 days after you miss pills. You must use another birth control method (such as condoms or spermicide) as a back-up method for those 7 days.

If you forget any of the 7 “reminder” pills in week 4:

1. Throw away the pills you missed.
2. Keep taking one pill each day until the pack is empty.
3. You do not need a back-up method.

If you are still not sure what to do about the pills you have missed:

1. Use a back-up method anytime you have sex.
2. Keep taking 1 “active” pill each day until you can reach your health care provider.

ORTHO EVRA® - CONTRACEPTIVE PATCH

Rationale

Oral contraceptive pills are very popular and effective, but poor compliance results in a significant rate of pregnancy. The transdermal contraceptive patch was developed to provide a similar reversible contraceptive with a more convenient dosing schedule that would enhance patient compliance and achieve high contraceptive efficacy.

The primary mechanism of action is inhibition of ovulation. In addition, the contraceptive patch produces an endometrium which is not receptive to ovum implantation, and cervical mucus which becomes thick and hostile to sperm transport. Tubal and endometrial motility are slowed.

Perfect use failure rate in the first year of use: 0.3%

Typical use failure rate in the first year of use: 8%

Ortho Evra® is a matchbook size, beige colored transdermal contraceptive patch that contains both estrogen and progestin. The patch has a contact surface area of 20 cm² and consists of 3 layers. The outer layer consists of polyethylene/polyester and provides support for the middle layer which contains the hormones. The third layer is a clear lining which protects the adhesive layer and is removed before use. Each patch contains 6.00 mg norelgestromin and 0.75 mg ethinyl estradiol, and releases 150 mcg of norelgestromin and 20 mcg of ethinyl estradiol to the bloodstream per 24 hours.

When applied to the skin, the patch delivers the two active ingredients into the systemic circulation. Because the patch is a transdermal delivery system, the doses of estrogen and progestin delivered cannot be compared with the doses of estrogen and progestin in an oral contraceptive. Recommended dosing is one patch applied once weekly for three consecutive weeks (21 days), followed by 1 patch-free week per cycle. Patches should be removed or changed on the same day each week.

The selection of clients for the transdermal patch involves the identical inclusion and exclusion criteria utilized for combined oral contraceptives. Clients with a history or presence of hypersensitivity in response to topical bandages or adhesive applications should be excluded.

On September 20, 2006, the FDA announced that a revised “bolded” warning was added to the labeling of the Ortho Evra® transdermal contraceptive patch. This warning states that a patient using the patch will be exposed to about 60% more estrogen than if the patient had been using a typical birth control pill containing 35 mcg of estrogen. The risk of venous thromboembolic disease (blood clots in the legs and/or the lungs) may be increased with Ortho Evra® compared with that of oral contraceptives containing a norgestimate and 35 mcg of estrogen. In one study the risk was 2-fold. All clients must be counseled on this increased risk.

Plan of Action

1. The client should be counseled regarding the benefits, disadvantages, and risks associated with transdermal contraceptive patch use and be given an information pamphlet containing method use and warning signs (Appendix A and B). In essence, the client who is eligible for oral contraception is a candidate for the contraceptive patch.
2. Consider the precautions prior to prescribing the contraceptive patch (Appendix C). Refrain from providing the contraceptive patch to those with major risk factors and use caution in prescribing for those with relative risk factors.
 - a. In healthy clients over age 35 or those with a family history of premature death from cardiovascular disease, it is desirable to obtain a lipid profile and fasting blood sugar prior to prescribing the contraceptive patch. If that is not feasible, those tests can be obtained at the time the next patch supply is given.
 - b. Be cautious in prescribing the contraceptive patch for clients with oligomenorrhea or amenorrhea. They may be infertile. Unless such a client's diagnosis is already known, she should be advised that an endocrine evaluation might be appropriate.
 - c. Clients with first-degree relatives (parent, sibling, or child) who have diabetes mellitus should have a fasting blood sugar ordered around the time of the initial visit and every 2-3 years.
 - d. Postpartum clients with a history of gestational diabetes should have a fasting blood sugar ordered around the time of the initial visit and every 2-3 years.
 - e. The contraceptive patch may interfere with lactation. Once lactation is well established, progestin-only contraceptives are preferable for those clients requesting to use a hormonal contraceptive while breastfeeding. For non-breastfeeding clients the contraceptive patch may be initiated at 3-4 weeks postpartum or with the first menstrual period.
 - f. Clients must be counseled that the contraceptive patch may be less effective in women with a body weight of 198 lbs. or more.
 - g. Contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D).
3. **METHOD INITIATION** – If a client is starting the contraceptive patch for the first time, she should wait until the day she begins her menstrual period. Either a First Day start or a Sunday start may be chosen. The day she applies her first patch is Day 1. Her “Patch Change Day” will be this day every week.
 - a. **FIRST DAY START** – The client should apply her first patch during the first 24 hours of her menstrual period. No back-up contraception is needed.

OR

- b. SUNDAY START – The client should apply her first patch on the first Sunday after her menstrual period starts. She must use condoms as back-up contraception for the first week of her first cycle. If the menstrual period begins on a Sunday, the first patch should be applied on that day and no back-up contraception is needed.

4. PATCH PLACEMENT

- a. The patch should be applied to clean, dry, intact, healthy skin on the buttock, abdomen, upper outer arm or upper torso, in a place where it will not be rubbed by tight clothing. The patch should not be placed on the breasts.
- b. The patch should not be placed on skin that is red, irritated or cut.
- c. To prevent interference with the adhesive properties of the patch, no make-up, creams, lotions, powders or other topical products should be applied to the skin area where the patch is or will be placed.
- d. No adhesive products should be placed over the patch.
- e. The patch should not be drawn on with any kind of pen, pencil or marker.
- f. The patch should not be placed on a tattoo.

5. PATCH APPLICATION

- a. The foil pouch is opened by tearing it along the top edge and one side edge.
- b. The foil pouch should be peeled apart and opened flat.
- c. A corner of the patch is grasped firmly and it is gently removed from the foil pouch. The patch is covered by a layer of clear plastic. It is important to remove the patch and the plastic together from the foil pouch. Sometimes patches can stick to the inside of the pouch – the client should be careful not to accidentally remove the clear liner as she removes the patch.
- d. Half of the clear protective liner is to be peeled away, being careful not to touch the exposed sticky surface of the patch with the fingers.
- e. The sticky surface of the patch is applied to the skin and the other half of the liner is removed. The client should press down firmly on the patch with the palm of her hand for 10 seconds, making sure the edges stick well. She should check her patch every day to make sure it is sticking well.

6. PATCH STORAGE AND DISPOSAL

- a. Contraceptive patches should be stored at room temperature.
- b. Contraceptive patches should be removed from their protective pouches only when it is time to apply them to the skin.

- c. Each used patch should be folded in half so that it adheres to itself before discarding it in a place inaccessible to children and pets, because used patches still contain some active hormones.

7. PATCH SCHEDULE

- a. The patch is worn for 7 days (1 week). On the “Patch Change Day” (Day 8), the used patch is removed and a new one is applied immediately.
- b. A new patch is applied for Week 2 (on Day 8) and again on Week 3 (Day 15), on the usual “Patch Change Day”. Patch changes may occur at any time on the “Patch Change Day”. Each new patch should be applied to a new spot on the skin to help avoid irritation, although they may be kept within the same anatomic area.
- c. Week 4 is patch-free (Day 22 through Day 28), thus completing the 4-week cycle. Vaginal bleeding is expected to begin during this time.
- d. The next 4-week cycle is started by applying a new patch on the usual “Patch Change Day”, the day after Day 28, no matter when the menstrual period begins or ends. Under no circumstances should there be more than a 7-day patch-free interval between cycles. If more than 7 days pass, the client may be a candidate for emergency contraception if intercourse has occurred within the past 5 days.

8. PATCH DETACHMENT

- a. If a patch is partially or completely detached for less than 1 day (24 hours),
 - 1) The woman should try to reapply it to the same place or replace it with a new patch immediately.
 - 2) The “Patch Change Day will remain the same.
 - 3) No back-up contraception is needed.
- b. If a patch is partially or completely detached for more than 1 day (24 hours or more) or if a woman is not sure how long the patch has been detached,
 - 1) She should remove the old patch and apply a new patch immediately.
 - 2) The new “Patch Change Day” and new “Day 1” is the day the replacement patch is applied.
 - 3) Back-up contraception must be used for the first 7 days of the new cycle.
 - 4) The client may be a candidate for emergency contraception if intercourse has occurred within the past 5 days.

A patch should not be reapplied if it is no longer sticky, if it has become stuck to itself or another surface, if it has other material stuck to it or if it has previously become loose or fallen off. If a patch cannot be reapplied, a new patch should be applied

immediately. Supplemental adhesives or wraps should not be used to hold the patch in place.

9. FORGETTING TO APPLY OR CHANGE PATCH

- a. If a woman forgets to apply a patch at the start of any patch cycle (week 1/day 1),
 - 1) She should apply the new patch of her new cycle as soon as she remembers.
 - 2) There is now a new “Patch Change Day” and a new “Day 1”.
 - 3) Back-up contraception must be used for the first 7 day of the new cycle, and the client may be a candidate for emergency contraception.
- b. If a woman forgets to change her patch in the middle of the patch cycle (week 2/day 8 or week 3/day 15) for 1 or 2 days (up to 48 hours),
 - 1) She should remove the old patch and apply a new patch immediately.
 - 2) The next patch should be applied in the usual “Patch Change Day”.
 - 3) No back-up contraception is needed.
- c. If a woman forgets to change her patch in the middle of the patch cycle (week 2/day 8 or week 3/day 15) for more than 2 days (48 hours or more),
 - 1) She should remove the old patch and apply a new patch immediately.
 - 2) She should stop the current contraceptive cycle and start a new four-week cycle immediately by putting on a new patch. There is now a new “Patch Change Day” and a new “Day 1”.
 - 3) Back-up contraception must be used for the first 7 days of the new cycle, and the client may be a candidate for emergency contraception if intercourse has occurred in the past 5 days.
- d. If a woman forgets to remove her patch at the end of the patch cycle (week 4/day 22),
 - 1) She should remove the patch as soon as she remembers.
 - 2) The next cycle should be started on the usual “Patch Change Day”, which is the day after Day 28.
 - 3) No back-up contraception is needed.

10. CHANGE DAY ADJUSTMENT – If a woman wishes to change her “Patch Change Day”,

- a. She removes her third patch on the correct day.

- b. She may select an earlier “Patch Change Day” by applying a new patch on the desired day.
- c. In no case should there be more than 7 consecutive patch-free days.

11. DISPENSING ORTHO EVRA

- a. Give the new Ortho Evra client a 1-3 month supply of Ortho Evra. Review the product insert with the client.
- b. When the need arises, an extra patch may be provided from the clinic supply or a prescription may be given for one patch.

12. Recommend the routine use of condoms to decrease the risk of acquiring sexually transmitted diseases.

Follow-up

1. The client should return in 1-3 months for evaluation of patch continuation. The client should have a blood pressure check and be evaluated for side effects. For cost containment purposes, it is recommended that the client be given no more than 3-6 months supply of patches at any one time.
2. Minor side effects of contraceptive patch use may occur.
 - a. Skin irritation, redness or rash may occur at the site of the application. The patch may be removed and a new patch may be applied to a new location until the next “Patch Change Day”.
 - b. Breakthrough bleeding or spotting may occur. This is usually limited to the first few cycles. The client should be advised to call the clinic to discuss her bleeding pattern prior to discontinuing the patch.
 - c. Other common side effects include nausea and vomiting, breast tenderness, headache, menstrual cramps, abdominal pain, changes in appetite, nervousness, depression, dizziness, loss of scalp hair, rash, and vaginal discharge.
3. Serious side effects that may warrant immediate consultation and discontinuation of the contraceptive patch include:
 - a. Sharp chest pain, coughing up blood, or sudden shortness of breath.
 - b. Pain in the calf or leg.
 - c. Crushing chest pain or tightness in the chest.
 - d. Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg.
 - e. Sudden partial or complete loss of vision.

- f. Breast lumps.
 - g. Severe abdominal pain or tenderness.
 - h. Severe problems with sleeping, weakness, lack of energy, fatigue, or change in mood.
 - i. Jaundice.
4. If a woman using a contraceptive patch misses a period, she should not remove her patch or stop her patch cycle. A urine pregnancy test may be obtained. The patch should be discontinued if pregnancy is confirmed.

Primary References

Hatcher RA et al. Contraceptive Technology. 18th Revised Edition. Ardent Media, Inc., New York, 2004

Hatcher RA, Ziemann M et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2004

Medical Eligibility Criteria For Contraceptive Use. 3rd Ed., Reproductive Health and Research, World Health Organization, Geneva, Switzerland, 2004

Ortho Evra Package Insert. Ortho-McNeil Pharmaceutical, Inc. November 2001

APPENDIX A

POSSIBLE HEALTH BENEFITS OF THE CONTRACEPTIVE PATCH

The possible health benefits of the transdermal contraceptive patch are considered to be the same as those of combined oral contraceptives.

1. Decreased menstrual bleeding
2. Less dysmenorrhea
3. Less pelvic inflammatory disease
4. Less risk for functional ovarian cyst
5. Less risk of ovarian and endometrial cancer
6. Less risk for benign breast disease
7. Decrease in frequency of ectopic pregnancy
8. Possible improvement of acne and hirsutism
9. Decrease in endometriosis
10. A protective effect against osteoporosis

APPENDIX B

POSSIBLE HEALTH RISKS OF THE CONTRACEPTIVE PATCH

The possible health risks of the transdermal contraceptive patch are considered to be the same as those of combined oral contraceptives.

1. Blood pressure elevation
2. Thrombophlebitis and venous thrombosis with or without embolism
3. Arterial thromboembolism
4. Pulmonary embolism
5. Myocardial infarction
6. Cerebral hemorrhage
7. Cerebral thrombosis
8. Gall bladder disease
9. Hepatic adenoma

Cigarette smoking increases the risk of serious cardiovascular side effects from hormonal contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use the transdermal contraceptive patch should be strongly advised not to smoke.

APPENDIX C

PRECAUTIONS IN PROVIDING THE CONTRACEPTIVE PATCH

The precautions in providing the transdermal contraceptive patch are considered to be the same as those of combined oral contraceptives.

Refrain from providing the transdermal contraceptive patch for women with:

1. Thrombophlebitis, thromboembolic disorders
2. A past history of deep vein thrombophlebitis or thromboembolic disorders
3. Cerebrovascular or coronary artery disease (current or past history)
4. Valvular heart disease with complications
5. Severe hypertension (>160/100 mm Hg)
6. Diabetes mellitus complicated by vascular disease or of more than 20 years' duration
7. Headaches with focal neurological symptoms and/or aura
8. Major surgery with prolonged immobilization
9. Known or suspected carcinoma of the breast or personal history of breast cancer
10. Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
11. Cholestatic jaundice of pregnancy or jaundice with prior hormonal contraceptive use
12. Acute or chronic hepatocellular disease with abnormal liver function
13. Hepatic adenomas or carcinomas
14. Known or suspected pregnancy
15. Hypersensitivity to any component of the transdermal contraceptive patch
16. Smoking and over age 35

Exercise caution in providing the transdermal contraceptive patch for women with:

1. Severe headache without aura
2. Hypertension
3. Chronic liver disease, congenital hyperbilirubinemia or active gall bladder disease
4. During the first 3-4 weeks postpartum
5. Surgery or injury requiring immobilization
6. Sickle cell disease or Sickle C disease (not sickle trait)
7. Hyperlipidemia or history thereof
8. Lactation
9. Diabetes mellitus, history of gestational diabetes or other high-risk factors for diabetes
10. Amenorrhea or oligomenorrhea
11. Difficulty in compliance, e.g., mental illness, drug abuse, etc.
12. Undiagnosed vaginal/uterine bleeding
13. Cardiac or renal disease or history thereof
14. Over 50 years of age
15. Family history of the death of a parent or sibling due to myocardial infarction before age 50

APPENDIX D

DRUG INTERACTIONS

Contraceptive effectiveness may be reduced when hormonal contraceptives are co-administered with some antibiotics, antifungals, anticonvulsants, and other drugs that increase metabolism of contraceptive steroids. This could result in unintended pregnancy or breakthrough bleeding. Examples include:

1. barbiturates (Phenobarbital)
2. griseofulvin
3. rifampin
4. phenylbutazone (Butazolidin®)
5. primidone (Mysoline®)
6. phenytoin (Dilantin®)
7. carbamazepine (Tegretol®)
8. felbamate (Felbatol®)
9. oxcarbazepine (Trileptal®)
10. topiramate (Topamax®)
11. St. John's Wort
12. anti-HIV protease inhibitors

PEDICULOSIS PUBIS

Rationale

Pediculosis pubis (pubic lice, also called “crabs”) is caused by the pubic or crab louse. Infestations are common in adolescents and young adults and are usually transmitted through sexual contact. The louse can be transferred by contaminated articles, such as towels. The most common symptom is pruritus of the anogenital area. Clients may also notice lice in the pubic hair. Other hairy areas of the body, including eyebrows, eyelashes, axilla, beard, and scalp, may be infected. The incubation period of the louse egg is 6 to 10 days. The mature adult appears in 2 to 3 weeks.

