# STANDARD NURSE PROTOCOLS FOR WOMEN'S HEALTH

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#### 2011-2012 WOMEN'S HEALTH CLINICAL REVIEW TEAM

Melinda Ford-Williams Family Planning Program Nurse Consultant

Lyndolyn Campbell, BSN, MPM Family Planning Program Nurse Manger

Barbara Gibson, MSN, APRN-BC Northwest Health District

Angela Perry, MPH, WHNP-BC Southeast Health District

Greg French RD, LD, CPT WIC Nutrition Program Consultant Paula C. Greaves, MD Medical Consultants

Jo Ann Cook, MSN, WHNP-BC West Central Health District

Randal Maret North Central Health District-Pharmacy

Elizabeth Daniels, RN, WHNP-BC Southwest Health District

Jennifer Parker, APRN-BC North Health District

Pamela Smith, MSN, WHNP-BC 2 Peachtree Street

Andrea Yeany, WHNP-BC Northeast Health District

#### Women's Health Nurse Protocol Approval

The District Health Director may approve and sign the Women's Health Nurse Protocols if no modifications/revisions are made.

It is recommended that the Women's Health Nurse Protocols be adopted without modification. However, if modifications/revisions are made to the Women's Health Nurse Protocols at the district level, it is recommended that a legal review be conducted at the district level to assure compliance with current statutes, rules, regulations and practice standards. A physician with family planning experience must also be included in the review process and provide an approval decision and signature on the attached Physician Signature form.

The approved revisions along with the Physician Signature form should then be forwarded to State Office Women's Health Program for an approval decision and signature by the Women's Health Medical Consultant.

#### **Physician Signature Form**

#### CERTIFIED NURSE PROTOCOL REVIEW Women's Health Nurse Protocols for 2011

Physician Name:	Phone
Signature:	
Date Reviewed	
Specialty	
Affiliations	

This certifies that the following **standard** nurse protocols have been reviewed for use by Public Health Nurses (**RNs**) in the expanded role and **Advance Practice Registered Nurses** (**APRNs**) in Public Health (list by title of nurse protocol):

Example: Standard Nurse Protocol For Combined Oral Contraceptives - Revision Date February 2011

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# TYPE OF CONTRACEPTIVECONDITIONCATEGORYCLARIFICATIONS/I=InitiationEVIDENCEC=ContinuationEVIDENCEConditionCondition classified from 1 to 4Clarifications and evidence<br/>regarding the classificationConditionCondition classified from 1 to 4Clarifications and evidence<br/>regarding the classification

#### World Health Organization (WHO) Medical Eligibility Criteria for Contraceptive Use

NA denotes a condition for which a ranking was not given by the Working Group but for which clarifications have been provided.

#### Classification of categories:

Each condition was defined as representing either an individual's characteristics (e.g., age, history of pregnancy) or a known pre-existing medical/pathological condition (e.g., diabetes, hypertension). It is expected that national and institutional health and service delivery environments will decide the most suitable means for screening for conditions according to their public health importance. Client history will often be the most appropriate approach.

The conditions affecting eligibility for the use of each contraceptive method were classified under one of the following four categories:

- 1. A condition for which there is no restriction for the use of the contraceptive method.
- 2. A condition where the advantages of using the method generally outweigh the theoretical or proven risks.
- 3. A condition where the theoretical or proven risks usually outweigh the advantages of using the method.
- 4. A condition which represents an unacceptable health risk if the contraceptive method is used.

#### Abbreviations:

COC - Combined oral contraceptive

- CIC Combined injectable contraceptive
- P/R Patch/Ring

POP – Progestin-only pill

DMPA – Depot medroxyprogesterone acetate

NET-EN – Norethinsterone enantate

LNG/ETG – Levonorgestrel/Etonorgestrel (Norplant & Jadell/Implanon)

Cu IUD – Copper IUD (ParaGard)

LNG IUD – Levonorgestrel IUD (Mirena)

Using the categories in practice:

Categories 1 and 4 are self-explanatory. Classification of a method/condition as category 2 indicates the method can generally be used, but careful follow-up may be required. However, provision of a method to a woman with a condition classified as category 3 requires careful clinical judgment and access to clinical services; for such a woman, the severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account. For a method/condition classified as category 3, use of that method is not usually recommended unless other more appropriate methods are not available or acceptable. Careful follow-up will be required.

Where resources for clinical judgment are limited, such as in community-based services, the four-category classification framework can be simplified into two categories. With this simplification, a classification of Category 3 indicates that a woman is not medically eligible to use the method.

CATEGORY	WITH CLINICAL JUDGMENT	WITH LIMITED CLINICAL JUDGMENT	
1	Use method in any circumstances	Yes (Use the method)	
2	Generally use the method		
3	Use of method not usually recommended unless other more appropriate methods are not available or not acceptable	No (Do not use the method)	
4	Method not to be used		

WHO Medical Eligibility Criteria for Contraceptive Use

The WHO Medical Eligibility Criteria for Contraceptive Use (4<sup>th</sup> edition) is available at <u>http://whqlibdoc.who.int/publications/2010/9789241563888\_eng.pdf</u>

This document aims to provide guidance to national family planning/reproductive health programs in the preparation of guidelines for service delivery of contraceptives. It should not be seen or used as the actual guidelines but rather as a reference.

A summary of the classification changes or major condition modifications from the *WHO Medical Eligibility Criteria for Contraceptive Use* (3<sup>rd</sup> edition) is given in Table 3.

The WHO has 4 cornerstones of family planning guidance. Together, the 4 cornerstones support the safe and effective provision and use of family planning methods.

The 4 cornerstones can be found on the WHO Web site at <a href="http://www.who.int/reproductivehealth/publications/family\_planning/en/index.html">http://www.who.int/reproductivehealth/publications/family\_planning/en/index.html</a>

#### 4 Cornerstones of Family Planning Guidance

1) *Medical Eligibility Criteria for Contraceptive Use* (4<sup>th</sup> edition) provides guidance on whether people with certain medical conditions can safely and effectively use specific contraceptive methods. <u>http://whqlibdoc.who.int/publications/2010/9789241563888\_eng.pdf</u>

- 2) Selected Practice Recommendations for Contraceptive Use (2<sup>nd</sup> edition) answers specific questions about how to use various contraceptive methods. <u>http://whqlibdoc.who.int/publications/2004/9241562846.pdf</u>
- 3) Decision-Making Tool for Family Planning Clients and Providers incorporates the guidance of the first 2 cornerstones and reflects evidence on how best to meet clients' family planning needs. It is intended for use during counseling. The tool leads the provider and client through a structured yet tailored process that facilitates choosing and using a family planning method. The Decision-Making Tool also helps to guide return visits. <u>http://www.who.int/reproductivehealth/publications/family\_planning/9241593229/ en/index.html</u>
- 4) Family Planning: A Global Handbook for Providers (2011 update) offers technical information to help health care providers deliver family planning methods appropriately and effectively. A thorough reference guide, the handbook provides specific guidance on 20 family planning methods and addresses many of providers' different needs, technical information to help health care providers deliver family planning methods appropriately and effectively. A thorough reference guide, the handbook provides specific guidance on 20 family planning methods and addresses many of providers' different needs, from correcting misunderstandings to managing side effects. Like the Decision-Making Tool, this handbook incorporates the guidance of the first 2 cornerstones. It also covers related health issues that may arise in the context of family planning.

http://whqlibdoc.who.int/publications/2011/9780978856373\_eng.pdf The handbook can also be found on the INFO Project Web site at http://www.fphandbook.org

#### STANDARD NURSE PROTOCOL FOR COMBINED ORAL CONTRACEPTIVES

- DEFINITION Combined oral contraceptives (OC) are birth-control pills that include a combination of an estrogen and a progestin. Estrogen and progesterone are two hormones which direct many of the processes surrounding the menstrual cycle. The amount of estrogen and progestin in each pill may vary depending on when the pill is taken. Combined OC are commonly referred to as the "pill(s)."
- **ETIOLOGY** Combined OC work primarily before fertilization. The estrogen works by preventing an egg from being released from the ovaries most of the time. The progestin in all combined OC provide most of the birth control activity by: thickening cervical mucus to prevent sperm penetration into the upper genital tract, blocking the luteinizing hormone (LH) surge prohibiting ovulation, and inhibiting capacitation of the sperm which may delay sperm transport.

Some progestin effects additionally alter the environment that would be required for embryogenesis to proceed by: disrupting transport of the fertilized ovum, inducing endometrial atrophy, changing underlying vascular function and structure and altering the metalloproteinase in the endometrium which may inhibit implantation.

- **SUBJECTIVE** 1. **Client provides a** detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and the WHO Medical Eligibility Criteria for Contraceptive Use.
  - 2. If breastfeeding, has been breastfeeding at least 6 months **postpartum.**
  - 3. If non-breastfeeding, is at least 21 days postpartum.
  - 4. If age 35 or older, does not smoke.
  - 5. If age 40 or older, and has any co-morbidities (to include the following: BMI of 30 or greater, diabetes, hypertension, smoking), must use other non-estrogen containing methods.
  - 6. If on Antiretroviral Therapy, does not take Ritonavir-boosted protease inhibitors. Refer to *WHO Medical Eligibility Criteria for Contraceptive Use* for clarification of this classification.

