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GUIDELINES FOR CONTRACEPTION
(FERTILITY REGULATION)

I. INTRODUCTION

Maryland Family Planning and Reproductive Health Program delegate agencies must offer a wide range of contraceptive methods to clients. Clients must receive accurate information about all contraceptive methods that are available and approved for use in the United States. In addition to counseling and education, delegate agencies must ensure that client participation in using a particular method is voluntary. Delegate agency staff must have training and education to appropriately advise clients on the most effective method for them.

II. 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 Methods	25		51
<i>Standard Days Method</i> ⁶		5	
<i>Two-Day Method</i> ⁶		4	
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/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, periodic abstinence, 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.

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

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 18 brands of oral contraceptives to be safe and effective for emergency contraception: Ogestrel or Ovral (1 dose is 2 white pills), Alesse, Lessina, Levlite, (1 dose is 5 pink pills), Levlen or Nordette (1 dose is 4 light-orange pills), Cryselle, Levora, Low-Ogestrel, or Lo/Ovral (1 dose is 4 white pills), Tri-Levlen or Triphasil (1 dose is 4 yellow pills), Portia, Seasonale, or Trivora (1 dose is 4 pink pills), Aviane (1 dose is 5 orange pills), and Empresse (1 dose is 4 orange pills).

¹⁰To 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.

REFERENCES

1. Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007
2. Ziemann M, Hatcher RA, et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2010

3. Speroff L, Darney P. A Clinical Guide for Contraception. 4th Ed., Lippincott Williams & Wilkins, Philadelphia, PA, 2004

REQUEST FOR REPRODUCTIVE HEALTH SERVICES

I, (print or type name) _____,
request family planning and reproductive services from the
_____ (agency name). 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
- * Pelvic (vaginal) examination
- * Pap test (Papanicolaou smear) – a screening test for cancer of the cervix and related conditions
- * Male genital examination
- * Screening tests for 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, when indicated
- * Skin test for tuberculosis (TB), when indicated
- * Other appropriate clinical tests, when indicated

- I understand my health information is confidential. Confidential means that no one outside of the (_____) 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) must be reported as required under State and Federal law.
- I understand that I may request information about the different types of approved family planning methods which are available to me. I understand that these methods include, but are not limited to: fertility awareness-based methods, condoms, diaphragm, spermicides (vaginal film, foam, or gel), birth control pills, emergency contraception, intrauterine (IUD), Injectable birth control “shot” (Depo-Provera), birth control skin patch, vaginal ring (NuvaRing) and subdermal “skin implant” (Implanon). With the help of my health care provider 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, or results for any other reportable infections will be sent to the Maryland State Department of Health and Mental Hygiene, Infectious Disease and Environmental Health Administration as required by law.
- 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 receive family planning services. I understand that I may withdraw this consent at any time.
- I understand and agree with the above statements. I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

Please complete the following if interpretation of informed consent was required:

An interpreter was offered to the client. yes no

This form has been read to the client in the client's spoken language. yes no

Patient's Language (specify):

Interpreter's Name: (print or type name of interpreter)

Interpreter Services provided by(agency):

Date: _____ Interpreter Signature: _____

Staff Use Only:

By my signature I affirm that:

- The client has read this form or had it read to her by an interpreter.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

INDIVIDUALIZED CONTACT PLAN FOR FAMILY PLANNING

I, (print or type name) _____,
request the following special plan to contact me regarding my family planning visits:

- I agree to call my health care provider 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.
- I will let the clinic staff know if I change my address, phone number, or my contact information.
- I will keep scheduled 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 (agency name) _____ staff may contact me by telephone, letter, or certified letter.
- I understand and agree with the above statements. I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

Please complete the following if interpretation of informed consent was required:

An interpreter was offered to the client. yes no

This form has been read to the client in the client's spoken language. yes no

Patient's Language (specify):

Interpreter's Name: (print or type name of interpreter)

Interpreter Services provided by (agency):

Date: _____ Interpreter Signature: _____

Staff Use Only:

By my signature I affirm that:

- The client has read this form or had it read to her by an interpreter.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date:

Staff Signature:

ABSTINENCE
and
COITUS INTERRUPTUS (WITHDRAWAL)

I. INTRODUCTION

Abstinence can be defined in different ways but most commonly is used to describe either the practice of avoiding vaginal intercourse or the practice of avoiding all sexual acts that carry risk of pregnancy or contact with infectious lesions or secretions (including oral and anal intercourse).

Abstinence is the only 100% effective way to prevent pregnancy with a perfect use failure rate of 0%. Abstinence can also greatly reduce or eliminate risk of sexually transmitted infections (STIs).

Abstinence can be primary (never had a sexual experience with another person) or secondary (sexually experienced person who becomes sexually inactive) and continuous (refraining from intercourse entirely) or periodic (refraining from intercourse during specific times such as those when a woman is most fertile). Periodic abstinence may require another method of contraception during the period of non-abstinence.

Coitus interruptus is the withdrawal of the penis from the vagina and away from the external genitalia prior to ejaculation with the intention of avoiding pregnancy.

Perfect use failure rate in the first year: 4%
Typical use failure rate in the first year: 27%

Coitus interruptus does not protect a couple against sexually transmitted infections.

II. GENERAL INFORMATION

- A. Physical exam and lab work are not required but should be offered (as indicated)
- B. During the family planning initial visit education regarding all contraceptive options should be provided.
- C. All clients choosing abstinence or coitus interruptus should be proactively offered condoms, advanced placement of emergency contraception and other methods of birth control.

III. CLIENT SELECTION

Any client may receive information on abstinence or coitus interruptus

IV. CLIENT EDUCATION

- A. Review with the client and partner definition of abstinence or coitus interruptus and the risks of pregnancy and STI transmission associated with their defined method of abstinence or coitus interruptus.
- B. Counseling may include the discussion of alternative methods of contraception for the time if and when the client decides not to use abstinence as his/her primary method of contraception.
- C. Offer condoms and advanced placement emergency contraception
- D. Educate the client regarding the advantages and disadvantages of abstinence:
 - 1. Advantages:
 - a. Can reduce or eliminate the risk of sexually transmitted infections by not allowing exposure to infectious lesions or secretions (vaginal, oral, anal)
 - b. Can reduce or eliminate the risk of pregnancy by refraining from penile-vaginal intercourse.
 - c. Has no medical or hormonal risk or side effects
 - d. Women who abstain until their 20s and who have fewer lifetime partners may have certain health advantages over women who do not such as:
 - i. Less likely to get STIs.
 - ii. Less likely to become infertile.
 - iii. Less likely to develop cervical cancer.
 - 2. Disadvantages:
 - a. Can be difficult for some to abstain from sexual activity
 - b. If client has not ensured a back-up method is available, he or she may be unable to protect herself/himself from pregnancy or STIs if sexual contact occurs
- E. Educate the client regarding the advantages and disadvantages of coitus interruptus:
 - 1. Advantages:
 - a. Has no medical or hormonal risk or side effects
 - 2. Disadvantages:
 - a. Can be difficult for some partners to reliably withdraw prior to ejaculation
 - b. Does not offer protection against STI transmission
 - c. If client has not ensured a back-up method is available, he or she may be unable to protect herself/himself from pregnancy or STIs if sexual contact occurs

V. DOCUMENTATION

Documentation of education must be in the client's record

VI. FOLLOW-UP

Assess client's effectiveness and satisfaction with practice of abstinence or coitus interruptus and offer appropriate counseling and/or alternate method(s) of contraception, including advanced placement emergency contraception.

REFERENCES

1. Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007
2. Ziemann M, Hatcher RA, et al. A Pocket Guide to Managing Contraception. Tiger, GA, Bridging the Gap Foundation, 2010
3. Speroff L, Darney P. A Clinical Guide for Contraception. 4th Ed., Lippincott Williams & Wilkins, Philadelphia, PA, 2004

LACTATIONAL AMENORRHEA AND OTHER FERTILITY AWARENESS BASED METHODS

I. INTRODUCTION

Fertility Awareness Based Methods (FAB) or Natural Family Planning (NFP) interprets signs and patterns of fertility to identify days in each menstrual cycle when intercourse is most likely to result in a pregnancy. This information may be used to avoid or achieve pregnancy. Couples who use a barrier method on fertile days or who abstain from intercourse during a woman's fertile period are using fertility awareness-combined method/natural family planning.

Natural family planning methods used to prevent pregnancy are 75-98% effective.

Women with conditions that make pregnancy an unacceptable risk should be advised that FAB methods might not be appropriate for them because of the relatively higher typical-use failure rates of these methods.

Natural Family Planning may be indicated for purposes of:

- A. Conception
- B. Avoiding pregnancy
- C. Detecting pregnancy (basal body temperature)
- D. Detecting impaired fertility (charting fertility signs and determining infrequent or absent ovulation with basal body temperature)
- E. Detecting need for medical attention (change in cervical secretions, abdominal pain, and other signs and symptoms may indicate need for medical attention- reproductive tract infections)

II. GENERAL INFORMATION

One or more indicators are used to identify the beginning and end of the fertile time in the menstrual cycle. In most cycles, ovulation occurs on or near the middle of the cycle. The fertile period lasts for about 6 days (5 days preceding ovulation and day of ovulation). In cycles that range between 26 and 32 days long (approx 78% of the cycles) the fertile period is highly likely to fall within days 8 to 19.

FAB Methods involve instruction, motivation commitment and periods of abstinence. Couples can learn how to use FABs by taking a course, or they can be taught by a specially trained health professional. Both partners should learn the methods together as both will know exactly what needs to be done to make the methods work.

Fertility Awareness Methods:

A. **Lactational Amenorrhea Method (LAM)**

May be used by postpartum women. It is based on a high frequency of anovulation in women who are breastfeeding exclusively and who are not having menstrual periods (secondary to high levels of prolactin which inhibits estrogen production). It is most reliable during the first six months postpartum (98% effectiveness) and only if the following criteria are met:

1. First 6 months postpartum
 2. Fully or nearly fully breastfeeding
 - a. Breastfeeding intervals do not exceed 4 hours in daytime and 6 hours at night
 - b. Minimal supplementation (<10% of infant's feedings)
 3. Amenorrhea since delivery
- B. Calendar Rhythm Method and Standard Days Method**
 These methods are based on the knowledge of when ovulation has occurred and is most effective with cycles between 26 and 32 days in length. These methods assume sperm viability of 3-5 days and ovum viability of 24 hours.
- C. Basal Body Temperature (BBT)**
 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.
- D. Ovulation Method (Cervical Mucus Method/Billings Method)**
 This 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.
- E. Symptothermal Method**
 This method combines the use of the BBT and Ovulation Methods as well as noting other possible signs of ovulation. Involves combination of the Temperature, Cervical Mucous (Billings/Ovulation) and Calendar based FABs. Observation of fertility signs such as presence or absence of secretions, change in characteristics of cervical secretions, or changes in basal body temperature. Changes in these signs are caused by fluctuations in hormone levels during the cycle. Clients using these methods determine the start of the fertile time by observing cervical secretions. The end of the fertile time can be determined by observing cervical secretions and a change in the basal body temperature.
- F. Two-Day Method**
 Is a simple method which involves consideration of vaginal secretions other than menstrual bleeding. A woman considers herself fertile on a given day if she notices vaginal secretions and/or remembers that she had vaginal secretions on the day before.

III. CLIENT SELECTION

- A. Indications for use:**
1. Have most menstrual cycles between 26 to 32 days long
 2. Desires to use a natural method
 3. Able to use a condom or avoid vaginal intercourse up to 12 consecutive days of the cycle. (days 8-19)
 4. Unable (or does not desire) to use a method that contains hormones or requires a medical procedure.
 5. Are at low risk of STIs/HIV
- B. Contraindications (Not an appropriate candidate if):**

1. Has irregular menstrual cycles (shorter than 26 days or longer than 32 days)
2. Unable to monitor cycle days, identify fertile/ infertile days and assess cycle length
3. Inability to interpret fertility signs correctly or to recognize the presence of secretions.
4. Has difficulty using a barrier method or abstaining from vaginal intercourse on days 8 through 19 of their cycles
5. Has persistent reproductive tract infections that effect signs of fertility
6. Has intermenstrual bleeding indistinguishable from menstruation or noticing secretions
7. For LAM – greater than 6 months postpartum or feedings spaced greater than 4 hours in day or 6 hours at night or more than 10% of feedings are supplemented

IV. CLIENT EDUCATION/ INFORMED CONSENT

- A. Discuss all available contraceptive options
- B. Provide STI/HIV prevention education and risk reduction counseling
- C. Review with the client fertility awareness based methods of family planning
- D. Discuss indications and use of emergency contraception as an option if unprotected intercourse during the fertile days.
- E. Educate the client regarding the advantages and disadvantages of Natural Family Planning:
 1. Advantages:
 - a. No side effects, complications or serious adverse effect.
 - b. Active involvement of male partner
 2. Disadvantages:
 - a. No protection against STIs/HIV.
 - b. Lack of male partner's cooperation (obstacle for women desiring to practice abstinence or use an alternative method during fertile time).
- F. Certain conditions make Natural Family Planning more difficult to use and require more extensive counseling and follow-up:
 1. Recent childbirth
 2. Recent menarche
 3. Approaching menopause
 4. Recent discontinuation of some hormonal contraceptive methods
- G. Provide written and verbal information on fertility awareness through monitoring
 1. Basal body temperature (may require more in depth training)
 2. Menstrual cycle (Standard Days Method)
 3. Cervical mucous (Two-Day Method)
- H. A signed consent is not required

V. MEDICAL SCREENING AND EVALUATION

A complete medical, social and sexual history must be completed for all family planning clients at the initial comprehensive clinical visit. Clients using non-prescriptive or non-contraceptive method must be counseled on the importance of preventive health maintenance, including physical exam and laboratory testing as indicated. This counseling must include the potential health risks associated with declining or delaying the following preventive screening tests or procedures. If the client declines or defers preventive services, this as well as the above counseling must be documented in the medical record.

- A. History specific for Natural Family Planning should include:
 - 1. Menstrual history and LNMP and if they are regular
 - 2. Pregnancy history – recent childbirth
 - 3. Assessment for factors that affect cycle length
 - a. Recent delivery
 - b. Breastfeeding
 - c. Current or recent use of hormonal contraception
 - d. Recent induced or spontaneous abortion
- B. Sexual history including risk assessment for STIs/HIV
- C. Assessment for factors that affect ability to use condoms or avoid vaginal intercourse on fertile days.
- D. Physical examination & lab testing (per agency protocol)

VI. REFERRAL

Referrals are made to support agencies if requested.

VII. DOCUMENTATION

Education provided must be documented in the client's medical record

REFERENCES

1. Hatcher, R., et. Al. Contraceptive Technology. 19th Edition., 2007
2. CDC Medical Eligibility Criteria for Contraceptive Use. MMWR, Vol. 57, No.RR-4, June 18, 2010

NON PRESCRIPTION BARRIER CONTRACEPTIVES
and
SPERMICIDES

I. INTRODUCTON

Non-prescription barrier contraceptives (male and female condoms) are an important contraceptive option because of their wide availability, relative ease of use, and efficacy when used correctly. Similarly, spermicides have several important advantages - they are simple to use, inexpensive, available without prescription, and provide freedom from systemic side effects, except the occasional allergic reaction. The effectiveness of spermicides as a sole method of contraception is less than that of condoms, but their use in combination with barrier methods (barrier method *plus* concurrent use of a spermicide) adds significantly to their effectiveness. In addition, lubricated male latex condoms (without nonoxynol-9) or female vaginal sheaths, when used consistently and correctly, provide a high degree of protection against both the acquisition and transmission of a number of sexually transmitted pathogens, including gonorrhea, chlamydia, syphilis, and some viral pathogens, including Hepatitis B virus, Herpes Simplex Virus, and Human Immunodeficiency Virus.

Efficacy rates for barrier methods and spermicidal preparations:

- A. Male Condoms
 - 1. Perfect use failure rate in the first year of use: 2%
 - 2. Typical use failure rate in the first year of use: 15%

- B. Female Condoms
 - 1. Perfect use failure rate in the first year of use: 5%
 - 2. Typical use failure rate in the first year of use: 21%

- C. Spermicidal Preparations
 - 1. Perfect use failure rate in the first year: 15%
 - 2. Typical use failure rate in the first year: 29%

Available non-prescription barrier and spermicidal contraceptives include:

- A. Condoms
 - 1. Male condoms: latex, polyurethane, and animal membrane
 - 2. Female condoms and polyurethane vaginal sheaths
- B. Spermicides
 - 1. Films
 - 2. Sponges
 - 3. Foams
 - 4. Jellies and creams
 - 5. Suppositories

II. GENERAL INFORMATION

- A. Condoms: Condoms are 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. Male and female condoms should **not** be used together as they can adhere to each other and cause slippage, breakage or dislodgement.
1. Male condoms: The male condom is a thin sheath that is placed over the erect penis prior to any sexual act and worn until after ejaculation. It 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.
 - a. If used consistently and correctly, prevents both unintended pregnancy and sexually transmitted infections (STIs).
 - b. Must be used with every act of vaginal intercourse to prevent pregnancy.
 - c. Intended for one-time use only; re-use is not recommended.
 - d. Synthetic condom use during oral or anal sex is recommended for STI protection.
 - e. Animal membrane condoms have small pores that may permit the passage of viruses and are **NOT** recommended for STI protection.
 - f. 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.
 - g. Should not be used along with a female condom
 2. Female condoms: The female condom acts as a mechanical barrier by preventing the sperm from penetrating the upper female reproductive tract and must be used with every act of intercourse.
 - a. It reduces the risk of acquiring sexually transmitted infections.
 - b. It may be inserted up to 8 hours before intercourse. It is intended for one-time use only; re-use is not recommended.
 - c. 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).
 - d. 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.
 - e. It is an excellent choice for barrier contraception when the client or her male partner has a latex allergy or sensitivity.
 - f. Disadvantages include high typical use failure rate (possibly due to higher difficulty to use correctly and acceptability to male partner), and relatively high cost.
 - g. Should not be used along with a male condom
- B. Spermicides consist of a spermicidal agent and an inert carrier substance. Spermicides act by immobilizing or killing sperm on contact. The most common spermicidal agent is nonoxynol-9, a surfactant agent that destroys the cell membrane of the spermatozoa.

1. Spermicides do **not** protect against HIV and frequent spermicide use may cause tissue irritation that theoretically could increase susceptibility to HIV.
2. They need to be placed into the vagina prior to each act of intercourse.
3. Spermicides are easy to use but require some instructions. Each formulation of spermicide requires slightly different insertion so client should follow the specific package instructions for the spermicide to be used.
4. They can be used as a primary method of contraception or as a supplemental method to other forms of birth control.
5. 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.
6. If symptoms persist more than a day or two after discontinuing the spermicide exposure, evaluate for underlying factors, including the possibility of STD exposure. Spermicides should not be used in the presence of genital epithelial disruption.

II. CLIENT SELECTION

Any comprehensive or limited service client or individual requesting the use of a non-prescription barrier contraceptive may be provided it as long as they do not have a contraindication.

Contraindications: (USMEC 3: Risks outweigh advantages for method use or USMEC 4: Unacceptable risk for method use)

- A. Latex barriers:
 1. Allergy to latex rubber (USMEC 3)
- B. Spermicidal products:
 1. Allergy or history of significant skin irritation with acute or chronic exposure to spermicides.
 2. Significant risk factors that make the use of nonoxynol-9 inappropriate
 - a. High risk for HIV (USMEC 4)
 - b. HIV infection (USMEC 3)
 - c. AIDS (USMEC 3)
 - d. Antiretroviral (ARV) therapy (USMEC 3)
 - e. History of toxic shock (sponge only USMEC 3)

III. CLIENT EDUCATION/ INFORMED CONSENT

Within the context of a limited or comprehensive contraceptive visit the client must be:

- A. Provided counseling regarding all contraceptive options available
- B. Advised regarding the risks and benefits of the method and instruction its effective use if a non-prescription barrier is chosen. Follow the manufacturer's instruction on use.
- C. Given counseling on STI/HIV risks

- D. Provided with the clinic site's request for medical service consent form
- E. Given written educational materials in the form of a client fact sheet for the chosen non-prescription method

For all other clients:

- A. Written educational materials should be available to clients and others regarding the use of each type of non-prescription contraceptive product
- B. Information on Family Planning Services and other contraceptive options

IV. MEDICAL SCREENING AND EVALUATION

None is required prior to the provision of a non-prescription barrier contraceptive methods or spermicides.

REFERENCES

1. CDC. Medical Eligibility Criteria for Contraceptive Use. MMWR, Vol. 59, No. RR-4, June 18,2010.
2. Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007.
3. Ziemann M , Hatcher RA, et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2010.

DIAPHRAGM

I. INTRODUCTION

The contraceptive diaphragm is a dome-shaped latex or silicone device that serves as a mechanical barrier against the cervix and holds a spermicidal preparation in place within the vagina. The diaphragm is one of the oldest contraceptive methods, is non-hormonal, and easy to use.