Plan of Action

1. Diagnosis is made by the identification of eggs or lice with the naked eye and can be confirmed by microscopic evaluation.
2. Recommended treatment options:
 - a. Permethrin (1%) cream rinse applied to affected area(s) and washed off after 10 minutes

NOTE: Do not apply any of the products to face, lips, mouth, eyes or any mucous membrane.

OR

- b. Pyrethrins with piperonyl butoxide applied to the affected area(s) and washed off after 10 minutes
- NOTE: Do not apply any of the products to face, lips, mouth, eyes, or any mucous membrane. They are contraindicated in persons allergic to ragweed or chrysanthemums.
3. Alternative treatment options are discussed in the CDC STD Guidelines and Red Book (both listed as primary references).
 4. Head lice (*Pediculosis capitis*) and body lice (*Pediculosis corporis*) are caused by different ectoparasites but respond to the same treatment.
 5. In infected individuals, screening for other sexually transmitted diseases should be considered.
 6. Advise treatment of recent sexual partner(s) (within the last month).
 7. Clothing, towels, washcloths and bed linen used by the client within the past 2 days should be washed and/or dried by machine (hot cycle), or dry-cleaned, or removed from body contact for at least 72 hours.

8. Fumigation of living or examination areas is unnecessary.

Follow-up

1. Re-treat at 1 week if signs indicate the need because by then any surviving nits would have had time to hatch.
2. Resistant cases may be treated with an alternative drug.

Primary References

CDC. Sexually Transmitted Diseases Treatment Guidelines. 2006

Red Book: 2006 Report of the Committee on Infectious Diseases. 27th Ed., American Academy of Pediatrics, Elk Grove Village, IL

POSTPARTUM EVALUATION AND CONTRACEPTION

Rationale

The postpartum period is defined as the time immediately after delivery extending to approximately 6 weeks postpartum. The majority of women resume sexual activity within several weeks of the delivery. Use of lubricants may make intercourse easier after childbirth. The amount of time following delivery that a woman is infertile is highly variable and dependent on multiple factors, including breastfeeding status. Ovulation may return 3-6 weeks postpartum. Ovulation can occur even if the mother has not resumed menstruation; the probability of ovulation occurring before resumption of menstruation increases over time.

Detailed contraception discussion can be found in the primary references listed and the Maryland State Family Planning Program Clinical Guidelines.

Plan of Action

1. Determine whether the client has been seen by her delivery care provider since delivery.
2. If the client has not been seen, complete the history and physical examination.
 - a. Include in the history current contraception usage, amount of bleeding, and resumption of sexual activity. Screen for postpartum depression.
 - b. Screen for postpartum depression (Appendix).
 - c. Include in the physical, examination of the breasts, surgical incision and/or episiotomy (if any), and Pap test, if indicated.
 - 1) Pregnancy does not change the timing of cytology evaluation.
 - 2) Consider performing a Pap test if: postpartum bleeding has stopped, AND one has not already been performed AND there is a history of abnormal Pap tests AND at least 8 weeks have passed since delivery.
 - 3) Otherwise, the Pap test can be delayed until 1-3 years has since her previous cervical evaluation.
3. General postpartum counseling
 - a. Pelvic rest (no sex, no douching, no tampons) is recommended for 4-6 weeks.
 - b. Clients should be strongly advised to abstain from sexual intercourse until the lochia has stopped.
 - c. Clients should be encouraged to resume sexual activity only when they feel comfortable and ready.

- d. Exercise should be encouraged and can resume gradually. Breastfeeding women should try to breastfeed just prior to exercise to minimize discomfort with engorgement and should try to delay breastfeeding until about an hour after exercise to allow any lactic acid accumulation to dissipate.
 - e. For breastfeeding women, caloric intake should be 500 kcal higher than usual.
 - f. For breastfeeding and non-breastfeeding women, calcium intake should be 1,000 mg/day. Adolescents may require 1,300 mg/day.
 - g. A daily multivitamin is recommended.
4. Discuss contraception options.
- a. General
 - 1) Multiple factors must be considered when making family planning decisions during this time period: (1) whether a woman is breastfeeding, (2) the woman's age and smoking status, (3) prior experience(s) with various family planning methods, (4) whether contraception was initiated in the hospital or at a follow-up visit, (5) timing of desired resumption of sexual activity, and general medical history.
 - 2) Contraception should be initiated immediately postpartum or at least by the beginning of the fourth postpartum week.
 - 3) Provide emergency contraception.
 - 4) Caution clients that it is difficult to practice fertility awareness before their cycles are reestablished.
 - 5) Vasectomy or tubal ligation is an appropriate option for couples who desire a permanent contraception option.
 - 6) Male or female condoms are appropriate for use upon resumption of sexual intercourse.
 - 7) Barrier methods (diaphragm, sponge) can be used 6 weeks postpartum if the episiotomy or surgical scar (if present) is well healed and bleeding has ceased.
 - 8) Copper-T IUDs can be inserted at 4-6 weeks postpartum.
 - b. Breastfeeding
 - 1) Lactational Amenorrhea Method (LAM) can be up to 99.5% effective as a form of contraception during the first 6 months postpartum if a woman is amenorrheic and breastfeeding regularly without any supplementation or pumping. However, when feeding supplements are given, a second form of contraception should be used.

- 2) Progestin-only contraceptives (minipills, injections, implants) do not have adverse effects on lactation. However, there is theoretical concern that early neonatal exposure to these hormones should be avoided until 6 weeks postpartum.
 - 3) Combined estrogen/progestin contraceptives (pills, patches, vaginal rings) should not be prescribed for breastfeeding women for the first 6 months postpartum because the estrogen component may decrease the quantity and quality of breast milk.
- c. Non-breastfeeding
- 1) Combined estrogen/progestin contraceptives (pills, patches, vaginal rings) should be avoided at least 3 weeks postpartum to decrease associated risks of postpartum thrombophlebitis and thromboembolism.
 - 2) Progestin-only contraceptives (minipills, injections, implants) can be begun immediately postpartum.
5. Post-miscarriage or termination of pregnancy
- a. General counseling
- 1) Ovulation may occur within 10 days.
 - 2) Review the need for contraception for the first intercourse.
 - 3) Address mental health needs after pregnancy loss.
- b. Provide contraception
- 1) Provide emergency contraception.
 - 2) Hormonal contraception may be given any time when the client is seen postpartum.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Cunningham FG et al. Williams Obstetrics. 22nd Ed., McGraw-Hill, New York, 2005

ACOG. Exercise During Pregnancy and the Postpartum Period. Committee Opinion #267, January 2002

Association of Reproductive Health Professionals. Postpartum Counseling: A Quick Reference Guide for Clinicians. 2006

APPENDIX

EDINBURGH POSTNATAL DEPRESSION SCALE (EPDS)

Postpartum depression is a serious problem that can affect any woman during the first year after she gives birth. This depression may interfere with a woman's ability to live a normal life and to have a happy, thriving baby.

To learn whether you have symptoms of depression, please complete these 10 statements by circling the response that best describes how you felt in the past 7 days, not just how you feel today.

1. **I have been able to laugh and see the funny side of things:**
 - a. As much as I always could
 - b. Not quite so much now
 - c. Definitely not so much now
 - d. Not at all
2. **I have looked forward to enjoyment to things:**
 - a. As much as I ever did
 - b. Rather less than I used to
 - c. Definitely less than I used to
 - d. Hardly at all
3. **I have blamed myself unnecessarily when things went wrong:**
 - a. Yes, most of the time
 - b. Yes, some of the time
 - c. Not very often
 - d. No, never
4. **I have been anxious or worried for no good reason:**
 - a. No, not at all
 - b. Hardly ever
 - c. Yes, sometimes
 - d. Yes, very often
5. **I have been scared or panicky for no good reason:**
 - a. Yes, quite a lot
 - b. Yes, sometimes
 - c. Not very often
 - d. No, not at all
6. **Things have been getting on top of me:**
 - a. Yes, most of the time I haven't been able to cope at all
 - b. Yes, sometimes I haven't been coping as well as usual
 - c. No, most of the time I have coped quite well
 - d. No, not at all
7. **I have been so unhappy that I have had difficulty sleeping:**
 - a. Yes, most of the time
 - b. Yes, sometimes
 - c. Not very often
 - d. No, not at all
8. **I have felt sad or miserable:**
 - a. Yes, most of the time
 - b. Yes, quite often
 - c. Not very often
 - d. No, not at all
9. **I have been so unhappy that I have been crying:**
 - a. Yes, most of the time
 - b. Yes, quite often
 - c. Only occasionally
 - d. No, never
10. **The thought of harming myself has occurred to me:**
 - a. Yes, quite often
 - b. Sometimes
 - c. Hardly ever
 - d. Never

(score the responses on the next page)

EPDS SCORING

Now, circle the score for the response you gave for each statement:

1. a) 0	3. a) 3	5. a) 3	7. a) 3	9. a) 3
b) 1	b) 2	b) 2	b) 2	b) 2
c) 2	c) 1	c) 1	c) 1	c) 1
d) 3	d) 0	d) 0	d) 0	d) 0
2. a) 0	4. a) 0	6. a) 3	8. a) 3	10.a) 3
b) 1	b) 1	b) 2	b) 2	b) 2
c) 2	c) 2	c) 1	c) 1	c) 1
d) 3	d) 3	d) 0	d) 0	d) 0

Add your total score here:

Total Score _____

A score of 12 or higher means that you may be depressed. Please call your doctor for further evaluation. Tell your doctor that you took the Edinburgh Depression Screen and what your score was. If you think you might have an immediate need for help, go to the Emergency Room of the nearest hospital.

PRECONCEPTION COUNSELING

Rationale

Preconception care is not limited to a single visit or limited time period just before conception. Instead it is a process of care during the lifespan (especially early childhood and adolescence) that meets the needs of a woman for her reproductive years.

Preconception counseling offers women an ideal time to plan their pregnancies and establish good health habits. Certain congenital anomalies and complications of pregnancy may be prevented if intervention occurs prior to conception. Fetal organogenesis occurs between 17-56 days after fertilization before many women have their first prenatal appointment or even realize they are pregnant. Promoting positive health behaviors and eliminating medical risks are most effective when initiated preconceptionally.

Since approximately 50% of all pregnancies are unintended, targeting only self-referred women who are planning their next conception will result in a significant number of missed opportunities for primary prevention. Counseling women of childbearing age allows for an identification of women with risk factors. As an example, we can educate women to avoid any teratogenic medications, get immunized to rubella, and take folic acid supplements to decrease their risk of neural tube defects. The active planning of pregnancy will maximize the benefits of appropriate interventions and adherence to good health habits to help insure a reduction of maternal and perinatal morbidity and mortality.

Plan of Action

1. A systematic identification of preconception risks should be offered through assessment of reproductive, family and medical histories, nutritional status, drug exposures, and social concerns of all fertile women (Appendix A). The March of Dimes checklist may be utilized (website in Appendix B).
2. Educate and counsel the clients based on the identified risks.
3. Discuss the possible effects of pregnancy on the existing medical conditions and offer medical consultation.
4. Discuss genetic concerns and refer if appropriate.
5. If indicated, immunize for rubella, varicella, tetanus, pertussis, diphtheria, human papilloma virus, meningococcus, and hepatitis B.
6. Recommended laboratory tests are essentially the same as those obtained at the first prenatal visit.
 - a. hgb/hct
 - b. blood type and Rh
 - c. antibody screen
 - d. rubella titer

- e. hepatitis B screen (HBsAg)
 - f. Pap, GC, CT, STS
 - g. PKU
 - h. urinalysis
 - i. hemoglobin electrophoresis
 - j. glucose screening, if indicated
 - k. PPD, if indicated
 - l. HIV, counseling and recommended screening
7. Nutritional counseling should include a review of appropriate weight for height, sources of folic acid, avoidance of vitamin oversupplementation, and eating a well-balanced diet. The U.S. Public Health Service recommends daily supplementation with 0.4 mg of folic acid for all U.S. women of childbearing age to reduce the risk of neural tube defects. Virtually all multivitamins contain 0.4 mg of folic acid. Also many breakfast cereals contain large amounts of folic acid – a bowl of Product 19 or Total satisfies the daily folic acid requirements. Although fortification of grains by the FDA aids folic acid intake supplementation is still necessary. Taking a multivitamin along with eating food rich in folic acid such as some of the breakfast cereals may be the easiest way to ensure that women get their daily requirement. Women who have had a previous pregnancy complicated by a neural tube defect should consume 4.0 mg a day of folic acid when they are planning to conceive. This dose is available by prescription only. Caution must be used when prescribing folic acid because it makes the diagnosis of a vitamin B-12 deficiency (with its neurologic sequelae) more difficult in certain individuals, such as the elderly.
 8. Discuss social, financial, and psychologic issues in preparation for pregnancy.
 9. Discuss contraceptive use, birth spacing and keeping a menstrual calendar.
 10. Emphasize early and continuous prenatal care.
 11. Encourage clients to minimize or avoid their use of caffeine, alcohol, cigarettes, street drugs, and to take appropriate precaution against occupational hazards. Advise clients on available resources (Appendix B).
 12. Discuss handling of cats and litter boxes, and dangers of eating undercooked meat to avoid toxoplasmosis.
 13. Clients identified with social, psychological, medicals and/or genetic risks should be referred appropriately.
 14. Counsel clients to avoid hyperthermia in the first trimester. Since a maternal core temperature over 100°F. has been associated with birth defects, clients should limit sauna and hot tub sessions to 15 minutes and also limit strenuous exercise (e.g., marathon running) in the first trimester.
 15. Review all medications, including prescribed, vitamins, herbal supplements, and over-the-counter preparations. Review the workplace and household for potential hazards to pregnancy. Discuss teratogenicity and toxicity of harmful agents.

Primary References

ACOG. Planning Your Pregnancy and Birth. 3rd Ed., 2000

ACOG. Neural Tube Defects. Practice Bulletin #44, July 2003

ACOG. The Importance of Preconception Care in the Continuum of Women's Health Care. Committee Opinion #313. September 2005

CDC. Recommendations to Improve Preconception Health and Health Care. April 2006

March of Dimes. National Preconception Health Care Curriculum: Before, Between & Beyond Pregnancy. June 2008

March of Dimes. Folic Acid. Fact Sheet. December 2008

March of Dimes. Preconception Screening and Counseling Checklist. January 2008

APPENDIX A

PRECONCEPTION RISK FACTORS

1. Medical

- a. Chronic conditions such as diabetes, epilepsy, hypertension, thyroid disease, anemia, hepatitis, pelvic infections, lupus, deep vein thrombosis, PKU, asthma, cancer, AIDS, kidney disease
- b. Medications – over-the-counter, vitamins, herbal, prescription
- c. Lack of immunity to rubella, varicella, hepatitis
- d. Ethnic origin of Black, Mediterranean, SE Asian, Ashkenazic Jewish
- e. Family history of birth defects, mental retardation, or genetic abnormalities

2. Obstetric History

- a. Previous stillbirth, neonatal death, miscarriages, need for neonatal intensive care
- b. Previous child with birth defect, mental retardation, or genetic abnormalities
- c. Delivery of a child >9 lbs. or <5.5 lbs.
- d. History of diabetes or hypertension during pregnancy

3. Lifestyle

- a. Cigarettes, alcohol, caffeine, street drugs
- b. Close association with cats
- c. Sauna or hot tub use
- d. Poor nutrition
- e. Exposure to lead, mercury, radiation, chemicals, or other toxins
- f. Occupational hazards
- g. Psychosocial stress
- h. Domestic violence

APPENDIX B

RESOURCES FOR CLIENTS

To quit smoking:	Maryland Tobacco QuitLine 1-800-784-8669 www.SmokingStopsHere.com
To stop drinking:	Alcoholics Anonymous (AA) Local chapter phone # in the white pages www.step12.com/maryland.html www.aa.org
To get alcohol or drug treatment:	Maryland Alcohol and Drug Rehab Centers 1-877-345-3281
To get help for depression:	Maryland Crisis and Suicide Prevention Hotline 1-800-422-0009 Perinatal Depression Help Line 1-800-773-6667 www.HealthyNewMoms.org
To get help for domestic violence:	Maryland Network Against Domestic Violence 1-800-MD-HELPS www.mnadv.org
Preconception Screening and Counseling Checklist: http://www.marchofdimes.com/files/preconception_tool_ed.pdf	

PREGNANCY TESTING

Rationale

Early pregnancy testing has a number of benefits. A positive pregnancy test allows for early entry into prenatal services for those who wish to be pregnant or a discussion of options for those who do not wish to be pregnant. A negative pregnancy test provides the opportunity to discuss contraception for those who wish not to be pregnant or preconception counseling for those wishing to become pregnant.