- 7. If on Anticonvulsant Therapy, does not take certain anticonvulsants (e.g., phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine, lamotrigine). Refer to *WHO Medical Eligibility Criteria for Contraceptive Use* for clarification of this classification.
- 8. If on Antimicrobial Therapy, does not take a rifamycin derivative. Refer to *WHO Medical Eligibility Criteria for Contraceptive Use* for clarification of this classification.
- 9. Refer to *WHO Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk for taking combined OC. Medical conditions include:
  - Hypertension
  - Deep vein thrombosis (DVT) / Pulmonary embolism
  - Known thrombogenic mutations
  - Ischaemic heart disease
  - Stroke
  - Known hyperlipidaemias
  - Valvular heart disease (complicated)
  - Positive (or unknown) antiphospholipid antibodies
  - Migraine headaches without aura and age 35 or older
  - Migraine headaches with aura (at any age)
  - Breast cancer
  - Diabetes nephropathy/retinopathy/neuropathy, other vascular disease or diabetes of greater than 20 years' duration
  - Gall-bladder disease (symptomatic) medically treated, current
  - History of cholestasis past combined OC-related
  - Viral Hepatitis acute or flare (initiation of combined OC)
  - Cirrhosis severe (decompensated)
  - Liver Tumours benign hepatocullular ademona, malignant (hepatoma)
- OBJECTIVE
- 1. Physical examination and laboratory tests according to programmatic guidelines.
- OR
  Physical exam deferred up to 3 months.
  Document reason for deferral on chart. Document on Request for and Consent to Family Planning Services (form 3700) that client agreed to have physical exam delayed.

**ASSESSMENT** Client has no condition representing an unacceptable health risk for taking combined OC.

#### PLAN DIAGNOSTIC STUDIES

- Lipid profile beginning by age 45. Rescreen every 5 years or 1. more often depending on test results and risk factors for CVD. Women with cardiovascular risk factors may need to be tested at a younger age. The need to perform a lipid profile on women age 20-44 should be based on the client's comprehensive health assessment, which includes the screening of risk factors for CVD. Cardiovascular risk factors include family history of CVD, hypertension, dyslipidemia, diabetes, obesity (BMI), and smoking. An individual's risk of heart disease increases as the number of risk factors increases. Refer to http://www.womenshealth.gov/hearthealth-stroke/heart-disease-risk-factors for more information on cardiovascular heart disease risk factors. The RN may consult with and/or refer client to the APRN/physician, if needed, to further determine the client's risk for CVD and the need for a lipid profile. The decision to draw a lipid profile will be based on a clinical evaluation that is determined by the RN and/or the APRN/physician. For more information on increased blood cholesterol levels and estrogen-containing contraceptives, refer to Standard Nurse Protocol for Abnormal Lipid Profiles While Using Hormonal Contraceptives.
- 2. Blood glucose beginning by age 45. Consider screening women at an earlier age in the presence of high-risk factors for diabetes. Rescreen every 3 years or more often depending on test results and high risk factors. For Recommended Tests and Immunizations for Women with High-Risk Factors refer to www.womenshealth.gov.
- 3. Screen women for colorectal cancer according to district policy/procedure for colorectal cancer screening.

#### THERAPEUTIC

#### PHARMACOLOGIC

1. Select a combined OC based on the hormonal dose, the client's medical history (clinical picture), preference, past experiences with combined OC and other contraceptives, cost and potential side effects. Both WHO and FDA recommend using the lowest dose pill (35 mcg or less) that is effective. (See Appendix A)

- 2. Determine appropriate pill initiation (start-up) method to begin taking pills.
- 3. Provide instructions on selected combined OC usage to include: pill initiation (start-up) method, daily pill routines, and missed pills.
- 4. Provide education/counseling to include: informed consent, side effects and danger signs, effectiveness and back-up methods, preconception health and future fertility, and risks of STD/HIV.
- 5. Dispense up to a 12-month supply of combined OC to client with current physical exam. OR
- 6. Dispense first 3-month supply of combined OC to client with deferred physical exam.
- 7. Schedule follow-up exam.

#### CLIENT EDUCATION/COUNSELING

- 1. Counsel **client** according to the seven basic elements of informed consent (BRAIDED Benefits Risks Alternatives Inquiries Decision Explanation Documentation).
- 2. **Educate client on the** choices for pill initiation:
  - a. <u>Quick Start</u>: This approach has been shown to be more successful than the other approach for starting pills.
    - 1) The **client** takes the first pill on the day of her clinic visit, as long as she is not pregnant.
    - 2) If she needs emergency contraception: Provide emergency contraception.
    - 3) Start the pills no later than the next day.
    - Use a back-up method for 7 days; unless quadphasic, then use back-up method for 9 days.
    - 5) If the **client** is worried about an undetectable early pregnancy:
      - a) She may choose to start the pills that day and return for a urine pregnancy test in 2 weeks **OR**
      - b) She may choose to wait until the 1<sup>st</sup> day of her menses.

#### b. First Day Start:

- 1) Start taking the pills on the first day of menses.
- 2) Use a back-up method for 7 days; unless quadphasic, then use back-up method for 9 days.
- c. <u>Sunday Start</u>
  - Start taking the pills on the first Sunday of menses. Don't wait to start the first pill on the Sunday after menses ends.
  - 2) Use a back-up method for 7 days; **unless quadphasic, then use back-up method for 9 days**.
- d. <u>Switching from other methods</u>:
  - 1) Start **combined OC** immediately following the guidelines for the quick start method.
  - 2) For clients with an IUD, go ahead and start combined OC when the appointment for IUD removal is made.
  - 3) If a woman is amenorrheic as a result of history of using Depo Provera injection and is late for reinjection, she can start the **combined OC** the same day with a 7-day use of back-up method; **unless quadphasic, then use back-up method for 9 days**. Add emergency contraception and follow up pregnancy test if she has had recent unprotected sex.

#### 3. **Explain instructions for combined OC** use.

- a. Take pills at the same time every day.
- b. Use a back-up barrier method for the first 7 days of combined OC initiation; unless quadphasic, then use back-up barrier method for 9 days.
- c. Use a back-up barrier method if a pill is missed. A missed pill(s) increase the risk of pregnancy. Refer to pill package insert for missed pill(s) instructions.
- d. Offer Plan B or emergency contraceptive pills (ECP) if pill(s) was missed and client had unprotected sex in the last 5 days.
- 4. **Discuss** side effects and danger signs (ACHES).
- 5. **Discuss effectiveness of combined OC** and back-up methods.
- 6. **Provide counseling on preconception health counseling and** future fertility. (Refer to Preconception Health Toolkit).
- 7. Counsel on the use of condoms to reduce the risk of STD/HIV.

- 8. Refer **client** to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867), if smoker or tobacco user.
- 9. Discuss common drug interaction risks between combined OC and herbal substances. Herbal supplements such as St. John's Wort may increase metabolism of estrogen and cause side effects, and/or decrease effectiveness.
- 10. Emphasize importance of keeping immunizations current; assess client's immunization status and administer vaccines indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If client declines vaccination, document refusal. See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current immunization schedules and administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at <a href="http://www.health.state.ga.us/programs/immunization/publications.asp">http://www.health.state.ga.us/programs/immunization/publications.asp</a>.

#### FOLLOW-UP

- 1. **Client should** return as scheduled for evaluation or contact clinic if side effects, danger signs, or **symptoms of pregnancy** develop. Outside of clinic hours, seek physician or emergency care if danger signs develop.
- 2. If **client** did not receive a physical exam, have her return within 3 months for an exam and reassessment.
- 3. Established **clients** should return for evaluation at the end of the current supply of pills, or sooner if side effects, danger signs, or **symptoms of pregnancy** develop.

#### CONSULTATION/REFERRAL

- 1. Refer client to physician if client develops any of the following danger signs:
  - a. Abdominal pain (severe).
  - b. Eye problems (vision loss or blurring).
  - c. Speech problems.
  - d. Chest pain (severe), coughs, shortness of breath.
  - e. Severe leg pain (calf or thigh).
  - f. Severe headaches that start or become worse after beginning to take **combined OC.**
  - g. Dizziness, weakness, numbness or depression.

- 2. **Seek consultation, as applicable**, on serious health concerns expressed by **client.**
- 3. Advise client to continue treatment with physician if client is under the supervision of physician for a health problem.
- 4. Seek consultation, as applicable, if client has abnormal initial laboratory values or develops abnormal laboratory values and/or physical findings that indicate combined OC should not be continued.
- 5. **Refer** to nutritionist if **client** has poor dietary intake, is overweight or underweight, is anemic or has any chronic disease related to poor nutrition.