Efficacy with perfect use results in 6 pregnancies in 100 users per year-- versus 16 pregnancies per 100 users per year with typical use.

II. CLIENT SELECTION

- A. Indications – The diaphragm may be an appropriate method of contraception for women who:
 - 1. Prefer an intercourse-related non-hormonal method of contraception
 - 2. Desire a barrier method that can provide continuous protection for up to 24 hours.
- B. Contraindications – (USMEC 3-- Risks outweigh advantages for method use; USMEC 4--Unacceptable risk for method use):
 - 1. History of toxic shock syndrome (TSS) (USMEC 3).
 - 2. Allergy to product components (USMEC 3).
 - 3. High Risk for HIV/AIDS (USMEC 4).
 - 4. HIV/AIDS (USMEC 3).
 - 5. Antiretroviral (ARV) (USMEC 3).

III. MANAGEMENT OF WOMEN WITH SPECIAL CONDITIONS REQUIRING FURTHER EVALUATION

Consultation with site Medical Director should occur before providing a diaphragm to clients in any of the following situations:

- A. Less than 3 months since cervical surgery (including colposcopy with biopsy cryotherapy, LEEP, laser therapy, or knife cone biopsy).
- B. Less than 2 weeks since mid-trimester abortion or less than 6 weeks post-partum.
- C. Recent history of frequent lower urinary tract infections, especially if associated with prior diaphragm use.

IV. MEDICAL SCREENING, FITTING AND EVALUATION

- A. Comprehensive medical database (history, physical examination and laboratory testing as indicated) should be completed prior to provision of a diaphragm.
- B. Diaphragm Fitting:
 - 1. The diaphragm should fit comfortably with the anterior rim lodged behind the pubic bone and the posterior rim seated deep in the posterior vaginal fornix.

2. The largest, most comfortable diaphragm that fits well should be chosen. It is essential to involve the patient in the evaluation of the fit of her Diaphragm. She should be asked to offer her impression of how easy or difficult removal is for each size, and if two diaphragms fit equally well, which one feels more comfortable.
 3. Following fitting of the diaphragm, sufficient time should be provided for the patient to practice insertion and removal.
 4. Use of a back-up method of contraception until the return visit, or until the patient is sure that the diaphragm is staying in place during intercourse should be advised.
- C. Guidelines for cleaning and disinfection of fitting sets must be followed (See package insert in fitting set).
- D. Delayed Exam
1. Physical exam and related preventative services should not be deferred beyond 3 months after the initial visit and may not be deferred beyond 6 months (unless there is a compelling reason for extending the deferral in the clinician's judgment).
 2. The reason for the deferral of pelvic exam must be documented in the client's medical record.
 3. A complete history, height, weight and BP is required in the medical record.
 4. Written results of a physical exam done by another provider within the last 12 months are acceptable.
 5. Pelvic exams are not required until age 21 years unless indicated (ACOG).
- E. Pap test screening protocols for the site must be followed.

V. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a diaphragm should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to diaphragms, including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues
- C. Instruction on care of diaphragm (cleaning and inspection)
- D. Information that the diaphragm may provide only limited protection against STIs/HIV
- E. Method specific informed consent
- F. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- G. Written and verbal instruction on method use (may use Package Insert)
- H. Upon request, a copy of the method specific consent form
- I. Emergency, 24-hour telephone number and location where emergency services can be obtained
- J. Clinic access information

VI. PRESCRIBING DIAPHRAGM

Diaphragm size will be determined by the clinician after examining the client and fitting for size.

VII. MANAGEMENT OF SIDE-EFFECTS AND COMPLICATIONS

- A. Recurrent vaginal or introital irritation, with no evidence of vaginal infection, may indicate an allergy or sensitivity to spermicide, latex, or silicone.
- B. Recurrent UTIs – consider method change.
- C. Toxic Shock Syndrome (TSS) signs or symptoms require urgent and intensive evaluation and treatment.
- D. Because TSS risk is increased for a woman who has had TSS in the past, the woman should avoid use of vaginal barrier methods in the future.

VIII. FOLLOW UP

- A. The diaphragm user should be advised to return (at each of these visits diaphragm fit should be reassessed):
 - 1. In 2-3 weeks for a re-check of diaphragm fit, to evaluate placement skills and to screen for possible problems.
 - 2. Annually, or more often as requested by the client.
- B. Diaphragm fit also should be reevaluated in the case of:
 - 1. Frequent dislodgment.
 - 2. Vaginal or lower abdominal discomfort coincident with diaphragm use
 - 3. Full term pregnancy.
 - 4. Pregnancy termination after the first trimester.
 - 5. Pelvic surgery.
 - 6. Recurrent lower urinary tract infection.
 - 7. Weight gain or loss of 10 pounds or more.

IX. DOCUMENTATION

- A. Order must be written in medical record initially, annually, and upon method change.
- B. Diaphragms dispensed must be documented in the medical record and/or computer system.
- C. All education/counseling must be documented.

REFERENCES

- 1. CDC. Medical Eligibility Criteria for Contraceptive Use. MMWR, Vol. 59, No. RR-4, June 18, 2010
- 2. Hatcher, R., et. Al. Contraceptive Technology. 19th Edition., 2007

CLIENT EDUCATION FOR DIAPHRAGM

Before using the diaphragm, you need to know the possible disadvantages, risks, and warning signs to watch for. It is important that you read the manufacturer's package insert. You will receive information about the use, effectiveness, advantages, disadvantages, risks, and warning signs of other methods. We are happy to answer any questions you may have.

The diaphragm is a barrier method of birth control.

The diaphragm is made of latex or silicone and is dome-shaped. It is used with a spermicidal cream or jelly. It is inserted into the vagina and fits over the cervix. Of 100 women using the diaphragm, 16 will become pregnant during the first year of use. With consistent and correct use, this drops to 6.

The diaphragm offers limited protection against STIs. Since it covers the cervix, it may protect the cervix from direct contact with bacteria and viruses. Condoms are always the best way for sexually active individuals to reduce the risk of STIs. Diaphragms and condoms can be used at the same time.

To Increase Diaphragm Effectiveness:

- Use it every time you have vaginal intercourse.
- Use contraceptive cream or jelly with every act of vaginal intercourse or if 6 hours or more has passed since the spermicide cream or jelly was inserted (even if no intercourse occurred)
- Use back-up method if more than one act of intercourse while diaphragm is in
- Leave the diaphragm in place for at least 6 hours after the last act of intercourse.
- Check diaphragm before each use for holes or weak spots.

Advantages of the Diaphragm

- It can be left in place for up to 24 hours (but should not be left in place for longer than 24 hours)
- It is non hormonal.
- No effect on menstrual cycle.

Disadvantages of the Diaphragm

- May have an allergic reaction to the latex or spermicide.
- May develop a bladder infection.
- May find it difficult to insert or remove.
- May be pushed out of place during intercourse.

You should not use the diaphragm if you have had, now have or develop in the future:

- Allergy to the products.
- HIV/AIDS or high risk for HIV.
- History of toxic shock syndrome.

Warning Signs – notify the clinic or your health care provider if you experience:

- Discomfort with diaphragm in place.
- Vaginal itching or irritation.
- Frequent bladder infections.
- Unusual vaginal discharge.
- Vulva/vaginal redness or swelling.

Sign or symptoms of toxic shock syndrome (rare). **If you have these symptoms, remove the diaphragm and seek immediate care.*

- Sudden high fever.
- A sunburn-like rash.
- Diarrhea or vomiting.
- Sore throat.
- Aching muscles and joints.
- Dizziness, faintness, weakness.

Return to the clinic to determine if the diaphragm still fits after:

- A delivery.
- Pelvic or abdominal surgery.
- An abortion or miscarriage.

Nonoxynol-9

- In order for the diaphragm to be effective, it must be used with a spermicidal cream or jelly. Most include the spermicide nonoxynol -9 (N-9).
- It was hoped that N-9 would reduce the risk of STIs, including HIV, but the studies show that it offers no protection against STIs. Using N-9 many times a day may actually increase the risk of the infections.

Regular physical exams for routine health care and for screening for STIs and cancer are strongly recommended for all sexually active women and men.

CONSENT FOR DIAPHRAGM

I, (print or type name) _____,
request the diaphragm as my family planning method.

- I have received and read information about the diaphragm in the Patient Package Insert about the benefits, risks of using this method. I was given an opportunity to ask questions about all forms of birth control, meaning all prescription, non-prescription, and natural methods. All of my questions were answered to my satisfaction and I understood all of those answers.
- I understand that no method of birth control, except abstinence, is 100% effective against pregnancy or contracting sexually transmitted diseases, including the Human Immunodeficiency Virus (HIV) infection I understand the diaphragm offers limited protection from sexually transmitted infections and that I need to use condoms for protection from these infections.
- I understand that the diaphragm is a barrier method of birth control, made of latex or silicone is dome shaped and is inserted into the vagina and fits over the cervix. It works by blocking sperm from entering the cervix.
- I understand the instructions for care and cleaning of the diaphragm.
- I understand that of 100 women using the diaphragm, 16 will become pregnant during the first year of use. With consistent and correct use, this drops to 6.
- I understand that in order to increase Diaphragm effectiveness I must:**
- Use it every time I have vaginal intercourse
 - Use contraceptive cream or jelly with every act of vaginal intercourse
 - Use back-up method if more than one act of intercourse while diaphragm is in
 - Leave the diaphragm in place for at least 6 hours after the last act of intercourse
 - Check diaphragm before each use for holes or weak spots
- I understand that the advantages of the diaphragm are as follows:**
- It can be left in place for up to 24 hours
 - It is non hormonal
 - No effect on menstrual cycle
- I understand that the disadvantages of the diaphragm are as follows:**
- I may have an allergic reaction to the latex or spermicide
 - I may develop a bladder infection
 - I may find it difficult to insert or remove the diaphragm and/or spermicide
 - It may be pushed out of place during intercourse
- I understand that I should not use the diaphragm if I have had, now have or develop in the future:**
- Allergy to the products that the diaphragms or spermicide are made of
 - HIV/AIDS or high risk for HIV

- History of toxic shock syndrome

I will notify the clinic or my health care provider if I experience:

- Discomfort with diaphragm in place
- Vaginal itching or irritation
- Frequent bladder infections
- Unusual vaginal discharge
- Vulva/vaginal redness or swelling

I will remove the diaphragm and seek immediate care if I develop signs and symptoms of Toxic Shock Syndrome:.

- Sudden high fever
- A sunburn-like rash
- Diarrhea or vomiting
- Sore throat
- Aching muscles and joints
- Dizziness, faintness, weakness

I will return to the clinic to determine if the diaphragm still fits after:

- A delivery of an infant
- Pelvic or abdominal surgery
- An abortion or miscarriage

I understand that most of the spermicides that are used with the diaphragm contain Nonoxynol-9 and that studies have shown that N-9 multiple times in a day (more than two) can increase the risk of infection with sexually transmitted infections including HIV.

I understand that regular physical exams for routine health care and for screening for STIs and cancer are strongly recommended for all sexually active women and men.

Date: _____ Client Signature: _____

Please complete the following if interpretation of informed consent was required:

An interpreter was offered to the client. yes no

This form has been read to the client in the client's spoken language. yes no

Patient's Language (specify):

Interpreter's Name: (print or type name of interpreter)

Interpreter Services provided by(agency):

Date: _____ Interpreter Signature: _____

Staff Use Only:

By my signature I affirm that:

- The client has read this form or had it read to her by an interpreter.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date:

Staff Signature:

COMBINED HORMONAL CONTRACEPTIVES (CHCS)

I. INTRODUCTION

Combined Hormonal Contraceptives contain both estrogen and progestin. The types of CHCs that are available include:

- A. **Combined oral contraceptives (COCs)** are the most widely used reversible method of contraception in the United States. Low dose COCs offer high efficacy, safety, and convenience and provides a number of significant non-contraceptive health benefits. COCs consisting of monophasic or multiphasic products (35 ug or less ethinyl estradiol and a low dose progestin) should be used.
- B. **Vaginal contraceptive ring (NuvaRing®)** is a non-biodegradable, flexible and transparent vaginal ring used for monthly combination hormonal contraception. It contains two active components - ethinyl estradiol (an estrogen) and etonogestrel (the biologically active metabolite of desogestrel, a third generation progestin). Etonogestrel is also known as 3-keto-desogestrel. When placed in the vagina each ring releases on average 120ug/day of etonogestrel and 15 ug/day of ethinyl estradiol over a three week period of use. The ring is made of ethylene vinyl acetate copolymers and magnesium stearate. It has an outer diameter of 54 mm (2 inches) and a cross sectional diameter of 4mm (1/8 inch).
- C. **Transdermal contraceptive patch (OrthoEvra®)** is a combination transdermal contraceptive patch containing 6.0 mg norelgestromin (NGMN) and 0.75mg of ethinyl estradiol (EE). The patch has a contact surface area of 20cm². It releases 150 micrograms of norelgestromin and 20 micrograms of ethinyl estradiol into the bloodstream per 24 hours. In 2008 the manufacturer changed the package insert to address the slight increase in the risk of adverse events including venous thromboembolism.***

***In 2005, the package labeling for OrthoEvra® was changed to include recent findings that 60% more estrogen is absorbed from the patch than from some low dose pills and the ring. Increased levels of estrogen may raise the risk of side effects, including VTE.

There are conflicting findings regarding increased risk of DVT. Two recent studies (one comparing the patch to a pill with levonorgestrel and the other to a pill with norgestimate) found a two-fold increased risk of blood clots among women using the patch, although in absolute numbers, the risk remains very low. Even a two-fold increase risk is dwarfed by the risk of VTE associated with pregnancy. A third study, recently updated with an additional 17 months of data, found no increase in risk for DVT in patch users compared to a norgestimate-containing pill. Clients need to be aware of this issue since there are ongoing lawsuits.

The FDA considers OrthoEvra® safe and effective when it is used according to the labeling. (Sources: FDA, Ortho, January 18, 2008)

II. CLIENT SELECTION

- A. Indications - CHCs may be provided when contraindications do not exist for contraception.
- B. Contraindications – (USMEC 3-- Risks outweigh advantages for method use; USMEC 4-- Unacceptable risk for method use): “Request for Hormonal Contraceptives by Women with Risk Factors Consent Form” must be signed and this must be documented in the medical record if medical conditions exist.
 1. History of or current deep vein thrombosis (DVT)/pulmonary embolism (PE) (USMEC 3, 4)
 2. Major surgery with prolonged immobilization (USMEC 4)
 3. Stroke (history of cerebrovascular accident) (USMEC 4)
 4. Known thrombogenic mutations (e.g. Factor V Leiden, Prothrombin mutation, Lupus Anticoagulant, Protein C, Protein S and Antithrombin deficiencies) (USMEC 4)
 5. Smoking \geq 35 years of age
 - a. < 15 cigarettes/day (USMEC 3)
 - b. 15 cigarettes/day (USMEC 4)
 6. History of or current ischemic heart disease (USMEC 4)
 7. Multiple cardiovascular risk factors (older age, smoking, diabetes, hypertension) (USMEC 3,4)
 8. Hypertension
 - a. Adequately controlled (USMEC 3)
 - b. Systolic \geq 160 or diastolic \geq 100 (USMEC 4);
 - c. Systolic \geq 140-159 or diastolic of 90-99 (USMEC 3)
 9. Known hyperlipidemia (USMEC 2,3) (consult with medical director)
 10. Diabetes mellitus with nephropathy, retinopathy, neuropathy (USMEC 3,4)
 11. Vascular disease or diabetes of > 20 years duration (USMEC 3,4)
 12. Medically Diagnosed Migraine
 - a. Without aura \geq 35 years of age (USMEC 4 for initiation; USMEC 3 for continuation)
 - b. With aura “any age” (USMEC 4)
 13. Viral hepatitis (acute or flare) (USMEC 3,4)
 14. Cirrhosis-severe (decompensated) (USMEC 4)
 15. Solid organ transplant (complicated) (USMEC 4)
 16. Liver tumor (adenoma or hepatoma) (USMEC 4)
 17. Breast cancer (current--USMEC 4); or (past--USMEC 3)
 18. Valvular heart disease -complicated (pulmonary hypertension, history of sub-acute bacterial endocarditis, risk for atrial fibrillation) (USMEC 4)
 19. Peripartum cardiomyopathy (USMEC 3,4)
 20. Post-partum (non-breastfeeding or breastfeeding) < 21 days (USMEC 4)
 21. Post-partum (non-breastfeeding or breastfeeding) 21- 42 days with other risk factors for VTE (age \geq 35 years previous VTE, thrombophilia, immobility, transfusion at delivery, BMI 30 or >, post-partum hemorrhage, post cesarean delivery, preeclampsia, or smoker) (USMEC 3)
 22. Post-partum (breastfeeding) 21 - 30 days without VTE risk factors (USMEC 3)
 23. Gallbladder disease– symptomatic (current or medically treated) (USMEC 3)
 24. History of cholestasis- (past COC related) (USMEC 3)
 25. Systemic Lupus Erythematosus – With positive (or unknown) antiphospholipid antibodies (USMEC 4)

- 26. Inflammatory bowel (ulcerative colitis, Crohns) (USMEC 2,3)
- 27. Bariatric surgery (history of)—malabsorption procedures (USMEC 3 for COC only)

The CDC 2010 Medical Eligibility Criteria for Contraceptive Use address headaches as follows: Among women with migraine, women who also had aura had a higher risk for stroke than did those without aura. Women with a history of migraine who use COCs are about 2-4 times as likely to have an ischemic stroke as nonusers with a history of migraine (USMEC 4).

See Clinician Information Sheet on Migraine Headaches attached the end of this guideline

III. Management of Women with Special Conditions Requiring Further Evaluation

- A. Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral must be made based on protocols approved by the site Medical Director. In addition, there should be consultation with the site Medical Director if needed.
- B. “Request for Hormonal Contraceptives by Women with Risk Factors Consent Form” must be signed and this must be documented in the medical record if medical conditions exist.
- C. Management of Medication Issues with Combined Hormonal Contraceptives

Drugs Known To Increase Liver Enzyme Metabolism/Decrease Contraceptive Effectiveness	
Anti Epilepsy Drugs (AEDs) – may also be used to treat certain psychiatric illnesses, headaches, chronic pain and other conditions (USMEC 3)	Carbamazepine (Tegretol) Oxcarbazepine (Trileptal) Phenobarbital, Phenytoin (Dilantin), Primidone (Mysoline), Topiramate (Topamax - mild decrease), Lamitrigene
Antiretroviral (ARV) therapy	Ritonavir-boosted protease inhibitors (USMEC 3)
Anti-Mycobacterials (Drugs used to treat tuberculosis) (USMEC 3)	Rifampin, Rifampicin – or rifabutin therapy, Rifamate

1. ARVs - HIV positive women who choose to use hormonal contraception should be encouraged to use condoms with each act of intercourse. Choice of hormonal contraceptive should be based on the woman’s ARV regimen and in consultation with the provider delivering HIV care.
2. Anti-Epileptic Drugs (AEDS) and others listed above –use of monophasic is preferred. Use of back-up barrier methods and the benefits and risks of using DMPA, IUD, or sterilization as alternatives should be discussed with women who need a high degree of protection.
3. Most broad-spectrum antibiotics do not affect the contraceptive effectiveness of CHCs (CDC 1).

III. Medical Screening and Evaluation

- A. Comprehensive medical evaluation (history, physical examination and laboratory testing as indicated) should be completed prior to the provision of combined hormonal contraceptives.
- B. Delayed Exam
 - 1. Physical exam and related preventative services should not be deferred beyond 3 months after the initial visit and may not be deferred beyond 6 months (unless there is a compelling reason for extending the deferral in the clinician's judgment).
 - 2. The reason for the deferral of pelvic exam must be documented in the client's medical record.
 - 3. A complete history, height, weight and BP is required in the medical record.
 - 4. Written results of a physical exam done by another provider within the last 12 months are acceptable.
 - 5. Clients transferring from another provider must have a blood pressure measurement prior to providing CHCs.
 - 6. Pelvic exams are not required until age 21 years unless indicated (ACOG).
- C. Agency site Medical Director approved Pap test screening protocols that are current must be in place and followed.