A number of different pregnancy tests are available. A list can be found on page 603 in 19th Revised Edition of Contraceptive Technology by Hatcher et al. The most common office pregnancy tests are urine immunometric assays that are specific for the Beta subunit of human chorionic gonadotropin (β -hCG). These tests provide accurate qualitative (positive or negative) test results for hCG levels of approximately 25 mIU/mL. Most of these tests can detect pregnancy 10 days after conception and within a few days before the next period is due. False-negative results can occur if the urine specimen is dilute or if the β -hCG level is too low to be detected by that specific test. False-positive results can occur due to product or laboratory error or due to a cross-reaction of hCG with luteinizing hormone.

After termination of pregnancy, β -hCG levels decrease slowly. A β -hCG level may be detected in the urine as long as 60 days (31-38 days usual range) after a first trimester abortion. After a full-term delivery, β -hCG levels are usually negative in a month. As long as the β -hCG levels are dropping this should not cause concern.

High levels of β -hCG can confirm trophoblastic activity. These tests can detect concentrations of β -hCG as low as 5 mIU/mL. Serum β -hCG can be effective as an aid to diagnosing ectopic pregnancy, trophoblastic disease, impending abortion or possible retained placental fragments.

Plan of Action

1. A urine pregnancy test should be performed upon the request of the client, when symptoms or physical findings suggest the possibility of pregnancy, and/or done in the process of monitoring certain contraceptive measures.
2. The pregnancy test result and subsequent counseling should be documented in the family planning record and/or on a pregnancy test encounter form.
3. The pregnancy test provides the “teachable moment”.
 - a. Positive pregnancy test – desires to continue pregnancy
 - 1) The client is encouraged to enter a prenatal care program within 2 weeks.
 - 2) The client should start taking a daily prenatal vitamin containing 0.4 mg of folic acid.

- 3) The client should be offered prenatal education to include the need for early prenatal care with emphasis on good health practices during pregnancy (e.g., good nutrition, avoidance of smoking, alcohol, drugs and exposure to other dangerous substances).
 - 4) There needs to be a discussion of all medications and supplements that the client is using.
 - 5) The client needs to be assessed for supportive interventions and offered appropriate referrals to MCHIP, WIC, Healthy Start, DSS (adoption, foster care), genetic counseling, etc.
- b. Positive pregnancy test – desires to terminate pregnancy
- 1) The client needs to be referred to an appropriate health care facility/provider for termination options, details, timing, and costs.
 - 2) The possibility of giving up the baby for adoption can be explored and resources and referrals made available.
 - 3) The need for a timely decision about termination should be emphasized, along with encouraging a safer and healthy lifestyle in the meantime.
 - 4) The need for effective contraception after pregnancy termination must be discussed.
- c. Negative pregnancy test – desires pregnancy
- 1) The client should be offered by preconception counseling as outlined in this Family Planning Program Clinical Guidelines manual.
 - 2) If infertility appears to be an issue, physician consultation and referral should be considered.
 - 3) The client should start taking a daily multivitamin containing 0.4 mg of folic acid.
- d. Negative pregnancy test – does not desire pregnancy
- 1) If a missed period was the reason for the pregnancy test, offer the client a repeat urine pregnancy test in 2 week if there is still no menses.
 - 2) If the need for contraception is immediate, offer the client one of the barrier methods of contraception.
 - 3) Offer the client emergency contraception for any unprotected vaginal intercourse that occurred in the 120 hours prior to the current visit.
 - 4) Offer advanced placement emergency contraception for future use.

- 5) Hormonal contraception may be offered if the client meets the criteria for the respective hormonal preparation being considered. No pelvic examination is required to begin the method.
- 6) Offer the client an appropriate family planning appointment or referral.

Follow-up

1. A serum quantitative β -hCG should be considered if repeat urine pregnancy tests are negative in spite of evidence suggesting possible pregnancy.
2. Follow-up appointments will depend on a client's contraceptive requirements, a client's menstrual history and clinical condition, and further need for pregnancy testing.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Zieman M, Hatcher RA et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2007

Cunningham FG et al. Williams Obstetrics. 22nd Ed., McGraw-Hill, New York, 2005

PREMENSTRUAL SYNDROME

Rationale

Premenstrual syndrome (PMS) is a psycho-neuroendocrine disorder with biologic, psychologic and social parameters which occur regularly in the luteal phase of the menstrual cycle. Although more than 150 symptoms have been attributed to PMS, a relatively discrete number of core symptoms have been shown through well-controlled studies to constitute the syndrome. The diagnosis depends on the demonstration of true cyclicity of symptoms and the exclusion of other medical and psychiatric disorders.

Criteria for the diagnosis of PMS:

1. The client has at least one of the following affective symptoms:
 - Depression
 - Angry outbursts
 - Irritability
 - Anxiety
 - Confusion
 - Social withdrawal
2. The client has at least one of the following somatic symptoms:
 - Breast tenderness
 - Abdominal bloating
 - Headache
 - Swelling of extremities
3. Symptoms occur during the 5 days before menses in each of 3 prior menstrual cycles, as demonstrated in a prospective symptom calendar.
4. The symptoms are relieved within 4 days of the onset of menses without recurrence until at least cycle day 13.
5. The problem is of a magnitude sufficient to affect a woman's work, lifestyle or interpersonal relationships.

The highest incidence of PMS is in women age 30-39. It is rarely encountered in adolescents. With both definition and etiology unclear, therapy is controversial.

Women with premenstrual dysphoric disorder (PMDD) are considered to be a subgroup with PMS who suffer primarily emotional symptoms.

Criteria for the diagnosis of PMDD:

1. The client has at least five of the following symptoms:
 - Marked sadness, depression, hopelessness, or self-deprecating thoughts
 - Marked anxiety
 - Marked affective lability
 - Marked anger or irritability

- Decreased interest in usual activities
 - Difficulty concentrating
 - Lethargy
 - Marked change in appetite, overeating, or specific food craving
 - Hypersomnia or insomnia
 - Feeling overwhelmed
 - Other physical symptoms, such as breast tenderness or swelling, headaches, joint or muscled pain, bloating, weight gain
2. A client must have at least a 1-year history of symptomatology, and at least 5 symptoms each month during the last week of the luteal phase and absent in the week post-menses.
 3. There is marked interference of symptoms in work, school, or usual social activities and relationships with others.

Plan of Action

1. A history and physical exam should be done to exclude organic causes of the client's symptoms.
2. The client should keep a 3-month calendar diary of symptoms and indicate whether they are mild or severe (Appendix). A woman who is overwhelmed by a series of complaints should chart only the 3 to 5 complaints that most profoundly bother her.
3. The absence of a symptom-free interval or presence of symptoms of PMDD suggests the need for further medical and/or psychiatric evaluation.
4. It is likely that several mechanisms are involved in producing the symptoms of PMS. Therapy should be individualized for each woman's specific problems.
5. General measures for management of PMS include:
 - a. Reassurance and informational counseling.
 - b. Reduction of salt, sugar, and caffeine consumption.
 - c. Increase complex carbohydrates in diet.
 - d. Relaxation techniques (including biofeedback), behavioral techniques, and group support.
 - e. A regular exercise program.
6. Taking 1,500 mg of elemental calcium daily might be beneficial for the reduction of PMS symptoms.
7. Vitamin B₆, 50-100 mg/day may be helpful.
8. Many clients find the use of oral contraceptives relieves PMS. For clients who have symptoms of PMS while taking oral contraceptives, an adjustment in formulation or dosage may be beneficial.

9. Clients diagnosed with PMS and not responding to lifestyle changes and non-medication therapy or those symptomatic of PMDD should be referred to a physician for pharmacologic intervention such as diuretic therapy and antidepressant therapy.
10. For information on PMS, clients may call PMS access toll free 800-222-4PMS.
11. Clients with PMS or PMDD need continuity of care since support is essential to management. These clients require frequent visits for evaluation and counseling, and referral to a specialty clinic or private physician should be considered.

Primary References

ACOG. *Precis: Primary and Preventive Care*. 3rd Ed., 2004

Hatcher RA et al. *Contraceptive Technology*. 19th Revised Edition. Ardent Media, Inc., New York, 2007

ACOG. *Premenstrual Syndrome*. Practice Bulletin #15, April 2000

APPENDIX

PREMENSTRUAL SYNDROME SYMPTOM CALENDAR

CODE	SYMPTOM LIST	DAY	MONTH	MONTH	MONTH	MONTH
T	Tension	1				
IR	Irritability	2				
D	Depression	3				
AX	Anxiety	4				
MS	Mood swings	5				
FO	Forgetfulness	6				
DC	Difficulty concentrating	7				
FA	Fatigue	8				
AS	Abdominal symptoms	9				
HA	Headaches	10				
BT	Breast tenderness	11				
S	Swelling	12				
BL	Bloating	13				
IN	Insomnia	14				
CS	Crying spells	15				
		16				
		17				
		18				
		19				
		20				
		21				
		22				
		23				
		24				
		25				
		26				
		27				
		28				
		29				
		30				
		31				

Instructions:

1. Check off the symptoms you experience most frequently. If you have other symptoms not on the list, write them in the spaces provided and give them a code different from any other on the list.
2. On the date you experience any symptom(s) on the list, fill in the code(s) in the space next to the date. Do not wait a few days to list your symptoms because on recall you may either minimize or over-emphasize your symptoms.
3. If your symptoms are mild, use small letters (example: ax); if severe, use capital letters (example: AX).
4. Each day you have menstrual bleeding write an "M" with a circle around it.

ROUTINE PELVIC EXAMINATION AND CERVICAL SCREENING

Rationale

The purpose of the pelvic examination is to assess the vulva, vagina, cervix, uterus, and adnexa. This examination includes inspection of the external genitalia, urethra, and introitus; with speculum examination of the vaginal and cervix; and bimanual examination of the cervix, uterus, adnexa, and ovaries.

The decision to perform a routine pelvic examination and cervical screening is based on the client's age, sexual history, current symptoms, and past history.

A rectovaginal examination is performed if the bimanual examination is abnormal or inadequate, or if there are pelvic or gastrointestinal symptoms.

Certain circumstances do not require a client to undergo a pelvic examination or any cervical testing.

Plan of Action

1. Client's age <21 years
 - a. General physical examination without a pelvic examination for the client age 13-18 years allows assessment of secondary sexual development, female hygiene, reassurance, and education
 - b. Routine pelvic examination if medically indicated
 - c. Client has never has been sexually active
 - 1) No routine pelvic examination
 - 2) No STD testing
 - 3) No cervical cytology
 - 4) No routine or reflex HPV DNA testing
 - d. Client has been sexually active
 - 1) Annual pelvic examination
 - 2) STD testing per guidelines
 - 3) Cervical cytology 3 years after onset of sexual activity, then annually
 - 4) No routine or reflex HPV DNA testing
2. Client's age 21-29 years
 - a. Annual pelvic examination
 - b. STD testing per guidelines
 - c. Annual cervical cytology
 - d. Reflex HPV DNA testing only

3. Client's age ≥ 30 years
 - a. Annual pelvic examination
 - b. STD testing per guidelines
 - c. Cervical cytology
 - d. Routine HPV DNA testing
 - 1) If HPV testing and cervical cytology are both negative, rescreen in 3 years.
 - 2) If either HPV testing or cervical cytology is positive, follow the "Cervical Cancer Screening" guidelines.
4. Clients who are immunosuppressed (organ transplant, cancer chemotherapy, chronic steroid use such as for chronic renal or bowel disease, conditions such as lupus, or on dialysis), were exposed to diethylstilbestrol in utero, or are HIV positive should continue annual pelvic examinations and cervical screening.

Primary References

ACOG. Routine Pelvic Examination and Cervical Cytology Screening. Committee Opinion #431, May 2009

ACOG. Evaluation and Management of Abnormal Cervical Cytology and Histology in Adolescents. Committee Opinion #436, June 2009

ACOG. Cervical Cytology Screening. Practice Bulletin #45, August 2003

RUBELLA

Rationale

Rubella or German measles is usually a mild viral illness and is characterized by fever, lymphadenopathy, and a transient erythematous rash. Maternal infection during pregnancy may involve the embryo or fetus, and the risk of infection for the fetus is greatest during the first trimester. The occurrence of congenital defects is up to 85% if infection occurs during the first 12 weeks of gestation, 54% during the first 13-16 weeks of gestation, and 25% during the end of the second trimester. The congenital rubella syndrome is most commonly associated with one or more of the following abnormalities: deafness, cataracts, glaucoma, cardiac anomalies, and CNS defects including mental retardation.

A major objective of rubella immunization programs is to prevent maternal rubella infection and the subsequent teratogenic effects on the fetus.

Plan of Action

1. All women should undergo a serum rubella antibody test. A laboratory test indicating a rubella serum antibody titer greater than 1:8 or stating "antibodies detected" indicates immunity. A laboratory test indicating a serum rubella titer equal to or less than 1:8 or stating "no antibodies detected" indicates susceptibility to rubella. If the titer is equivocal, repeat the rubella titer with the next lab work. If a second titer is equivocal, the client should be considered susceptible to rubella.
2. Common side effects from the rubella vaccine include fever, rash, headache, nausea and joint pain. These side effects usually occur within a month after immunization and last less than one week.
3. If the rubella antibody titer is equal to or less than 1:8, MMR (combined vaccine) should be offered. If the rubella titer demonstrates no antibodies after a documented immunization, a second immunization (MMR) may be given. After age 12 months, 2 doses of vaccine should confer immunity in spite of any future negative testing.
4. Pregnancy should be deferred for a least 1 month following immunization. Clients who become pregnant within 1 month after vaccination should be counseled about possible effects on the fetus, though the risk appears small. Receipt of rubella vaccination during pregnancy is not an indication for interruption of that pregnancy.
5. Rubella vaccine may be given immediately postpartum and also to breastfeeding mothers. There is no risk of transmission of the virus to the newborn.
6. All health care workers should be immunized against rubella if they are not already immune.

Primary References

ACOG. Rubella Vaccination. Committee Opinion #281, December 2002

ACOG. Primary and Preventive Care: Periodic Assessments. Committee Opinion #292, November 2003

Red Book: 2006 Report of the Committee on Infectious Diseases. 27th Ed., American Academy of Pediatrics, Elk Grove Village, IL

ACOG. Precis: Primary and Preventive Care. 3rd Ed., 2004

ACOG. Precis: Obstetrics. 3rd Ed., 2005

SCABIES

Rationale

Scabies is caused by a mite, *Sarcoptes scabiei*. Transmission usually occurs by close, prolonged, personal contact. Scabies in adults frequently is sexually acquired. It affects persons from all socioeconomic levels without regard to age, sex, or standards of personal hygiene. The disease manifests itself as an intensely pruritic, erythematous, papular eruption. Itching is most intense at night. Sites of predilection are the interdigital folds, flexor aspects of wrists, extensor surfaces of elbows, anterior axillary folds, waistline, thighs, navel, genitalia, areolae, abdomen, intergluteal cleft, and buttocks. Incubation period in previously exposed individuals is 1 to 4 days; in those without previous exposure it is 4 to 6 weeks. The mite burrow appears as a grey or white, tortuous, thread-like line which may be obliterated by any scratching done prior to the client being seen.