#### REFERENCES

- 1. Robert Hatcher et al., *Contraceptive Technology,* 19<sup>th</sup> ed., Ardent Media, Inc., New York, 2007. (Current)
- 2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 9<sup>th</sup> ed., Springer Publishing Co., New York, 2007. **(Current)**
- World Health Organization (WHO), Medical Eligibility Criteria for Contraceptive Use, 4<sup>th</sup> ed., 2009,
   <a href="http://whqlibdoc.who.int/publications/2010/9789241563888\_eng.pdf">http://whqlibdoc.who.int/publications/2010/9789241563888\_eng.pdf</a> (May 16, 2011)
- 4. "General Screenings and Immunizations for Women," Office on Women's Health, <<u>http://www.womenshealth.gov/prevention/general</u>> (May 16, 2011)
- 5. M. Zieman, R.A. Hatcher et al., *A Pocket Guide to Managing Contraception*, Tiger, Georgia: Bridging the Gap Foundation, 2010. (Current)
- 6. "A Resource for Contraception and Healthy Sex," <<u>http://www.contracept.org</u>> (May 16, 2011)
- 7. *"Every Woman, Every Time," A Preconception Care Toolkit for Georgia*, 2010, <<u>http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm</u>> (May 16, 2011)
- 8. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," MMWR 2010; 59, <<u>http://www.cdc.gov/mmwr</u>> (June 6, 2011)
- 9. "Lexi-Drugs Online," *Lexi-Comp Database*, Lexi-Comp, Inc., Hudson, Ohio <<u>http://online.lexi.com></u> (August 22, 2011)

#### STANDARD NURSE PROTOCOL FOR ABNORMAL LIPID PROFILES WHILE USING HORMONAL CONTRACEPTIVES

- **DEFINITION** Increased blood cholesterol levels are causally related to an increased risk of coronary heart disease. Coronary risk rises progressively with cholesterol levels, particularly when total cholesterol levels rise above 200 mg/dL. Borderline total cholesterol levels are 200-239 mg/dL and high levels are 240 mg/dL or greater. Desirable levels of low-density lipoprotein cholesterol (LDL) are less than 100 mg/dL. Desirable levels of high-density lipoprotein cholesterol (HDL) are greater than 60 mg/dL and are as significant as total cholesterol levels.
- **ETIOLOGY** Ethinyl estradiol increases HDL cholesterol and reduces LDL cholesterol. Progestins diminish the magnitude of the favorable impact; the more androgenic formulations have a more pronounced negative effect. Although triglyceride levels increase somewhat with estrogen-containing contraception, there is little concern because those remnants are not atherogenic. However, estrogen-containing contraceptives should be avoided if their use will be anticipated to raise triglycerides levels to more than 350 mg/dL and place the woman at risk for pancreatitis.

## SUBJECTIVE Client provides a detailed health history that may include risk factors for increased cholesterol levels. Risk factors include:

- Family history of cardiovascular disease prior to age 50
- History of hypertension
- History of smoking cigarettes
- Diabetes or gestational diabetes
- BMI of 27 or greater

# OBJECTIVE Abnormal blood cholesterol levels which includes at least one of the following:

- Fasting total cholesterol 200 mg/dL or greater
- Fasting HDL cholesterol less than 50 mg/dL
- Fasting LDL cholesterol greater than 130 mg/dL
- Fasting triglycerides greater than 150mg/dL

#### **ASSESSMENT** Elevated Cholesterol and/or Triglycerides (hypertriglyceridemia)

#### PLAN DIAGNOSTIC STUDIES

Fasting total cholesterol, lipid profile (to include HDL, LDL) and triglycerides. Assessment cannot be made on screening total cholesterol only.

#### THERAPEUTIC

#### PHARMACOLOGIC

Change to nonhormonal contraceptive method, such as IUD

#### CLIENT EDUCATION/COUNSELING

- 1. **Counsel client on increased** risk factors associated with **CVD**, smoking, hypertension, diabetes and obesity.
- 2. If smoker or tobacco user, refer to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867).
- 3. **Counsel client on** lifestyle changes such as diet modifications to lower blood cholesterol, diet low in fat, high in fiber (plenty of whole grains, vegetables and fruits).
- 4. Advise **client** to increase exercise and/or physical activity.
- 5. **Advise client that** lower dose OC probably do not adversely affect lipid levels in most women.

#### FOLLOW-UP

Recheck lipid profile in 3–6 months **or as directed by managing physician.** 

#### CONSULTATION/REFERRAL

- 1. Refer to physician immediately **if client has at least one of the following abnormal blood cholesterol levels:** 
  - Total cholesterol 200 mg/dL or greater
  - HDL cholesterol less than 50 mg/dL
  - LDL cholesterol greater than 130 mg/dL
  - Triglycerides greater than 150 mg/dL
  - a. If client has elevated cholesterol and/or triglycerides (hypertriglyceridemia) and no other risk factors for CVD (e.g., diabetes, hypertension, BMI greater than 30, age 40 or greater, smoking), client may restart hormonal contraceptive with physician's written approval. (Refer to WHO Medical Eligibility Criteria Use for medical conditions that represent an unacceptable health risk for taking hormonal contraceptives.)

- b. If client has elevated cholesterol and/or triglycerides (hypertriglyceridemia) and multiple risk factors for CVD (such as diabetes, hypertension, BMI greater than 30, age 40 or greater, smoking) that represent an unacceptable health risk for taking hormonal contraceptives, client must be managed by physician for hormonal contraceptive methods. (Refer to WHO Medical Eligibility Criteria Use.)
- 2. Refer to nutritionist for dietary counseling as needed.

#### REFERENCES

- 1. Robert Hatcher et al., *Contraceptive Technology*, 19<sup>th</sup> ed., Ardent Media, Inc., New York, 2007. **(Current)**
- 2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 9<sup>th</sup> ed., Springer Publishing Co., New York, 2007. **(Current)**
- 3. Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), Executive Summary, NIH, Publication No. 01-3670, National Heart, Lung, and Blood Institute, HHS, Bethesda, MD, 2002. (Current)
- 4. "Cholesterol," American Heart Association, <<u>http://www.heart.org/HEARTORG/Conditions/Cholesterol/Cholesterol\_UCM\_001089</u> <u>SubHomePage.jsp</u>> (May 16, 2011)
- 5. World Health Organization (WHO), *Medical Eligibility Criteria for Contraceptive Use,* 4<sup>th</sup> ed., 2009, <<u>http://whqlibdoc.who.int/publications/2010/9789241563888\_eng.pdf</u>> (May 16, 2011)
- 6. M. Zieman, R.A. Hatcher et al., *A Pocket Guide to Managing Contraception*, Tiger, Georgia: Bridging the Gap Foundation, 2010. (Current)
- 7. CDC, *"U.S. Medical Eligibility Criteria for Contraceptive Use, 2010,"* MMWR 2010; 59, <<u>http://www.cdc.gov/mmwr</u>> (June 6, 2011)

#### STANDARD NURSE PROTOCOL FOR HYPERTENSION WHILE TAKING COMBINED ORAL CONTRACEPTIVES

- **DEFINITION** Women who use **combined** oral contraceptives **(OC)** rarely develop hypertension. However, the probability of developing hypertension increases with age. Hypertension may appear at any time and is not limited to the first months of use. **Combined OC**-related hypertension is usually mild to moderate (a rise over baseline of 10-20 mmHg diastolic and/or 20 to 40 mmHg systolic). The hypertension is usually reversible within one to three months after discontinuing **combined OC**. Only a few cases progressing to malignant hypertension have been reported.
- **ETIOLOGY** Variables such as previous toxemia of pregnancy or previous renal disease do not predict whether a woman will develop hypertension while using **combined OC**. The mechanism for an effect of **combined OC** on blood pressure is thought to involve the renin angiotensin system.
- SUBJECTIVE 1. Client provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history) that may reveal risk factors for hypertension. Risk factors include:
  - Family history of hypertension
  - Race (African American)
  - BMI equal to or greater than 30 kg/m<sup>2</sup> and/or waist circumference in female equal to or greater than 35 inches.
  - Habitual high salt intake
  - Lifestyle elements: sedentary, smoking, stress
  - Certain chronic conditions such diabetes and high cholesterol
  - 2. Client is currently taking combined OC and hypertension has developed.
- **OBJECTIVE** Blood pressure, measured according to Nurse Protocol for Primary Hypertension in Adults, shows:
  - 1. Systolic blood pressure 140 mmHg or greater on three or more separate occasions.
    - OR
  - 2. Diastolic blood pressure 90 mmHg or greater on three or more separate occasions.
  - **NOTE:** See Standard Nurse Protocol for Primary Hypertension in Adults
- ASSESSMENT Hypertension, possibly related to combined OC

#### PLAN THERAPEUTIC

#### PHARMACOLOGIC

Change to another contraceptive method. For appropriate selection, please refer to Standard Nurse Protocol for Progestin-Only Pill, Standard APRN Protocol for IUD Insertion: Copper T380A, or Standard APRN Protocol for IUD Insertion: Mirena LNG IUD.

#### NON-PHARMACOLOGIC MEASURES

Review the following lifestyle modifications, as applicable, with all clients:

- 1. Achieve/maintain desirable body weight or BMI of 18.5-24.9 kg/m<sup>2</sup>.
- Reduction of dietary sodium (1500 mg to no more than 2300 mg/day) and dietary counsel regarding the Dietary Approaches to Stop Hypertension (DASH), Reduced Sodium Diet. Persons who are 40 years of age or older, African Americans, and persons with high blood pressure should consume no more than 1,500 mg per day. For specific recommendations, see:

<<u>http://www.nhlbi.nih.gov/health/public/heart/hbp/dash/</u> index.htm>

- 3. Reduction of dietary fats and cholesterol **to meet DASH** recommendations.
- Moderation of alcohol intake (less than one ounce [30mL] ethanol/day for men and less than 0.5 oz. [15mL] for women). One ounce of ethanol equals 24 oz. beer, 10 oz. wine, or 3 oz. 80-proof whiskey.
- 5. Adequate dietary potassium intake (if renal function is normal and not taking drugs known to raise potassium, such as Angiotensin-Converting Enzyme Inhibitors) of 4700 mg/day.
- 6. Regular aerobic physical activity at least 30 minutes per day, most days of the week.