IV. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a diaphragm should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to diaphragms, including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues
- C. Instruction on care of diaphragm (cleaning and inspection)
- D. Information that that CHCs provides no protection against STIs/HIV
- E. Method specific informed consent
- F. "Request for Hormonal Contraceptives by Women with Risk Factors Consent Form" must be signed by clients with special conditions/risk factors (such as diabetes, chronic hypertension, or multiple cardiovascular risk factors), as indicated.
- G. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- H. Written and verbal instruction on method use (may use Package Insert)
- I. Upon request, a copy of the method specific consent form
- J. Emergency, 24-hour telephone number and location where emergency services can be obtained
- K. Clinic access information

V. PRESCRIBING COMBINED HORMONAL CONTRACEPTIVES

- A. Up to 14 cycles of CHCs may be prescribed for initial and annual clients
- B. Quick Start (same day start method) can be initiated if it is reasonably certain client is not pregnant and the client is not in need of emergency contraception.
 - 1. Instruct the client on the day of the clinic visit to:
 - a. Take the first pill in the pill pack, or
 - b. Insert the vaginal ring, or
 - c. Apply the first patch

2. Instruct client to use a backup method (condoms, etc.) for 7 days.
 3. If there is concern about undetectable early pregnancy, the client should return for a repeat pregnancy test in 2 weeks. If the repeat pregnancy test is negative and the client has no signs of pregnancy (i.e. nausea, breast tenderness), continue the method.
- C. Prescribing vaginal contraceptive ring:
1. Follow the Package Insert Dispensing Information
 2. Only four rings may be dispensed to the client at any one time due to the expiration and storage condition requirements.
 3. An expiration date must be placed on the label of each ring package. This date should not exceed either four months from the date of dispensing or the product expiration date, whichever comes first.
 4. Prior to dispensing, ring must be stored in the refrigerator.
 5. After dispensing to the client, contraceptive ring can be stored for up to 4 months at 25°C (77°F). If vaginal ring becomes frozen, they are considered unusable.
 6. Vaginal ring should never be stored in direct sunlight or at temperatures above 30°C (86°F).
- D. Prescribing COC with Drospirenone (progesterone used in some combined hormonal contraceptives): If this progesterone is provided to a woman taking any of the medications (listed below) that predispose to hyperkalemia on a daily, long-term basis, the package insert states the client should have their potassium level checked during the first month of COC use.

Medications to Check Prior to Prescribing Drospirenone

- Nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Motrin, Advil) and Naprosyn (Aleve), when taken long-term and daily for treatment of arthritis or other problems;
- Potassium-sparing diuretics such as spironolactone;
- Potassium supplementation;
- ACE (angiotensin converting enzyme) inhibitors such as Capoten (captopril), Vasotec (enalapril) and Zestril (lisinopril).
- Angiotensin - II receptor antagonists such as Cozaar (losartan potassium,) Diovan (valsartan) and Avapro (irbesartan);
- Heparin

Source : Contraceptive Technology, 19th Edition

- E. Prescribing Transdermal Patch: the effectiveness of the patch may be decreased among women who weigh >90 kg (198 lbs.) (USMEC 2).
- F. Timing of Initiation — The table below should be followed when initiating CHC. Alternative timings must be individualized to ensure contraceptive protection.

Current Method	CHC Initiation	Back-Up
No effective contraception	Anytime in cycle if it is reasonably certain client is not pregnant. If possibility of pregnancy is suspected, a highly sensitive urine test must be completed. If pregnancy test is negative, initiate COC and advise client to repeat urine test in 2 weeks.	If more than 5 days since menstrual bleeding started, back-up for 7 days
Correct use of vaginal contraceptive ring or transdermal contraceptive patch (changing to COC)	Within 24 hours of the removal of ring or patch	None
	At end of cycle, anytime within 7 days of last patch or ring removed.	None
Correct use of COC or patch (Changing to vaginal contraceptive ring)	Within 24 hours of the last COC tablet taken or patch removed	None
	At end of cycle, anytime within 7 days of last COC tablet or patch removed.	None
Correct use of COC or vaginal contraceptive ring (Changing to patch)	Anytime within 5 days of the last active COC tablet	None
	Within 24 hours of ring removal	None
Progestin-Only Pills	Any day of the month. There should be no skipped days between last pill and first day of COC use.	None
Implant	On same day implant is removed	Back-up method for 7 days
DMPA	On day when next injection is due	None
Intrauterine contraception in place	On same day IUD is removed	Back-up method for 7 days
Post-surgical abortion	Within five days of a completed procedure	None
Post-medical abortion (Can initiate prior to ultrasound confirmation of termination of pregnancy)	Day of Misoprostol up to seven days after Mifepristone	None
	Beyond seven days after Mifepristone if intercourse not already resumed	Back-up method for 7 days

- A. Clients should be provided an instruction sheet regarding management of deviations (e.g. missed pills, ring left in vagina >3 weeks) from the recommended CHC regimen

VI. MANAGEMENT OF SIDE EFFECTS AND COMPLICATIONS

- A. Warning Signs (ACHES) – May or may not be related to CHC use and further clinical evaluation is necessary to determine whether continuation of CHC is appropriate
 - A—Abdominal pain
 - C—Chest pain
 - H—Headaches
 - E—Eye Problems
 - S—Severe Leg Pain
- B. Vaginal Bleeding - Irregular menstrual patterns (spotting to menstrual flow) are common in the first 2-3 cycles of use. If these patterns continue past the first three cycles or if heavy bleeding continues, the client needs to be assessed.
 - 1. Irregular Bleeding – After determining consistent usage; no underlying pathology; R/O pregnancy; and if not at risk of STI's, reassure patient. Use of a three-day course of NSAID's may help.
 - 2. Amenorrhea – R/O pregnancy
- C. Other side effects such as nausea, vomiting, breast tenderness, and headache should be further assessed to determine possible etiology and whether change in contraceptive method is needed.

VII. FOLLOW-UP

- A. A blood pressure check should be conducted within 3 weeks of initiation when patient is on active part of CHC (not when she is on placebo week or week off ring, patch, etc.). At this visit response to and satisfaction with method can be assessed.
- B. CHC user must be advised to return to the clinic for additional follow-up if:
 - 1. A significant CHC related problem is suspected
 - 2. She is at increased risk for complications resulting from CHC use
 - 3. Pre-hypertensive (SBP is 120-139 or DBP is 80-89) on two consecutive visits):
 - a. The client may continue CHCs but should be counseled regarding lifestyle modifications.
 - b. Referral to a primary care provider is also recommended.
- C. At each CHC related medical visit, the client should be queried about changes in personal history, headaches, blurred or double vision, pain or swelling in arms or legs, chest pain or shortness of breath, abdominal pain, jaundice, or severe depression.
- D. When starting a new method, especially with teens, can consider follow-up visit to check for adherence to method and to assess for method satisfaction.

VIII. DOCUMENTATION

- A. Orders must be written in medical record initially, annually and upon method change.
- B. All CHCs distributed must be documented in the medical record and/or computer system.
- C. All education/counseling must be documented

REFERENCES

1. CDC Medical Eligibility Criteria for Contraceptive Use. MMWR, Vol. 57, No.RR-4, June 18, 2010
2. Manufacturer's FDA Product Patient Insert (Ring Dispensing)

Management of Clients Using CHC Who Develop High Blood Pressure Algorithm A

Systolic (SBP) 140-159 or Diastolic (DBP) 90-99 (USMEC 3)

Instruct client to return two or more times within a four week period for BP checks. At each visit, take two readings, five minutes apart, sitting in a chair. Confirm elevated readings in contralateral arm. Base decision on the average of these readings.

- A. If the average of at least two properly measured BPs at any visit is SBP ≥ 160 or DBP ≥ 100 :
 1. **Discontinue CHC.** (USMEC 4)
 2. Recommend or refer for medical evaluation

- B. If the average of at least two properly measured BPs is SBP $\geq 140-159$ or DBP $\geq 90-99$ on at least two different visits:
 1. **Discontinue CHC** (USMEC 3)
 2. Educate client on alternative methods of birth control.
 3. With client's consent, initiate a non-estrogen containing method. (Please note if prescribing DMPA, BP $\geq 160/100$ is a special condition requiring further evaluation)
 4. Re-check BP within three months
 5. If BP returns to normal ($<120/80$) or prehypertensive range (SBP 120-139 or DBP 80-89), may consider initiating lower dose CHC, if available.

- C. If the average of two properly obtained readings each visit is SBP 120-139 or DBP 80-89 (prehypertension)
 1. May continue CHC
 2. Provide education on lifestyle modifications (dietary and exercise)
 3. Consider BP re-check in three to six months

- D. If $<120/80$ on all readings:
 1. May continue CHC.

(Source: NIH Publication No. 03-5231, 2003)

CLIENT EDUCATION FOR COMBINED HORMONAL CONTRACEPTIVES (CHCs)

Before you start taking CHCs, be sure you understand both the benefits and the possible problems of using them. This information sheet also lists the danger signs you should watch for. If you have any questions as you read, we will be happy to talk about them with you.

You will begin written information explaining the use, effectiveness, and medically recognized benefits and risks of the available birth control methods and devices. You should read the package insert or the CHC fact sheet and ask questions about anything you do not understand.

Combined Hormonal Contraceptives contain the hormones estrogen and progesterone, similar to hormones produced by a woman's body. They primarily work to prevent pregnancy by keeping eggs from being released by the ovaries. You should not take CHC's if you have reason to think you might be pregnant.

In addition to its value as a method of birth control, most women will have the following benefits from using a CHC:

- Predictable, regular menstrual cycles;
- Decreased menstrual cramps and blood loss;
- Less iron deficiency anemia;
- Less acne;
- Some protection from non-cancerous breast tumors and ovarian cysts;
- Some protection from ovarian and uterine lining cancer;
- Decreased risk of infection of the pelvis (PID);
- Fewer ectopic pregnancies.

There may be less protection from pregnancy when CHCs are taken with certain drugs, especially those used to control seizures. You should talk to your clinician about what to do if you take any other medicine with CHCs. If you see a health care provider for any reason, you should tell them you are taking a CHC.

CHC users have a slightly greater chance than non-users of developing certain serious problems that may cause death in rare cases including:

- Blood clots in the legs that can travel to the lungs
- Stroke
- Heart attack
- Liver tumors

You should **NOT** use any CHC if you have had, now have, or develop in the future any of the following:

- Blood clots in the veins or arteries
- Serious liver disease
- A heart attack or stroke
- Cancer of the breast
- Headaches with numbness or weakness in the arms or legs
- Headaches with vision problems or feeling as if the room is spinning

- Multiple cardiovascular risk factors (tobacco use, diabetes, high blood pressure, high cholesterol)
- Valvular heart disease with complications
- Known blood clotting conditions
- Jaundice with prior hormonal contraceptive use or with pregnancy
- Prolonged immobilization due to recent/anticipated surgery or illness
- Known or suspected pregnancy
- Gallbladder disease (currently symptomatic or medically treated)
- Systemic lupus
- History of bariatric surgery-malabsorptive procedure (pill only)
- Less than 21 days post-partum delivery (breastfeeding or not breastfeeding)
- Less than 21-42 days (breastfeeding or not breastfeeding) with risk factors for blood clots (age \geq 35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI 30 or $>$, post-partum hemorrhage, post cesarean delivery, preeclampsia, or smoker)
- Smoking and age 35 and over
- Cardiac disease related to pregnancy (before or after)
- Organ transplant

Minor reactions to CHCs may include:

- Nausea, vomiting, headache
- Breast tenderness
- Weight gain or loss
- Spotting between periods
- Skin irritation (Patch only)
- Increased vaginal discharge (Ring only)

You should watch for the following danger signals and report any to a clinician **immediately**:

- Sharp or crushing chest pain or coughing blood
- Shortness of breath
- Unusual swelling or pain in the legs or arms
- Sudden severe headaches
- Changes in the frequency, severity, or associated symptoms of your headache
- Eye problems such as loss of vision
- Severe pain in the stomach or abdomen
- Yellowing of the skin or eyes
- Severe depression
- Unusually heavy bleeding from the vagina
- New lump in your breast
- No period after having a period every month

Some other things to be aware of:

- The patch may be less effective for women who weigh more than 198# (90 kg); (Patch only).
- If you are using oil-based vaginal medications on a regular basis or for more than several days in a row, you should discuss this with your clinician. (vaginal contraceptive ring only).
- Using a CHC does not protect against sexually transmitted infections/HIV and a serious infection could cause sterility. If you or your partner has other sexual partners, you should use latex condoms to prevent infections.

CONSENT FOR COMBINED HORMONAL CONTRACEPTION

I, (print or type name) _____,
request Combined Hormonal Contraceptives as my family planning method.

- I have received educational materials as well as the patient package insert that explains the, benefits and risks of using _____ which is the type of combined hormonal contraception I have selected.
- I understand that no birth control method is perfect and that some women have gotten pregnant while on the CHC (3 out of every 1000 women during the first year of perfect use).
- I understand CHCs 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 CHC to decrease the effectiveness of the CHC. I know it is important to tell all my health care providers that I am on the CHC.
- I understand that while using the CHC 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 CHC
- 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 CHC 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: _____

Please complete the following if interpretation of informed consent was required:

An interpreter was offered to the client. yes no

This form has been read to the client in the client’s spoken language. yes no

Patient’s Language (specify):

Interpreter’s Name: (print or type name of interpreter)

Interpreter Services provided by(agency):

Date: _____ Interpreter Signature: _____

Staff Use Only:

By my signature I affirm that:

- The client has read this form or had it read to her by an interpreter.
- The client states that she understands this information.
- The client has indicated that she has no further questions.
-

Date: _____ Staff Signature: _____

COMBINED HORMONAL CONTRACEPTION INITIATION RECORD

Date _____
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
Migraines (including without aura) if age 35 or older [] 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

Clinician Comments _____

Assessment: Combined oral contraception candidate? [] yes [] no

Contraception Plan:

Combined oral contraceptive initiated? [] yes [] no

Brand name _____

Number of cycles _____

Start date _____

Other contraceptive method initiated/continued/restarted? [] yes [] no

Method name _____

Back-up and STI Protection Plan:

Plan B [] offered [] give

Condoms [] offered [] given

Return Visit _____

Interpreter Name _____

Staff Signature

Date

REQUEST FOR HORMONAL CONTRACEPTIVES
FOR WOMEN WITH SPECIAL CONDITIONS/RISK FACTORS

Name of Client: _____

Client Chart Number _____

Agency Clinic _____

Before you give your consent, be sure you understand the information we have given you. If you have any questions as you read, we will be happy to discuss them with you. You can change your mind at any time about using this method. Remember that your consent is entirely voluntary. You may ask for a copy of this form.

There are special risk factors that increase the chance of developing a serious problem while using Combined Hormonal Contraceptives. The more risk factors you have the greater your risk. The following risk factors have been identified:

- _____ Tobacco use with Age \geq 35 years
- _____ Reported Hyperlipidemia
- _____ Diabetes
- _____ Chronic Hypertension
- _____ Other _____

I have been counseled, read the client education materials and the informed consent and the above statement. I understand the risk factors. After thorough discussion with the clinician regarding my risk factors and alternative non-hormonal methods of contraception we have agreed that combined hormonal contraceptives will be prescribed for me.

Interpreter Name _____

Patient Signature _____ **Date** _____

Witness _____ **Date** _____

ORAL CONTRACEPTION

I. INTRODUCTION

Oral contraceptives (OCs), also known as “the pill”, are the most popular method of contraception among female adolescents. The primary mechanism of action is inhibition of ovulation. In addition, oral contraceptives produce an endometrium that is not receptive to ovum implantation and cervical mucus that 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%

Typical use failure is directly related to patient compliance with use. Studies show that teens have a difficult time complying with daily use of OCs, therefore, alternative methods of contraception should be encouraged.

The progestin-only pill (the minipill) is less effective than combined oral contraceptives in preventing pregnancy.

Patients using oral contraceptives (COC or POP) should receive counseling about and, as needed, prescriptions for emergency contraception (EC).

II. ORAL CONTRACEPTIVE PILL TYPES, FORMULATIONS, AND PILL-USE PATTERNS

- A. There are two types of oral contraceptives:
 - 1. Combined oral contraceptives (COCs), which contain an estrogen and a progestin
 - 2. Progestin-only contraceptives (POPs), which contain a progestin but no estrogen. This pill is often referred to as “the minipill”
- B. Combined oral contraceptives are available in 2 basic formulations:
 - 1. The monophasic formulation, in which each active pill contains the same doses of estrogen and progestin.
 - 2. The multiphasic formulations can have varying amounts of estrogen and/or progestin in the active pills.
- C. There are multiple different patterns of combined oral contraceptive pill use that are options
 - 1. **28-Day Cycling** – Most pill packs have 21 active hormone pills and 7 inactive (placebo) pills.
 - 2. **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.
 - 3. **Extended regimens** – There is no biological reason to have monthly withdrawal bleeding on oral contraception. There are multiple extended regimens, and there are some pills that are formulated and packaged specifically for this type of extended regimen. If a client chooses an extended regimen, a monophasic, combined oral contraceptives must be used.

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. All clients using extended regimens have the potential for breakthrough bleeding and must be counseled as such.

- a. Bi-Cycling – Skipping the placebo pills at the end of every other pack of pills yields one period after 6 weeks of active pills.
 - b. Tri-Cycling – 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.
 - c. Other Extended Regimens (e.g. Seasonale®) - COCs may be packaged by manufacturers as extended regimens. Seasonale®, for example, has 84 active pills followed by 7 inactive pills. The progestin and estrogen are the same as Nordette®.
 - d. Continuous – The client takes only active pills daily continuously. Breakthrough bleeding will occur.
- D. The progestin-only contraceptive pill is taken every day without interruption.

III. BENEFITS AND DISADVANTAGES OF COCs and POCs

- A. Combined oral contraceptives (COCs) benefits:
 1. Effectiveness
 2. Safety in years of consecutive use without risk of complications
 3. Ease of reversibility
 4. Positive menstrual effects such as
 - a. Decreased cramps
 - b. Decreased blood loss
 - c. Reduction of premenstrual symptoms
 5. Health benefits are listed in Appendix A.
- B. Combined oral contraceptives (COCs) disadvantages:
 1. Must be taken daily
 2. Expensive
 3. Provide no protection against sexually transmitted infections including HIV.
 4. Have Possible side effects including
 - a. Missed periods
 - b. Breakthrough bleeding
 - c. Nausea
 - d. Vomiting
 - e. Headaches
 - f. Depression
 - g. Decreased libido
 5. Have potential health risks (listed in Appendix B)
- C. Progestin-only contraceptive pill (POCs) benefits:
 1. Estrogen-free, and therefore, useful for clients unable to tolerate the estrogen effects of combined oral contraceptives or who have contraindications against taking an estrogen-containing contraceptive
 2. Can be taken during lactation
 3. Appears to have no harmful effect on blood pressure or on coagulation
- D. Progestin-only contraceptive pills (POCs) disadvantages:
 1. Irregular menstruation

2. 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.

IV. CLIENT SELECTION

Refer to section on Combined Hormonal Contraception for a review of indications and contraindications for OCP use.

- A. 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.
- B. 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.
- C. 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.
- D. The ADA recommends that health care providers consider screening patients at 3-year intervals beginning at age 45, particularly in those with BMI ≥ 25 kg/m. Testing should be considered at a younger age or be carried out more frequently in individuals who are overweight and have one or more of the other risk factors such as a first-degree relatives (parent, sibling, or child) who have diabetes mellitus, history of gestational diabetes, history of PCOS, or hyperlipidemia.
- E. Postpartum clients with a history of gestational diabetes should have a fasting 75-g oral glucose tolerance test 6 weeks postpartum to assess for ongoing diabetes.
- F. 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. Do not wait for the first menses to start contraception, as most women will ovulate before their first menstrual period. See section below on method initiation for specific postpartum initiation instructions and precautions.
- G. Contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D)

V. INITIATION OF ORAL CONTRACEPTIVE PILLS

- A. Patients starting on OCP are not required to have a pelvic examination, and access to contraception should not be delayed while waiting for cervical cancer screening. For women at risk, STI testing is encouraged, but can be performed through urine testing.
- B. Pill choice principles:
 1. Use the lowest dose of oral contraceptives that will provide pregnancy protection, provide non-contraceptive benefits, and minimize side effects.

2. Monophasic formulations should be ordered if cycle lengths are to be extended with elimination of some pill-free intervals.
 3. 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.
- C. QuickStart: **QuickStart protocols are highly encouraged** when a patient is starting (or restarting) oral contraceptive pills (COC or POP). Quickstart improves compliance with starting the second month of OCP, and may decrease risk of unintended pregnancy.
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.
 6. The client should check a pregnancy test if she has not seen a normal menses within 4 weeks of starting OCP.
- D. 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.
- E. 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.
- F. COC Start in post partum, non-breastfeeding women:
1. In women who are <21 days postpartum, combined hormonal contraceptives should not be used (USMEC category 4).
 2. In women who are 21--42 days postpartum and have other risk factors for VTE in addition to being postpartum, the risks for combined hormonal contraceptives usually outweigh the advantages and therefore combined hormonal contraceptives generally should not be used (USMEC Category 3); however, in the absence of other risk factors for VTE, the advantages of combined hormonal contraceptives generally outweigh the risks, and they can usually be used (USMEC Category 2).
 3. In women who are >42 days postpartum, no restriction applies for the use of combined hormonal contraceptives related to postpartum status.
 4. Do not wait for the first menses to start contraception, as most women will ovulate before their first menstrual period.
- G. For new COC starts, dispense a 3-month supply. Also provide the client with a prescription for a year-supply of the OCP, so access to contraception is not limited by requiring the client to return to clinic. Clients may return for additional pills to be dispensed as needed.
- H. New users should return in 1-3 months for a blood pressure check, and to assess compliance.