Plan of Action

1. Diagnosis is usually made by observation of the characteristic skin lesions and may be confirmed by microscopic identification of the mite from skin scrapings of the burrow or papules.
2. Recommended treatment:

Permethrin cream (5%) applied to all areas of the body from the neck down and washed off after 8-14 hours
3. Alternative treatment options are discussed in the CDC STD Guidelines and Red Book (both listed as primary references).
4. Household members and sexual partners should be referred for evaluation and possible prophylactic treatment.
5. Bedding and clothing should be laundered in hot water and dried using a hot cycle, or dry-cleaned. Clothing that cannot be laundered may be stored several days to a week since the parasite does not survive more than 3 to 4 days without contact with the skin.
6. Fumigation of living or examination areas is unnecessary.

Follow-up

1. Pruritus may persist for 2-4 weeks and may require the use of topical corticosteroids and oral antihistamines.
2. Clients who are still symptomatic after 2 weeks may be re-treated.
3. Clients not responding to recommended treatment should be re-treated with an alternative regimen.

Primary References

CDC. Sexually Transmitted Diseases Treatment Guidelines. 2006

Red Book: 2006 Report of the Committee on Infectious Diseases. 27th Ed., American Academy of Pediatrics, Elk Grove Village, IL

SPERMICIDES (VAGINAL FILM, FOAM, CREAM, GEL, TABLET, SPONGE, SUPPOSITORY)

Rationale

Spermicides consist of a spermicidal agent and an inert carrier substance. Those two substances provide a dual mechanism of action that provides the contraceptive activity. Spermicides act by immobilizing or killing sperm on contact. They act as mechanical barriers to sperm and need to be placed into the vagina prior to each act of intercourse. The active ingredients are contained in suppositories, aerosol foams, creams, gels, tablets, and vaginal contraceptive film. The most common spermicidal agent is nonoxynol-9, a surfactant agent that destroys the cell membrane of the spermatozoa.

Perfect use failure rate in the first year: 18%

Typical use failure rate in the first year: 29%

Spermicides have several important advantages. They are simple, inexpensive, available without prescription, and provide freedom from systemic side effects, except the occasional allergic reaction. Spermicides are easy to use but require some instructions. They can be used as a primary method of contraception or as a supplemental method to other forms of birth control.

Spermicides containing nonoxynol-9 are not effective in preventing STDs or HIV. When HIV exposure is a concern, the client should be advised against the frequent use of spermicides (two or more times per day) which can cause vulvovaginal epithelial disruption and theoretically increase susceptibility to HIV.

If irritation occurs immediately after insertion of the spermicide, changing to an alternative product with different carrier constituents or changing to a less concentrated product may help.

If symptoms persist more than a day or two after discontinuing the spermicide exposure, evaluate for underlying factors, including the possibility of STD exposure.

Plan of Action

1. The client should follow the manufacturer's package instructions on the proper use of the specific spermicide preparation.
2. The client should use a spermicide every time she has intercourse.
3. The client should have sufficient supplies available and be familiar with the recommended waiting time between the application of a spermicide and the onset of sexual activity.
4. The client must apply a new application of spermicide with every act of intercourse.
5. The spermicide must be left in place for at least 6-8 hours after intercourse.

6. Douching is not recommended. However, if the client should douche, she should wait at least 6-8 hours after intercourse before doing so.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Zieman M, Hatcher RA et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2007

Medical Eligibility Criteria For Contraceptive Use. 3rd Ed., Reproductive Health and Research, World Health Organization, Geneva, Switzerland, 2004

STANDARD DAYS METHOD

Rationale

The Standard Days Method (SDM) is one of the Fertility Awareness-Based (FAB) methods that uses a couple's understanding, acceptance and use of their phases of fertility and infertility for the purpose of achieving or avoiding pregnancy.

For contraception, SDM requires that a woman have regular menstrual intervals or cycles between 26 and 32 days. It further requires that she avoid unprotected sexual intercourse on days 8-19 of the cycle, if she wishes to avoid pregnancy.

Perfect use failure rate in the first year of use: 5%
Typical use failure rate in the first year of use: 12%

SDM is a safe, natural method of contraception with no side effects. It is inexpensive, acceptable to any religious belief, and promotes fertility awareness. However, SDM requires periodic abstinence and offers no STI protection.

Certain circumstances are not optimal for SDM use, such as recent childbirth, current breastfeeding, recent menarche, approaching menopause, and recent discontinuation of hormonal contraceptive methods.

Plan of Action

1. The client's cycle length must be 26-32 days, counting day 1 as the first day of menstrual bleeding.
2. The client can have unprotected intercourse on days 1-7 of the menstrual cycle.
3. The client should abstain from sexual intercourse or use a barrier method on days 8-19 of the menstrual cycle.
4. The client can have unprotected sexual intercourse from day 20 until the end of the menstrual cycle.
5. The client can use CycleBeads™, a color-coded string of beads to help her track her cycle days and know when she is fertile. For more information about CycleBeads, visit the website at www.cyclebeads.com.
6. More information about SDM, contact the Institute for Reproductive Health at 202-687-1392, e-mail at irhinfo@georgetown.edu, or the website at www.irh.org.
7. Offer advanced placement emergency contraception to be used if, during days 8-19 of the menstrual cycle, abstinence is not possible or there is a failure of barrier method use.

Follow-up

1. Re-evaluate the client's success in using the Standard Days Method.
2. Provide advanced placement emergency contraception if indicated.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Zieman M, Hatcher RA et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2007

Medical Eligibility Criteria For Contraceptive Use. 3rd Ed., Reproductive Health and Research, World Health Organization, Geneva, Switzerland, 2004

Selected Practice Recommendations For Contraceptive Use. 2nd Ed., Reproductive Health and Research, World Health Organization, Geneva, Switzerland, 2004

STERILIZATION – FEMALE

Rationale

Female sterilization, also called tubal ligation, is the most frequently used method of contraception by women in the United States. It is the method of choice for women who have completed their families and are over age 35.

Female sterilization involves cutting or mechanically blocking the fallopian tubes to prevent the sperm and eggs from uniting. Tubal ligation can be done as an outpatient operation or in the immediate postpartum period. Laparoscopy and mini-laparotomy are the procedures generally used. The tubal lumen may be occluded by procedures that include electrocoagulation, rings or clips or partial tubal removal. The failure rate is approximately 0.5%. Failure rates vary depending on the skill and experience of the surgeon, type of procedure performed and the age of the client. No procedure provides protection against sexually transmitted infections.

Recently an operation has been developed for occluding the tubes through a hysteroscopy approach using Essure® micro-inserts. One insert is placed in the proximal section of each fallopian tube lumen using a standard hysteroscope. The micro-insert expands upon release and tissue in-growth into the micro-insert permanently anchors the device and occludes the fallopian tube, resulting in sterilization. Benefits include safety, effectiveness and permanency. The Essure failure rate is less than 0.2%. Backup contraception must be used for at least 3 months when a hysterosalpingogram is required to demonstrate both satisfactory location of the micro-inserts and bilateral tubal occlusion.

Sterilization should be considered a permanent procedure. The client must be fully informed, and the benefits and risks discussed. An estimated 1% of sterilized women will subsequently request reversal. Most of these are young women, many with new partners. Reversal surgery following tubal ligation is difficult and expensive. The subsequent pregnancy rates average only about 50%.

Plan of Action

1. A client requesting sterilization should be informed that it is considered a permanent procedure, but also that the potential for failure does exist.
2. Inform the client of the benefits and risks of the procedure.
3. Refer the client to a physician who will do the procedure.
4. See Maryland State Family Planning Program Administrative Guidelines for information on tubal ligation referral.

Primary References

ACOG. Precis: Gynecology. 3rd Ed., 2006

ACOG. Benefits and Risks of Sterilization. Practice Bulletin #46, September 2003

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Zieman M, Hatcher RA et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2007

STERILIZATION – MALE

Rationale

Vasectomy is the male permanent sterilization procedure. It is an outpatient procedure that takes about 20 minutes and is usually performed under local anesthesia. Vasectomy is safer, less expensive, and at least as effective as tubal ligation.

The vasectomy involves cutting and/or blocking the vas deferens and preventing the passage of sperm into the seminal fluid.

The perfect use failure rate in the first year is 0.10%. Failure rates vary depending on the skill and experience of the surgeon and the manner in which the procedure is done.

Vasectomy should be considered a permanent procedure. Reversal is a difficult procedure and is successful only 50% of the time, if done within 10 years of the vasectomy.

Vasectomy is not immediately effective as it takes up to 3 months to empty the vas of sperm. Another form of contraception should be used during the first 3 months after the vasectomy. A semen analysis 3 months after the procedure is recommended to verify azospermia. Studies have failed to show that either autoimmune or cardiovascular diseases are more common after vasectomy. Also, there is no increased risk for prostate cancer among men who have undergone vasectomy. This method does not protect against sexually transmitted infection.

Plan of Action

1. A client requesting vasectomy should be informed that it is considered a permanent procedure, but also that the potential for failure does exist.
2. Inform the client of the benefits and risks of the procedure.
3. Refer the client to a physician who will do the procedure.
4. See Maryland State Family Planning Program Administrative Guidelines for information on vasectomy referral.

Primary References

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Zieman M, Hatcher RA et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2007

ACOG. Benefits and Risks of Sterilization. Practice Bulletin #46. September 2003

SUBSTANCE ABUSE

Rationale

Drug abuse can be thought of as taking drugs prohibited by law or taking drugs in a manner not intended by the prescriber. However, it has now become difficult to draw a line between drug abuse and the recreational use of legal agents such as alcohol, tobacco, and prescription medication.

A common trait among drug abusers is the repetitive consumption of a given agent. Dependence is a term often used to describe the relationship between the drug user and the drug. The use of illegal drugs is associated with a complex drug-seeking behavior and a unique lifestyle.

Substance abuse is associated with early sexual activity. This early sexual activity and associated risk-taking behavior increase the risk of unintended pregnancy and exposure to sexually transmitted diseases.

Tobacco use is the principal cause of premature death in this country and a major cause of disability. The use of combined estrogen/progestin contraceptives is contraindicated for clients age 35 and over who smoke.

Plan of Action

1. All clients should be questioned about drug, alcohol, and tobacco use (Appendix A, B, and C).
2. Clinicians should discuss the risks of drug, alcohol, and tobacco use relevant to sexual activity, STD protection, and contraception choices and use.
3. The treatment plan includes consultation with social services and referral to appropriate agencies for care.

Primary References

ACOG. *Precis: Primary and Preventive Care*. 3rd Ed., 2004

Hatcher RA et al. *Contraceptive Technology*. 19th Revised Edition. Ardent Media, Inc., New York, 2007

ACOG. *At-Risk Drinking and Illicit Drug Use: Ethical Issues in Obstetric and Gynecologic Practice*. Committee Opinion #294, May 2004

APPENDIX A

SIGNS AND SYMPTOMS OF SUBSTANCE ABUSE

Physical Findings

- Track marks and other evidence of intravenous drug use
- Alcohol on the breath
- Scars, injuries
- Hypertension
- Tachycardia or bradycardia
- Tremors
- Slurred speech
- Self-neglect or poor hygiene
- Liver or renal disease
- Runny nose
- Chronic cough
- Cheilosis
- Nervous mannerisms (e.g., frequent licking lips, jitters, foot tapping)
- Pinpoint or dilated pupils
- Reproductive dysfunction (hypogonadism, irregular menses, miscarriage, infertility, fetal alcohol syndrome)

Psychologic Problems

- Memory loss
- Depression
- Anxiety
- Panic
- Paranoia
- Unexplained mood swings
- Personality changes
- Intellectual changes
- Sexual promiscuity
- Dishonesty
- Unreliability

APPENDIX B

SIGNS AND SYMPTOMS OF SUBSTANCE ABUSE

SUBSTANCE	MAIN PHYSICAL SYMPTOMS AND SIGNS	DANGERS OF ABUSE
Alcohol: (beer, wine, liquor)	Slurred speech, relaxed inhibitions, impaired, coordination, slowed reflexes, glazed eyes, smell of alcohol on clothes/body, hangover. LOOK FOR: New bottles or less in family supplies.	Addiction, accidents as result of impaired ability and judgment, overdoses when mixed with other depressants, heart and liver damage.
Marijuana: (pot, dope, grass, weed, herb, hash, joint)	Altered perceptions, red eyes, dry mouth, reduced concentration and euphoria. LOOK FOR: Rolling papers, pipes, dried plant material, odor of burnt hemp rope, roach clips.	Panic reaction, impaired short-term memory, hampered judgment, accelerated heartbeat, possible increased blood pressure.
Cocaine: (coke, rock, crack, base)	Euphoria followed by depression, elevated blood pressure and heart rate, irritability, anxiety, paranoia. LOOK FOR: Glass vials, glass pipe, white powder, razor blades, syringes, needle marks.	Nasal problems, addiction, heart attack, seizures, lung damage, severe depression, paranoia.
Hallucinogens: LSD, PCP, MDMA, psilocybin (acid, mushrooms, Ecstasy, peyote)	Altered mood and perceptions, focus on detail, anxiety, panic nausea, synaesthesia. (ex: smell colors, see sounds) LOOK FOR: capsules, tablets, "microdots", blotter squares.	Unpredictable behavior, emotional instability, violent behavior (with PCP).
Inhalants: (gas, glue, aerosols, nitrates, Rush, Whiteout)	Nausea, dizziness, headaches, lack or coordination and control, drowsiness. LOOK FOR: Odor of substance on clothing and breath.	Unconsciousness, suffocation, nausea and vomiting, damage to brain and central nervous system, sudden death.
Narcotics: Heroin (junk, dope, black tar, China white), Demerol (D's), Morphine, Codeine	Euphoria, drowsiness, respiratory depression, nausea, vomiting, constricted pupils. LOOK FOR: Syringes, spoons, needles, needle marks on arms.	Addiction, lethargy, weight loss, contamination from unsterile needles (hepatitis, HIV/AIDS), accidental overdose.
Stimulants: Caffeine, Nicotine, Cocaine, amphetamines, (speed, uppers, crank, bam, black beauties, crystal, dexies)	Alertness, talkativeness, increased blood pressure, loss of appetite, wakefulness, loss of weight, mood elevation, irritability, hyperactivity, LOOK FOR: Capsules and pills.	Fatigue leading to exhaustion, aggressiveness, severe anxiety, paranoia, depression, confusion, possible hallucinations, addiction.
Depressants: Barbiturates, Sedatives, Alcohol, Tranquillizers (downers, tanks, ludes, reds, yellow jackets)	Depressed breathing and heartbeat, intoxication, drowsiness, longer periods of sleep, uncoordinated movements, slurred speech, confused behavior. LOOK FOR: Capsules and pills.	Possible overdose, especially in combination with alcohol: muscle rigidity, addiction, withdrawal and overdose requiring medical treatment.

ADDITIONAL INFORMATION AVAILABLE FROM:

National Clearinghouse for Alcohol for Alcohol and Drug Information
 11300 Rockville Pike, Suite 901
 Rockville, MD 20852
 1-800-729-6686

APPENDIX C

CAGE QUESTIONNAIRE

- C** Have you ever felt you ought to **C**ut down on your drinking?
- A** Have people **A**nnoyed you by criticizing your drinking?
- G** Have you ever felt bad or **G**uilty about your drinking?
- E** Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (**E**ye opener)?

Any “yes” answers to these questions requires further assessment of the client’s potential for alcohol abuse.

Assessment and source materials can be ordered from the NIAA Publications Distribution Center, P.O. Box 10686, Rockville MD 20849-0686; phone: 301-443-3860. They are also available in full text on NIAAA’s Web site (www.niaaa.nih.gov).

SYPHILIS

Rationale

Syphilis is caused by a spirochete, *Treponema pallidum*, and is considered a chronic systemic infection. It remains a serious health problem. Treponemal antibody test (FTA), once positive usually remains so for life regardless of the treatment or disease activity.

Nontreponemal antibody titers (VDRL or RPR) tend to correlate with disease activity. A high titer (>1:16) usually indicates disease. A fourfold change in titer, equivalent to a change of two dilutions (e.g., from 1:16 – 1:4 or from 1:8 – 1:32), is considered necessary to demonstrate a clinically significant difference between two nontreponemal test results that were obtained using the same serologic test. Sequential serologic tests in individual clients should be performed by using the same testing method (e.g., VDRL or RPR), preferably by the same laboratory. Nontreponemal tests usually become nonreactive with time after treatment.