- 7. Smokers and tobacco users should receive cessation counseling and be referred to the Georgia Quit Line 1-877-270-STOP (7867).
- 8. Adequate intake of calcium, 1000-1500 mg/day **based on** age.

NOTE: Refer to Georgia Dietetic Association Diet Manual and Nutrition Practice Guidelines: A Manual of the Georgia Dietetic Association 4<sup>th</sup> edition, 2010, for lists of foods rich in potassium and calcium.

#### **CLIENT EDUCATION/COUNSELING**

- 1. **Counsel client** on lifestyle changes that may help lower blood pressure, including recommendations to:
  - Limit sodium intake to no more than 1500-2300 mg/day.
  - Eat a diet rich in vegetables, fruits and low-fat dairy products such as low-fat milk and yogurt.
  - Exercise and/or increase physical activity.
  - Quit smoking.
  - Decrease intake of caffeine and alcohol.
  - Avoid over-the-counter oral decongestants and diet pills.
  - Attain and maintain optimal weight.
  - Attain and maintain adequate calcium.
- 2. Discuss possible risks and complications of hypertension.

#### FOLLOW-UP

Monitor blood pressure monthly, for 3 months.

#### CONSULTATION/REFERRAL

- 1. Immediately refer client to the Emergency Room with accelerated hypertension characterized by systolic pressure 180 mmHg or greater or diastolic pressure 110 mmHg or greater on any occasion.
- 2. For uncontrolled blood pressure consistently 140 mmHg or greater systolic, or 90 mmHg or greater diastolic, refer to physician. Discontinue combined OC until further instructions or recommendations from physician.
- 3. **Refer client** to nutritionist for diet counseling about optimal food intake to attain/maintain normal blood pressure, Na intake and weight.

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#### STANDARD NURSE PROTOCOL FOR SPOTTING OR BREAKTHROUGH BLEEDING WHILE TAKING ORAL CONTRACEPTIVES

- DEFINITION Breakthrough bleeding (BTB) is an abnormal uterine bleeding that occurs between menstrual periods in women taking OC. A light amount of BTB is referred to as spotting. Spotting and BTB are generally not a sign of any serious problems.
- ETIOLOGY Spotting and BTB are most common (30-50%) in women taking combined OC, but also may occur with other hormonal contraceptives. Spotting and BTB are most likely to occur during the first few months after a woman begins taking OC and generally resolves by the third or fourth month of use.
- SUBJECTIVE 1. Client provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history).
  - 2. **Client** may have a recent history **which includes the following**:
    - started new OC or changed OC
    - missed OC or incorrect usage
    - intermenstrual spotting/ bleeding for several months
    - GI problems such as vomiting or diarrhea
    - abnormal vaginal discharge and/or odor
    - dyspareunia or pelvic pain
    - history of abnormal pap
    - pain during menses
    - pain or bleeding at sexual intercourse
    - new sex partner
    - smoking
    - new medications
  - 3. **Client** may have history of taking antiseizure medications (phenobarbital, phenytoin, carbamazepine, or promidone), **antibiotic use**, rifampin, topiramate or griseofulvin.
- **OBJECTIVE** Pelvic exam is negative for other causes of bleeding.
- **ASSESSMENT** Spotting or BTB while taking OC.

#### PLAN DIAGNOSTIC STUDIES

- 1. Urine dipstick if indicated.
- 2. Gonorrhea and chlamydia tests, if indicated.

- 3. Pregnancy test if indicated.
- 4. Hemoglobin/hematocrit if indicated.
- 5. Wet prep if indicated.

#### THERAPEUTIC

#### PHARMACOLOGIC

## **NOTE:** Please refer to Appendix A to determine appropriate OC formulation.

- 1. For women with persistent irregular bleeding after 2-3 months, consider changing to other formulations, although no research indicates any specific OC is best at eliminating spotting or bleeding.
- 2. If spotting or bleeding before completion of active OC, increase the progestin content of the OC either by changing to a different monophasic formulation or by switching to a triphasic formulation that increases the progestin level of active OC.
- 3. If spotting continues after the withdrawal bleed, increase the estrogen in the each tablet or decrease the progestin in the early pills (especially with triphasic formulation).
- 4. For mid-cycle spotting/bleeding, increase both estrogen/ progestin mid-cycle with OC such as Triphasil and Tri-Levlen.

#### CLIENT EDUCATION/COUNSELING

- 1. Reassure new OC users that breakthrough bleeding **generally** decreases dramatically over the first 3-4 months of pill **initiation**.
- 2. Reinforce proper **administration** of OC, especially **the importance of** taking pills at the same time each day.
- 3. Counsel on use of alternate **contraceptive** method if OC are discontinued.
- 4. Counsel on use of condoms to reduce the risk of STD/HIV.
- 5. **Advise that** BTB occurs at a higher rate in women who smoke.

- 6. Refer **client** to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867), **if smoker or tobacco user.**
- 7. Discuss common drug interaction risks between OC and herbal substances. Herbal substances such as St. John's Wort may increase metabolism of estrogen and cause side effects and/or decreased effectiveness.
- 8. Discuss the decreased efficacy of OC when taking antibiotics, and the need for additional back-up method during this time.

#### FOLLOW-UP

Reassess **spotting or BTB** in 3 months depending on the acuity of the problem.

#### CONSULTATION/REFERRAL

- 1. **Seek consultation, as applicable**, if spotting or BTB continues.
- 2. Seek consultation, as applicable, if client has abnormal diagnostic test results.
- 3. **Refer client to physician** for pelvic pathology.

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#### STANDARD NURSE PROTOCOL FOR PROGESTIN-ONLY PILL (MINIPILL)

- DEFINITION Progestin-only pills are also known as minipills. Minipills contain only a progestin and are taken daily with no hormone free days. Minipills have lower progestin doses than combined pills and no estrogen. The amount of progestin in the minipill is less than the amount in the lowest-dose combination oral contraceptives.
- **ETIOLOGY** Minipills prevent pregnancy by: inhibiting ovulation, thickening and decreasing cervical mucus preventing sperm penetration, suppressing mid-cycle peaks of LH and FSH, inhibiting progesterone-receptor synthesis, reducing number/size of endometrial glands associated with a thin atrophic endometrium, reducing activity of the cilia in the fallopian tubes, arresting movement of the blastocyst, and premature luteolysis (diminished function of the corpus luteum).

Minipills do not suppress the milk supply once breastfeeding is well established and studies have found no adverse effects on infant health. The minipill is often used after a woman has experienced one of the estrogen-excess side effects with use of combination pills.

Because minipills often cause irregular bleeding, undiagnosed abnormal vaginal bleeding is one of the more important contraindications to their use. Also, minipills do not protect against ectopic pregnancy as effectively as they protect against intrauterine pregnancy.

- **SUBJECTIVE** 1. **Client provides a** detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and the *WHO Medical Eligibility Criteria for Contraceptive Use*.
  - 2. If breastfeeding, has been breastfeeding at least 6 weeks postpartum.
  - 3. If on Antiretroviral Therapy, does not take Ritonavir-boosted protease inhibitors. Refer to *WHO Medical Eligibility Criteria for Contraceptive Use* for clarification of this classification.
  - 4. If on Anticonvulsant Therapy, does not take certain anticonvulsants (e.g., phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine). Refer to *WHO Medical Eligibility Criteria for Contraceptive Use* for clarification of this classification.

- 5. If on Antimicrobial Therapy, does not take a rifamycin derivative. Refer to *WHO Medical Eligibility Criteria for Contraceptive Use* for clarification of this classification.
- 6. Refer to WHO Medical Eligibility Criteria for Contraceptive Use for medical conditions that represent an unacceptable health risk for taking the minipill. Medical conditions include:
  - Deep vein thrombosis (DVT)
  - Pulmonary embolism acute
  - Ischaemic heart disease (continuation of minipill)
  - Stroke (continuation of minipill)
  - Positive (or unknown) antiphospholipid antibodies
  - Migraine headaches with aura (continuation of minipill)
  - Breast cancer
  - Cirrhosis severe (decompensated)
  - Liver Tumours benign hepatocellular adenoma; malignant (hepatoma)
- 7. May complain of estrogen-excess side effects while taking combined oral contraceptives, such as headaches, leg pain, weight gain, nausea.
- 8. Breastfeeding **client** must give a history of no unprotected intercourse within the prior two weeks **of starting minipills.**
- 9. May want lowest-dose oral contraceptive available.
- **OBJECTIVE** 1. Physical examination and laboratory tests according to programmatic guidelines.
  - OR
  - Physical exam deferred up to 3 months. Document reason for deferral on chart. Document on Request for and Consent to Family Planning Services (form 3700) that client agreed to have physical exam delayed.
  - 3. Pregnancy test, if indicated, is negative.
- **ASSESSMENT** Client has no condition representing an unacceptable health risk if taking minipills.

#### PLAN DIAGNOSTIC STUDIES

1. The lipid profile may be obtained at the clinician's discretion if needed. The decision to draw a lipid profile will be determined by the RN and/or the APRN/physician, which is based on a clinical evaluation of the individual client. The RN may consult with and/or refer client to the APRN/physician, if needed, to further determine the client's risk for CVD and the need for a lipid profile.