VI. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided an oral contraceptive should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to oral contraceptive method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues (Appendix A and B).
- C. Prescription/counseling about emergency contraception, and, for teens, a prescription with multiple refills.
- D. Instruction that contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D).
- E. Instruction on 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.
- F. Information that oral contraceptives do not offer protection against STIs/HIV, the routine use of condoms should be encouraged to decrease STI risk.
- G. Informed consent (form attached to this guideline) and a copy of the same upon request
- H. If COC is being provided/prescribed, then CHC consent form should be reviewed and signed.
- I. If COC is being provided/prescribed to client with risk factors then Request for CHC for Women with Risk Factors form should be reviewed and signed.
- J. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- K. Written and verbal instruction on method use (may use Package Insert)
- L. Emergency, 24-hour telephone number and location where emergency services can be obtained
- M. Clinic access information

VII. FOLLOW-UP

- A. The client should return in 1-3 months for evaluation for oral contraception continuation. The client should have a blood pressure check and be evaluated for side effects.
- B. Serious side effects that may warrant immediate consultation and discontinuation of combined oral contraceptives include:
 - 1. Sharp chest pain, coughing up blood, or sudden shortness of breath
 - 2. Pain in calf or leg
 - 3. Crushing chest pain or tightness in the chest
 - 4. Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg
 - 5. Sudden partial or complete loss of vision
 - 6. Breast masses suspicious for potential malignancy
 - 7. Severe abdominal pain or tenderness.
 - 8. Severe problems with sleeping, weakness, lack of energy, fatigue, or change in mood.
 - 9. Jaundice
 - 10. Swelling of the fingers or ankles

VIII. MANAGEMENT OF SIDE EFFECTS AND COMPLICATIONS

Refer to section on Combined Hormonal Contraception for more detailed information regarding side effects and complications related to CHC use.

- 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.
- E. If a woman experiences signs or symptoms of serious side effects related to CHC use reviewed above, discontinuation of oral contraceptive and immediate evaluation is warranted.
- F. In addition to signs or symptoms of DVT or other clotting disorders or liver dysfunction, sometimes discontinuation of oral contraception may be necessary for other reasons. Reasons for stopping combined oral contraceptives:
 - 1. 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.
 - 2. An elevated blood pressure (BP) with a systolic of 140-160 or a diastolic of 90-100 on 3 separate visits or any BP \geq 160/100 are reasons to discontinue oral contraception and refer the client for medical evaluation. Begin the client on a progestin-only or non-hormonal method of contraception immediately.
 - 3. With evidence of severe clinical depression, refer the client for psychiatric evaluation. If depression is felt to be worsened by the oral contraceptives, you may consider stopping the method and initiating a non-hormonal method immediately. For mild mood changes a different formulation may be offered.
 - 4. Any client desiring to become pregnant may be advised to continue use of OCP until pregnancy is desired. Most women can become pregnant within a year of stopping OCP, similar to women who are not using hormonal contraception. 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.
 - 5. Any client with post-pill amenorrhea of more than 6 months should be referred for evaluation.

IX. DOCUMENTATION

- A. Order must be written in medical record initially, annually, and upon method change.

- B. Oral contraceptives dispensed must be documented in the medical record and/or computer system.
- C. All education/counseling must be documented.

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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
11. Decreased number of sickle cell crises

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 hepatocellular disease with abnormal liver function. Women who are hepatitis carriers, or who have had a history of hepatitis, but now have normal liver function may use estrogen-containing birth control.
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
17. Migraine headaches (without aura) and age > 35
18. Migraine headaches (without aura) and other risk factors for cardiovascular events, such as smoking or hypertension.

Exercise caution in providing combined oral contraceptives for women with:

1. Severe migraine
2. Hypertension (<160/100 mm Hg)
3. Active gall bladder disease
4. During the first 3-4 weeks postpartum
5. Surgery or injury requiring immobilization
6. Hyperlipidemia or history thereof
7. Lactation
8. Diabetes mellitus, history of gestational diabetes or other high-risk factors for diabetes
9. Amenorrhea or oligomenorrhea
10. Difficulty in compliance, e.g., mental illness, drug abuse, etc.
11. Undiagnosed vaginal/uterine bleeding
12. Cardiac or renal disease or history thereof
13. Over 50 years of age
14. 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.

You should still have a “period” each month. If this is delayed, or if you have a lighter-than-normal period, you should check a pregnancy test immediately. If this test is positive, please call your clinician.

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 (8 out of every 100 women during the first year of typical 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: _____

VAGINAL CONTRACEPTIVE RING

I. INTRODUCTION

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.

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 primary mechanism of action is inhibition of ovulation. In addition, the vaginal contraceptive ring produces an endometrium that is not receptive to ovum implantation, and cervical mucus that 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%

Patients using NuvaRing should receive counseling about and, as needed, prescriptions for emergency contraception.

II. VAGINAL CONTRACEPTIVE RING DOSING SCHEDULE

A. Standard

1. Each ring is to remain in the vaginal 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.

III. CLIENT SELECTION

Refer to section on Combined Hormonal Contraception for a review of indications and contraindications for vaginal contraceptive ring use.

- A. Appropriate candidates for vaginal contraceptive ring use include:
 - 1. Any client who meets criteria for any of the estrogen/progestin contraceptives.
 - 2. Any client who cannot remember to take the pill, deal with the patch, does not like shots or use local contraception at the time of intercourse.
- B. 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.
- C. 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.
- D. 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.
- E. The ADA recommends that health care providers consider screening patients at 3-year intervals beginning at age 45, particularly in those with BMI ≥ 25 kg/m. Testing should be considered at a younger age or be carried out more frequently in individuals who are overweight and have one or more of the other risk factors such as a first-degree relatives (parent, sibling, or child) who have diabetes mellitus, history of gestational diabetes, history of PCOS, or hyperlipidemia.
- F. Postpartum clients with a history of gestational diabetes should have a fasting 75-g oral glucose tolerance test 6 weeks postpartum to assess for ongoing diabetes.
- G. 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. Do not wait for the first menses to start contraception, as most women will ovulate before their first menstrual period. See section below on method initiation for specific postpartum initiation instructions and precautions.
- H. Contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D)
- I. 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.

IV. VAGINAL CONTRACEPTIVE RING METHOD INITIATION

- A. Patients starting on the vaginal contraceptive ring are not required to have a pelvic examination. Access to contraception should not be delayed while waiting for cervical cancer screening. For women at risk, STI testing is encouraged, but can be performed through urine testing.
- B. QuickStart: **QuickStart protocols are highly encouraged** when a patient is starting (or restarting) the vaginal contraceptive ring. Quickstart improves compliance with starting the second month of contraceptive ring use, and may decrease risk of unintended pregnancy.
 - 1. The clinician must be reasonably certain the client is not pregnant.
 - 2. Insert the first ring on the day of the visit.
 - 3. A back-up method of contraception is recommended for 7 days.
 - 4. If the client is in need of emergency contraception (unprotected vaginal intercourse has occurred within the past 5 days), she should take both tablets of Plan B® at once on the visit day and start her ring no later than the next day.
 - 5. Her next menses may be delayed until she completes her first cycle of the ring.
 - 6. Quick start does not increase irregular spotting or bleeding.
- C. 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.
- D. 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.
- E. 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.
- F. 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.
- G. 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.
- H. 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.
- I. 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.
- J. Following a second trimester abortion:

1. A new ring may be inserted immediately after the second trimester abortion.
 2. A back-up method of contraception is recommended for 7 days if the NuvaRing® is started a week or more after the abortion procedure.
- K. Following a delivery:
1. Women who breastfeed should not use NuvaRing®.
 2. For non-breastfeeding women:
 - a. In women who are <21 days postpartum, use of combined hormonal contraceptives should not be used (USMEC category 4).
 - b. In women who are 21--42 days postpartum and have other risk factors for VTE in addition to being postpartum, the risks for combined hormonal contraceptives usually outweigh the advantages and therefore combined hormonal contraceptives generally should not be used (USMEC Category 3); however, in the absence of other risk factors for VTE, the advantages of combined hormonal contraceptives generally outweigh the risks, and they can usually be used (USMEC Category 2).
 - c. In women who are >42 days postpartum, no restriction applies for the use of combined hormonal contraceptives related to postpartum status.
 - d. Any other medical conditions should be taken into consideration when determining the safety of the contraceptive method.

V. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a vaginal contraceptive ring should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to oral contraceptive method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues (Appendix A and B).
- C. Prescription/counseling about emergency contraception, and, for teens, a prescription with multiple refills.
- D. Instruction that contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D).
- E. Instruction on how to insert and remove the vaginal contraceptive ring (see section below and refer to Patient Package Insert).
- F. Instruction on what to do if ring is expelled or left in for longer than 3 week period. Additionally, for some situations the use of emergency contraceptive pills may be considered.
- G. Information that vaginal contraceptive ring does not offer protection against STIs/HIV, the routine use of condoms should be encouraged to decrease STI risk.
- H. Informed consent (form attached to this guideline) should be reviewed and signed and a copy of the same upon request
- I. If vaginal contraceptive ring is being provided/prescribed, then CHC consent form should be reviewed and signed.
- J. If vaginal contraceptive ring is being provided/prescribed to a client with risk factors, then a Request for CHC for Women with Risk Factors form should be reviewed and signed.
- K. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- L. Emergency, 24-hour telephone number and location where emergency services can be obtained

M. Clinic access information

VI. INSTRUCTIONS FOR VAGINAL CONTRACEPTIVE RING INSERTION, REMOVAL AND STORAGE

A. General use instructions:

1. 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).
2. Removal of the ring for sexual intercourse is not recommended, but efficacy is maintained if the ring is replaced within 3 hours.
3. Tampon use is acceptable.
4. 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.

B. Vaginal ring insertion:

1. The client washes and dries her hands.
2. The ring is removed from its reclosable foil pouch. The pouch is kept for proper disposal of the ring after use.
3. Client position for ring placement are lying down, squatting, or standing with one leg up.
4. The ring is held between the thumb and index finger and the opposite sides of the ring are pressed together.
5. The folded ring is gently placed into the vagina. The exact position of the ring is not important for it to work.
 - a. Most women do not feel the ring in place.
 - b. If the ring is causing discomfort, it should be gently pushed farther into the vagina.
6. The ring is to remain in place for 3 weeks in a row.

C. Vaginal ring removal:

1. The ring should be removed 3 weeks after the insertion on the same day of the week as it was inserted.
2. 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.
3. 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.
4. The menstrual period will start in 2-3 days and may not be finished before the next ring is inserted.

VII. INSTRUCTIONS FOR MANAGEMENT OF INADVERTENT PROLONGED USE, EXPULSION OR PROLONGED RING-FREE PERIOD

A. Instructions for inadvertent prolonged use:

1. If the ring has been left in the vagina for an extra week or less (4 weeks or less),
 - a. Remove the ring and insert a new ring after a 1-week ring-free break.
 - b. No back-up contraception is needed.
2. If the ring has been left in the vagina for 4 or more weeks,

- a. Remove the ring and insert a new ring.
 - b. Pregnancy should be ruled out.
 - c. A back-up method of contraception must be used until a new ring has been in place for 7 days.
- B. Instructions for prolonged ring-free interval
- 1. If the ring-free interval has extended beyond 1 week:
 - a. The possibility of pregnancy should be considered.
 - b. A new ring may be inserted immediately.
 - c. A back-up method of contraception must be used until a new ring has been in place for 7 days.
- C. Instructions for inadvertent ring removal or expulsion
- 1. If the ring has slipped out or been removed from the vagina for less than 3 hours,
 - a. The client is still protected from pregnancy.
 - b. 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.
 - c. No back-up method of contraception is needed.
 - 2. If the ring has been out of the vagina for more than 3 hours,
 - a. The client may not be adequately protected from pregnancy.
 - b. The ring can be rinsed with cool to lukewarm (not hot) water and re-inserted as soon as possible.
 - c. A back-up method of contraception must be used until the ring has been place for 7 days in a row.

VIII. INSTRUCTIONS FOR VAGINAL RING CONTRACEPTIVE STORAGE AND DISPENSING

- A. Storage instructions:
- 1. Prior to dispensing to the client, NuvaRing should be refrigerated at 36-46°F.
 - 2. 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.
 - 3. A client may refrigerate the ring if so desired, but it is not recommended unless the client's refrigerator has a working thermometer.
- B. Dispensing instructions:
- 1. Give the new NuvaRing client a 1- or 2-month supply (1 or 2 rings).
 - 2. Clients may receive a prescription for a one-year supply of NuvaRing.
 - 3. Remind patients that NuvaRing should be stored at room temperature, range 59-86°F away from direct sunlight. NuvaRing can be stored for up to 4 months, which is why it is recommended that NuvaRing be dispensed at a maximum of 3 rings at a time.
 - 4. Dispensing more than 3 rings at a time may be necessary – women should be reminded regarding possible decreased product effectiveness after 4 months of storage or after the expiration date on the packaging.
 - 5. The routine use of condoms is recommended when a back-up method of contraception is warranted.
 - 6. The routine use of condoms is recommended to decrease the risk of acquiring sexually transmitted diseases.

IX. FOLLOW-UP

- A. 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.
- B. Serious side effects that may warrant immediate consultation and discontinuation of vaginal contraceptive ring include:
 - 1. Sharp chest pain, coughing up blood, or sudden shortness of breath
 - 2. Pain in calf or leg
 - 3. Crushing chest pain or tightness in the chest
 - 4. Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg
 - 5. Sudden partial or complete loss of vision
 - 6. Breast masses suspicious for potential malignancy
 - 7. Severe abdominal pain or tenderness.
 - 8. Severe problems with sleeping, weakness, lack of energy, fatigue, or change in mood.
 - 9. Jaundice

X. MANAGEMENT OF SIDE EFFECTS AND COMPLICATIONS

Refer to section on Combined Hormonal Contraception for more detailed information regarding side effects and complications related to CHC use.

- A. 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.
- B. 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.
- C. 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.
- D. If a woman experiences signs or symptoms of serious side effects related to CHC use reviewed above, the vaginal ring should be removed immediately and further evaluation is warranted.
- E. Other reasons for stopping the contraceptive ring:
 - 1. 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.
 - 2. 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.
 - 3. 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.
- F. Any client with post-ring amenorrhea of more than 6 months should be referred for evaluation.

- G. 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.
- H. Any client desiring to become pregnant may be advised to use contraceptive ring until pregnancy is desired. Fertility may return immediately following discontinuation of the ring. 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.

XI. DOCUMENTATION

- A. Order must be written in medical record initially, annually, and upon method change.
- B. Oral contraceptives dispensed must be documented in the medical record and/or computer system.
- C. All education/counseling must be documented.

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1. US Medical Eligibility Criteria for Contraceptive Use, 2010. Adapted from the World Health Organization Medical Eligibility Criteria for Contraceptive Use, 4th Edition. MMWR, May 28, 2010; Vol 59.
2. Hatcher RA et al. Contraceptive Technology. 18th Revised Edition. Ardent Media, Inc., New York, 2004
3. Hatcher RA, Ziemann M et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2004
4. Medical Eligibility Criteria For Contraceptive Use. 3rd Ed., Reproductive Health and Research, World Health Organization, Geneva Switzerland, 2004
5. Speroff L, Darney P. A Clinical Guide For Contraception. 4th Ed., Lippincott Williams & Wilkins, Philadelphia, PA, 2005
6. NuvaRing® Package Insert. West Orange, NJ: Organon USA Inc., 2004
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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
11. Possible fewer sickle cell crises

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 ($\geq 160/100$ 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 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
17. Migraine headaches (without aura) and age > 35
18. Migraine headaches (without aura) and other risk factors for cardiovascular events, such as smoking or hypertension.
19. Use prior to 3 weeks post-partum.

Exercise caution in providing the vaginal contraceptive ring for women with:

1. Severe headache without aura
2. Hypertension (mild, or controlled with medication)
3. Active gall bladder disease
4. Surgery or injury requiring immobilization
5. Hyperlipidemia or history thereof
6. Lactation
7. Amenorrhea or oligomenorrhea (prior to evaluation)
8. Difficulty in compliance, e.g., mental illness, drug abuse, etc.
9. Undiagnosed vaginal/uterine bleeding

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

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 (8 out of every 100 women during the first year of typical 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: _____

TRANSDERMAL CONTRACEPTIVE PATCH

I. INTRODUCTION

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.

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 that 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. The primary mechanism of action is inhibition of ovulation. In addition, the contraceptive patch produces an endometrium that 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%

Patients using the patch should receive counseling about and, as needed, prescriptions for emergency contraception.

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 possible increased risk. Overall, risk of DVT with use of the patch is much less than the risk of DVT during pregnancy.

II. TRANSDERMAL CONTRACEPTIVE PATCH DOSING SCHEDULE

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.

- 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.

III. CLIENT SELECTION

Refer to section on Combined Hormonal Contraception for a review of indications and contraindications for transdermal contraceptive patch.

- A. Appropriate candidates for transdermal contraceptive patch use include:
 - 1. Any client who meets criteria for any of the estrogen/progestin contraceptives.
 - 2. Any client who cannot remember to take the pill, objects to vaginal ring use, does not like shots or use local contraception at the time of intercourse.
- B. 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.
- C. Clients with a history or presence of hypersensitivity in response to topical bandages or adhesive applications should be excluded.
- D. 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.
- E. 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.
- F. The ADA recommends that health care providers consider screening patients at 3-year intervals beginning at age 45, particularly in those with BMI ≥ 25 kg/m. Testing should be considered at a younger age or be carried out more frequently in individuals who are overweight and have one or more of the other risk factors such as a first-degree relatives (parent, sibling, or child) who have diabetes mellitus, history of gestational diabetes, history of PCOS, or hyperlipidemia.
- G. Postpartum clients with a history of gestational diabetes should have a fasting 75-g oral glucose tolerance test 6 weeks postpartum to assess for ongoing diabetes.

- H. The contraceptive patch 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. Do not wait for the first menses to start contraception, as most women will ovulate before their first menstrual period. See section below on method initiation for specific postpartum initiation instructions and precautions.
- I. Clients must be counseled that the contraceptive patch may be less effective in women with a body weight of 198 lbs. or more. Weight >198 pounds is not an absolute contraindication to use of the patch. Women who weight more than 198 pounds should be counseled about and encouraged to use other, more effective, methods of contraception. However, if the client requests the patch, she should be provided with this method and you should document your counseling.
- J. Contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D)

IV. TRANSDERMAL CONTRACPETIVE PATCH INITIATION

- A. Patients starting on the patch are not required to have a pelvic examination. Access to contraception should not be delayed while waiting for cervical cancer screening. For women at risk, STI testing is encouraged, but can be performed through urine testing.
- B. If a client is starting the contraceptive patch for the first time, she should wait until the day she begins her menstrual period. A Quickstart, 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.
- C. **Quickstart protocols are highly encouraged** when a patient is starting (or restarting) the patch. Quickstart improves compliance with starting the second month of contraception, and may decrease risk of unintended pregnancy.
- D. Quickstart:
 - 1. Start the first patch 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 if emergency contraception, she should take both tablets of Plan B® at once on the visit day and start her patch no later than the next day.
 - 4. Her next menses may be delayed until she completes her first 3 patches.
 - 5. Quickstart does not increase irregular spotting or bleeding.
 - 6. The client should check a pregnancy test if she has not seen a normal menses within 4 weeks of starting the patch.
- E. First-day start:
 - 1. The client should apply her first patch during the first 24 hours of her menstrual period.
 - 2. No back-up contraception is needed.
- F. Sunday start:
 - 1. The client should apply her first patch on the first Sunday after her menstrual period starts.
 - 2. She must use condoms as back-up contraception for the first week of her first cycle.
 - 3. If the menstrual period begins on a Sunday, the first patch should be applied on that day and no back-up contraception is needed.

- G. Postpartum, breastfeeding women should not use transdermal contraceptive patch.
- H. Postpartum, non-breastfeeding women
 - 1. In women who are <21 days postpartum, use of combined hormonal contraceptives should not be used (USMEC category 4).
 - 2. In women who are 21--42 days postpartum and have other risk factors for VTE in addition to being postpartum, the risks for combined hormonal contraceptives usually outweigh the advantages and therefore combined hormonal contraceptives generally should not be used (USMEC Category 3); however, in the absence of other risk factors for VTE, the advantages of combined hormonal contraceptives generally outweigh the risks, and they can usually be used (USMEC Category 2).
 - 3. In women who are >42 days postpartum, no restriction applies for the use of combined hormonal contraceptives related to postpartum status.
 - 4. Do not wait for client's first menses, as most women will have ovulated before first menstruation.

I. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided an oral contraceptive should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to oral contraceptive method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues (Appendix A and B).
- C. Prescription/counseling about emergency contraception, and, for teens, a prescription with multiple refills.
- D. Instruction that contraceptive effectiveness may be reduced with co-administration of other drugs (Appendix D).
- E. Instruction on how to select a site for patch application and how to apply patch (see section below and refer to Patient Package Insert).
- F. Instruction on what to do if patch becomes detached or client forgets to put a new patch on. Additionally, for some situations the use of emergency contraceptive pills may be considered.
- G. Information that contraceptive patch does not offer protection against STIs/HIV, the routine use of condoms should be encouraged to decrease STI risk.
- H. Informed consent (form attached to this guideline) should be reviewed and signed and a copy of the same upon request
- I. If transdermal contraceptive patch is being provided/prescribed, then CHC consent form should be reviewed and signed.
- J. If transdermal contraceptive patch is being provided/prescribed to a client with risk factors, then a Request for CHC for Women with Risk Factors form should be reviewed and signed.
- K. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- L. Emergency, 24-hour telephone number and location where emergency services can be obtained
- M. Clinic access information

V. INSTRUCTIONS FOR PATCH PLACEMENT AND APPLICATION

- A. Choosing a placement site for patch:
1. 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.
 2. The patch should not be placed on skin that is red, irritated or cut.
 3. 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.
 4. No adhesive products should be placed over the patch.
 5. The patch should not be drawn on with any kind of pen, pencil or marker.
 6. The patch should not be placed on a tattoo.
- B. Instructions for patch application:
1. The foil pouch is opened by tearing it along the top edge and one side edge.
 2. The foil pouch should be peeled apart and opened flat.
 3. 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.
 4. 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.
 5. 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.

VI. INSTRUCTIONS FOR MANAGEMENT OF INADVERTENT PATCH DETACHMENT, PROLONGED USE PERIOD OR PROLONGED PATCH-FREE PERIOD

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.

- 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.

- C. 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.
- D. 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.
- E. 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.
- F. 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.
- G. If a woman wishes to change her "Patch Change Day":
 1. She removes her third patch on the correct day.
 2. She may select an earlier "Patch Change Day" by applying a new patch on the desired day.
 3. In no case should there be more than 7 consecutive patch-free days.
- H. The patient should still see a period of bleeding each month. If this is delayed, or if she has unusual or abnormal bleeding, she should check a pregnancy test immediately.

VII. INSTRUCTIONS FOR CONTRACEPTIVE PATCH STORAGE, DISPOSAL AND DISPENSING

- 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.
- D. Dispensing instructions for transdermal contraceptive patch:
 1. Give the new Ortho Evra client a 1-3 month supply of Ortho Evra, and a prescription for a year's supply. Review the product insert with the client.
 2. When the need arises, an extra patch may be provided from the clinic supply or a prescription may be given for one patch.
 3. Recommend the routine use of condoms to decrease the risk of acquiring sexually transmitted diseases.

VIII. FOLLOW-UP

- A. 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. However, patients may be provided a prescription for a year's supply so that access to her method of contraception is not limited.
- B. Serious side effects that may warrant immediate consultation and discontinuation of combined oral contraceptives include:
 - 1. Sharp chest pain, coughing up blood, or sudden shortness of breath
 - 2. Pain in calf or leg
 - 3. Crushing chest pain or tightness in the chest
 - 4. Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg
 - 5. Sudden partial or complete loss of vision
 - 6. Breast masses suspicious for potential malignancy
 - 7. Severe abdominal pain or tenderness.
 - 8. Severe problems with sleeping, weakness, lack of energy, fatigue, or change in mood.
 - 9. Jaundice

IX. MANAGEMENT OF SIDE EFFECTS AND COMPLICATIONS

Refer to section on Combined Hormonal Contraception for more detailed information regarding side effects and complications related to CHC use.

- A. Minor side effects of contraceptive patch use may occur:
 - 1. 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".
 - 2. 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.
 - 3. 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.
- B. If a woman experiences signs or symptoms of serious side effects related to CHC use reviewed above, the contraceptive patch should be removed immediately and further evaluation is warranted.
- C. Other reasons for stopping the contraceptive ring:
 - 1. 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.
 - 2. 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.

3. 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.
- D. Any client with post-patch amenorrhea of more than 6 months should be referred for evaluation.
- E. 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.
- F. Any client desiring to become pregnant may be advised to use contraceptive ring until pregnancy is desired. Fertility may return immediately following discontinuation of the ring. 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.
- G. 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.

X. DOCUMENTATION

- A. Order must be written in medical record initially, annually, and upon method change.
- B. Oral contraceptives dispensed must be documented in the medical record and/or computer system.
- C. All education/counseling must be documented.

REFERENCES

1. US Medical Eligibility Criteria for Contraceptive Use, 2010. Adapted from the World Health Organization Medical Eligibility Criteria for Contraceptive Use, 4th Edition. MMWR, May 28, 2010; Vol 59.
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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
11. Possible decreased number of sickle cell crises

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. Women who are hepatitis carriers, or who have had a history of hepatitis, but now have normal liver function may use estrogen-containing birth control.
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
17. Migraine headaches (without aura) and age > 35
18. Migraine headaches (without aura) and other risk factors for cardiovascular events, such as smoking or hypertension.

Exercise caution in providing the transdermal contraceptive patch for women with:

1. Severe headache without aura
2. Hypertension
3. Active gall bladder disease
4. During the first 3-4 weeks postpartum
5. Surgery or injury requiring immobilization
6. Hyperlipidemia or history thereof
7. Lactation
8. Diabetes mellitus, history of gestational diabetes or other high-risk factors for diabetes
9. Amenorrhea or oligomenorrhea
10. Difficulty in compliance, e.g., mental illness, drug abuse, etc.
11. Undiagnosed vaginal/uterine bleeding
12. Cardiac or renal disease or history thereof
13. Over 50 years of age
14. 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:

- Barbiturates (Phenobarbital)
- Griseofulvin
- Rifampin
- Phenylbutazone (Butazolidin®)
- Primidone (Mysoline®)
- Phenytoin (Dilantin®)
- Carbamazepine (Tegretol®)
- Felbamate (Felbatol®)
- Oxcarbazepine (Trileptal®)
- Topiramate (Topamax®)
- St. John's Wort
- Anti-HIV protease inhibitors

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 (8 out of every 100 women during the first year of typical use).

I understand the patch is less effective in women who weigh 190 pounds or more. If I choose to use the patch in this circumstance, I understand my risk of becoming pregnant may be elevated, and that my healthcare provider recommends I use a second type of birth control, such as condoms, in addition to the birth control patch.

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: _____

DEPO-MEDROXYPROGESTERONE ACETATE (DMPA)
INJECTION
(SUB-Q AND IM)

I. INTRODUCTION

DMPA is a progestin-only, injectable method of birth control available in two formulations:

- A. A 1 cc crystalline suspension of 150 mg depo medroxyprogesterone acetate that is injected intramuscularly (IM) every three months (11-13 weeks)
- B. A low dose 104 mg of medroxyprogesterone acetate in a 0.65 ml solution that is injected subcutaneously (subQ) every three months. (12-14 weeks)

Perfect use failure rate in the first year of use: 0.3%
Typical use failure rate in the first year of use: 3%

When administered at the recommended dose to women every 3 months, DMPA works as a contraceptive by inhibiting the secretion of gonadotropins which, in turn, prevents follicular maturation and ovulation and results in endometrial thinning.

II. CLIENT SELECTION

- A. Indications:
 - 1. DMPA may be provided when contraindications do not exist.
 - 2. May be a good choice for clients that cannot use/have medical contraindications to estrogen-containing method.
 - 3. May be a good choice for clients that desire a long-term, highly efficacious, non-coitus dependent, private contraceptive method.
- B. Contraindications (USMEC 3-- Risks outweigh advantages for method use; USMEC 4- - Unacceptable risk for method use):
 - 1. Unexplained vaginal bleeding (USMEC 3 before evaluation)
 - 2. Breast cancer (current USMEC 4) (past USMEC 3)
 - 3. History of myocardial infarction, ischemic heart disease or stroke (USMEC 3)
 - 4. Cirrhosis (severe-decompensated) (USMEC 3)
 - 5. Liver tumors – adenoma or hepatoma (USMEC 3)
 - 6. Hypertension (≥ 160 systolic or ≥ 100 diastolic) (USMEC 3)
 - 7. Diabetes with nephropathy/retinopathy/neuropathy (USMEC 3)
 - 8. Other vascular disease or diabetes of >20 years duration (USMEC 3)
 - 9. Systemic Lupus Erythematosus –positive (or unknown) antiphospholipid antibodies, and severe thrombocytopenia (USMEC 3)
 - 10. Rheumatoid Arthritis-Immunosuppressive therapy – (USMEC 3 for continuation)
 - 11. Migraine with aura at any age (USMEC 3 for continuation)

FDA Labeling Changes

The following black box warning has been added to the package labeling:

- 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 the 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 later in life.
- Depo-Provera Contraceptive Injection should be used as long-term birth control methods (e.g. longer than two years) only if other birth control methods are inadequate.

Reference:

FDA Package Labeling, November 2004

Risk Benefit Analysis

- Available studies have not demonstrated an increase in the rate of bone fractures in women who have used DMPA.
- However, other birth control methods should be considered in the risk/benefit analysis for the use of DMPA in women with osteoporosis risk factors – alcoholism, strong family history of osteoporosis, metabolic bone disease, anorexia nervosa, chronic use of drugs that can reduce bone mass (such as anticonvulsants or corticosteroids) and tobacco use. Osteoporosis information sheet should be provided if requested.

III. MEDICAL SCREENING AND EVALUATION

- A. Comprehensive medical evaluation (history, physical examination and laboratory testing, as indicated) should be completed prior to the provision of DMPA.
- B. Physical exam and related preventative services should not be deferred beyond 3 months after the initial visit and may not be deferred beyond 6 months (unless there is a compelling reason for extending the deferral in the clinician's judgment). The reason for the deferral must be documented in the client's medical record. A complete history, height, weight and blood pressure measurement is required in the medical record and cannot be deferred/delayed.
- C. Written results of a physical exam done elsewhere within the last 12 months are acceptable (with the exception of history, height, weight and blood pressure - which must be taken and documented prior to providing DMPA).
- D. Pelvic exams are not required until age 21 years unless indicated (ACOG).
- E. There is no time at which a pelvic exam is required for continued provision of the method as long as all eligibility requirements are met
- F. Pap test screening according to current screening recommendations and site-approved protocols must be followed.

IV. WOMEN WITH SPECIAL CONDITIONS REQUIRING FURTHER EVALUATION

- A. Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral must be made based on protocols approved by the site Medical Director. In addition, there should be consultation with the site Medical Director if needed.
- B. A request for hormonal contraceptives by women with special conditions/risk factors must be signed and this must be documented in the medical record for any client with the following medical conditions:
- C. Multiple risk factors for arterial cardiovascular disease (USMEC 3)
 - 1. Older age
 - 2. Smoking
 - 3. Diabetes
 - 4. Hypertension

V. DMPA METHOD INITIATION

- A. QuickStart: **QuickStart protocols are highly encouraged** when a patient is starting (or restarting) DMPA. Quickstart improves compliance with starting the second month of contraceptive ring use, and may decrease risk of unintended pregnancy
 - 1. Administer the first injection on the day of the clinic visit and use a backup method (condoms, etc.) for 7 days.
 - 2. If there is concern about undetectable early pregnancy, the client should have a repeat pregnancy test prior to the next depo injection.
 - 3. If the repeat pregnancy test is negative and the client has no sign of pregnancy (i.e. nausea, breast tenderness), continue the method.
- B. Timing of Initiation: The table below should be followed when initiating DMPA. Alternative timings must be individualized to ensure contraceptive protection.

Current Method	First DMPA Injection	Back-Up
No hormonal method or no IUD in current cycle	<p>Anytime in cycle if it is reasonably certain client is not pregnant.</p> <p>If possibility of pregnancy is suspected, a highly sensitive urine pregnancy test must be completed prior to initiation. If pregnancy test is negative, give DMPA and advise client to repeat pregnancy test in two weeks.</p> <p>For any woman who receives DMPA beyond first 5 days of menstrual bleeding, urine pregnancy test must be performed before the subsequent DMPA injection may be given.</p> <p>For post-ECP DMPA administration the following are options for the initiation of DMPA after ECP:</p> <ul style="list-style-type: none"> A. Initiate during 1st 5 days of next menses B. Initiate within 24 hours post ECP use and: <ul style="list-style-type: none"> 1. Perform a highly sensitive urine 	If more than 5 days since menstrual bleeding started, back-up for 7 days.

	<p>pregnancy test prior to initiation unless 1st day LNMP within past 5 days.</p> <ol style="list-style-type: none"> 2. Advise client to repeat pregnancy test in 3-4 weeks 3. Advise back-up method for 7 days unless first day LNMP within past 5 days 4. For these women, a urine pregnancy test must be performed before the next DMPA injection may be given 	
Correct use of COCs, patch or ring in current cycle	Any time in cycle	None
IUD	<p>Any time in cycle</p> <ol style="list-style-type: none"> A. Within five days of onset of menses B. Beyond first five days and has had sexual intercourse this cycle C. Beyond first five days and has not had sexual intercourse this cycle <p>If initiated beyond first five days of menstrual bleeding and IUD is removed prior to next menses (or >3 weeks since LMP), urine pregnancy test must be performed before the subsequent DMPA injection may be given.</p>	<p>None, may remove IUD at time of injection</p> <p>Delay removal of IUD until next menses or x3 wks if no menses</p> <p>Back-up for seven days, if IUD is used as back-up. Delay removal of IUD until next menses or x3 wks if no menses.</p>
Post partum or post-surgical abortion or post spontaneous abortion	Any time before onset of intercourse	Back-up for seven days
Post medical abortion	<p>No sooner than the day after Misoprostol and up to seven days after Mifepristone</p> <p>Beyond seven days after Mifepristone and before onset of intercourse</p>	<p>None</p> <p>Back-up for seven days</p>

VI. DISPENSING, ADMINISTRATING AND PRESCRIBING DMPA

A. Up to five injections of DMPA may be prescribed for initial and annual clients.

- B. Trained clinic personnel may administer injections. Providers must be familiar with proper injection procedures, timing of injections, and infection control guidelines.
- C. Selection of DMPA formulation:
 - 1. It is NOT acceptable to use the 400 mg/ml concentration for contraceptive purposes.
 - 2. SubQ injections: 0.65 ml of a 104 mg/0.65 ml solution of DMPA must be used.
 - 3. For IM injections: 1.0 ml of a 150 mg/ml solution of DMPA must be used.
- D. Giving the injection
 - 1. Shake vial vigorously for at least one minute just prior to use
 - 2. Give SubQ injection in the upper thigh or abdomen (do not use the arm), using the safety needle provided (may follow the directions for injection from package insert).
 - 3. Give deep IM injection in gluteus or deltoid, using 1 ½ inch 21-23 gauge needle.
 - 4. Do not massage injection site whether IM or SubQ
 - 5. Document the procedure in the clients medical record
 - 6. Protocols must be in place for the management of vaso-vagal fainting episodes and possible anaphylactic reactions.

VII. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a DMPA should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to oral contraceptive method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues (Appendix A and B).
- C. DMPA users must be advised on the importance of regular weight bearing exercise, not smoking and taking extra calcium, either through diet or by added Calcium and Vitamin D supplements. Recommended daily amounts of Calcium (1300-1500 mg) and Vitamin D (400 – 800 mg) should be encouraged.
- D. Information that DMPA does not offer protection against STIs/HIV, the routine use of condoms should be encouraged to decrease STI risk.
- E. Informed consent (form attached to this guideline) should be reviewed and signed and a copy of the same upon request
- F. If DMPA is being provided/prescribed to a client with risk factors, then a Request for Contraception in Women with Risk Factors form should be reviewed and signed.
- G. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- H. Emergency, 24-hour telephone number and location where emergency services can be obtained
- I. Clinic access information

VIII. MANAGEMENT OF SIDE-EFFECTS AND COMPLICATIONS

- A. Irregular Bleeding Patterns:
 - 1. Bleeding patterns tend to regularize after the first year of use.
 - 2. Obtain/perform the following:
 - a. Interval history with focus on the possibility of pregnancy or genital tract infection
 - b. Pelvic examination, as indicated, to exclude pregnancy, infection, or an anatomic lesion

- c. Return for a repeat pregnancy test in 2 weeks. If the repeat pregnancy test is negative and the client has no signs of pregnancy (i.e. nausea, breast tenderness), continue the method
- d. Laboratory tests:
 - i. Highly sensitive pregnancy test, if indicated.
 - ii. Hemoglobin, if history suggests prolonged or heavy bleeding. If **<10**, refer for medical evaluation.
 - iii. Gonorrhea and Chlamydia tests, if a cervical or upper tract infection is suspected.
- 3. If no obvious cause of bleeding is found, reassure the client that bleeding patterns are not dangerous and may resolve with time.
- 4. If inter-menstrual bleeding becomes problematic, the client may try over the counter (OTC) medication such as Ibuprofen 800 mg PO TID for 5 days.
- 5. Instruct the client that treatment may temporarily improve bleeding pattern, but there is substantial possibility that the irregular pattern will return after discontinuation of treatment.
- 6. Discontinuation may be required if the client continues to find the bleeding bothersome.
- B. Possible Pregnancy:
 - 1. There is an increased risk of ectopic for DMPA failures
 - 2. Obtain/perform the following:
 - a. Interim history update, focusing on pregnancy signs and symptoms
 - b. Pelvic examination, as indicated, to evaluate uterine softening or enlargement, adnexal tenderness or mass
 - c. Highly sensitive urine pregnancy test.
 - i. If positive, evaluate for symptoms and signs of ectopic pregnancy; begin workup or refer immediately if suspected.
 - ii. If negative, counsel and reassure the client that amenorrhea while using DMPA is an expected side effect and not dangerous.
- C. Headache: (NOTE: migraine with aura any age is a "USMEC 3" for continuation on DMPA)
 - 1. Obtain a headache history in an attempt to differentiate tension headache from migraine.
 - 2. If the headaches seem to be of the tension variety, explain that discontinuation of DMPA is unlikely to change the pattern.
 - 3. For mild headaches without neurological symptoms, attempt treatment with ibuprofen or other analgesic.
 - 4. If analgesics fail or signs of migraine aura are present, weigh the risks and benefits of continuing DMPA.
- D. Weight Change:
 - 1. Instruct regarding control of weight gain with adequate exercise and moderate dietary restriction.
 - 2. If these measures fail and weight gain becomes problematic, discontinuing DMPA may become necessary.
- E. Pain or inflammation at injection site:
 - 1. Examine site for signs/symptoms of infection (redness, swelling, pain, tenderness, warmth).
 - a. Measure affected area
 - b. Document findings
 - 2. Mild inflammation:

- a. Advise warm compresses, elevation, and rest the area as appropriate.
 - b. Communicate with client in 24-48 hours to evaluate and assess for improvement and/or need for antibiotics.
 - c. Refer as indicated.
3. Significant inflammation:
- a. Advise warm compresses, elevation, and rest the area as appropriate.
 - b. If minimal or no improvement in 24 hours, refer to private physician or refer immediately to emergency room.
 - c. Ensure that client has written agency contact information to use in case of emergency.
- F. Injection site reactions (refer to above as well): 5% report injection site reactions with 1% having persistent changes, typically described as small areas of indurations or atrophy.

IX. FOLLOW-UP

DMPA Re-injection Visit:

- A. Every 12-14 weeks for Sub-Q and 11-13 weeks for IM.
- B. While the repeat DMPA injection can be given up to 4 weeks late without requiring additional contraceptive protection, this **does not** mean that goal should be to extend the regular DMPA injection interval by 4 weeks. (Note: The WHO expert working group considers the risk of ovulation to be minimal within 4 weeks following the time for a repeat injection of DMPA, i.e. 3 months).
- C. Client should be queried about changes in personal history, possible side effects, and menstrual cycle/bleeding pattern over the previous 3 months.
- D. Re-educate on side effects:
 - a. Severe headaches
 - b. Depression
 - c. Pain, pus, allergic reaction at the injection site

X. DOCUMENTATION

- A. Order for DMPA must be written in the medical record initially, annually and upon method change.
- B. All DMPA administered must be documented in the medical record and family planning data system.
- C. All education/counseling must be documented.

REFERENCES

1. CDC. Medical Eligibility Criteria for Contraceptive Use. MMWR, Vol. 59, No. RR-4, June 18, 2010
2. Ziemann, M., et al. Managing Contraception for Your Pocket. 2010-2012

CLIENT EDUCATION FOR DEPO-PROVERA

PLEASE READ CAREFULLY

- Depo-Provera is a progestin only contraceptive method. Depo-Provera is 99.7% effective if given on schedule:
- Every 11 to 13 weeks as a deep intramuscular injection of 150 milligrams (mg) or
- Every 12 to 14 weeks as a subcutaneous injection of 104 milligrams (mg).