Sexual transmission of *T. pallidum* occurs only when mucocutaneous syphilitic lesions are present; such manifestations are uncommon after the first year of infection. However, persons exposed sexually to an individual who has syphilis at any stage should be evaluated clinically and serologically and treated.

Plan of Action

1. Women who attend family planning clinics should be offered nontreponemal serologic screening for syphilis annually if they are at risk and especially if they meet any one of the following criteria:
 - a. Persons with a sexually transmitted disease within the last year, including HIV
 - b. Exchange of sex for drugs or money (client or partners)
 - c. Illicit drug use (client or partners)
 - d. History of admittance to jail or other detention facility (client or partners)
 - e. Sex with partner with high-risk behavior, including men having sex with men
 - f. Sexual partner diagnosed with active syphilis
 - g. Any skin lesions suggesting syphilis
2. A positive nontreponemal serologic test (VDRL or RPR) should be followed immediately with a treponemal antibody serologic test (FTA) to confirm the diagnosis of syphilis. If the RPR or VDRL serologic test for syphilis is reactive, but the FTA is non-reactive, and there is no clinical evidence of syphilis, treatment is not indicated. In this instance, both tests should be repeated within 4 weeks. The nontreponemal tests may yield false-positive results in individuals who recently experienced an

acute febrile illness, recent immunization, or are pregnant. Persistent false-positive results are seen in individuals with chronic infections, autoimmune disease, or narcotic addiction. The titers are usually less than 1:8.

3. In the public health setting clients with suspicious lesions should be evaluated promptly by the local STD clinic. Darkfield examination and direct fluorescent antibody tests of lesion exudate or tissue are the definitive methods of diagnosis.
4. In the public health setting treatment of syphilis is accomplished by the local STD clinic using the CDC's 2006 Sexually Transmitted Diseases Treatment Guidelines. Parenterally administered penicillin G is the preferred drug for the treatment of all stages of syphilis.
5. All clients who have syphilis should be tested for HIV.
6. Women exposed to syphilis through an infected partner should be tested and then treated presumptively by the local STD clinic.
7. Treatment of the male sexual partner is an important part of the therapeutic regimen. The partner should be referred for treatment and evaluation for other reproductive tract infections.
8. The time periods before treatment used for identifying at-risk sexual partners are:
 - a) 3 months plus duration of symptoms for primary syphilis,
 - b) 6 months plus duration of symptoms for secondary syphilis,
 - c) 1 year for early latent syphilis.

Follow-up

Ideally follow-up is coordinated with the STD provider. Treatment failure can occur with any regimen of treatment. Quantitative nontreponemal serologic test should be repeated at 6, 12, and 24 months. Failure of nontreponemal test titers to decline fourfold within 6 months after therapy for primary or secondary syphilis might be indicative of probable treatment failure. Promptly refer the client back to STD clinic.

Primary References

CDC. Sexually Transmitted Diseases Treatment Guidelines. 2006

ACOG. Precip: Primary and Preventive Care. 3rd Ed., 2004

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

ACOG. Health Care for Adolescents. 2003

ACOG. Sexually Transmitted Diseases in Adolescents. Committee Opinion #301, October 2004

TRICHOMONIASIS

Rationale

Trichomoniasis is caused by *Trichomonas vaginalis*, an anaerobic flagellated motile parasite that is usually sexually transmitted. This vaginitis is characterized by a yellow-green homogenous discharge that can be symptomatic or asymptomatic. Vulvar irritation and odor are common. This infection can occur via fomites. The infecting organism has been shown to survive in swimming pools and hot tubs.

Trichomoniasis has been associated with premature rupture of membranes, preterm birth, ectopic pregnancy, infertility, PID, and endometritis. It often coexists with other STIs and BV. Trichomoniasis facilitates HIV transmission.

Plan of Action

1. Diagnosis is usually made by direct microscopic visualization (saline wet prep) with the observation of motile trichomonads. Even with classic symptoms and speculum examination, trichomonads may be absent in 30% of wet prep examinations.
2. Cultures and DNA probe tests are usually not necessary for diagnosis and treatment.
3. Recommended treatment:
 - a. Metronidazole (Flagyl®) 2 g orally in a single dose

OR

 - b. Tinidazole (Tindamax®) 2 g orally in a single dose
4. Alternate treatment option:

Metronidazole (Flagyl®) 500 mg orally twice a day for 7 days
5. The client should avoid alcoholic beverages during metronidazole or tinidazole therapy because the combination may produce symptoms including abdominal cramps and vomiting. Refraining from alcohol use should continue for 24 hours after completion of metronidazole or 72 hours after completion of tinidazole.
6. Simultaneous treatment of the sexual partner(s) must be done to prevent the spread and/or recurrence of this infection. The partner(s) should be referred for treatment or may be treated in the FP clinic with appropriate documentation.
7. Sexual intercourse must be avoided until the treatment is completed and both the client and partner(s) have been treated and are asymptomatic.

Follow-up

1. Clients should return for follow-up visits if symptoms persist or recur.

2. Confirm that both client and partner(s) were treated and that sexual intercourse has been avoided during the treatment. Re-treatment may be necessary.
3. The initial regimen for treatment failure is metronidazole 500 mg orally twice a day for 7 days or tinidazole 2 g orally in a single dose.
4. The regimen for repeated treatment failures is metronidazole or tinidazole 2 g orally in a single dose daily for 5 days.
5. When trichomonads are reported on a Pap smear, a client may be treated if symptomatic. A repeat Pap smear is not necessary but a wet prep may be done to confirm the diagnosis or rule out co-infection.

Primary References

CDC. Sexually Transmitted Diseases Treatment Guidelines. 2006

ACOG. Precis: Gynecology. 3rd Ed., 2006

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

TUBERCULOSIS

Rationale

Tuberculosis (TB) results from infection by *Mycobacterium tuberculosis*. TB is primarily an infection of the pulmonary system. Transmission is by aerosolized droplets of liquid containing bacteria, which are inhaled by a noninfected individual and taken into the lung. The bacteria become lodged in the alveoli, where they may implant and cause infection.

Individuals who contract TB infection but do not yet have the disease are asymptomatic because the bacteria are not active and can not be spread to others. It may be years later that clinical signs and symptoms of disease occur. People with TB disease are sick from TB bacteria that are active and may be capable of spreading the disease to others.

Symptomatic individuals may present with cough, fatigue, loss of appetite, weight loss, fever and night sweats.

Skin testing should be performed as a screening test for selected high-risk populations. A definitive diagnosis depends on demonstration of *Mycobacterium tuberculosis* by culture or identification of the organism by DNA or RNA amplification techniques.

Plan of Action

1. Offer tuberculin skin testing (TST) and a Tuberculosis fact sheet (Appendix A) to high-risk clients who meet any of the following criteria listed below or in Appendices B and/or C:
 - a. The client has spent time with a person known or suspected to have active TB disease; or
 - b. The client has HIV infection or another condition that weakens the immune system and puts her at high risk for active TB disease; or
 - c. The client has symptoms of active TB disease; or
 - d. The client is from a country where active TB disease is very common (Appendix C); or
 - e. The client lives or works somewhere in the United States where active TB disease is more common, such as a homeless shelter, migrant farm camp, prison or jail, and some nursing homes (Appendix B); or
 - f. The client injects illegal drugs.
2. Skin testing should not be administered to clients with a documented history of a positive tuberculin skin test in the past.

3. Interpretation of the tuberculin skin test reaction size should be made in accordance with the CDC and State of Maryland Guidelines (Appendix B).
4. If the tuberculin skin test is negative, no further evaluation is needed unless the client has symptoms, is HIV-positive or an identified contact to an active case. This group should be referred to the local health department's TB Control Program for further evaluation.
5. Clients who have a positive skin test and a normal chest x-ray should be referred for possible chemoprophylaxis which usually consists of isoniazid for 9 months.
6. Clients with suspected active disease or positive skin test and abnormal chest x-ray should be referred to the local health department for additional evaluation and treatment. The initial treatment regimen for TB generally consists of isoniazid (INH), rifampin (RIF), ethambutol (EMB) and pyrazinamide (PZA). PZA is not used during pregnancy.
7. Refer the client to the local health department TB program. It is responsible for follow-up of all TB related issues.
8. In discussions about family planning for clients being treated for TB, remember that any of the rifampins will increase the hepatic clearance of ethinyl estradiol and progestins; therefore hormonal contraceptives with these components should not be used. Pregnancy should be delayed for women receiving TB treatment or chemoprophylaxis.

Primary References

Red Book: 2006 Report of the Committee on Infectious Diseases. 27th Ed., American Academy of Pediatrics, Elk Grove Village, IL

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

Tierney LM Jr. et al. Current Medical Diagnosis and Treatment. 44th Ed., McGraw-Hill, New York, 2005

Maryland TB Guidelines for Prevention and Treatment of Tuberculosis. Maryland Department of Health and Mental Hygiene. 2007

ACOG. Precis: Primary and Preventive Care. 3rd Ed., 2004

DHMH. Tuberculosis Fact Sheet. April 2009

CDC. Questions and Answers about TB. 2009

APPENDIX A

TUBERCULOSIS FACT SHEET

Tuberculosis (TB) is a disease caused by a germ called *Mycobacterium tuberculosis*

Tuberculosis (TB) is a disease that is spread from person to person through the air. TB usually affects the lungs. The TB germs are put into the air when a person with TB of the lung coughs, sneezes, laughs, or sings. TB can also affect other parts of the body, such as the brain, the kidney, or the spine. Tuberculosis is a disease that can be cured if treated properly.

What are the symptoms of TB disease?

The general symptoms of TB disease include feelings of sickness or weakness, weight loss, fever, and night sweats. The symptoms of TB disease of the lungs also include coughing, chest pain, and the coughing up of blood. Symptoms of TB disease in other parts of the body depend on the area affected.

What is the difference between latent TB infection and TB disease?

People with latent TB infection have TB germs in their bodies, but they are not sick because the germs are not active. These people do not have symptoms of TB disease, and they cannot spread the germs to others. However, they may develop TB disease in the future. They are often prescribed treatment to prevent them from developing TB disease. People with TB disease are sick from TB germs that are active; multiplying and destroying tissue in their bodies. They usually have symptoms of TB disease. People with TB disease of the lungs or throat are capable of spreading germs to others. They are prescribed drugs that can treat TB disease.

How to you get tested for TB?

There are several tests that can be used to help detect TB infection: a skin test or a special TB blood test. The Mantoux tuberculin skin test is performed by injecting a small amount of fluid (called tuberculin) into the skin in the lower part of the arm. A person given the tuberculin skin test must return within 48 to 72 hours to have a trained health care worker look for a reaction on the arm. The special TB blood test measures how the patient's immune system reacts to the germs that cause TB.

What does a positive test for TB infection mean?

A positive test for TB infection only tells that a person has been infected with TB germs. It does not tell whether or not the person has progressed to TB disease. Other tests, such as a chest x-ray and a sample of sputum, are needed to see whether the person has TB disease.

Why is latent TB infection treated?

If you have latent TB infection but not TB disease, your doctor may want you to take a drug to kill the TB germs and prevent you from developing TB disease. The decision about taking treatment for latent infection will be based on your chances of developing TB disease. Some people are more likely than others to develop TB disease once they have TB infection. This includes people with HIV infection, people who were recently exposed to someone with TB disease, and people with certain medical conditions.

(continued)

TUBERCULOSIS FACT SHEET – page 2

How is TB disease treated?

TB disease can be treated by taking several drugs for 6 to 12 months. It is very important that people who have TB disease finish the medicine, and take the drugs exactly as prescribed. If they stop taking the drugs too soon, they can become sick again; if they do not take the drugs correctly, the germs that are still alive may become resistant to those drugs. TB that is resistant to drugs is harder and more expensive to treat. Staff of the local health departments meets regularly with patients who have TB to watch them take their medications. This is called directly observed therapy (DOT). DOT helps the patient complete treatment in the least amount of time.

What should I do if I have been exposed to someone with TB disease?

People with TB disease are most likely to spread the germs to people they spend time with every day, such as family members or coworkers. If you have been around someone who has TB disease, you should go to your doctor or your local health department for tests.

Tuberculosis Fact Sheet. April 2009
Maryland Department of Health and Mental Hygiene
Office of Epidemiology and Disease Control Program
Adapted from Centers for Disease Control “Tuberculosis – Get the Facts!”

APPENDIX B

**RISK GROUPS FOR TARGETED TESTING AND TREATMENT
OF LATENT TB INFECTION (ADULTS) WITH TUBERCULIN SKIN TESTING
(TST) CUT-POINTS¹**

TST Positive	Risk Group
≥5 mm	<ul style="list-style-type: none"> • HIV infection • Recent contacts of TB case patients • Fibrotic changes on chest x-ray consistent with prior TB • Clinical findings or x-rays suggesting TB • Immunosuppressed patients (organ transplants or those receiving equivalent of >15 mg/d of prednisone for 1 month or more) • Persons taking infliximab (Remicade®) and other anti-TNF-alpha drugs
≥10 mm	<ul style="list-style-type: none"> • Recent immigrants (i.e., within the last 5 years) from high-incidence countries (Appendix C) • Injection drug users • Residents of long-term care facilities and assisted living facilities • Prison and jail inmates • Homeless persons/migrant farm workers • Employees² of: <ul style="list-style-type: none"> -prisons and jails -long-term care facilities for the elderly -hospitals and other health care facilities -residential facilities for AIDS patients -homeless shelters • Mycobacteriology laboratory personnel • Persons with the following clinical conditions: <ul style="list-style-type: none"> -silicosis -diabetes mellitus -chronic renal failure -some malignancies (e.g., leukemias and lymphomas, carcinoma of the head or neck and lung) -underweight (>10% under ideal body weight) -gastrectomy and jejunio-ileal bypass
≥10 mm increase	<ul style="list-style-type: none"> • Skin test converters (TST converts) (TST converts from negative to positive within 2 years)
≥15 mm	<ul style="list-style-type: none"> • Low-risk adults

¹Adapted from: Maryland State Guidelines for Prevention and Treatment of Tuberculosis. 2007.

²For pre-employment testing of employees, previously at low risk, use a ≥15 mm cut-point.

APPENDIX C

COUNTRIES/AREAS WITH AN ESTIMATED OR REPORTED HIGH TUBERCULOSIS INCIDENCE, 2001

Africa	All countries, except Libya		
Asia	All countries		
Australia and South Pacific	American Samoa French Polynesia Marshall Islands New Caledonia Palau Solomon Islands Tuvalu	Cook Islands Guam Micronesia Niue Papua New Guinea Tokelau Vanuatu	Fiji Kiribati Nauru Northern Mariana Islands Samoa Tonga Wallis and Futina Islands
North, Central and South America	Argentina Bolivia Dominican Republic Guatemala Honduras Panama Suriname	Bahamas Brazil Ecuador Guyana Mexico Paraguay Venezuela	Belize Columbia El Salvador Haiti Nicaragua Peru
Europe	Belarus Croatia Latvia Moldova, Republic of Romania Yugoslavia	Bosnia-Herzegovina Estonia Lithuania Poland Russian Federation	Bulgaria Hungary Macedonia Portugal Ukraine
Middle East	Bahrain Saudi Arabia Yemen	Iran Syrian Arab Republic	Iraq Turkey

Source: Global Tuberculosis Programme. World Health Organization. Global Tuberculosis Control: WHO Report 2003. "High-incidence areas" are defined by the Maryland State Department of Health and Mental Hygiene, Division of Tuberculosis Control as areas with reported or estimated incidence of ≥ 15 smear-positive cases per 100,000 persons.

Most countries/areas that are not listed should be considered low incidence (<15 smear-positive cases per 100,000 persons) based on estimated or reported rates. However, for Liechtenstein there was not enough data available to be considered low or high incidence.

URINARY TRACT INFECTION

Rationale

More than half of women will have at least one UTI in her lifetime and 3-5% of all women will have multiple recurrences. They most commonly result from ascending transurethral invasion of the bladder by bacilli normally present in the large bowel and perineum. *Escherichia coli* represent 80-90% of the infections. Other organisms found are *Klebsiella*, *Proteus*, *Enterobacter*, *Pseudomonas*, and *Staphylococcus*.

Risk factors for UTI in women include frequent or recent sexual activity, diaphragm contraception use, use of spermicidal agents, increasing parity, diabetes mellitus, obesity, sickle cell trait, anatomic congenital abnormalities, urinary tract calculi, and use of indwelling or repetitive bladder catheterization.