- Blood glucose beginning by age 45. Consider screening women at an earlier age in the presence of high-risk factors for diabetes. Rescreen every 3 years or more often depending on test results and high risk factors. For Recommended Tests and Immunizations for Women with High-Risk Factors refer to <u>www.womenshealth.gov</u>.
- 3. Screen women for colorectal cancer according to district policy/procedure for colorectal cancer screening.

#### THERAPEUTIC

#### PHARMACOLOGIC

- Order any FDA approved progestin-only OC. (See Appendix A)
- If breastfeeding, wait until breastfeeding well established (usually at six weeks postpartum) before starting mini pills. May begin mini pills on the first day of menses or on any day that pregnancy has been ruled out.
- 3. Always take one pill every day at the same time. Taking a pill more than a few hours late increases the risk of pregnancy, and missing two or more pills in a row greatly increases the risk. When one packet is finished, take the first pill from the next packet on the very next day. All pills are active, hormonal pills. There is no wait between packets.
- 4. With missed pills or more than three hours late taking the pills, use a barrier method or avoid sex for two days. Take the last missed pill as soon as possible and continue taking one pill each day as usual.
- 5. If pills were not taken on schedule and **client** has had unprotected sex in the past 72 hours **(3 days)**, may want to use emergency contraceptive pills (ECP) to reduce the risk of pregnancy (See Nurse Protocol for Emergency Contraceptive Pills).

- 6. If **client** currently taking OC or took previously without problems, may dispense appropriate number of cycles until next exam is to be performed.
- 7. If client is amenorrhoeic, client can start minipills at any time, as long as pregnancy test is negative. She will need back-up method for the next 2 days.
- 8. <u>Postpartum (breastfeeding)</u>:
  - a. If client is between 6 weeks and 6 months postpartum and amenorrheic, she can start minipills at any time. If she is fully or nearly fully breastfeeding, no back-up method is needed.
  - b. If she is more than 6 weeks postpartum and her menstrual cycles have returned, she can start minipills as advised for other women having menstrual cycles.
- 9. <u>Postpartum (non-breastfeeding)</u>:
  - a. If client is less than 21 days postpartum, she can start minipills at any time. No back-up method is needed.
  - b. If client is 21 or more days postpartum and her menstrual cycles have not returned, she can start minipills at any time, as long as pregnancy test is negative. She will need back-up method for the next 2 days.
  - c. If her menstrual cycles have returned, she can start minipills as advised for other women having menstrual cycles.

#### CLIENT EDUCATION/COUNSELING

- 1. Counsel **client** according to seven basic elements of informed consent (BRAIDED Benefits Risks Alternatives Inquiries Decision Explanation Documentation).
- 2. The minipill may cause irregular bleeding or amenorrhea.
- 3. Danger signs:
  - a. Abdominal pain may be due to an ovarian cyst or ectopic pregnancy.
  - b. A delayed period after several months of regular cycles may be a sign of pregnancy.
  - c. Repeated, very severe headaches.

- 4. The minipill must be taken at about the same time every day. The margin for error is less with the minipill than with the combined OC.
- 5. There appear to be no significant metabolic effects and there is an immediate return to fertility upon discontinuation of the minipill.
- 6. Advise client to refer to the pill package insert for missed pill(s) instructions.
- 7. Offer Plan B or emergency contraceptive pills (ECP) if pill was missed or taken late and client had unprotected sex in the past 72 hours. ECP reduce the risk of pregnancy. (See Nurse Protocol of Emergency Contraceptive Pills.) Restart the pill no later than the next day after emergency contraception was used.
- 8. **Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit)**
- 9. Counsel on the use of condoms to reduce the risk of STD/HIV.
- 10. Refer **client** to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867), if smoker or tobacco user.
- 11. Emphasize importance of keeping immunizations current; assess client's immunization status and administer vaccines indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If client declines vaccination, document refusal. See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current immunization schedules and administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at <a href="http://www.health.state.ga.us/programs/immunization/publications.asp">http://www.health.state.ga.us/programs/immunization/publications.asp</a>

#### FOLLOW- UP

- 1. **Client should** return as scheduled for evaluation or contact clinic if side effects, danger signs, or symptoms of possible pregnancy **develop**. Outside of clinic hours, seek physician or emergency care if danger signs develop.
- 2. If **client** did not receive a physical exam, have her return within 3 months for an exam and reassessment.

3. Established **clients** should return for an evaluation at the end of the current supply of pills, or sooner if side effects, danger signs, or **symptoms of pregnancy** develop.

#### CONSULTATION/REFERRAL

- 1. **Refer client to physician if client develops** danger signs.
- 2. **Refer to nutritionist if client** has poor dietary intake, is overweight or underweight, is anemic or has any chronic disease related to poor nutrition.
- 3. Seek consultation, as applicable, if client has abnormal initial laboratory values or develops abnormal laboratory values and/or physical findings that indicate the minipill should not be continued.
- 4. **Refer to physician if client has** suspected pregnancy (e.g., missed menses after several regular cycles), especially if she has signs of ectopic pregnancy such as abdominal pain or tenderness, or fainting.

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#### STANDARD NURSE PROTOCOL FOR EMERGENCY CONTRACEPTIVE PILLS (ECP)

- DEFINITION Emergency Contraception is a contraceptive method used to prevent pregnancy. Emergency Contraceptive Pills (ECP) are increased doses of oral contraceptives taken after sexual intercourse to prevent pregnancy. ECP are ineffective if a woman is already pregnant.
- ETIOLOGY ECP work by delaying or preventing ovulation. ECP are most effective if given within 72 hours of unprotected intercourse. The sooner ECP are initiated, the more effective the treatment. ECP will not disrupt a pregnancy once implantation has occurred. There is no evidence that ECP will harm a developing baby once implantation has occurred. The effectiveness of treatment depends on when in the woman's menstrual cycle the emergency contraception is used.

There is no evidence-based medical contraindications to the use of ECP. The duration of use of ECP is less than that of regular use of combined oral contraceptives and progestin only pills and thus would be expected to have less clinical impact.

**SUBJECTIVE** 1. **Client provides history of unprotected sexual intercourse within the last 120 hours (5 days) and** requests postcoital contraception as an emergency measure only (not as ongoing routine contraception).

**NOTE:** Emergency Contraceptive is most effective if given within 72 hours of unprotected intercourse. The sooner ECP are initiated, the more effective the treatment.

#### 2. Precautions:

When dispensing **Plan B<sup>®</sup> One-Step or** Plan B**® Two-Step** or **Next Choice:** 

- a. History of hypersensitivity to any component of progestin only pills.
- b. Undiagnosed vaginal bleeding.
- c. Known or suspected pregnancy.

Contraindications when dispensing combined oral contraceptives:

- a. Known or suspected pregnancy.
- b. Hypersensitivity to any component of combined OC.
- c. Acute migraine headaches at the time **client** plans to take the OC.

- d. History of thromboembolic disease or pulmonary embolus (Use Plan B<sup>®</sup> One-Step or Plan B<sup>®</sup> Two-Step or Next Choice).
- 3. If client seeks emergency contraception as a result of rape, non-consensual sex or other concerns with partner, seek STD work up.
- **OBJECTIVE** 1. Negative pregnancy test.
  - 2. Pelvic exam, if indicated.
  - 3. Availability of **Plan B<sup>®</sup> One-Step and** Plan B<sup>®</sup> **Two-Step** or **Next Choice**:
    - a. 17 years of age or older Over the counter (OTC).
    - b. 16 years of age or younger Prescription only for females.
- **ASSESSMENT** Client requests emergency contraception: no contraindications.

#### PLAN THERAPEUTIC

#### PHARMACOLOGIC

#### One-Step

Brand	Manufacturer	Directions	Levo- norgestrel per tablet (mg)	Anti-nausea Rx Recom- mended
Plan B® <b>One-Step</b>	Teva	Take one tablet as soon as possible within 72 hours after unprotected intercourse.	1.5	No

OR

#### <u>Two-Step</u>

Brand	Manufacturer	Directions	Levo- norgestrel per Dose (mg)	Anti-nausea Rx Recom- mended
Plan B® Two-Step	Teva	Take one tablet as soon as possible within 72 hours after unprotected	0.75	No
Brand	Manufacturer	Directions	Levo- norgestrel per Dose (mg)	Anti-nausea Rx Recom- mended
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Next Choice		intercourse, and another tablet 12 hours later.	0.75	Νο

- Plan B<sup>®</sup> One-Step <u>one single dose</u> of 1.5 mg levonorgestrel (1 white pill – 1.5 mg each) as soon as possible within 72 hours after unprotected intercourse.
- 2. Plan B® Two-Step or Next Choice one single dose of 0.75 mg levonorgestrel (1 white pill – 0.75 mg each) as soon as possible within 72 hours after unprotected intercourse, and another single dose of 0.75 mg levonorgestrel 12 hours later. If necessary, adjust the timing for the second dose by a few hours to avoid a middle-of-the-night dose.

NOTE: Antiemetics not needed with **Plan B<sup>®</sup> One-Step**, Plan B<sup>®</sup> **Two-Step or Next Choice.** 

3. If **client** wants to use OC as an ongoing method, initiate a new pack of OC according to manufacturer's directions at the next menstrual cycle, or begin taking OC one tablet daily the day after ECP treatment is complete. Use a back-up method for 7 days if OC started immediately.