BENEFITS: In addition to prevention of pregnancy, some women experience the following benefits from using Depo-Provera:

- Scanty or no menstrual bleeding
 - Less anemia
 - It can be used by breast feeding mothers as it does not contain estrogen
 - Decreased menstrual cramps and pain
 - Suppression of pain associated with ovulation
 - Decreased risk of endometrial cancer, ovarian cancer
 - Decreased risk of PID (Pelvic Inflammatory Disease)
 - Management of pain associated with endometriosis
 - Long-term effective contraception
 - Low risk of ectopic (tubal) pregnancy
 - Decreased incidence of seizures in women with seizure disorders

You should not use the shot if you:

- Are or think you are pregnant
- Have abnormal bleeding from the vagina that has not been evaluated
- Have a known or suspected cancer of the breast
- Liver tumors (hepatocellular adenoma or malignant (hepatoma)
- Have multiple cardiovascular risk factors (45 years of age or older, heavy cigarette smoking, high blood pressure, high levels of cholesterol, diabetes)
- Have history of heart attack or stroke

While using Depo-Provera you may experience the following side effects:

- Menstrual cycle disturbances
- Weight gain
- Breast tenderness
- Depression
- Increased or decreased sex drive
- Allergic reactions (rare)
- Skin rash or spotty darkening of the skin
- Headaches
- Nausea, abdominal discomfort
- Nervousness, dizziness
- Hair (loss/increased) on face or body
- Decrease in bone density
- Decrease in HDL lipid values

Depo-Provera use may decrease the amount of calcium in your bones. The longer you are on Depo-Provera the more calcium you may lose. This increases the risk of your bones weakening if you use Depo-Provera continuously for a long time (for more than 2

years). Calcium levels may not return completely once you stop using Depo-Provera. The loss of calcium may increase your risk of osteoporosis and broken bones, particularly after your menopause. Calcium is generally added to bones during teenage years. The decrease of calcium in your bones is of most concern if you are a teenager or having the following risk factors:

- * Bone disease
- * A strong family history of osteoporosis
- * An eating disorder
- * Drug use that can lower the amount of calcium in bones (drugs for epilepsy or steroids)
- * Smoking cigarettes
- * Drinking a lot of alcohol

Women who use Depo-Provera contraceptive injection may lose significant bone mineral density. Depo-Provera should be used as a long-term birth control method (that is, longer than 2 years) only if other birth control methods are inadequate.

To lessen the chances of serious problems, you should seek medical care if experiencing any of the following symptoms:

- Repeated, very painful headaches - Yellowing of the skin or eyes
- Unusually heavy bleeding from the vagina - New lump in your breast
- Severe depression
- Severe lower abdominal pain (may be a sign of pregnancy)
- Pus, prolonged pain or bleeding at the injection site

Use of Depo-Provera requires a clinic visit every 12 weeks for a reinjection.

Depo-Provera does not provide protection from sexually transmitted infections.

Stopping Depo-Provera and Future Fertility: Depo-Provera may prevent a woman from getting pregnant for more than 12 weeks after her last injection. The average delay in return of fertility is 10 months following the last injection. Depo-Provera does not decrease a woman's fertility in the long run.

Bone Mineral Testing: This testing provides information of your current bone density status. You may desire to discuss this with your primary care physician if you are at high risk (smoker, high alcohol use, teenager, strong family history of bone density disease, eating disorder or you are on medications that lower calcium in your bones).

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 104ä, Depo, or “the Shot”), as my family planning method.

I have received a educational information packages with the DMPA 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 a risk of osteoporosis (thinning of the bones) with use of DMPA and that after stopping DMPA the bone structure might not return to normal. Current evidence does not show an increased risk of bone fractures in later years. Other types of contraception are not associated with changes in bone density (thinning).

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

Please complete the following if interpretation of informed consent was required:

- An interpreter was offered to the client. Yes No
- This form has been read to the client in the client’s spoken language. Yes No
- Patient’s Language (specify): _____
- Interpreter Name: _____
(print or type name of interpreter)
- Interpreter Services provided by (agency): _____
- Date: _____ Interpreter Signature: _____

Staff Use only

By my signature I affirm that:

- The client has read this form or had it read to her by an interpreter.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

SUBDERMAL CONTRACEPTIVE IMPLANT

I. INTRODUCTION

The subdermal contraceptive implant (IMPLANON®/NEXPLANON®) is a long-acting, reversible, hormonal contraceptive that contains 68 mg etonogestrel (progesterone-only) and is effective for up to 3 years. The implant is a sterile, latex-free single-rod 4 cm in length and 2 mm wide. The rod initially releases between 60-70 mcg per day but declines slowly over time (etonogestrel blood levels inhibit ovulation for at least three years in most women).

In 2010 Implanon® was replaced by Nexplanon®. The hormone type and dose have not changed and the only difference in the implant itself was the addition of barium sulfate to allow x-ray location of the implant (Implanon® was not radio-opaque, making it difficult to locate when there was a question about implant location). The only other difference between the two products is the inserter.

The primary mechanisms of action of the subdermal contraceptive implant include suppression of ovulation, increased viscosity of cervical mucus and alterations in the endometrium.

In order to provide this contraceptive method, providers must undergo training for inserting and removals by a manufacturer-approved trainer.

II. CLIENT SELECTION

A. Indications:

1. A contraceptive implant may be provided when contraindications do not exist.
2. May be a good choice for clients that cannot use/have medical contraindications to estrogen-containing method.
3. May be a good choice for clients that desire a long-term, highly efficacious, non-coitus dependent, private contraceptive method.

B. Contraindications (USMEC 3-- Risks outweigh advantages for method use; USMEC 4-- Unacceptable risk for method use):

1. Unexplained vaginal bleeding (USMEC 3 before evaluation)
2. Breast cancer (current USMEC 4) (past USMEC 3)
3. History of myocardial infarction, ischemic heart disease or stroke (USMEC 3)
4. Cirrhosis (severe-decompensated) (USMEC 3)
5. Liver tumors – adenoma or hepatoma (USMEC 3)
6. Hypertension (≥ 160 systolic or ≥ 100 diastolic) (USMEC 3)
7. Diabetes with nephropathy/retinopathy/neuropathy (USMEC 3)
8. Other vascular disease or diabetes of >20 years duration (USMEC 3)
9. Systemic Lupus Erythematosus –positive (or unknown) antiphospholipid antibodies, and severe thrombocytopenia (USMEC 3)
10. Rheumatoid Arthritis-Immunosuppressive therapy – (USMEC 3 for continuation)
11. Migraine with aura at any age (USMEC 3 for continuation)

III. MEDICAL SCREENING AND EVALUATION

- A. Comprehensive medical evaluation (history, physical examination and laboratory testing, as indicated) should be completed prior to the provision of subdermal contraceptive implant.
- B. Physical exam and related preventative services should not be deferred beyond 3 months after the initial visit and may not be deferred beyond 6 months (unless there is a compelling reason for extending the deferral in the clinician's judgment). The reason for the deferral must be documented in the client's medical record. A complete history, height, weight and blood pressure measurement is required in the medical record and cannot be deferred/delayed.
- C. Written results of a physical exam done elsewhere within the last 12 months are acceptable (with the exception of history, height, weight and blood pressure - which must be taken and documented prior to providing implant).
- D. Pelvic exams are not required until age 21 years unless indicated (ACOG).
- E. There is no time at which a pelvic exam is required for continued provision of the method as long as all eligibility requirements are met
- F. Pap test screening according to current screening recommendations and site- approved protocols must be followed.

IV. WOMEN WITH SPECIAL CONDITIONS REQUIRING FURTHER EVALUATION

- A. Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral must be made based on protocols approved by the site Medical Director. In addition, there should be consultation with the site Medical Director if needed.
- B. Consultation should be conducted when a client develops migraine with aura during use of contraceptive implant use (USMEC 3)
- C. A request for hormonal contraceptives by women with special conditions/risk factors must be signed and this must be documented in the medical record for any client with multiple risk factors for arterial cardiovascular disease (USMEC 3)
 - 1. Older age
 - 2. Smoking
 - 3. Diabetes
 - 4. Hypertension
- D. Efficacy in overweight women has not been studied (Refer to Patient Package Insert).

V. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a subdermal contraceptive implant should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to oral contraceptive method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues
- C. Information that implant does not offer protection against STIs/HIV, the routine use of condoms should be encouraged to decrease STI risk.
- D. Informed consent (form attached to this guideline) should be reviewed and signed and a copy of the same upon request

- E. If implant is being provided/prescribed to a client with risk factors, then a Request for Contraception in Women with Risk Factors form should be reviewed and signed.
- F. A copy of the FDA approved Patient Package Insert (PPI)
- G. User card in the implant kit (write in insertion date, lot #, removal date)
- H. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- I. Emergency, 24-hour telephone number and location where emergency services can be obtained
- J. Clinic access information

VI. SUBDERMAL CONTRACEPTIVE IMPLANT INITIATION

- A. Follow manufacturers instructions for insertion and removal
- B. Pregnancy must be excluded before insertion
- C. Emergency procedure must be in place to manage vaso-vagal fainting episodes.
- D. Timing of Initiation - the table below should be followed when initiating the contraceptive implant. Alternative timings must be individualized to ensure contraceptive protection.

Current Method	IMPLANON®/NEXPLANON® Insertion	Back-Up
None (in the past month)	Days 1 thru 5 of the menstrual cycle	If more than 5 days since menstrual bleeding started, backup for 7 days
Combination Hormonal Contraceptive a. COC b. Ring c. Patch Progestin Only Pill d. POP	Can insert anytime in cycle if R/O pregnancy OR a. Anytime within 7 days of the last active COC pill b. Anytime during the 7 day ring-free period c. Anytime during the 7 day patch-free period d. Any day of the month (do not skip any days between the last POP pill and insertion of IMPLANON™)	None
IMPLANON™	On same day implant is removed	None
DMPA	On the day the next injection is due	None
IUCs	Any time in cycle (assure not pregnant) Within first 5 days of menses (remove IUC same day) Beyond first 5 days of menses (admits to sexual intercourse this cycle)---Delay removal of IUC until next menses Beyond first 5 days of menses (admits to no sexual intercourse this cycle)	None Delay removal of IUC until next menses Back-up for 7 days
1st trimester abortion or miscarriage	a. Within first 5 days following a complete first trimester abortion b. If beyond 5 days following complete first trimester abortion, follow instructions for “No hormonal contraceptive use in past month”	None

Post partum or 2 nd trimester abortion	a. Between 21-28 days post-partum (if not exclusively breast feeding)	None
	b. Between 21-28 days following 2 nd trimester abortion (no intercourse)	Back-up for 7 days
	c. If >4 weeks post-partum (and exclusively breastfeeding) assure client is not pregnant	Back-up for 7 days with non-hormonal method

VII. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a subdermal contraceptive implant should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to oral contraceptive method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues.
- C. Information that implant does not offer protection against STIs/HIV, the routine use of condoms should be encouraged to decrease STI risk.
- D. Informed consent (form attached to this guideline) should be reviewed and signed and a copy of the same upon request
- E. If implant is being provided to a client with risk factors, then a Request for Contraception in Women with Risk Factors form should be reviewed and signed.
- F. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- G. Emergency, 24-hour telephone number and location where emergency services can be obtained
- H. Clinic access information

VIII. MANAGEMENT OF SIDE-EFFECTS AND COMPLICATIONS

A. Irregular Bleeding Patterns:

- 1. Clients are likely to have changes in their vaginal bleeding patterns. The unpredictable changes include frequency or duration or amenorrhea. An average of 17.7 days of bleeding or spotting every 90 days.
- 2. Obtain/perform the following:
 - a. Interval history with focus on the possibility of pregnancy or genital tract infection
 - b. Pelvic examination, as indicated, to exclude pregnancy, infection, or an anatomic lesion
 - c. Return for a repeat pregnancy test in 2 weeks. If the repeat pregnancy test is negative and the client has no signs of pregnancy (i.e. nausea, breast tenderness), continue the method
 - d. Laboratory tests:
 - i. Highly sensitive pregnancy test, if indicated.
 - ii. Hemoglobin, if history suggests prolonged or heavy bleeding. If <10, refer for medical evaluation.
 - iii. Gonorrhea and Chlamydia tests, if a cervical or upper tract infection is suspected.
- 3. If no obvious cause of bleeding is found, reassure the client that bleeding patterns are not dangerous and may resolve with time.
- 4. If inter-menstrual bleeding becomes problematic, the client may try over the counter (OTC) medication such as Ibuprofen 800 mg PO TID for 5 days.

5. Instruct the client that treatment may temporarily improve bleeding pattern, but there is substantial possibility that the irregular pattern will return after discontinuation of treatment.
 6. Discontinuation may be required if the client continues to find the bleeding bothersome.
- B. Possible Pregnancy:
1. There is an increased risk of ectopic for contraceptive implant failure
 2. Obtain/perform the following:
 - a. Interim history update, focusing on pregnancy signs and symptoms
 - b. Pelvic examination, as indicated, to evaluate uterine softening or enlargement, adnexal tenderness or mass
 - c. Highly sensitive urine pregnancy test.
 - i. If positive, evaluate for symptoms and signs of ectopic pregnancy; begin workup or refer immediately if suspected.
- C. Headache: (NOTE: migraine with aura any age is a "USMEC 3" for continuation on implant)
1. In clinical trials, 24.9% of IMPLANON™ users reported headache as an adverse event.
 2. Obtain a headache history in an attempt to differentiate tension headache from migraine
 3. If the headaches seem to be of the tension variety, explain that discontinuation of DMPA is unlikely to change the pattern.
 4. For mild headaches without neurological symptoms, attempt treatment with ibuprofen or other analgesic.
 5. If analgesics fail or signs of migraine aura are present, weigh the risks and benefits of continuing DMPA.
- D. Weight Change:
1. In clinical trials, 6.4% gained weight with an average of 2.8 pounds after 1 year and 3.7 pounds after 2 years.
 2. Instruct regarding control of weight gain with adequate exercise and moderate dietary restriction.
 3. If these measures fail and weight gain becomes problematic, discontinuing implant may become necessary.
- E. Carbohydrate and Lipid Metabolic Effects: implant may induce mild insulin resistance and small changes in glucose concentrations. Women with diabetes or impaired glucose tolerance must be carefully observed by the provider managing the diabetes.
- F. Liver Function: If jaundice develops using implant removal is recommended as the hormone in IMPLANON™ may be poorly metabolized in clients with impaired liver function.
- G. Depression: Clients with a history of depression should be monitored and implant removed if depression becomes significantly increased.
- H. Contact Lens Users: Clients who develop visual changes or changes in lens tolerance should be referred to an ophthalmologist for assessment.

IX. FOLLOW-UP

- A. Post-insertion site check is not indicated unless the client has signs of infection at the site (red, inflamed, discharge) or other implant related complications.
- B. Advise client to report any of the following:
 1. Unable to palpate rod

2. Heavy vaginal bleeding (lasting 14 days or longer)
 3. Delayed menses after a long interval of regular cycles
 4. Concern about possible pregnancy
 5. Arm pain, redness, bleeding/discharge at the insertion site
 6. Onset/worsening of migraine, aura, or severe headache
 7. Desire for removal
- C. Annual exams are to be scheduled by the client.
- D. Removal:
1. Implant should be removed when method change desired, pregnancy desired or implant has reached expiration date (3 years from insertion).
 2. Removal should be conducted only by clinicians who have completed the manufacturer-approved implant insertion and removal training.
 3. Follow removal guidelines in the manufacturer's package insert
 4. Removal consent is needed
 5. Counsel the client as indicated on alternate contraceptive methods or provide preconception health information if pregnancy is desired.
 6. If client desires another implant, insertion may occur immediately upon removal of the current implant.

X. DOCUMENTATION

- A. Order must be written in medical record
- B. Document on the medical record and the client's user card:
1. Date of the insertion
 2. Type and amount of topical anesthetic
 3. 3 year removal date
 4. Location (left or right arm)
 5. Client identification (ID) number
 6. Client and provider palpated inserted rod
 7. Lot number
 8. Expiration date of IUC
 9. Full Name of inserter
- C. Removal Documentation
1. Reason for removal
 2. Type and amount of topical anesthetic
 3. Length of incision
 4. Length of time to remove
 5. Any problems encountered
 6. Site care instructions provided
 7. Full Name of remover
- D. All education/counseling must be documented.

REFERENCES

1. Medical Eligibility Criteria for Contraceptive Use. MMWR, Vol. 59, No. RR-4, June 18, 2010
2. Manufacturers FDA approved Patient Package Insert (PPI)

CLIENT EDUCATION FOR CONTRACEPTIVE IMPLANT

(May use the information provided by the manufacturer)

I understand the Patient Labeling for IMPLANON®/NEXPLANON®. I have discussed the implant with my healthcare provider who has answered all my questions. I understand that there are benefits as well as risks from using the implant. I understand that there are other birth control methods and that each has its own benefits and risks.

I also understand that this Patient Consent Form is important. I understand that I need to sign this form to show that I am making an informed and careful decision to use

IMPLANON®/NEXPLANON®, and that I have read and understand the following points:

- The implant helps to keep me from getting pregnant.
- No contraceptive method is 100% effective, including the implant.
- IMPLANON®/NEXPLANON® is made of a hormone mixed in a plastic rod.
- It is important to have IMPLANON®/NEXPLANON® inserted at the right time of my menstrual cycle.
- After IMPLANON®/NEXPLANON® is inserted, I should check that it is in place by gently pressing my fingertips over the skin in my arm where it was inserted. I should be able to feel the small rod.
- IMPLANON®/NEXPLANON® must be removed at the end of three years, but can be removed sooner if I want.
- If I have trouble finding a healthcare provider to remove IMPLANON®/NEXPLANON®, I can call 1-877- IMPLANON™ (1-877-467-5266) for help.
- The implant is placed under the skin of my arm during a procedure done in my healthcare provider's office. There is a slight risk of getting a scar or an infection from this procedure.
- Removal is usually a small office procedure. However, removal may be difficult. Rarely, the implant cannot be located when it is time to remove it. Special procedures, including surgery in the hospital may be needed. Difficult removals may cause pain and scarring. If IMPLANON®/NEXPLANON® cannot be found/removed its effects may continue while it is still in place, even beyond the three years.
- Most women have changes in their menstrual bleeding while using IMPLANON®/NEXPLANON®. My bleeding may be irregular, lighter or heavier, or my bleeding may completely stop. If I think I am pregnant, I should see my healthcare provider as soon as possible.
- I understand the warning signs for problems with IMPLANON®/NEXPLANON®. I understand that I should seek medical attention if any warning signs appear.
- I should tell all my healthcare providers that I am using IMPLANON®/NEXPLANON®
- I need to have a medical checkup regularly and at any time I am having problems.
- IMPLANON®/NEXPLANON® does not protect me from HIV infection (AIDS) or any other sexually transmitted disease.

**CONSENT FOR SUBDERMAL CONTRACEPTIVE IMPLANT
(OR USE MANUFACTURERS CONSENT FORM)**

I, (print or type name) _____, request subdermal contraceptive implant (IMPLANON®/NEXPLANON®) as my family planning method.

I understand the implant is good for 3 years and I have received information about the benefits, risks, side effects, and the use of a subdermal contraceptive implant as my method of birth control.

I understand that no birth control method is perfect and that some women have gotten pregnant while using the implant (1 out of every 1000 women during the first year of use).

I understand the implant 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 insert to decrease the effectiveness of the insert as a contraceptive. I know it is important to tell all my health care providers that I am using an implant 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 a subdermal contraceptive implant:

- 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 a subdermal contraceptive implant:

- Diabetes
- High cholesterol
- Headaches
- Seizures or epilepsy
- Gall bladder or kidney disease
- Depression
- High blood pressure

I understand that side effects sometimes associated with the subdermal contraceptive implant 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 the implant:

- Pain, irritation, swelling, or bruising at the insertion/removal site on the arm
- Thick scar tissue around the implant making it difficult to remove
- Infection at the insertion/removal site
- Need for hospitalization to remove the implant (the cost is your responsibility)
- IMPLANON®/NEXPLANON® must be removed at the end of three years, but can be removed sooner if I want.
- If I have trouble finding a healthcare provider to remove IMPLANON®/NEXPLANON®, I can call **1-877- IMPLANON™ (1-877-467-5266)** for help.

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: _____

Please complete the following if interpretation of informed consent was required:

- An interpreter was offered to the client. Yes No
- This form has been read to the client in the client’s spoken language. Yes No
- Patient’s Language (specify): _____
- Interpreter Name: _____
(print or type name of interpreter)
- Interpreter Services provided by (agency): _____
- Date: _____ Interpreter Signature: _____

Staff Use only:

By my signature I affirm that:

- The client has read this form or had it read to her by an interpreter.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

SUBDERMAL CONTRACEPTIVE 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 in implant 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
Known or suspected breast cancer 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 _____

**Subdermal Contraceptive Implant
INSERTION RECORD (page 2)**

Name _____
Date _____

Assessment:

Appropriate candidate for implant? yes no
Consent signed yes no

Insertion:

Implant type _____
Insertion site left upper arm right upper arm
Antiseptic iodine alcohol
Anesthetic Lidocaine ____% ____ mL other _____

Implant inserted according to protocol yes no
If no, explain _____

Implant Lot # _____ Expiration. 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 implant 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 _____

SUBDERMAL CONTRACEPTIVE IMPLANT
REMOVAL RECORD

Date _____
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 implant removed:

- New implant inserted (refer to insertion record)
- Condoms offered given
- Combined oral contraceptive initiated brand name _____
of cycles _____ start date _____
- Other method of contraception initiated _____

Return Visit _____

Date _____ **Interpreter Name** _____

Clinician Signature _____

INTRAUTERINE CONTRACEPTION (IUC)

I. INTRODUCTION

There are two FDA approved long-term intrauterine contraceptive methods available in the United States:

- A. Mirena® Levonorgestrel releasing intrauterine system (LNG-IUS)
- B. Copper T- 380 Paragard® Intrauterine Device (CU IUD).