Typical symptoms of UTI include dysuria, frequency and urgency.

Traditionally, an active urinary tract infection is a bacterial count over 100,000 organisms of the same species per milliliter in a fresh "clean-catch" midstream specimen. Lower counts ($\geq 1,000$) may require treatment in symptomatic women.

Plan of Action

1. In an otherwise healthy woman with no risk factors and little or no history of lower urinary tract infections, a short course of therapy may be given without obtaining a culture. Persistent symptoms of cystitis or urethritis for >48 hours after treatment would require urine culture and sensitivity studies.
 2. If laboratory evaluation is preferred, urine dipstick testing for leukocyte esterase or nitrite is a good screening test for UTI. However women with negative results and symptoms should still have a clean-catch midstream urine culture.
 3. Recommended treatment options for uncomplicated UTI (prior to culture):
 - a. Trimethoprim-sulfamethoxazole (Bactrim DS® or Septra DS®) 1 tablet orally twice a day for 3 days (Main disadvantages are increasing drug resistance and allergy to sulfa)
- OR
- b. Trimethoprim (Trimplex®, Proloprim®, Primisol®) 100 mg orally twice a day for 3 days
- OR
- c. Ciprofloxacin (Cipro®) 250 mg orally twice a day for 3 days (Do not use during pregnancy or for teens under 18 years old due to potential joint arthropathy)

OR

- d. Nitrofurantoin monohydrate macrocrystals (Macrobid®) 100 mg orally twice a day for 7 days (Main advantage is lack of effect on vaginal flora - but it not effective against Proteus)
4. Consider a urine culture for women who have had >3 UTIs in past year, medical disorders (such as diabetes, immunosuppression, sickle cell disease) or other conditions predisposing to complicated UTIs. Presumptive treatment is appropriate for symptomatic clients before culture and sensitivity results are available. These patients may also need longer courses of antibiotics.
5. Clients with symptoms of upper UTI or pyelonephritis (such as fever, flank pain, abdominal pain, and nausea) should have a urine culture and be referred promptly for physician evaluation and treatment, since they may require IV antibiotics and hospitalization.
6. For pain relief in clients with severe symptoms, clients may purchase phenazopyridine 95 mg (AZO®, Uristat®, and Proidium®) over-the-counter.

Follow-up

1. High-risk clients and those with recurrent urinary tract infections should have follow-up urine cultures one to two weeks after treatment is completed.
2. Clients on oral contraceptives should be advised to use a back-up method (such as VCF/condoms) while on antibiotic treatment.
3. A diaphragm with spermicide for contraception should be avoided in clients with documented recurrent urinary tract infections. This method alters normal vaginal bacterial flora and increases the risk for cystitis.
4. Clients with persistent or recurrent infections, documented by culture, should be referred to a physician for evaluation. Long-term antibiotic therapy may be indicated, or the client may be a candidate for urologic evaluation.

Primary References

ACOG. Treatment of Urinary Tract Infections in Nonpregnant Women. Committee Opinion #91, March 2008

Institute for Clinical Systems Improvement (ICSI). Uncomplicated Urinary Tract Infection in Women. July 2006

VULVOVAGINAL CANDIDIASIS

Rationale

The most frequent cause of candida vulvovaginitis is candida albicans. The usual clinical picture is that of itching, burning, irritation, dyspareunia, and erythema. The discharge is usually thick, white, odorless and adherent to the vaginal walls. Risk factors include antibiotic use, corticosteroid use, diabetes, pregnancy, and immunosuppressive disorders, although most women with sporadic infections do not have any risk factors.

Plan of Action

1. Diagnosis is usually made by direct microscopic visualization of hyphae or spores (10% KOH wet prep). A negative KOH test does not exclude the diagnosis. Candida found on a Pap smear may represent an asymptomatic carrier, not necessarily needing treatment, rather than a woman with vulvovaginitis.
2. Recommended treatment options:
 - a. Terconazole (Terazol®)
 - 1) Terconazole 0.4% cream, 5 g intravaginally at bedtime for 7 days
OR
 - 2) Terconazole 0.8% cream, 5 g intravaginally at bedtime for 3 days
OR
 - 3) Terconazole 80 mg vaginal suppository, 1 suppository intravaginally at bedtime for 3 days
OR
 - b. Fluconazole (Diflucan®) 150 mg oral tablet, 1 tablet orally in a single dose
OR
 - c. Miconazole (Monistat®)
 - 1) Miconazole 2% cream, 5 g intravaginally at bedtime for 7 days*
OR
 - 2) Miconazole 100 mg vaginal suppository, 1 suppository intravaginally at bedtime for 7 days*
OR

- 3) Miconazole 200 mg vaginal suppository, 1 suppository intravaginally at bedtime for 3 days*

OR

- 4) Miconazole 1,200 mg vaginal suppository, 1 suppository intravaginally at bedtime for 1 day*

OR

d. Clotrimazole

- 1) Clotrimazole 1% cream, 5 g intravaginally at bedtime for 7-14 days*

OR

- 2) Clotrimazole 100 mg vaginal tablet, 1 tablet intravaginally at bedtime for 7 days

OR

- 3) Clotrimazole 100 mg vaginal tablet, 2 tablets intravaginally at bedtime for 3 days

OR

e. Butoconazole (Gynazole•1®)

- 1) Butoconazole 2% cream, 5 g intravaginally at bedtime for 3 days*

OR

- 2) Butoconazole 2% cream, 5g (Butoconazole 1 – sustained release) single application intravaginally at bedtime

OR

- f. Tioconazole (Vagistat-1®, 1-Day®) 6.5% ointment, 5 g intravaginally at bedtime in a single application*

OR

- g. Nystatin 100,000 unit vaginal tablet, one tablet intravaginally at bedtime for 14 days

* = over-the-counter (OTC) medications

3. Certain antifungal drugs interact with other medications. Miconazole and warfarin can lead to bleeding or bruising. Fluconazole may interact with coumarin-type anticoagulants, cyclosporine, oral hypoglycemics, phenytoin, rifabutin, rifampin, tacrolimus, theophylline, and COX-2 inhibitors (Vioxx®, Bextra®, and Celebrex®).
4. Many of the OTC vaginal preparations also have in the packaging a tube of the same ingredient for external vulvar use.
5. Latex barrier devices, including latex condoms and diaphragms, may break down when in contact with oil-based vaginal medications, such as miconazole, clotrimazole, terconazole, tioconazole, and butoconazole.
6. When there is vulvar inflammation, the use of an antifungal cream with or without a corticosteroid (such as hydrocortisone cream 0.5-1.0%, OTC) will reduce symptoms more readily.
7. Routine treatment of sex partners is usually unnecessary since this infection is not acquired through sexual intercourse.

Follow-up

1. Clients should return for follow-up visits if symptoms persist or recur.
2. Women with frequent or persistent infections should be evaluated for risk factors and be treated with the weekly therapies. Multiple treatments and/or maintenance regimens may be required.

Primary References

CDC. Sexually Transmitted Diseases Treatment Guidelines. 2006

ACOG. Precip: Gynecology. 3rd Ed., 2006

Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007

ACOG. Vaginitis. Practice Bulletin #72, May 2006

CONSENT FOR COLPOSCOPIC EXAMINATION

I, (print or type name) _____, give my consent for colposcopy, cervical biopsy, and endocervical curettage. Colposcopy is a diagnostic examination that permits a clinician to examine the cervix, vagina, and vulva with a special microscope to determine the cause of abnormal findings from an examination or Pap smear. The colposcopic examination will assist the clinician in determining or finding an abnormal area that is visible. In order to establish the degree of abnormality and to assist in the type of treatment, one or more biopsies may be taken. A cervical biopsy is a small sample of tissue that is obtained from the surface of the cervix. An endocervical curettage yields a small sample of tissue removed from just inside the opening in the cervix. After analysis of tissue specimens, the laboratory provides a diagnosis for guidance in possible treatment.

I understand that a single colposcopic examination might not explain my problem, and that additional examinations and testing might be recommended.

I understand that during or after the procedure one or more of the following might occur:

- Dizziness
- Fainting
- Cramping
- Mild bleeding
- Vaginal discharge
- Infection

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

Date: _____ Parent/Guardian Signature: _____

If translation of CONSENT FOR COLPOSCOPIC EXAMINATION was required:

- A translator was offered to the client. yes no
- The client chose to use her own translator. yes no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
(print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

Clinician Signature: _____

CONSENT FOR CRYOTHERAPY

I, (print or type name) _____, give my consent for cryotherapy. Cryotherapy is a form of treatment in which a freezing probe is applied to the cervix or other areas to accomplish the destruction of abnormal cells and the regrowth of normal tissue.

I acknowledge that no guarantees have been made or implied to me as to the result of this treatment. Follow-up evaluations for about two years should be anticipated.

I understand that during or after the procedure one or more of the following might occur:

- Dizziness
- Fainting
- Cramping
- Mild bleeding
- Vaginal discharge
- Infection

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

Date: _____ Parent/Guardian Signature: _____

If translation of CONSENT FOR CRYOTHERAPY was required:

- A translator was offered to the client. yes no
- The client chose to use her own translator. yes no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
(print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

Clinician Signature: _____

CONSENT FOR DEPOT MEDROXYPROGESTERONE ACETATE (DMPA)

I, (print or type name) _____, request the contraceptive injection of depot medroxyprogesterone acetate (also known as DMPA, Depo-Provera™, depo-subQ provera 104™, Depo, or “the Shot”), as my family planning method.

I have received a pamphlet (included with each injection) that has information about the benefits and risks of DMPA and how to use DMPA.

I understand that no birth control method is perfect and that some women have gotten pregnant while on DMPA (3 out of every 1000 women during the first year of use).

I understand DMPA will not protect me from sexually transmitted infections and that I need to use condoms for protection from these infections.

I understand that certain medicines may interact with DMPA to decrease the effectiveness of DMPA. I know it is important to tell all my health care providers that I am on DMPA.

I understand that when using DMPA, the chances of developing health problems increase with certain conditions such as:

- High cholesterol
- Age 35 or older
- Diabetes
- High blood pressure

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before using DMPA:

- Blood clots in the lungs, legs, or brain
- Unexplained bleeding from the vagina
- Inflammation of the veins
- Cancer of the breast
- Liver disease
- Heart disease or stroke

I understand that side effects sometimes associated with DMPA include:

- Weight gain
- Irregular bleeding or spotting
- Breast tenderness
- Hair loss
- Acne
- Depression

I know to watch for "A.C.H.E.S." as danger signals and to contact a health care provider immediately if these signs occur:

- Abdominal pains
- Chest pains or shortness of breath
- Headaches (severe), numbness, or dizziness
- Eye problems such as blurred vision or double vision
- Severe leg pain

I understand that there may be thinning of the bones with use of DMPA and that after stopping DMPA the bone structure might not return to normal. It is not known if use of DMPA as a teenager or young adult will increase the risk of fractures in the later years. DMPA should be used long-term (over 2 years) only if other forms of birth control are not satisfactory.

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

If translation of CONSENT FOR DEPOT MEDROXYPROGESTERONE ACETATE (DMPA) was required:

- A translator was offered to the client. yes no
- The client chose to use her own translator. yes no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
(print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

CONSENT FOR EMERGENCY CONTRACEPTIVE PILLS

I, (print or type name) _____, request emergency contraceptive pills (ECPs) to minimize a possible pregnancy risk. I understand it is not a main method of birth control.

I have received package instructions that have information about the benefits and risks of the ECPs that I have been given.

I understand that taking ECPs does not prevent pregnancy 100% of the time. Some pregnancies do occur. In spite of this, I wish to try to prevent pregnancy at this time.

I understand that the risk of development of birth defects in the fetus is unknown and that if treatment fails, I must accept this risk should I decide to continue with this pregnancy. No known increased fetal risk of congenital anomalies has been detected so far.

I understand that possible side effects of ECPs may include:

- Nausea and vomiting
- Breast tenderness
- Headaches and dizziness
- Tiredness
- Irregular vaginal bleeding
- Abdominal pain
- Menstrual cycle disturbances
- Diarrhea

I understand that if I see a health care provider for any reason before I get my period, I should tell him/her that I have taken ECPs.

I understand that I should expect my period within 1-3 weeks and I agree to have a pregnancy test if it has not occurred within that time. I will inform a health care provider of any severe lower abdominal pain. It may be a sign of a more serious condition such as ectopic pregnancy (pregnancy outside the uterus).

I understand that ECPs will not protect me against pregnancy from unprotected sexual intercourse after I have taken ECPs.

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

If translation of CONSENT FOR EMERGENCY CONTRACEPTIVE PILLS was required:

- A translator was offered to the client. yes no
- The client chose to use her own translator. yes no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
(print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

CONSENT FOR IMPLANON™ - SUBDERMAL CONTRACEPTIVE IMPLANT

I, (print or type name) _____,
request Implanon™- subdermal contraceptive implant as my family planning method.

I understand Implanon is good for 3 years and I have received a pamphlet that has information about the benefits, risks, and side effects of Implanon.

I understand that no birth control method is perfect and that some women have gotten pregnant while using Implanon (1 out of every 1000 women during the first year of use).

I understand Implanon will not protect me from HIV infection or other sexually transmitted infections and I need to use condoms for protection from these infections.

I understand that certain medicines may interact with the Implanon to decrease the effectiveness of Implanon. I know it is important to tell all my health care providers that I am using Implanon for birth control.

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before using Implanon:

- Blood clots in the lungs, legs, or brain
- Unexplained bleeding from the vagina
- Inflammation of the veins
- Cancer of the breast or uterus
- Liver disease
- Heart disease or stroke

I understand that it is important to tell my health care provider if I have ever had any of the following conditions so my health care provider can explain problems that could happen if I use Implanon:

- Diabetes
- High cholesterol
- Headaches
- Seizures or epilepsy
- Gall bladder or kidney disease
- Depression
- High blood pressure

I understand that side effects sometimes associated with Implanon include:

- Changes in menstrual bleeding pattern, or even no periods
- Spotting or bleeding between periods
- Weight gain
- Headaches
- Acne
- Depression, mood swings, nervousness

I understand that certain problems can be related to the insertion or removal of Implanon:

- Pain, irritation, swelling, or bruising at the insertion/removal site on the arm
- Thick scar tissue around the Implanon making it difficult to remove
- Infection at the insertion/removal site
- Need for hospitalization to remove Implanon (the cost is your responsibility)

I know to watch for "A.C.H.E.S." as danger signals and to contact a health care provider immediately if these signs occur:

- Abdominal pains
- Chest pains or shortness of breath
- Headaches (severe), numbness, or dizziness
- Eye problems such as blurred vision or double vision
- Severe leg pain

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

If translation of CONSENT FOR IMPLANON – SUBDERMAL CONTRACEPTIVE IMPLANT was required:

- A translator was offered to the client. yes no
- The client chose to use her own translator. yes no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
(print or type name of translator)
- Translator employed by, or relationship to the client: _____
- Date: _____ Translator Signature: _____

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

Clinician Signature: _____

CONSENT FOR NUVARING® - VAGINAL CONTRACEPTIVE RING

I, (print or type name) _____,
request the vaginal contraceptive ring as my family planning method.

I have received a pamphlet (included with each ring) that has information about the benefits and risks of the vaginal contraceptive ring and how to properly use the ring.

I understand that no birth control method is perfect and that some women have gotten pregnant while using the ring (3 out of every 1000 women during the first year of perfect use).

I understand the ring will not protect me from sexually transmitted infections and that I need to use condoms for protection from these infections.

I understand that certain medicines may interact with the ring to decrease the effectiveness of the ring. I know it is important to tell all my health care providers that I am on the ring.

I understand that when using the ring, the chances of developing health problems increase with certain conditions such as:

- Cigarette smoking
- High cholesterol
- Age 35 or older
- Diabetes
- High blood pressure

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before using the ring:

- Blood clots in the lungs, legs, or brain
- Unexplained bleeding from the vagina
- Inflammation of the veins
- Cancer of the breast or uterus
- Liver disease
- Heart disease or stroke

I understand that side effects sometimes associated with the ring include:

- Nausea and vomiting
- Weight gain or loss
- Breast tenderness
- Spotting between periods
- Vaginal discharge

I know to watch for "A.C.H.E.S." as danger signals and to contact a health care provider immediately if these signs occur:

- Abdominal pains
- Chest pains or shortness of breath
- Headaches (severe), numbness, or dizziness
- Eye problems such as blurred vision or double vision
- Severe leg pain

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

If translation of CONSENT FOR NUVARING – VAGINAL CONTRACEPTIVE RING was required:

- A translator was offered to the client. yes no
- The client chose to use her own translator. yes no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
(print or type name of translator)
- Translator employed by, or relationship to the client: _____
- Date: _____ Translator Signature: _____

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

CONSENT FOR ORAL CONTRACEPTIVES (BIRTH CONTROL PILLS)

I, (print or type name) _____,
request birth control pills (“the Pill”) as my family planning method.