# CLIENT EDUCATION/COUNSELING

- 1. **Provide the client with** exact directions for taking medication.
  - a. Swallow Plan B<sup>®</sup> One-Step dosage (1.5 mg) as soon as possible within 72 hours after unprotected sex. OR
  - b. Swallow the first dose of Plan B<sup>®</sup> Two-Step or Next Choice as soon as possible within 72 hours after unprotected sex. AND

Swallow the second dose of Plan B<sup>®</sup> Two-Step or Next Choice 12 hours after taking the first dose.

2. Advise client to not take any extra pills. More pills will not decrease the risk of pregnancy any further but may increase the risk of nausea, possible causing vomiting.

- 3. Inform client that next menstrual period may start a few days earlier or later than usual. The next menstrual period should begin within the next 2 or 3 weeks. If no menses in 3 weeks advise client to return to clinic for pregnancy test.
- 4. **Discuss the** risks of nausea and emesis.
  - a. The nausea is usually mild and should stop within a day or so after treatment.
  - b. If severe gastrointestinal side effects occur after the first dose of combined ECP, **client** may need additional medication.
  - c. If **client** vomits within **two** hour**s** after either dose, take an additional dose.
  - d. If **client** vomits more than two hours after taking the pills, additional pills are not recommended.
- 5. Strongly encourage **client** to choose an acceptable, ongoing method of birth control.
- 6. **Provide counseling on preconception health counseling and** future fertility. (Refer to Preconception Health Toolkit)
- 7. Advise client that ECP does not protect against STD/HIV. Counsel on the use of condoms to reduce the risk of STD/HIV.
- 8. Provide information to the Emergency Contraception Hotline (1-888-NOT-2-LATE). The Hotline is an automated, toll free confidential service available 24 hours a day in English and Spanish. In addition to basic information, each caller hears a recording of the names and telephone numbers of the five closest ECP providers.
- 9. Refer **client** to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867), if smoker or tobacco user.

# FOLLOW-UP

- 1. **Return to clinic if menses** has not started in 3 weeks, or if next menses is unusually light or painful.
- 2. Return to clinic for long-term birth control method if not provided at visit.

#### CONSULTATION/REFERRAL

- 1. **Refer client to physician** immediately, if nausea/vomiting cannot be controlled.
- 2. **Refer client to physician if client develops** any serious side effects of **oral contraceptives**.

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### STANDARD NURSE PROTOCOL FOR IUD-RELATED DYSMENORRHEA

- **DEFINITION** Dysmenorrhea is pain during menstruation that interferes with daily activities. Intrauterine device (IUD) related dysmenorrhea is painful menses during IUD use.
- ETIOLOGY The main symptom of dysmenorrhea is pain with menses. The pain is concentrated in the abdomen, pelvic region, or lower back. Symptoms often co-occurring with menstrual pain include nausea, vomiting, diarrhea, headaches, weakness, dizziness or lightheadedness. Moderate to severe dysmenorrhea may be an indication for removal of the IUD.

Differential diagnosis includes mechanical pressure of IUD against wall of uterus, partial expulsion, pelvic inflammatory disease (PID), endometriosis, cancer, leiomyomata and ectopic pregnancy. Since cramping and abdominal pain may be signs of pregnancy or infection, those two problems must always be ruled out.

# SUBJECTIVE 1. Client provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history).

- 2. Client reports painful menses and gives history of current IUD.
- 3. Client may have a recent history which includes the following:
  - heavy or late menses
  - PID/STD
  - vaginal infection/discharge
  - recent **sexual** partner change or multiple **sexual** partners
  - pain with IUD in past
- 4. Client provides IUD type, insertion date, and date of last string check.
- **OBJECTIVE** 1. External exam usually within normal limits.
  - 2. Internal exam usually within normal limits; may note vaginal discharge or partially-expelled IUD. Note length of IUD strings.
  - 3. Bimanual exam usually within normal limits; may note tenderness on examination; may feel partially-expelled IUD.
- ASSESSMENT IUD-related dysmenorrhea

# PLAN DIAGNOSTIC STUDIES

- 1. Sensitive urine pregnancy test.
- 2. Hemoglobin/hematocrit, if indicated.
- 3. Gonorrhea and chlamydia tests; vaginal wet mount, if indicated.
- 4. Pap smear, if indicated.

# THERAPEUTIC

# PHARMACOLOGIC

Prostaglandin inhibitors/nonsteroidal anti-inflammatory drugs such as:

- Ibuprofen 400 mg PO every 4 hours as needed for pain. (Maximum dose 1.2 gm/day)
   OR
- Naproxen 500 mg PO for one dose, then 250 mg PO every 6-8 hours as needed for pain. (Maximum dose 1250 mg/day)
   OR
- 3. Over-the-counter-strength products (e.g., Advil, Nuprin, Aleve, Motrin IB, coated aspirin, or acetaminophen) per package directions prn.

# NON-PHARMACOLOGIC MEASURES

- 1. Heating pad or hot-water bottle to pelvic region; hot baths or showers; warm liquids taken orally.
- 2. For moderate to severe dysmenorrhea not relieved by any of the above, the IUD may be removed by APRN/physician if the **client** desires and replaced with progestin-releasing IUD.

# **CLIENT EDUCATION/COUNSELING**

- 1. Discuss findings, treatment rationale.
- 2. Counsel on the use of condoms to reduce the risk of STD/ HIV.
- **3.** Discuss correct use and side effects of medications.

#### FOLLOW-UP

Return to the clinic if symptoms are not relieved or if foul discharge begins.

## CONSULTATION/REFERRAL

**Refer client to physician if** symptoms not relieved by the above measures.

# REFERENCES

- 1. Robert Hatcher et al, *Contraceptive Technology,* 19th ed., Ardent Media, Inc., New York, 2007. (Current)
- 2. Joellen Hawkins et al, *Protocols for Nurse Practitioners in Gynecologic Settings*, 9th ed., Springer Publishing Co., New York, 2007. (Current)
- 3. M. Zieman, R.A. Hatcher et al., *A Pocket Guide to Managing Contraception*, Tiger, Georgia: Bridging the Gap Foundation, 2010. (Current)
- 4. "Lexi-Drugs Online," *Lexi-Comp Database*, Lexi-Comp, Inc., Hudson, Ohio <a href="http://online.lexi.com">http://online.lexi.com</a>> (July 5, 2011)

## STANDARD NURSE PROTOCOL FOR IUD-RELATED MENORRHAGIA

- DEFINITION Menorrhagia refer to menstrual periods that occur at regular intervals but are marked by prolonged bleeding (greater than 7 days) or excessive blood loss (greater than 80 mL.) IUD-related menorrhagia is prolonged or excessive bleeding with an IUD in place.
- ETIOLOGY Presence of IUD in utero. Bleeding problems constitute one of the more common IUD complications. Women using the copperreleasing IUD (Cooper T380A) usually have heavier menses. Excessive bleeding with the Cooper T380A can be treated with nonsteroidal anti-inflammatory drugs. Since local prostaglandin production is involved with excessive bleeding, any prostaglandin synthetase inhibitor should help. Starting in advance of menses does not give better results than starting with the onset of flow. If hemoglobin levels drop, oral iron supplementation can be started. Excessive menstrual bleeding may be an indication for removal of the IUD.

Other causes to consider may be: pelvic inflammatory disease (PID), partial expulsion of the IUD, dysfunctional uterine bleeding as a result of an endocrine imbalance, cancer of the cervix or endometrium, cervical or uterine polyps, abnormal perimenopausal bleeding, fibroids, and pregnancy.

- SUBJECTIVE 1. Client provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history).
  - 2. Client reports prolonged or excessive menstrual bleeding and gives history of current IUD.
  - 3. Client may have a recent history which includes the following:
    - decrease in appetite
    - dizziness, weakness or tiredness
    - pale skin color

#### **OBJECTIVE** 1. External exam usually within normal limits.

2. Internal exam may be within normal limits; or may note partiallyexpelled IUD or feel **IUD** in the cervical canal; and/or may elicit pain upon cervical motion.

- 3. Bimanual exam may be within normal limits; or may elicit tenderness or pain in uterus and adnexal areas, characteristic of PID.
- **ASSESSMENT** IUD-related menorrhagia.

#### PLAN DIAGNOSTIC STUDIES

- 1. Hematocrit or hemoglobin.
- 2. Sensitive urine pregnancy test.
- 3. Gonorrhea and chlamydia tests; vaginal wet mounts, if indicated.
- 4. Pap smear, if indicated.

### THERAPEUTIC

#### PHARMACOLOGIC

- 1. If hemoglobin below normal, treat according to Nurse Protocol for Iron-Deficiency Anemia.
- 2. Prostaglandin inhibitors/nonsteroidal anti-inflammatory drugs as needed to help reduce menstrual blood loss and for relief of pain. Begin at the onset of menses and continue for at least 3 days.
  - a. Ibuprofen 400 mg PO every 4 hours as needed for pain. (Maximum dose 1.2 gm/day) OR
  - Naproxen 500 mg PO for one dose, then 250 mg PO every 6-8 hours as needed for pain. (Maximum dose 1250 mg/day) OR
  - c. Over-the-counter-strength products (e.g., Advil, Nuprin, Aleve, Motrin IB, coated aspirin, or acetaminophen) per package directions prn.