Both methods are extremely effective once inserted to prevent pregnancy.

LNG-IUS perfect use failure rate: 0.1%, typical use 0.1%.
Over 5 years the LNG-IUS typical use failure rate is 0.71%.

Copper IUD perfect use failure rate/year: 0.6%, typical use 0.8%.
Over the 10 years of use the failure rate is 2%.

The mechanisms of action for the methods are as follows:

- A. Levonorgestrel IUS – approved for 5 years of use
 - 1. Thickened mucus impairs sperm penetration
 - 2. Foreign body reaction is spermicidal
- B. Copper T – 380 IUD – approved for 10 years of use
 - 1. Foreign body reaction is spermicidal
 - 2. Copper impairs sperm motility and capacitation

Only clinicians (physicians, NP, PAs, CNMs) with training and demonstrated skill in successful IUC insertion should insert IUCs. The site medical director should approve clinicians to be eligible to provide this service.

II. CLIENT SELECTION

- A. Indications:
 - 1. IUC may be provided when contraindications do not exist
 - 2. IUC is a good choice for a woman who desires long-term, continuous contraception with a highly efficacious method.
 - 3. The Copper T – IUD is a good choice for women who cannot use/have medical contraindications hormonal methods of contraception
- B. Contraindications (USMEC 3--Risks outweigh advantages for method use; USMEC 4- Unacceptable risk for method use).
 - 1. Pregnancy (USMEC 4)
 - 2. Postpartum puerperal sepsis (USMEC 4)
 - 3. Post-septic abortion (immediate) (USMEC 4)
 - 4. Ischemic heart disease (current and history of) (LNG continuation is USMEC 3)
 - 5. Systemic Lupus Erythematosus- Positive (or unknown) antiphospholipid antibodies (LNG USMEC 3)
 - 6. Systemic Lupus Erythematosus with severe thrombocytopenia (CU initiation USMEC 3)

7. Headaches with aura—any age (LNG continuation USMEC 3)
 8. Gestational trophoblastic disease (decreasing or undetectable β -hCG) (USMEC 3) or persistently elevated β -hCG levels (USMEC 4)
 9. Unexplained vaginal bleeding (initiation USMEC 4)
 10. Breast cancer (current, LNG USMEC 4) (past and no evidence of current disease for 5 years, LNG USMEC 3)
 11. Distorted uterine cavity or other anatomical abnormalities (USMEC 4)
 12. Cervical cancer (initiation USMEC 4)
 13. Endometrial cancer (initiation USMEC 4)
 14. Pelvic inflammatory disease (current USMEC 4)
 15. Current purulent cervicitis, chlamydial infection or gonorrhea (initiation USMEC 4)
 16. AIDS (initiation USMEC 3)
 17. STIs—increased risk for (USMEC 2/3)
 18. Cirrhosis (severe-decompensated) (LNG USMEC 3)
 19. Liver tumors (benign hepatocellular adenoma or malignant hepatoma) (LNG USMEC 3)
 20. Solid organ transplantation- complicated (initiation USMEC 3)
 21. Antiretroviral (ARV) therapy (initiation USMEC 2/3)
 22. Pelvic tuberculosis (initiation USMEC 4) (continuation USMEC 3)
 23. Known or suspected allergy to copper (Copper IUD only) (PI)
 24. History of Wilson's Disease (Copper IUD only) (PI)
 25. Small uterine cavity with sounding less than 6.0 cm (PI)
 26. Suspected or known uterine perforation occurring with the placement of a
 27. Uterine sound during the current insertion procedure
- C. The following factors should be considered in the risk/benefit evaluation and decisions regarding individualized management must be based on protocols approved by the site Medical Director or clinic physician. The client must sign the consent form IUC for Women with Special Considerations if she has:
1. Client or her partner with multiple sexual partners (LNG-IUS only) (PI)
 2. Increased risk for STIs, (USMEC 2, 3)
 3. Previous IUC intolerance, expulsion or failure

III. WOMEN WITH SPECIAL CONDITIONS REQUIRING FURTHER EVALUATION

- A. Decisions regarding individualized management, follow-up intervals, the need for additional testing or referral must be made based on protocols approved by the site Medical Director. In addition, there should be consultation with the site Medical Director if needed.
- B. Consultation should be conducted when a client develops migraine with aura during use of contraceptive implant use LNG IUS (USMEC 3)

IV. MEDICAL SCREENING AND EVALUATION

- A. Comprehensive medical evaluation (history, physical examination and laboratory testing as indicated) should be completed prior to the provision of an IUC.
- B. The client must complete a medical history which the clinician will review for determination of conditions which might affect the decision for IUC use (for example, possible pregnancy, risk for STIs).

- C. A hemoglobin/hematocrit test should be done, if indicated.
- D. Gonorrhea/Chlamydia testing:
 1. There should be a negative history or risk for gonorrhea or chlamydia exposure within 60 days prior to insertion.
 2. Chlamydia/gonorrhea testing can be done in high-risk populations to assure negative results.
 3. In the absence of signs or symptoms of cervicitis, testing can be done at time of insertion.
 4. If testing at time of insertion is positive, the patient should be treated, but the IUC does not need to be removed unless there are signs or symptoms of PID.
- E. Prior to insertion, a pelvic exam including a speculum and bimanual exam must be done to determine uterine size, position and any degree of uterine flexion.
- F. Clients transferring from another provider must have a blood pressure measurement prior to providing IUC.

V. TIMING OF INSERTION AND INSERTION PROCEDURE

- A. For Insertion Procedure, follow manufacturer’s instructions in package insert.
- B. For an IUC Insertion Check List Template see Appendix A
- C. A system & protocol must be in place for the management of vaso-vagal reactions.
- D. The table below should be followed when inserting an IUC. Alternative timings must be individualized to ensure adequate contraceptive protection and client safety

Current Method	IUC Insertion	Back- up
None	<ul style="list-style-type: none"> ■ First 7 days of normal menses ■ Anytime during cycle if certain client is not pregnant ** 	<ul style="list-style-type: none"> ■ None ■ For LNG, Back up required if more than 7 days since onset of normal menses.
All hormonal methods (when used reliably)	<ul style="list-style-type: none"> ■ For users of OCs, Ring, or Patch, may insert any time in cycle. Or client may continue her method for rest of cycle. 	<ul style="list-style-type: none"> ■ For Copper T users, hormonal method may be stopped immediately. ■ For LNG users, continue method for seven days.
Non-hormonal methods	<ul style="list-style-type: none"> ■ At any time in the cycle if pregnancy is reliably excluded.** 	<ul style="list-style-type: none"> ■ For copper T users, No back-up needed ■ For LNG users, back up is required if it has been more than seven days

		since the onset of a normal menses.
First-Trimester Spontaneous or Induced Abortion	<ul style="list-style-type: none"> ■ Immediately ■ Or any time thereafter in appropriate candidates 	<ul style="list-style-type: none"> ■ None
Second-Trimester Abortion	<ul style="list-style-type: none"> ■ Immediately, by an experienced, specially-trained clinician only. The client must be informed of the increased risk of expulsion. ■ Or wait at least four weeks 	<ul style="list-style-type: none"> ■ For copper T users, no back-up needed ■ For LNG users, back up method for 7 days
Post Delivery (breast feeding or non breast feeding) (vaginal or caesarean delivery)	<ul style="list-style-type: none"> ■ ≥ 4 weeks for both, assure client is not pregnant** 	<ul style="list-style-type: none"> ■ For copper T users, no back-up needed ■ For LNG users, back-up method for 7 days
As form of Emergency Contraception (EC)	<ul style="list-style-type: none"> ■ Within 5 days of first act of unprotected intercourse 	Can be left in as long-term contraceptive.

**The provider can be reasonably certain that the woman is not pregnant if she has no symptoms or signs of pregnancy, has a negative urine pregnancy test and meets any of the following criteria:

- A. Has not had intercourse since last normal menses
- B. Has been correctly and consistently using a reliable method of contraception
- C. Is within the first seven days after normal menses
- D. Is within four weeks postpartum for non-lactating women
- E. Is within the first seven days post-abortion or miscarriage
- F. Is fully or nearly fully breastfeeding, amenorrheic, and less than six months postpartum

(World Health Organization, 2002)

VI. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided a vaginal contraceptive ring should receive the following:

- A. Information/counseling regarding all contraceptive options available

- B. Information specific to IUC method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues. (Appendix A)
- C. Information that IUC does not offer protection against STIs/HIV, the routine use of condoms should be encouraged to decrease STI risk.
- D. Informed consent (form attached to this guideline) should be reviewed and signed and a copy of the same upon request
- E. If IUC is being provided/prescribed to a client with risk factors, then a Request for Contraception for Women with Risk Factors form should be reviewed and signed (Appendix B).
- F. Patient should be provided with and given instruction/counseling on importance of reading the Patient Package Insert (PPI)
- G. Client should be provided with user card that comes with the IUC kit (insertion date, lot #, removal date)
- H. Client should be provided with post-insertion instructions
- I. Emergency, 24-hour telephone number and location where emergency services can be obtained
- J. Clinic access information

VII. MANAGEMENT OF SIDE EFFECTS AND COMPLICATIONS

- A. Irregular Bleeding and Amenorrhea
 - 1. LNG-IUS: It is expected that users will have an increased number of days of spotting and bleeding, especially in the first 90-180 days of use.
 - a. Approximately 50% of users will have amenorrhea after 12 months of use.
 - b. Advise pregnancy test after 6 weeks past last bleeding episode. If negative test, no further pregnancy tests are required.
 - 2. Copper T-380: Intra-menstrual bleeding may occur during the first 2-3 months of use. Menses may be heavier and longer. Rule out pregnancy if any missed menstrual period.
- B. Client unable to feel strings:
 - 1. Appointment ASAP. Advise client to use back-up birth control method until she can be evaluated.
 - 2. If coitus within last 120 hours, emergency contraception should be considered.
- C. Clinician unable to see strings upon exam: Attempt retrieval using cytobrush insertion into the endocervical canal. Rotate brush 180 degrees and remove brush gently. If strings retrieved, reassure client. If strings not retrievable:
 - 1. Determine if the IUC is in the uterus. Advise client to use back-up method until evaluation can be made whether IUC is in uterus, has been expelled or has translocated into the abdominal cavity.
 - 2. Consult with medical director regarding referral for ultrasound. (If IUC cannot be located by ultrasound, may need to refer for abdominal x-ray).
 - 3. If IUC has not been expelled, consult with OB/GYN for management/removal
- D. Client presents with:
 - 1. Trichomoniasis, Chlamydia, +/-or Gonorrhea, PID
 - a. Treat infection per current CDC STD Treatment Guidelines.
 - b. Discuss with client risk factors for infection and sequelae. Advise removal if history indicates high risk for repeat infections.

- c. If client elects to continue with IUC, document counseling in chart.
- 2. Vulvocandidiasis or Bacterial Vaginosis: treat per CDC guidelines; no need to remove IUC
- 3. Actinomyces on pap smear – note a large majority of IUC users have asymptomatic colonization.
 - a. Client must be examined for evaluation of pelvic infection.
 - b. If client has symptoms for infection, treat per CDC PID guidelines. Review treatment plan with site Medical Director or OB/GYN physician consultant. IUC is removed within 48 hours of initiation of therapy.
 - c. Repeat pap smear 4-6 weeks after treatment.
 - d. IUC is contraindicated in the future. Counsel on alternate methods.
 - e. If client does not have symptoms of infection, the IUC may be left in or removed – client preference.
- 4. Pregnancy – failure rate of IUC is extremely low.
 - a. Perform highly sensitive pregnancy test. If positive, perform pelvic exam and order ultrasound to insure pregnancy is not ectopic.
 - b. If ectopic suspected or confirmed, refer out for emergency care.
 - c. If pregnancy is in situ, the IUC must be removed whether the client intends to continue the pregnancy or not continue. Removal of IUC reduces the risk of spontaneous abortion (45% if IUC is left in place versus if removed). If IUC cannot be removed (strings not visible), refer immediately to OB/ GYN.
 - d. Inform client of risk of spontaneous abortion and sepsis and advise to report for emergency care if these develop prior to referral visit.

VIII. FOLLOW-UP

- A. Advise client to report any of the following:
 - 1. Pregnancy symptoms
 - 2. If unable to feel string
 - 3. Suspected or confirmed IUC expulsion
 - 4. Bleeding that is extremely heavy or lasts longer than 2 weeks
 - 5. Continuous lower abdominal pain, or pelvic pain with a fever
 - 6. Any severe medical problem that develops such as headache with aura, DVT or pulmonary embolism, stroke, myocardial infarction, jaundice, hypertension (LNG-IUS only)
- B. Post insertion exams – clients should return for a post insertion check approximately 2-4 weeks (after first menses) to visualize strings, confirm placement and assess for signs of infection.
- C. Annual exams are to be scheduled by the client
- D. Removal-- When method change desired, pregnancy desired or IUC has reached expiration date:
 - 1. Follow removal guidelines in the manufacturer's package insert
 - 2. Clients who have had intercourse without a barrier method should wait 5-7 days post coitus for removal.
 - 3. Counsel clients as indicated for alternate contraceptive methods or preconception health care information if pregnancy is desired. If client desires another IUC, it may be inserted immediately after removal of the current IUC.

4. If there is difficulty with removal or IUC is embedded, consult with the site medical director or refer to an OB/GYN physician.

IX. DOCUMENTATION

A. Insertion Documentation:

1. Order must be written in the medical record
2. Documentation in the medical record for insertion must contain:
 - a. Position of uterus
 - b. Sounding measurement
 - c. Documentation of sterile technique
 - d. Information related to client tolerance/problems
 - e. Lot number of IUC (must also be given to client)
 - f. Client checklists, consents

B. Removal Documentation:

1. Reason for removal
2. Notations specific to removal
3. Last coitus date

3. All education/counseling must be documented.

REFERENCES

1. Medical Eligibility Criteria for Contraceptive Use. MMWR, Vol. 59, No. RR-4, June 18,2010
2. Manufacturers FDA approved patient package insert

Appendix A

CLIENT EDUCATION FOR INTRAUTERINE CONTRACEPTION (IUC)

Before using intrauterine contraception, you need to know about all forms of birth control, meaning all prescription, non-prescription, and natural methods. It is important that your questions are answered and that you understood all of the instructions in the manufacturers insert. It is important that you understand that no method of birth control, except abstinence, is 100% effective against pregnancy or contracting sexually transmitted diseases, including the Human Immunodeficiency Virus (HIV) infection that leads to the Acquired Immunodeficiency Syndrome (AIDS) disease.

The following benefits, risks/side effects, warning signs, alternatives, instructions, and decision to discontinue use option, regarding the birth control method, intrauterine contraception, were explained to me before I voluntarily decided to use this method of birth control.

BENEFITS:

The IUC is 98 -99% effective. IUCs containing progestin (Mirena) which may decrease menstrual flow and painful menstrual periods. The IUC provides protection from pregnancy (Paragard – 10 years; Mirena – 5 years).

YOU SHOULD NOT USE AN IUC IF YOU HAVE:

- Cirrhosis or liver tumors (Mirena only)
- Breast cancer (Mirena only)
- Serious blood clots in your deep veins (Mirena only)
- Current pelvic infection (PID), (Chlamydia, gonorrhea)
- HIV/AIDS – taking antiretroviral medications
- Cancer of the uterus, cervix, or ovaries
- Blood clotting problems or taking medications for clotting problems
- Vaginal bleeding (undiagnosed – i.e. with no known reason)
- Wilsons Disease
- Lupus
- Headaches with aura
- Ischemic heart disease (current or history of)
- Pelvic Tuberculosis
- Solid organ transplant
- Allergy to copper
- Uterine fibroids

RISKS/ SIDE EFFECTS

1. Menstrual bleeding changes and/or spotting between periods – very common and will vary with the IUC used
2. Partial or complete expulsion of device – you can become pregnant if this happens
3. Puncturing of the uterus (called perforation) rarely occurs, but sometimes surgery is needed to remove the IUC.

WARNING SIGNS: You need to call your provider if I have any of the following early warning signs develop:

- Period late (pregnancy), abnormal spotting or bleeding
- Abdominal pain, pain with intercourse
- Infection exposure (such as gonorrhea), abnormal discharge
- Not feeling well, fever, chills
- String missing, shorter or longer

ALTERNATIVES: There are alternative methods of contraception and you can receive upon request, information about any of those choices and the ability to discuss with your provider whether alternative methods may be a good choice for you.

INSTRUCTIONS: You should check for the IUC string after each monthly period and report to your provider if you cannot feel the strings or if you have another reason to believe that your IUC has been expelled.

DECISION TO DISCONTINUE USE: You can choose to have the IUC removed at any time. If at the time of removal you want to prevent pregnancy, you can have another IUC inserted or choose to use another method of birth control.

**REQUEST FOR AN INTRAUTERINE CONTRACEPTION (IUC)
BY WOMEN WITH RISK FACTORS**

IUCs, like any method of birth control, are not always suitable for all women. Risks versus benefits are determined for each woman.

Your medical history and an examination may show risk(s) for using an IUC. Checked below are symptoms or conditions which might lead to serious side effects if you use an IUC.

- Cirrhosis or liver tumors
- Current pelvic infection (PID), (Chlamydia, gonorrhea)
- Exposure to multiple sexual partners
- Partner who has multiple sexual partners
- Have HIV/AIDS – taking antiretroviral medications
- Have breast, cervical, endometrial or ovarian cancer (or being evaluated for)
- Have serious blood clots in your deep veins (Mirena only)
- Have blood clotting problems or taking medications for clotting problems
- Have vaginal bleeding (undiagnosed)
- History of Wilsons Disease
- Lupus
- Headaches with aura
- Ischemic heart disease (current or history of)
- Pelvic Tuberculosis
- Solid organ transplant
- Allergy to copper

The above side effects, symptoms, and conditions have been explained to me. I read the instruction sheet, the manufacturer’s booklet, and I desire to have the IUC prescribed. Once the IUC is inserted, I will return to the clinic following my first menstrual cycle or within 3 months for a follow-up exam.

I have been advised of and accept the possible serious risk and harm that may result from my using an IUC. The health care provider has explained my condition in a satisfactory manner. The health care professional answered all my questions. I may ask any questions at any time. I may seek an alternate method of birth control at any time.

I release the _____ (agency name), its employees or agents from any and all claims, damages, or liabilities which I may have against them as a result of the receipt of medical services, supplies and/or procedures.

Client Signature

Date

Witness Signature

Date

CONSENT FOR INTRAUTERINE CONTRACEPTION

I, (print or type name) _____,
request Intrauterine Contraception as my family planning method.

I have received and read information for (print or type kind of intrauterine contraceptive) _____ in the Patient Package Insert that has information about the benefits and risks of using this method. I was given an opportunity to ask questions about all forms of birth control, meaning all prescription, non-prescription, and natural methods. All of my questions were answered to my satisfaction and I understood all of those answers.

I understand that no method of birth control, except abstinence, is 100% effective against pregnancy or contracting sexually transmitted diseases, including the Human Immunodeficiency Virus (HIV) infection that leads to the Acquired Immunodeficiency Syndrome (AIDS) disease. 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 have been told that the IUC is 98 -99% effective. IUCs containing progestin (Mirena) may decrease menstrual flow and painful menstrual periods. I have been told the IUC provides protection from pregnancy (Paragard – 10 years; Mirena – 5 years).

I understand that I should not use an IUC if I have:

1. Allergy to copper (for Paragard, the Copper T IUD)
2. Blood clotting problems or taking medications for clotting problems
3. Breast cancer (Mirena only)
4. Cancer of the uterus, cervix, or ovaries
5. Cirrhosis or liver tumors (Mirena only)
6. Current pelvic infection (PID), (Chlamydia, gonorrhea)
7. Headaches with aura
8. HIV/AIDS – taking antiretroviral medications
9. Ischemic heart disease (current or history of)
10. Lupus
11. Pelvic Tuberculosis
12. Serious blood clots in your deep veins (Mirena only)
13. Solid organ transplant
14. Uterine fibroids
15. Vaginal bleeding (undiagnosed)
16. Wilsons Disease

RISKS/ SIDE EFFECTS

1. Menstrual bleeding changes and/or spotting between periods – very common and will vary with the IUC used
2. Partial or complete expulsion of device – you can become pregnant if this happens
3. Puncturing of the uterus (called perforation) rarely occurs, but sometimes surgery is needed to remove the IUC.