I have received a pamphlet (included with each pack of pills) that has information about the benefits and risks of birth control pills and how to properly take birth control pills.

I understand that no birth control method is perfect and that some women have gotten pregnant while on the Pill (3 out of every 1000 women during the first year of perfect use).

I understand the Pill will not protect me from sexually transmitted infections and that I need to use condoms for protection from these infections.

I understand that certain medicines may interact with the Pill to decrease the effectiveness of the Pill. I know it is important to tell all my health care providers that I am on the Pill.

I understand that when taking the Pill, the chances of developing health problems increase with certain conditions such as:

- Cigarette smoking
- High cholesterol
- Age 35 or older
- Diabetes
- High blood pressure

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before taking the Pill:

- Blood clots in the lungs, legs, or brain
- Unexplained bleeding from the vagina
- Inflammation of the veins
- Cancer of the breast or uterus
- Liver disease
- Heart disease or stroke

I understand that side effects sometimes associated with the Pill include:

- Nausea and vomiting
- Weight gain or loss
- Breast tenderness
- Spotting between periods

I know to watch for "A.C.H.E.S." as danger signals and to contact a health care provider immediately if these signs occur:

- Abdominal pains
- Chest pains or shortness of breath
- Headaches (severe), numbness, or dizziness
- Eye problems such as blurred vision or double vision
- Severe leg pain

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

If translation of CONSENT FOR ORAL CONTRACEPTIVES (BIRTH CONTROL PILLS) was required:

- A translator was offered to the client. yes no
- The client chose to use her own translator. yes no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
(print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

CONSENT FOR ORTHO EVRA® - CONTRACEPTIVE PATCH

I, (print or type name) _____,
request the birth control patch as my family planning method.

I have received a pamphlet (included with each box of patches) that has information about the benefits and risks of the patch and how to properly apply the patch.

I understand that no birth control method is perfect and that some women have gotten pregnant while on the patch (1 out of every 100 women during the first year of use).

I understand the patch will not protect me from sexually transmitted infections and that I need to use condoms for protection from these infections.

I understand that certain medicines may interact with the patch to decrease the effectiveness of the patch. I know it is important to tell all my health care providers that I am on the patch.

I understand that when using the patch, the chances of developing health problems increase with certain conditions such as:

- Cigarette smoking
- High cholesterol
- Age 35 or older
- Diabetes
- High blood pressure

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before using the patch:

- Blood clots in the lungs, legs, or brain
- Unexplained bleeding from the vagina
- Inflammation of the veins
- Cancer of the breast or uterus
- Liver disease
- Heart disease or stroke

I understand that side effects sometimes associated with the patch include:

- Nausea and vomiting
- Weight gain or loss
- Breast tenderness
- Spotting between periods
- Skin irritation

I know to watch for "A.C.H.E.S." as danger signals and to contact a health care provider immediately if these signs occur:

- Abdominal pains
- Chest pains or shortness of breath
- Headaches (severe), numbness, or dizziness
- Eye problems such as blurred vision or double vision
- Severe leg pain

I understand that by using the birth control patch I will have a higher overall level of estrogen in my body than if I had used the typical birth control pill. This higher estrogen level may increase my risk of side effects, including blood clots in the lungs or legs.

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

If translation of CONSENT FOR ORTHO EVRA – CONTRACEPTIVE PATCH was required:

- A translator was offered to the client. yes no
- The client chose to use her own translator. yes no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
(print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

CONSENT FOR PARAGARD® INTRAUTERINE DEVICE

I, (print or type name) _____, request ParaGard® T 380A Intrauterine Copper Contraceptive (IUD) as my family planning method.

I have received “Information for Patients” in the Patient Package Insert for the ParaGard IUD that has information about the benefits and risks of using this IUD.

I understand that no birth control method is perfect and that some women have gotten pregnant while using the IUD (less than 1 in 100 women during the first year of use).

I understand the IUD will not protect me from sexually transmitted infections and that I need to use condoms for protection from these infections.

I understand that the ParaGard IUD is good for 10 years of use.

I understand that it is important to tell my health care provider if I have ever had any of the following conditions before using the ParaGard IUD:

- Might be pregnant now
- Uterus with abnormal shape
- Previous surgery of the uterus
- Cancer of the uterus or cervix
- Unexplained vaginal bleeding
- An infection in the uterus after pregnancy or abortion in the last 3 months
- A pelvic infection called PID, an infection of the uterus, tubes, and ovaries
- An infection of the cervix
- A new sex partner in the last 3 months
- Multiple partners in the last year
- A partner who is having sex with other people
- Other high-risk behavior for sexually transmitted diseases
- Wilson’s disease (a disorder in how the body handles copper)
- Allergy to copper

I understand that side effects sometimes associated with the ParaGard IUD include:

- Heavier or longer periods
- Spotting between periods
- Menstrual cramps
- Anemia
- Back pain
- Pain during sex
- Vaginal discharge
- Faintness
- Pain

I understand that rare but more serious side effects associated with the ParaGard IUD include:

- Pelvic inflammatory disease (PID), most likely to occur in the first 20 days after IUD insertion, or if you or your partner get a sexually transmitted disease
- Perforation of the uterus (the IUD goes through the uterus wall)
- Expulsion (the IUD may partially or completely fall out of the uterus)

I understand that I should contact a health care provider if I have any of the following:

- Miss a period or think that I might be pregnant
- Pelvic pain or pain during sex
- Unusual vaginal discharge
- Unexplained fever and/or chills
- Might be exposed to a sexually transmitted disease
- Can no longer feel the IUD string
- Severe or prolonged vaginal bleeding

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

If translation of CONSENT FOR PARAGARD® INTRAUTERINE DEVICE was required:

- A translator was offered to the client. yes no
- The client chose to use her own translator. yes no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
(print or type name of translator)
- Translator employed by, or relationship to the client: _____
- Date: _____ Translator Signature: _____

- The client has read this form or had it read to her by a translator or other person.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

Clinician Signature: _____

CONSENT FOR REPRODUCTIVE HEALTH SERVICES

I, (print or type name) _____, request family planning services from the _____ Health Department. I understand that I will give a medical history, have a physical examination, and may get several tests including but not limited to:

- Measurement of height, weight, and blood pressure
- Breast examination – for tumors and abnormalities
- Pelvic (vaginal) examination
- Pap test (Papanicolaou smear) – a screening test for cancer of the cervix and related conditions
- Male genital examination
- Tests for gonorrhea, chlamydia, and human papillomavirus (sexually transmitted infections)
- Urine test to check for diabetes and urine infection
- Urine and/or blood tests to check for pregnancy
- Blood tests to check for syphilis, anemia, and immunity to rubella
- Blood test for hemoglobin disorders
- Blood test for HIV (AIDS) infection
- Skin test for tuberculosis (TB)

I understand my health information is confidential. Confidential means that no one outside of the Health Department will be told about my visits or given information about my health care without my written permission. I understand that in certain cases (suspected child abuse/sexual abuse, child neglect) confidentiality cannot be kept because of Maryland law.

I request information about the different types of family planning methods which are available to me. I understand that these methods include, but are not limited to: fertility awareness methods, condoms, diaphragm, spermicide (vaginal film, foam, or gel), birth control pills, emergency contraception pills, intrauterine device (IUD), birth control “shot” (Depo-Provera), birth control skin patch (Ortho Evra), vaginal ring (NuvaRing) and skin implant (Implanon). With the help of my clinician I will decide on the family planning method which is best for me.

If it is found that I have a sexually transmitted infection, bladder infection, or other infection, I may request treatment for the infection.

If my test for gonorrhea, chlamydia, syphilis, or HIV is found to be positive, I understand that, by law, this result will be reported to the Division of Communicable Diseases of the Maryland State Department of Health and Mental Hygiene.

I understand that my health is my responsibility. I agree to call the family planning clinic for regular check-ups and to find out the results of my lab tests. I will tell the clinic if I change my address, phone number, or contact information. If I decide not to return to the clinic, I will seek care from another provider.

I understand that information in my health record may be disclosed in summary, statistical, or other forms without my consent when the information does not identify me by name.

I voluntarily agree to have family planning services. I understand that I may withdraw this consent at any time.

I understand and agree with the above statements.

Date: _____ Client Signature: _____

If translation of CONSENT FOR FAMILY PLANNING SERVICES was required:

- A translator was offered to the client. yes no
- The client chose to use his/her own translator. yes no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
(print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

- The client has read this form or had it read to him/her by a translator or other person.
- The client states that he/she understands this information.
- The client has indicated that he/she has no further questions.

Date: _____ Staff Signature: _____

FAMILY PLANNING INDIVIDUALIZED CONTACT PLAN

I, (print or type name) _____, request the following plan to contact me regarding my family planning visits:

It is my responsibility to call the clinic for my test results in 10 to 14 days after each clinic visit. I may be asked to call again at a later date if all the test results are not ready.

It is my responsibility to let the clinic know if I change my address, phone number, or my contact information.

I will call for appointments so I can continue to receive good health care.

If I fail to call the clinic within 10 to 14 days of my visit or fail to respond to the above written plan, and if a serious health problem is found, I understand the Health Department staff may contact me by telephone, letter, or certified letter.

I understand and agree with the above statements.

Date: _____ Client Signature: _____

If translation of FAMILY PLANNING INDIVIDUALIZED CONTACT PLAN was required:

- A translator was offered to the client. yes no
- The client chose to use his/her own translator. yes no
- This form has been orally translated to the client in the client's spoken language.
- Language translated: _____
- Translation provided by: _____
(print or type name of translator)
- Translator employed by, or relationship to client: _____
- Date: _____ Translator Signature: _____

- The client has read the form or had it read to him/her by a translator or other person.
- The client states that he/she understands this information.
- The client has indicated that he/she has no further questions.

Date: _____ Staff Signature: _____

FAMILY PLANNING ANNUAL/INTERVAL RECORD

Name _____

Age _____ Date of Birth _____

Allergies _____

G ___ T ___ P ___ A ___ L ___ LNMP _____ PMP _____

Current Method of Contraception _____

Current Medications (prescription, OTC, vitamins, herbal) _____

Reason(s) for Visit _____

INTERIM HISTORY (within the last 12 months or since the last exam or annual exam)

Date of last Pap _____ Results _____

Colposcopy/Abnormal Pap(s)/Rx _____

Changes in menstrual or bleeding pattern _____

Ever had sexual intercourse yes no Age of 1st intercourse _____

Type of sex vaginal oral rectal # of lifetime sexual partners _____

Sexual partners men women both Sexually active now yes no

Date of last sexual activity _____ vaginal oral rectal

Length of time with current partner _____

Condom use always sometimes never

New sexual partner in the last 3 months yes no

2 or more sexual partners in last year yes no

History of STD in the last year yes no Name of STD: _____

Any concern about a possible STD now yes no _____

Exchange of sex for drugs or money yes no

Illicit, street, or recreational drug use yes no

Sex partner: with STD in the last year yes no Name of STD _____

with IV drug use yes no

with exchange of sex for drugs or money yes no

with admittance to jail or other detention facility yes no

having sex with men yes no

with other high-risk behavior yes no

Smoking yes no (# cig/day) _____ Alcohol yes no (# drinks/wk) _____

Pregnant since last visit yes no _____

Breastfeeding yes no _____

Planning pregnancy in the next 12 months yes no _____

Sexual assault/domestic violence yes no _____

Sexual coercion yes no _____

Child abuse/neglect/sexual abuse yes no _____

Personal medical history update _____

Surgery/hospitalization update _____

Mental health update _____

Parental involvement yes no encouraged _____

Family history update (CV, BP, Stroke, Ca) _____

Date _____ Interpreter Name _____

Staff Signature _____

FAMILY PLANNING INTERVAL RECORD

Name _____

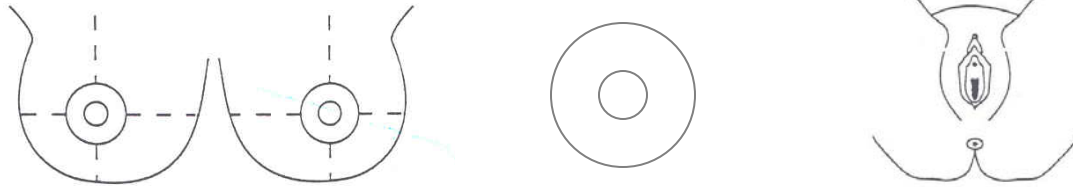
SUBJECTIVE _____

PHYSICAL EXAM BP _____ Wt _____ Ht _____ BMI _____ UCG _____

NORMAL			NORMAL		
HEAD			VULVA		
NECK			VAGINA		
HEART			CERVIX		
LUNGS			UTERUS		
BREASTS			ADNEXA		
ABDOMEN			RECTAL		
EXTREMITIES			OTHER		

PAP HPV CT GC HSV OTHER _____

WET MOUNT _____



COMMENTS _____

ASSESSMENT _____

PLAN _____

RETURN VISIT _____ **Chaperone Signature** _____

Date _____ **Interpreter Name** _____

Clinician Signature _____

FAMILY PLANNING COLPOSCOPY RECORD

Name _____

Age _____ Date of Birth _____

Allergies _____

G ___ T ___ P ___ A ___ L ___ LNMP _____ UCG _____

Current Method of Contraception _____

Current Medications (prescription, OTC, vitamins, herbal) _____

Initial colposcopy visit Follow-up colposcopy visit

Reason(s) for Visit _____

Pertinent past GYN history, medical history, history of abnormal Pap(s) and/or HPV test(s), colposcopy, related treatment and/or procedures _____

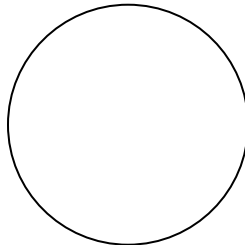
Date _____ Interpreter Signature _____

Date _____ Staff Signature _____

Colposcopy Findings:

Satisfactory yes no Pap HPV CT GC HSV Biopsy(s) ECC

Wet Mount _____



Assessment _____

Plan(s) after Colposcopy _____

Date _____ Chaperone Signature _____

Interpreter Signature _____ Colposcopist Signature _____

Summary of laboratory reports from this evaluation _____

Plan after reports _____

Date _____ Staff Signature _____

Interpreter Signature _____ Colposcopist Signature _____

FAMILY PLANNING DMPA INITIATION RECORD

Name _____

Age _____ Date of Birth _____

Allergies _____

Current Method of Contraception _____

Current Medications _____

LNMP _____ Last sexual intercourse _____

History

- Current known pregnancy or suspected pregnancy yes no
- Currently breastfeeding yes no
- Unexplained vaginal bleeding yes no
- Headaches with focal neurological symptoms and/or aura yes no
- Known or suspected breast cancer or history thereof yes no
- Hypertension (>140/90 mm Hg) or history thereof yes no
- Diabetes mellitus (vascular disease or >20 yrs duration) yes no
- Current thromboembolic disease or history thereof yes no
- Cerebrovascular or coronary artery disease or history thereof yes no
- Hepatic disease (tumors, hepatitis, cirrhosis) yes no
- Cancer of the endometrium (or estrogen dependent tumor) yes no

BP _____ Urine Pregnancy Test (if indicated) pos neg

Date _____ Interpreter Name _____

Staff Signature _____

Clinician Comments _____

Assessment DMPA contraception candidate yes no

Contraception Plan

- EC _____ offered given
- Condoms offered given
- DMPA (150 mg IM) offered given
- DMPA (104 mg SQ) offered given
- Other method of contraception initiated/continued/restarted _____