#### NON-PHARMACOLOGIC MEASURES

- 1. Remove the IUD (by APRN **or physician**) for the following:
  - a. Partial expulsion.
  - b. Excessive menstrual blood loss.
  - c. **Client's** request for removal of IUD for any reason.

- 2. Strongly consider IUD removal (by APRN or physician) for the following:
  - a. hemoglobin has dropped 2 gm/dL or more from previous reading
  - b. hemoglobin is less than 9 gm/dL
  - c. hematocrit has dropped 6% or more over 4-6 weeks
  - d. hematocrit is less than 27%.
- 3. If IUD is removed, may initiate alternate contraceptive method. Combined contraceptives (combined oral pills, Ortho Evra Patch, Nuvaring, Depo-Provera) may decrease bleeding and blood loss. Also the levonorgestrel IUD (Mirena) generally improves menorrhagia. Refer to WHO Medical Eligibility Criteria for Contraceptive Use for medical conditions that represent an unacceptable health risk for the selected contraceptive method.

# CLIENT EDUCATION/COUNSELING

- 1. Counsel client on the importance of iron rich foods in the daily diet of menstruating women.
- 2. **Discuss** signs of possible pelvic infection and excessive bleeding.
- 3. **Reinforce importance of** check**ing** for IUD string after each period.
- 4. Refer **client** to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867), if smoker or tobacco user.

# FOLLOW-UP

Return in 4-6 weeks for evaluation of bleeding and hematocrit/ hemoglobin.

# CONSULTATION/REFERRAL

- 1. **Immediately** refer **client to physician** if suspect ectopic pregnancy.
- 2. Refer client to physician if menorrhagia continues for 1-2 menstrual periods after pharmacologic measures started.
- 3. **Refer client to physician** if no improvement in anemia after 4 weeks of **iron supplemental** therapy.

# REFERENCES

- 1. Robert Hatcher et al., *Contraceptive Technology,* 19th ed., Ardent Media, Inc., New York, 2007. (Current)
- 2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 9th ed., Springer Publishing Co., New York, 2007. **(Current)**
- 3. Leon Speroff et al., *Clinical Gynecologic Endocrinology and Infertility*, **8th** ed., Lippincott Williams and Wilkins, Baltimore, MD, **2010. (Current)**
- 4. K. Joseph Hurt, et al., *John Hopkins Manual of Gynecology and Obstetrics*, 4<sup>th</sup> ed., Lippincott Williams and Wilkins, Philadelphia, PA, 2011.
- World Health Organization (WHO), Medical Eligibility Criteria for Contraceptive Use, 4<sup>th</sup> ed., 2009, <<u>http://whqlibdoc.who.int/publications/2010/9789241563888\_eng.pdf</u>> (May 16, 2011)
- 6. M. Zieman, R.A. Hatcher et al., A Pocket Guide to Managing Contraception, Tiger, Georgia: Bridging the Gap Foundation, 2010. (Current)
- 7. "Lexi-Drugs Online," *Lexi-Comp Database*, Lexi-Comp, Inc., Hudson, Ohio <<u>http://online.lexi.com</u>> (July 5, 2011)

### STANDARD NURSE PROTOCOL FOR MEDROXYPROGESTERONE ACETATE (Injectable Contraceptive)

- DEFINITION Medroxyprogesterone acetate is a progestin-only (estrogen-free) long acting reversible hormonal contraceptive birth control drug which is injected every 3 months or 12 weeks. Medroxyprogesterone acetate is commonly known as Depo-Provera.
- **ETIOLOGY Depo-Provera** inhibits ovulation by suppressing levels of follicularstimulating hormone (FSH) and luteinizing hormone (LH) and by eliminating the LH surge. The pituitary gland remains responsive to gonadatropin-releasing hormone, which suggests that the site of action of medroxyprogesterone acetate is the hypothalamus.
- **SUBJECTIVE** 1. **Client** desires **Depo-Provera** as choice of contraception.
  - 2. **Client provides** detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and to the *WHO Medical Eligibility Criteria for Contraceptive Use*.
  - 3. **Client provides** known risk factor(s), medical condition(s) or medication use that can increase the risk of developing osteoporosis.
    - a. Women with medical co-morbidities that place them at risk for osteoporosis and fracture, such as chronic corticosteroid use, disorders of bone metabolism, a strong family history of osteoporosis or women with anorexia nervosa, may not be well suited for long-term Depo-Provera use. Consider alternative contraceptives in client with significant risk factors for osteoporosis.
  - 4. If breastfeeding, has been breastfeeding at least 6 weeks postpartum.
  - 5. Refer to WHO Medical Eligibility Criteria for Contraceptive Use for medical conditions that represent an unacceptable health risk for taking Depo-Provera. Medical conditions include:
    - Multiple risk factors for arterial cardiovascular disease (such as older age, smoking, diabetes and hypertension)

- Elevated blood pressure levels (systolic equal to or greater than 160 mmHg or diastolic equal to or greater than 100 mmHg)
- Vascular disease
- Deep vein thrombosis (DVT) / Pulmonary embolism acute
- Ischaemic heart disease
- Stroke
- Positive (or unknown) antiphospholipid antibodies
- Severe thrombocytopenia (initiation)
- Migraine headaches with aura (continuation)
- Unexplained vaginal bleeding
- Breast cancer
- Diabetes nephropathy/retinopathy/neuropathy
- Cirrhosis severe (decompensated)
- Liver Tumours benign hepatocullular ademona; malignant (hepatoma)
- **OBJECTIVE** 1. Physical examination and laboratory tests according to programmatic guidelines.

OR

- Physical exam deferred up to 3 months. Document reason for deferral on chart. Document on Request for and Consent to Family Planning Services (Form 3700) that client agreed to have physical exam delayed.
- 3. Pregnancy test, if indicated, is negative. If necessary, (amenorrhea or irregular menses) repeat pregnancy test after a two-week interval of abstinence or consistent use of a reliable method of contraception.

# 4. Age Range:

2.

The WHO Medical Eligibility Criteria for Contraceptive Use indicates the following for the use of Depo-Provera:

- a. Women in the age range of 18 through 45 years WHO Category 1 (use method in any circumstances).
- b. Women who are less than 18 or more than 45 years of age WHO Category 2 (generally use the method).
- c. Women who are less than 18 years of age and have a BMI greater than 30 WHO Category 2 (generally use the method).
- 5. Bone Mineral Density
  - a. According to the WHO, most studies have found that women lose bone mineral density while using Depo-Provera, but regain bone mineral density after

discontinuing Depo-Provera. Therefore, all Depo-Provera users should have the FDA black box warning clearly explained to them and a discussion of alternatives if they choose to change methods.

- b. Hatcher recommends that all women using Depo-Provera, including teens, should be taking in sufficient calcium in diet or be encouraged to take calcium supplements. Also encourage users to exercise regularly and avoid smoking.
- c. If needing a birth control for more than 2 years may consider another birth control method or test of bone density. Use longer than 2 years is not recommend.
- NOTE: In November 2004, the FDA issued the following "black box warning" in the Depo-Provera package labeling. Clinicians are advised to review the following warning, which has been added to the prescribing information: "Women who use Depo-Provera Contraceptive Injection may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible. It is unknown if use of Depo-Provera Contraceptive Injection during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk of osteoporotic fracture in later life. Depo-Provera Contraceptive Injection should be used as a long-term birth control method (e.g., longer than 2 years) only if other birth control methods are inadequate."
  - In June 2005, WHO reviewed the evidence on this subject and concluded:

"there should be no restriction on the use of Depo-Provera (DMPA), including no restriction on duration of use, among women aged 18 to 45 who are otherwise eligible to use the method."

WHO further recommended:

"Among adolescents (menarch to age17) and women over age 45, the advantages of using Depo-Provera usually outweigh the theoretical safety concerns regarding fracture risk. Since data are insufficient to determine if this is the case with longterm use among these age groups, the overall risks and benefits for continuing use of the method should be reconsidered over time with the individual user."

ASSESSMENT Client has no condition representing an unacceptable health risk if using Depo-Provera.

# PLAN DIAGNOSTIC STUDIES

- 1. The lipid profile may be obtained at the clinician's discretion if needed. The decision to draw a lipid profile will be determined by the RN and/or the APRN/physician, which is based on a clinical evaluation of the individual client. The RN may consult with and/or refer client to the APRN/physician, if needed, to further determine the client's risk for CVD and the need for a lipid profile.
- 2. Blood glucose beginning by age 45. Consider screening women at an earlier age in the presence of high-risk factors for diabetes. Rescreen every 3 years or more often depending on test results and high risk factors. For Recommended Tests and Immunizations for Women with High-Risk Factors refer to www.womenshealth.gov.
- 3. Screen women for colorectal cancer according to district policy/procedure for colorectal cancer screening.

# THERAPEUTIC

# PHARMACOLOGIC

**NOTE:** Allergic reactions may occur. Encourage client to remain in the clinic at least 20 minutes after each injection. Refer to the Allergic Reaction Nurse Protocol as needed.

# 1. Availability:

Depo-Provera is provided in either 1 mL vials or prefilled syringes containing 150 mg.

# 2. Storage:

**Depo-Provera** is to be stored at room temperature 20° to 25°C (68° to 77° F). Both the vial and the pre-filled syringe should be vigorously shaken at least one minute just before use to ensure the dose is uniformly suspended (refer to package insert).