WARNING SIGNS: I have been told that I need to call if I have any of the following early warning signs develop:

- Period late (pregnancy), abnormal spotting or bleeding
- Abdominal pain, pain with intercourse
- Infection exposure (such as gonorrhea), abnormal discharge (PID)
- Not feeling well, fever, chills, faintness
- String missing, shorter or longer

ALTERNATIVES: I have received written information about other methods of birth control and I choose an IUC.

INSTRUCTIONS: I have been told how the IUC is inserted. I have read and will follow the instructions provided to me. I understand I should check for the IUC string after each monthly period.

DECISION TO DISCONTINUE USE: I understand that I may have the IUC removed at any time. If I do not desire to become pregnant, I have been told I may request to have another IUC inserted or choose to use another method of birth control
I understand that side effects sometimes associated with the ParaGard IUD include:

I have had a chance to ask questions and have had my questions answered.

Date: _____ Client Signature: _____

Please complete the following if interpretation of informed consent was required:

- An interpreter was offered to the client. yes no
- This form has been read to the client in the client's spoken language. yes no
- Patient's Language (specify): _____
- Interpreter Name: _____
(print or type name of interpreter)
- Interpreter Services provided by(agency): _____
- Date: _____ Interpreter Signature: _____

Staff Use only

By my signature I affirm that:

- The client has read this form or had it read to her by an interpreter.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____

EMERGENCY CONTRACEPTION (EC)

I. INTRODUCTION

Emergency contraception is an important option for pregnancy prevention following unprotected intercourse or a known contraceptive failure. While a number of drug regimens and contraceptive devices have been investigated for this purpose, only a specified regimen of oral contraceptives may be used.

Although the risk of pregnancy is greatest with mid-cycle exposure, emergency contraception may be offered for unprotected sexual exposure at any time during the cycle. If another instance of unprotected intercourse has occurred since their last menstrual period (LMP) emergency contraception may not protect against pregnancy.

II. CLIENT SELECTION

Emergency contraception order may be provided at the client's request or as a back up order written at the time of their initial/annual visit to be used when needed during the upcoming year (as an emergency measure). However, emergency contraceptive pills may be reissued to a client for use at a future time if the need arises. EC may be offered at any time during a woman's cycle.

A. Indications:

1. Emergency contraception may be used by women who have had unprotected intercourse, within the previous 120 hours. (FDA approved Emergency Contraception use within 72 hours of unprotected intercourse to be most effective).
2. EC may be ordered/issued for use should an act of unprotected intercourse occur.

B. Contraindications: Frequently repeated EC use may be harmful for women with conditions classified as USMEC 2, 3, or 4 for CHC or POC use.

III. MEDICAL SCREENING AND EVALUATION

A. EC is available without a prescription for clients ages 17 or older. A prescription/order is needed if the client is under age 17.

B. Prior to providing emergency contraception, the following must be done:

1. Obtain history as indicated
2. Perform highly sensitive urine pregnancy test if indicated
3. Perform examination and obtain lab tests only if indicated

IV. EMERGENCY CONTRACEPTION OPTIONS AND PRESCRIBING INFORMATION

- A. FDA-approved progestin-only pill specifically manufactured and marketed for emergency contraception: Two tablets (0.75 mg levonorgestrel each) as soon as possible within 120 hours after intercourse
OR
- B. One tablet (0.75 mg levonorgestrel) as soon as possible within 120 hours after intercourse followed by a second dose (0.75 mg) 12 hours later
OR
- C. One tablet (1.5 mg levonorgestrel) as soon as possible within 120 hours after intercourse
OR
- D. One tablet (30 mg ulipristal acetate—progesterone receptor modulator) as soon as possible within 120 hour after unprotected intercourse
OR
- E. Copper T – 380 IUD (Paraguard) – as soon as possible within 120 hours after first act of unprotected intercourse. IUD can stay in place and be used for ongoing contraception.

V. INITIATION OF CONTRACEPTION POST EMERGENCY CONTRACEPTION (EC)

Client must meet eligibility requirements for each method discussed in the following table refer to method specific guidelines.

Method	Initiation Instructions post EC
Combine Hormonal Contraception: Oral Contraceptives (COCs or POPs); contraceptive vaginal ring; transdermal contraceptive patch; or subdermal contraceptive implant	<p>The following are options for initiation of methods after EC:</p> <ul style="list-style-type: none"> • Initiate a new pill pack, ring, patch or Implanon after beginning the next menses • Start a new pill pack, ring, patch or implant the day after EC treatment is completed. Advise back-up method for 7 days (2 days for POPs) <p>Additional information/instructions:</p> <ul style="list-style-type: none"> • For implant, perform a highly sensitive urine pregnancy test prior to initiation unless first day of LNMP within past 7 days. Advise client to repeat pregnancy test if no menses in four weeks. • If a regimen of monophasic OC's was used as EC, the patient may continue to take one pill per day from the same pack. Advise back-up method for 7 days.
Depot-Medroxyprogesteron Acetate (DMPA)	<p>The following are options for the initiation of DMPA after use of EC:</p> <ul style="list-style-type: none"> • Initiate during first 5 days of next menses or • Initiate within 24 hours post EC use and: • Perform a highly sensitive urine pregnancy test prior to

	<p>initiation unless 1st day of LNMP was within past 5 days.</p> <p>Additional information/instructions:</p> <ul style="list-style-type: none"> • Advise client to repeat pregnancy test in 3-4 weeks • Advise back-up method for 7 days unless first day LNMP within past 5 days performed before the next DMPA injection may be given. • For these women, a urine pregnancy test must be performed before next DMPA injection given.
Copper-T IUD	<ul style="list-style-type: none"> • Inserted within 5 days of first act of unprotected intercourse • The Copper-T IUD can be used as both the EC method and for ongoing contraception (Copper-T Only). • Is the most effective type of EC

VI. CLIENT EDUCATION/ INFORMED CONSENT

- A. Clients receiving EC must receive education/consent that should include:
1. Information that for maximum effectiveness, EC treatment should be started as soon as possible after unprotected intercourse and within 120 hours.
 2. Information specific to EC, including effectiveness, benefits, risks, use, danger signs, potential side effects and complications.
 3. Client Education/Informed consent.
 4. Instructions to the client about returning to the clinic in 3-4 weeks if no menses occurs for a pregnancy test and options counseling.
 5. Advise to read the Patient Package Insert (PPI)
- B. The Client Must be Given:
1. Written and verbal instructions on EC (may use package insert)
 2. A copy of the method specific consent Form, if the client so requests
 3. Emergency 24 hour telephone number and location where emergency services can be obtained
 4. Clinic access information
 5. Counseling regarding the importance of a regular use of birth control
 6. Information regarding STIs/HIV as indicated, including:
 - a. Prevention
 - b. Modes of transmission
 - c. Signs and symptoms
 - d. The availability of confidential testing
 - e. Safer sex practices
 - f. Use of latex condoms must be encouraged for all sexually active clients as indicated
- C. Obtain a signed general consent for agency reproductive health services.

VII. MANAGEMENT OF SIDE-EFFECTS

- A. Nausea/Vomiting:
1. Nausea/vomiting may occur up to 24 hours.

2. OTC antiemetics (Dramamine) may be taken (most effective 1 hour prior to ingestion).
 3. If vomiting occurs more than 30 minutes after EC ingestion, a replacement dose is not needed.
- B. Dizziness, headaches, breast tenderness, abdominal pain, fatigue or menstrual changes may occur but are usually of short duration and should not require special management. If symptoms persist, client should seek medical attention to rule out pregnancy or other cause of symptoms.

VIII. FOLLOW-UP

- A. Inform the client of EC failure possibility and chance of pregnancy.
- B. Advise client to go to an emergency room if any early pregnancy danger signs occur, such as:
1. Possible Tubal (Ectopic) Pregnancy:
 - a. Sudden pain, or pain that lasts, or strong cramps low in your abdomen, usually on one side or the other –with or without bleeding.
 - b. Fainting or dizziness that lasts more than a few seconds (that could be a sign of bleeding inside your abdomen).
 2. Possible miscarriage:
 - a. Heavy bleeding, sometimes with clots, pieces of tissue or bad cramps.
 - b. A period that is heavy and longer.
 - c. Fever or pain in your abdomen.
- C. Return to the clinic in 3-4 weeks post EC to:
1. Rule out pregnancy if no menses have occurred (If signs and symptoms of ectopic pregnancy and/or miscarriage patient should report earlier)
 2. STI check
 3. For contraceptive and EC supply visit

IX. DOCUMENTATION

- A. Order written in medical record at time of visit or as a standing order.
- B. EC's dispensed must be documented in the medical record and the family planning data system.

REFERENCES

1. Medical Eligibility Criteria for Contraceptive Use. MMWR, Vol. 59, No. RR-4, June 18, 2010
2. Ziemann, M., et. al. Managing Contraception for Your Pocket. 2010 (pg 621)
3. Hatcher, R., et al. Contraceptive Technology. 19th Edition, 2007.

CLIENT EDUCATION FOR EMERGENCY CONTRACEPTION (EC)

Before you take emergency contraceptive pills (ECPs), be sure you understand both the benefits and the possible problems of using ECPs. This information sheet also lists the danger signs you should watch for. If you have any questions as you read, we will be happy to talk about them with you.

Emergency contraceptive pills (ECPs) are hormonal pills (similar to birth control pills) that you take to try to prevent pregnancy after you have unprotected vaginal intercourse. Either your birth control method failed (for example your condom broke) or you didn't use a method.

ECP is believed to act by preventing ovulation or fertilization (by altering tubal transport of sperm and/or ova). In addition, it may inhibit implantation (by altering the endometrium). It is not effective if implantation has already begun.

There are alternatives to ECPs. When a copper intrauterine device (IUD) is inserted within 5 days of a single act of unprotected intercourse, it may prevent pregnancy. It may also be left in place for ongoing contraception. Or you can choose to "wait and see." Discuss all of the choices with your health care provider.

The sooner ECPs are taken, the better they work to prevent pregnancy. It is best to start the pills within 72 hours (3 days) of unprotected vaginal intercourse. When taken within the first 72 hours after intercourse, emergency contraception pills prevent pregnancy about 75 – 89% of the time. Studies have shown that even if ECPs are taken as late as 120 hours (5 days) after unprotected intercourse they may prevent pregnancy. It appears to be less effective the later it is used.

How well the pills work depends on how soon after intercourse they are started and what day in your menstrual cycle unprotected intercourse takes place. This method fails to prevent pregnancy in some cases, because:

- A fertilized egg already has implanted in the uterus
- Too much time passed since unprotected vaginal intercourse
- Failure of the drug itself.

You will get the FDA approved information provided by the pill manufacturer if you get these pills here. You should read the information and ask questions about anything you do not understand.

A sensitive urine pregnancy test should be done before taking ECPs if you think there is any chance that you could already be pregnant (if your last period was late, light, or short, or if you feel pregnant).

You should not use ECPs if you are (or think you are) already pregnant. However, if you are pregnant, or if the pills fail and pregnancy occurs, there have not been any reports of serious side effects to the woman or to the fetus from taking the pills. As with any pregnancy you would still need to be aware of signs and symptoms of ectopic pregnancy or miscarriage as discussed and seek immediate medical attention.

Some reactions to these pills (for about 24 hours) may include:

- Nausea, vomiting and/or abdominal pain
- Breast tenderness
- Irregular bleeding
- Headache or dizziness
- Fatigue

After taking ECPs, your next period could be early or late, or could be lighter or heavier, or could be the same as usual. If you use ECPs more than once in a monthly cycle, the chances of having problems with your next period will be greater.

If you see a clinician before you have your next period, you should tell him/her that you have taken ECPs.

If you do not want to become pregnant, it is important to begin a more reliable form of ongoing birth control. Ask about the options at your clinic.

Having unprotected sex may have put you at risk for sexually transmitted infections (STIs/HIV) and a serious infection could cause sterility. If you think you could be at risk for STIs/HIV, you should talk to your clinician about getting tested.

You should come back to the clinic for a checkup 3-4 weeks after taking these pills if you have not had a normal period, or if you feel like you could be pregnant, or if you have any early signs of pregnancy (such as feeling sick to your stomach, feeling very tired, breast swelling or tenderness).

FAMILY PLANNING EMERGENCY CONTRACEPTION RECORD

Date _____
Name _____
Age _____ Date of Birth _____
Allergies _____
Current Method of Contraception _____
Current Medications _____
Last Normal Menstrual Period (LNMP) _____
Last bleeding episode, if not LNMP _____

Reason for requesting Plan B _____
Date of most recent unprotected sexual intercourse _____ Time _____ AM/PM
Number of hours since unprotected intercourse _____
Any other unprotected intercourse since LNMP or other bleeding episode yes no
If yes, list dates and times of other unprotected intercourse _____

History

Now pregnant? yes no
Unexplained vaginal bleeding? yes no
Allergy to any ingredient in Emergency Contraception? yes no

Urine Pregnancy Test pos neg

Exam (if indicated) _____

EC Consent signed? yes no

EC Rx: _____

PO immediately yes Time given _____
 no

Follow-up Appt/Plan _____

Contraception (initiated, continued, or restarted)

- Post-Emergency Contraception Instructions discussed
- Condoms offered given
- Quick Start contraception initiated (Indicate method) _____
- Established method of contraception continued/restarted (Indicate method) _____

Comments _____

Date _____ **RN Signature** _____

Interpreter Signature _____ **Clinician Signature** _____

STERILIZATION

I. INTRODUCTION

Sterilization in women is the purposeful occlusion of the fallopian tubes by surgical disruption. Several methods are practiced, including excision of a portion of each tube and suturing of the ends; excision of the fimbriated end; excision of a portion and then suturing of the proximal end into the muscle of the uterus and the distal end in the broad ligament; banding with Silastic bands or clips; occlusion by electro cautery; and transuterine occlusion with silicone rubber plugs at the proximal opening.

Male sterilization (vasectomy) is done by sealing the vas deferens tubes that carry sperm to mix with the semen. A male will still have ejaculate fluid, but it will no longer contain sperm.

Female sterilization typical use failure rate: 0.5%, perfect use failure rate 0.5%
Male sterilization typical use failure rate: 0.15%; perfect use failure rate 0.10%

A client requesting sterilization should be referred to a provider who will do the procedure. The cost is the responsibility of the client's if no insurance coverage exists.

Note: All sterilizations are done on a referral basis to private providers. When referring a client to private providers, a physical examination and laboratory testing are not required through the delegate agency family planning clinic.

Note: If a client is a Title X client prior to sterilization (tubal ligation or vasectomy) they may continue to access services through the Title X clinic and be counted as a Title X client. This allows for continuity of care. If a client is a Title X client prior to hysterectomy, they may NOT be counted as a continuing Title X user.

II. CLIENT SELECTION

- A. Indications: Decision by the client to seek a permanent, safe, highly effective method of contraception.
- B. Contraindications:
 - 1. Clients who wish to maintain the option of having children in the future. These individuals should be encouraged to use an alternative method of birth control.
 - 2. High surgical risks/contraindications are determined by the physician/clinician who will be performing the procedure (i.e. nickel allergy with Essure® procedure).

III. MEDICAL SCREENING, EVALUATION AND COUNSELING

- A. Client's knowledge about all family planning methods available.
- B. Psychosocial and cultural aspects; size of family desired, cultural beliefs about sterilization, family attitudes.
- C. Client's knowledge about the sterilization procedures available.
- D. Gynecological history: partial or total hysterectomy, oophorectomy, salpingectomy.
- E. Medical history, present use of medications.
- F. Obstetric history: pregnancies, live births, abortions, ectopic pregnancy.

NOTE: The delegate agency may do the consultation and/or pre-op and post-op physicals for men and women if arrangements are made with the provider who will be performing the procedure.

III. CLIENT EDUCATION/INFORMED CONSENT

- A. The role of the family planning provider is to provide information and education to enable the client to make a voluntary informed consent with full knowledge of the permanence, risk, and benefits associated with both male and female sterilization and the knowledge that sterilization provides no protection from STIs/HIV.
- B. If the client is to receive financial assistance through funding provided by the Federal Government, certain conditions must be met. These include:
- C. The client must be at least 21 years old and mentally competent.
- D. He/she must wait at least 30 days to have the procedure done after the consent form is signed, except in instances of premature delivery or emergency abdominal surgery that takes place at least 72 hours after consent is obtained.
- E. The consent cannot be obtained while the client is in the hospital for childbirth or abortion, or under the influence of alcohol or other substances that affect his/her state of awareness.
- F. The consent is effective for 180 days from the date it is signed. Consent forms can be obtained from the Office of Population Affairs at www.hhs.gov/opa or 1/866-64007827.
- G. Inform the client they have a right to change their mind (electing sterilization) at any time prior to the procedure.

IV. REFERRALS

- A. See the Maryland Family Planning Program Administrative Guidelines for information on male sterilization referral services.
- B. The agency must maintain a current list of providers that perform sterilization and this list must be available for clients and updated annually.
- C. Clients are responsible for the cost of the procedure

V. FOLLOW UP

- A. A post-operative follow-up exam should be conducted by the provider who preformed the procedure unless other arrangements have been made.

- B. Female clients who have been sterilized should continue to have regular exams (physical and pap testing) as indicated.

VI. DOCUMENTATION

- A. The details of discussion regarding sterilization and client's decision should be recorded in the medical record during initial, annual, and medical visits.
- B. Referral list provided.

NORPLANT® REMOVAL

I. INTRODUCTION

Norplant® is a subdermal contraceptive insert that is no longer available on the U.S. market. The last insertions were in 2004. However, because the implants are effective for 5 years of use, a few women may still have the implants in place and there exists the possibility that a clinician may be asked to remove Norplant.

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.

Six silicone rubber capsules were surgically placed subdermally in the client's upper arm during the Norplant® insertion procedure. 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.

II. NORPLANT® REMOVAL

Instructions for Norplant® removal are as follows:

- A. Have the client read and sign the informed consent.
- B. Position the client on table with her arm flexed and externally rotated as for the insertion.
- C. Identify position of all 6 capsules; the skin may be marked with a marking pencil.
- D. Prep the skin with Hibiclens and Betadine.
- E. Put on sterile gloves and position sterile drapes.
- F. Draw up 6.5 cc 1% Lidocaine.
- G. Anesthetize the site of incision and under the implant tips.
- H. Remove the capsules.
- I. Apply pressure to incision (1-2 minutes).
- J. Apply steri -strips over incision.
- K. Cleanse area with alcohol and apply pressure bandage.
- L. Show all 6 capsules to the client.
- M. 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.
- N. The client should return in 1-2 weeks for arm check.
- O. If any capsule cannot be removed, a second attempt at removal should be done in 4-6 weeks.
- P. Any "lost" implant may be located with a high frequency (7-10) megahertz, short focus ultrasound.

REFERENCES

1. Hatcher RA et al. Contraceptive Technology. 19th Revised Edition. Ardent Media, Inc., New York, 2007.
2. Ziemann M , Hatcher RA, et al. A Pocket Guide to Managing Contraception. Bridging the Gap Foundation, Tiger, GA, 2007.
3. ACOG. Precip: Primary and Preventive Care. 3rd Ed., 2004.
4. Norplant Management Guidelines. 1992.

CONSENT FOR REMOVAL OF NORPLANTâ

I, (print or type name) _____, request removal of Norplantâ as my family planning method. All my questions have been answered and I have been advised of the risks involved in Norplant removal. I have considered these factors and voluntarily choose to have the Norplantâ capsules removed. It understand that it is my responsibility to seek another method of birth control if I so desire.

I understand the following about how Norplantâ is removed:

- o The process requires that I be able to lie on my back on the examination table.
- o After cleaning the removal site on my arm, a local anesthetic is injected.
- o A small incision approximately ¼ inch will be made with a scalpel. After healing I may still have a small scar.
- o The Norplantâ capsules are then separated from the surrounding tissue and removed. In some cases, removal of the capsules may be difficult. A second incision may be necessary to remove all of the Norplantâ capsules.
- o I may be asked to return in 4 to 6 weeks (after the site has healed) in order to remove the remaining capsules.
- o With difficult removals, I may have to be referred to another provider (at my own expense) in order to have all of the capsules removed under anesthesia
- o Removals usually take about 20 to 30 minutes.

I will contact my provider if the following g warning signs of possible problems develop:

- Redness, pus or bleeding at the removal site
- Swelling, bruising
- Fever
- Reaction to anesthesia

I understand that within 24 hours after removal, most women return to their pre-insertion fertility rate; therefore, another method should be started immediately if I wish to have birth control

I have reviewed this consent and all my questions have been answered. I h voluntarily choose to have the Norplantâ capsules removed.

Date: _____ Client Signature: _____

Please complete the following if interpretation of informed consent was required:

- An interpreter was offered to the client. Yes No

- This form has been read to the client in the client's spoken language. Yes No
- Patient's Language (specify): _____

- Interpretator Name: _____
(print or type name of interpreter)
- Interpreter Services provided by(agency): _____
- Date: _____ Interpreter Signature: _____

Staff Use only

By my signature I affirm that:

- The client has read this form or had it read to her by an interpreter.
- The client states that she understands this information.
- The client has indicated that she has no further questions.

Date: _____ Staff Signature: _____