Clinician Comments _____

Return Visit _____

Date _____ Interpreter Name _____

Clinician Signature _____

FAMILY PLANNING EMERGENCY CONTRACEPTIVE PILLS RECORD

Name _____

Age _____ Date of Birth _____

Allergies _____

Current Method of Contraception _____

Current Medications _____

Last Normal Menstrual Period (LNMP) _____

Last bleeding episode, if not LNMP _____

Unprotected sexual intercourse

Reason for requesting ECPs _____

Date _____ Time _____ AM / PM

of hours since last unprotected intercourse _____

Any other unprotected intercourse since LNMP or other bleeding episode yes no

If yes, # of episodes of unprotected intercourse _____

List dates and times of other unprotected intercourse _____

History

Now pregnant yes no

Unexplained vaginal bleeding yes no

Allergy to any ingredient in ECPs yes no

Urine Pregnancy Test (if indicated) pos neg

Exam (if indicated) _____

Consent signed

Rx (check medication given)

- Plan B, 2 tablets PO immediately
- Plan B One-Step, 1 tablet PO immediately
- Next Choice, 2 tablets PO immediately

Follow-up Appt/Plan _____

Contraception (initiated, continued, or restarted)

- Post-ECPs instructions discussed
- Condoms offered given
- Quick Start contraception initiated _____
- Established method of contraception continued/restarted _____

Comments _____

Date _____ **CHN Signature** _____

Interpreter Signature _____ **Clinician Signature** _____

FAMILY PLANNING FLOW RECORD

Name _____ D.O.B _____

DATE				
Reason for visit				
Contraception used				
LNMP				
Last intercourse				
B/P				
Weight				
BMI				
Urine P/G				
Urine hCG				
PAP				
HPV				
Chlamydia				
GC				
STS				
HIV				
Hgb/Hct				
Abd pain				
Chest pains				
Headaches				
Eye problems				
Severe leg pain				
Irregular bleeding				
Smoking/amount				
Current medications				
Allergies				
CHN signature				
POST/CONF				
Contraception/amt				
Other medications				
RTC date				
Reason				
CHN signature				

**FAMILY PLANNING IMPLANON™
INSERTION RECORD**

Name _____

Age _____ Date of Birth _____

Allergies _____

Current Method of Contraception _____

Current Medications _____

LNMP _____ Day of client's cycle _____

Last sexual intercourse _____

History

Annual examination within 1 year yes no

Allergic or hypersensitivity to iodine yes no

Allergic or hypersensitivity to Lidocaine yes no

Allergic or hypersensitivity to any component of Implanon yes no

Current medications on Appendix D list yes no

Current known pregnancy or suspected pregnancy yes no

Currently breastfeeding (at least 4 weeks postpartum) yes no

Unexplained vaginal bleeding yes no

Current thromboembolic disease or history thereof yes no

Known or suspected breast cancer or history thereof yes no

Cerebrovascular or coronary artery disease or history thereof yes no

Hepatic disease (tumors, hepatitis, cirrhosis) yes no

Comments _____

BP _____

Urine Pregnancy Test (if indicated) pos neg

Date _____ **Interpreter Name** _____

Staff Signature _____

**FAMILY PLANNING IMPLANON™
INSERTION RECORD**

Name _____

Clinician Comments _____

Assessment Implanon candidate yes no

Consent signed yes no

Implanon Insertion

Insertion site left upper arm right upper arm

Antiseptic iodine alcohol

Anesthetic Lidocaine _____% _____ mL other _____

Implanon inserted according to protocol yes no

If no, explain _____

Implanon Lot # _____ Exp. Date _____

Confirm implant placement by palpation yes no

If no, what action planned or taken

Implant localization protocol initiated yes no

Referral for localization yes no

Backup contraception initiated _____

Complete USER CARD and give to client yes no

Complete Patient Chart Label, affix to chart yes no

Difficulty with implant insertion yes no

If yes, specify _____

If Implanon not inserted:

Condoms offered given

Combined oral contraceptive initiated brand name _____

of cycles _____ start date _____

Other method of contraception initiated/continued/restarted _____

Return Visit _____

Date _____ **Interpreter Name** _____

Chaperone Signature _____

Clinician Signature _____

**FAMILY PLANNING IMPLANON™
REMOVAL RECORD**

Name _____

Age _____ Date of Birth _____

Allergies _____

Current Method of Contraception _____

Current Medications _____

LNMP _____

Date of insertion _____ Insertion Record reviewed yes no

Reason(s) for removal

- 3 years since insertion
- Desire pregnancy
- Pregnancy occurred
- Irregular bleeding
- Other side effects _____
- Other _____

Implant palpable before removal yes no

If no, how was implant localized _____

Implant removed intact yes no

Difficulty with removal yes no

If yes, specify

- Significant fibrosis
- Implant broken or fractured
- Implant in fascia or muscle
- Incision needed to be enlarged
- Implant not found
- Referral for removal _____

After Implanon removed

- Condoms offered given
- Combined oral contraceptive initiated brand name _____
of cycles _____ start date _____
- Other method of contraception initiated _____

Return Visit _____

Date _____ **Interpreter Name** _____

Chaperone Signature _____

Clinician Signature _____

FAMILY PLANNING INITIAL RECORD

Name _____

Age _____ Race _____

Date of Birth _____

Allergies _____

Current Method of Contraception _____

Current Medications (prescription, OTC, vitamins, herbal) _____

Reason(s) for Visit _____

OBSTETRIC HISTORY

Total # Preg	Full Term	Premature	Induced Abs	Spon Abs	Ectopics	Multiple Births	Living
--------------	-----------	-----------	-------------	----------	----------	-----------------	--------

Date of last delivery _____ Breastfeeding now yes no

Cesarean # _____ Indication(s) _____

Pregnancy Complications _____

Planning pregnancy in the next 12 months yes no

GYNECOLOGIC HISTORY

1st day last menstrual period _____ 1st day prior menstrual period _____

Usual duration of flow _____ # days length of cycle _____

Pain with periods yes no DES exposure yes no

Prior contraception use OCs DMPA IUD Implant Condoms Other _____

Date of last Pap _____ Results _____

Colposcopy/Abnormal Pap(s)/Rx _____

GYN cancer/Surgery/Hospitalization _____

SEXUAL HISTORY

Ever had sexual intercourse yes no Age of 1st intercourse _____

Type of sex vaginal oral rectal # of lifetime sexual partners _____

Sexual partners men women both Sexually active now yes no

Date of last sexual activity _____ vaginal oral rectal

Length of time with current partner _____

Condom use always sometimes never

New sexual partner in the last 3 months yes no

2 or more sexual partners in the last year yes no

History of STD in the last year yes no (list in Infectious Disease History)

Any concern about a possible STD now yes no _____

Exchange of sex for drugs or money yes no

Illicit, street, or recreational drug use yes no

Sex partner: with STD in the last year yes no Name of STD _____

with IV drug use yes no

with exchange of sex for drugs or money yes no

with admittance to jail or other detention facility yes no

is male having sex with men yes no

with other high-risk behavior yes no _____

FAMILY PLANNING INITIAL RECORD

Name _____

INFECTIOUS DISEASE HISTORY

Chlamydia _____ HPV _____ Hepatitis _____
Gonorrhea _____ Herpes _____ HIV _____
Trichomoniasis _____ Syphilis _____ Other _____
TB exposure _____

SOCIAL HISTORY

Alcohol (# drinks/wk) _____ (age begun) _____
Smoking (# cig/day) _____ (age begun) _____
Illicit, street, or recreational drug use (type/frequency/age onset) _____
Sexual assault/domestic violence yes no _____
Sexual coercion yes no _____
Child abuse/neglect/sexual abuse yes no _____
Parental involvement yes no encouraged _____

PAST MEDICAL HISTORY

Heart disease _____ Headaches/migraine _____
Hypertension _____ Seizures _____
Stroke _____ Kidney disease/UTI _____
Blood clots (lungs/legs) _____ Gastrointestinal _____
Anemia _____ Hepatitis/liver disease _____
Blood transfusions _____ Lung/TB/asthma _____
Diabetes _____ Thyroid _____
Breast Cancer _____ Eating disorders _____
Other Cancer _____ Injuries _____
Operations/other hospitalization _____
Immunodeficiency _____
Mental health _____
Other _____
Immunizations HBV _____ Rubella _____

FAMILY HISTORY

Heart disease _____ Breast cancer (with age onset) _____
Hypertension _____ GYN cancer _____
Stroke _____ Diabetes _____
Blood clots _____ Other _____

COMMENTS _____

Date _____ Interpreter Name _____

Staff Signature _____

FAMILY PLANNING INITIAL RECORD

Name _____

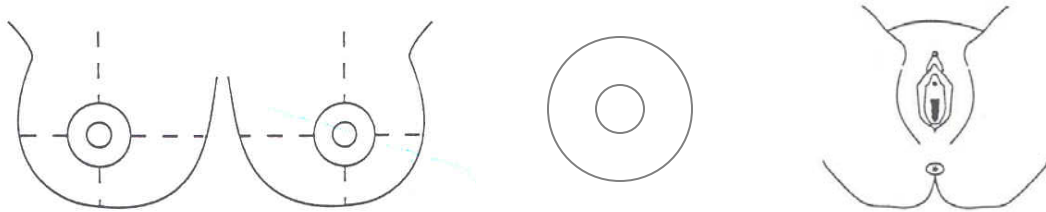
SUBJECTIVE _____

PHYSICAL EXAM BP _____ Wt _____ Ht _____ BMI _____ UCG _____

NORMAL			NORMAL		
HEAD			VULVA		
NECK			VAGINA		
HEART			CERVIX		
LUNGS			UTERUS		
BREASTS			ADNEXA		
ABDOMEN			RECTAL		
EXTREMITES			OTHER		

PAP HPV CT GC HSV OTHER _____

WET MOUNT _____



COMMENTS _____

ASSESSMENT _____

PLAN _____

RETURN VISIT _____ **Chaperone Signature** _____

Date _____ **Interpreter Name** _____

Clinician Signature _____

FAMILY PLANNING IUC
INSERTION RECORD

Name _____

Age _____ Date of Birth _____

Allergies _____

G _____ T _____ P _____ A _____ L _____

Current Method of Contraception _____

Current Medications _____

LNMP _____ Last sexual intercourse _____

History

Confirmed or suspected pregnancy yes no

Multiple sexual partners in the past 3 months yes no

Known or suspected cervical or uterine malignancy yes no

Acute cervicitis (current or within the past 3 months) yes no

Pelvic inflammatory disease (current or within the past 3 months) yes no

Sexually transmitted infection (current or within the past 3 months) yes no

Postpartum endometritis (current or within the past 3 months) yes no

Postabortion endometritis (current or within the past 3 months) yes no

Severe dysmenorrhea yes no

Hypermenorrhea yes no

Allergy or hypersensitivity to iodine yes no

Allergy or hypersensitivity to copper or history of Wilson's disease yes no

Undiagnosed abnormal vaginal bleeding yes no

History of Cesarean section(s) yes no

History of cervix treatment (cone, LEEP, cryo) yes no

Uterine fibroids that may interfere with IUC placement yes no

Uterine distortion (congenital or acquired) yes no

Current thromboembolic disease or history thereof yes no

Known or suspected breast cancer or history thereof yes no

Cerebrovascular or coronary artery disease or history thereof yes no

Hepatic disease (tumors, hepatitis, cirrhosis) yes no

Signs or symptoms of anemia yes no

If yes, hgb/hct _____

Comments _____

BP _____

Urine Pregnancy Test pos neg

Date _____ Interpreter Name _____

Staff Signature _____

**FAMILY PLANNING IUC
INSERTION RECORD**

Name _____

Clinician Comments _____

Assessment IUC candidate yes no

Consent signed yes no

IUC Insertion

Pelvic examination

- Vulva normal _____
- Vagina normal _____
- Cervix normal _____
- Uterus normal _____
 anteflexed axial retroflexed
- Adnexa normal _____

IUC name ParaGard® Mirena® Lot # _____ Exp. Date _____

Cervical prep antiseptic iodine none other _____

Anesthetic yes no

If yes, describe _____

Tenaculum for cervical traction yes no

Uterus sounded _____ cm/inches

IUC inserted per product directions yes no

If no, explain _____

Difficulty with IUC insertion yes no

If yes, specify _____

IUC string cut to _____ cm/inches

Bleeding at tenaculum site yes no

If yes, action taken

- Pressure only
- Silver nitrate applied
- Monsel's solution applied
- Other _____

If IUC not inserted:

- Condoms offered given
- Oral contraceptive initiated (brand name) _____
of cycles _____ start date _____
- Other method of contraception initiated/continued/restarted _____

Return Visit _____ **Interpreter Name** _____

Date _____ **Chaperone Signature** _____

Clinician Signature _____

FAMILY PLANNING ORAL CONTRACEPTIVE INITIATION RECORD

Name _____

Age _____ Date of Birth _____

Allergies _____

Current Method of Contraception _____

Current Medications _____

LNMP _____ Last sexual intercourse _____

History

Current known pregnancy or suspected pregnancy yes no

Currently breastfeeding yes no

Unexplained vaginal bleeding yes no

Cigarette smoker age 35 or older yes no

Headaches with focal neurological symptoms and/or aura yes no

Known or suspected breast cancer or history thereof yes no

Hypertension (>140/90 mm Hg) or history thereof yes no

Diabetes mellitus (vascular disease or >20 yrs duration) yes no

Current thromboembolic disease or history thereof yes no

Cerebrovascular or coronary artery disease or history thereof yes no

Hepatic disease (tumors, hepatitis, cirrhosis) yes no

Cancer of the endometrium (or estrogen dependent tumor) yes no

BP _____ Urine Pregnancy Test (if indicated) pos neg

Date _____ Interpreter Name _____

Staff Signature _____

Clinician Comments _____

Assessment Combined oral contraception candidate yes no

Contraception Plan

Plan B offered given

Condoms offered given

Combined oral contraceptive initiated brand name _____

of cycles _____ start date _____

Other method of contraception initiated/continued/restarted _____

Return Visit _____

Date _____ Interpreter Name _____

Clinician Signature _____

**FAMILY PLANNING PLAN B®
EMERGENCY CONTRACEPTION RECORD**

Name _____

Age _____ Date of Birth _____

Allergies _____

Current Method of Contraception _____

Current Medications _____

Last Normal Menstrual Period (LNMP) _____

Last bleeding episode, if not LNMP _____

Unprotected sexual intercourse

Reason for requesting Plan B _____

Date _____ Time _____ AM / PM

of hours since last unprotected intercourse _____

Any other unprotected intercourse since LNMP or other bleeding episode yes no

If yes, # of episodes of unprotected intercourse _____

List dates and times of other unprotected intercourse _____

History

Now pregnant yes no

Unexplained vaginal bleeding yes no

Allergy to any ingredient in Plan B yes no

Urine Pregnancy Test (if indicated) pos neg

Exam (if indicated) _____

Consent signed yes no

Rx Plan B, 2 tablets PO immediately yes Time given _____ no

Follow-up Appt/Plan _____

Contraception (initiated, continued, or restarted)

Post-Plan B instructions discussed

Condoms offered given

Quick Start oral contraception initiated _____

Established method of contraception continued/restarted _____

Comments _____

Date _____ **CHN Signature** _____

Interpreter Signature _____ **Clinician Signature** _____

PREGNANCY TESTING ENCOUNTER RECORD

Name _____

Age _____ Date of Birth _____

Allergies _____

Current Method of Contraception _____

Current Medications (prescription, OTC, vitamins, herbal) _____

Last Normal Menstrual Period (LNMP) _____

Last bleeding episode, if not LNMP _____

Reason for requesting pregnancy test _____

Positive urine pregnancy test: (check all that apply) **EDC (by LMP)** _____

- Verification form given
- Options counseling
- Multivitamin with folic acid recommended
- Prenatal education
- Prenatal care recommended
- Refer for supportive services (WIC, MCHP, Healthy Start, DSS)

Negative urine pregnancy test: (check all that apply)

- Repeat pregnancy test recommended if no menses in 2 weeks
- Preconception counseling
- Family planning appointment given Date _____ Time _____
- Contraception education
- Emergency contraception offered given
- Condoms offered given
- Quick Start contraception initiated (name) _____
- Multivitamin with folic acid recommended

I understand that the pregnancy test is not always 100% accurate and that actual diagnosis of pregnancy or other condition depends on a clinical evaluation which should be performed in 2 weeks. I assume full responsibility for any decisions I make. I have been offered non-directive options counseling and state without reservation that I have not been influenced or advised by any member of the Health Department staff to accept any one particular option.

Date _____ Client Signature _____

Interpreter Signature _____ CHN Signature _____