# 3. Administration:

**Depo-Provera** 150 mg IM, injected deeply into the deltoid or **gluteus maximus** muscle. Depending on the size of the client, may need to use a 1.5-inch needle. Do not massage the injection site, and also instruct client not to massage site. (Massaging area may reduce duration of action and thereby effectiveness).

- 4. Initiation:
  - a. To ensure the client is not pregnant at the time of the first injection, the first injection should be given ONLY during the first 5 days of a normal menstrual period; ONLY within the first 5-days postpartum if not breastfeeding; and if exclusively breastfeeding, ONLY at the sixth postpartum week. No back-up method needed.
- 5. Continuation:
  - a. The manufacturer recommends re-injection of Depo-Provera IM between 11 and 13 weeks after a previous injection.
  - b. At each re-injection follow-up visit, ask the date of the last menses, ask about any problems or concerns, specifically signs and symptoms of pregnancy, any changes in contraceptive or STD prevention needs. If the client is not having any unacceptable symptoms or problems, she may receive re-injection.
- 6. Managing Late Injections:
  - a. Ensure negative pregnancy test.
  - b. The manufacturer recommends excluding pregnancy before proceeding with re-injection in a client who returns more than 13 weeks (91 days) after a previous Depo-Provera IM injection. A back-up method is recommended for the first 7 days after the injection.
- 7. Switching from Hormonal Method:
  - a. When switching other contraceptive methods, Depo-Provera CI should be given in a manner that ensures continuous contraceptive coverage based upon the mechanism of action of both methods, (eg., clients switching from oral contraceptives should have their first injection of Depo-Provera CI on the day after the last active tablet or at the latest, on the day following the final inactive tablet).
- 8. Assess the client for risk factors for osteoporosis. Depo-Provera use plus risk factors for osteoporosis may pose an increased risk of osteoporosis. Discuss potential risk for bone loss and consider alternative contraceptives in clients with significant risk factors for osteoporosis. It is up to the clinician along with the client to consider bone

density monitoring if **Depo-Provera** is the desired method and there are concerns about particular risk factors for osteoporosis.

- 9. Recommend calcium/vitamin D supplement(s) daily if client's diet is calcium deficient.
- 10. Treatment of side effects: Heavy bleeding Consult/referral.
  - a. For bleeding irregularities, rule out infection or cervical lesions. May give:
    - 1) A combined low-dose oral contraceptive for 1-3 cycles.
    - 2) Ibuprofen 400 mg PO every 4 to 6 hours as necessary. (Maximum dose 1.2 gm/day)

# **CLIENT EDUCATION/COUNSELING**

- Counsel client according to seven basic elements of informed consent (BRAIDED – Benefits Risks Alternatives Inquiries Decision Explanation Documentation).
- 2. Emphasize the importance of the schedule associated with use of this method of contraception. Instruct client to use back-up contraception during the first week after the injection if injections are late.
- 3. **Discuss danger signs (ACHES) and other warning signs including** repeated painful headaches, heavy bleeding, jaundice, severe lower abdominal pain (may be sign of pregnancy), and pus, prolonged pain, or bleeding at the injection site.
- 4. Common side effects may include: bleeding/menstrual irregularities, weight changes, headache, nervousness, abdominal pain, dizziness, and weakness or fatigue. Less common side effects include: decreased libido, backache, leg cramps, depression, nausea, acne, vaginitis, breast pain, hair loss, bloating, rash, and hot flashes. Common side effects may not be relieved until the drug clears the body 6-8 months after the last injection. Bleeding irregularities are very common (30% in the first year and 10% thereafter). If necessary, bleeding can be treated with medication.

- 5. Call or return if there are questions about possible side effects or development of reasons to avoid use, such as weight gain, heavy bleeding, headaches or depression.
- 6. Advise client that amenorrhea usually occurs in one year or less after Depo-Provera initiation. Reassure that this is not a medical problem. Counsel women in their 40s not to think they are going through menopause when amenorrhea occurs.
- 7. Review the FDA black box warning and WHO recommendations on Depo-Provera and bone mineral density.
- 8. **Depo-Provera** may decrease the amount of calcium in the bones. It is not known if use during the reproductive years affects the risk of fracture in later postmenopausal years.
- 9. **Discuss the importance of calcium in the bones.** The critical years for building bone mass are from prior to adolescence to about age 30. A decrease of calcium in the bones is of most concern for teenagers and those women who have the following risk factors: low body weight, bone disease, anorexia nervosa, strong family history of osteoporosis, drugs that can lower the amount of calcium in the bones (drugs for epilepsy or steroids), high intake of alcohol, sodas, caffeine and smoking.
- 10. Counsel **client** on adequate calcium intake from foods like milk, cheese, yogurt or ice cream or a calcium/vitamin D supplement daily; regular exercise; and avoiding alcohol, smoking and excessive intake of sodas and caffeine.
- 11. Discuss effectiveness of Depo-Provera and back-up methods.
- 12. Advise client that Depo-Provera is a long acting contraceptive and not easily reversible. It takes at least 3 months for fertility to return after last injection. Anovulation may last for more than 1 year after discontinuation. The average delay to ovulation is about 9 months (range of 4-31 months) after the last injection and does not increase with longer duration of use.
- 13. There is minimal to no apparent increased risk for breast cancer.
- 14. No adverse effects have been noted in infants of mothers using **Depo-Provera** during lactation. Quality and quantity of breast milk is not adversely affected.
- 15. The effects of medroxyprogesterone acetate on lipid metabolism are inconsistent. Both increases and decreases

in total cholesterol, triglycerides, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol have been observed in studies.

- 16. **Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit)**
- 17. Counsel on the use of condoms to reduce the risk of STD/ HIV. Medroxyprogesterone acetate offers no protection from STD/HIV.
- 18. Refer **client** to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867), if smoker or tobacco user.
- 19. Emphasize importance of keeping immunizations current; assess client's immunization status and administer vaccines as indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If client declines vaccination, document the refusal. See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current **immunization** schedules and administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at <a href="http://www.health.state.ga.us/programs/immunization/publications.asp">http://www.health.state.ga.us/programs/immunization/publications.asp</a>.

# FOLLOW-UP

- 1. Return for re-injection of Depo-Provera between 11 and 13 weeks after previous injection.
- 2. Outside of clinic hours, seek physician or emergency care if warning signs develop.

# CONSULTATION/REFERRAL

- 1. Refer client to physician if client develops any danger signs.
- 2. Refer client to physician for development of prolonged side effects (e.g. irregular bleeding) or contraindicating conditions.
- 3. Management of chronic coexisting medical problems. Advise client to continue treatment with physician if client is under the supervision of physician for a health problem.
- 4. Refer to nutritionist, if applicable, for calcium deficiency related to poor nutrition.

# 5. Call appropriate manufacturer for product information.

# REFERENCES

- 1. "Black Box Warning Added Concerning Long-Term Use of Depo-Provera Contraceptive Injection," *FDA Talk Paper*, T04-50, FDA, November 17, 2004. (Current)
- 2. Depo-Provera Contraceptive Injection Physician Prescribing Information, Pharmacia and Upjohn Company, 2004,
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  http://labeling.pfizer.com/ShowLabeling.aspx?id=522 > (August 23, 2011)
- 3. Robert Hatcher et al., *Contraceptive Technology,* 19th ed., Ardent Media, Inc., New York, 2007. (Current)
- 4. World Health Organization (WHO), Medical Eligibility Criteria for Contraceptive Use, 4<sup>th</sup> ed., 2009,
   <a href="http://whqlibdoc.who.int/publications/2010/9789241563888\_eng.pdf">http://whqlibdoc.who.int/publications/2010/9789241563888\_eng.pdf</a> (May 16, 2011)
- 5. WHO, Hormonal Contraception and Bone Health, **2007**, <u>http://www.who.int/reproductivehealth/publications/family\_planning/pbrief1/en/i</u> <u>ndex.html</u>> (May 16, 2011)
- 6. "General Screenings and Immunizations for Women," Office on Women's Health,

<<u>http://www.womenshealth.gov/prevention/general</u>> (May 16, 2011)

- 7. M. Zieman, R.A. Hatcher et al., *A Pocket Guide to Managing Contraception*, Tiger, Georgia: Bridging the Gap Foundation, 2010. (Current)
- 8. "A Resource for Contraception and Healthy Sex," <<u>http://www.contracept.org</u>> (May 16, 2011)
- 9. "Every Woman, Every Time," A Preconception Care Toolkit for Georgia, 2010, <<u>http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm</u>> (May 16, 2011)
- 10. World Health Organization (WHO), Selected Practice Recommendations for Contraceptive Use, 2<sup>nd</sup> ed., 2004, <<u>http://www.who.int/reproductivehealth/publications/family\_planning/924156284</u> 6index/en/index.html> (May 16, 2011)
- 11. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," MMWR 2010; 59, <<u>http://www.cdc.gov/mmwr</u>> (June 6, 2011)

#### STANDARD NURSE PROTOCOL FOR ORTHO EVRA™ TRANSDERMAL SYSTEM (CONTRACEPTIVE PATCH)

- **DEFINITION** ORTHO EVRA<sup>™</sup> is a transdermal patch applied to the skin that releases ethinyl estradiol (an estrogen hormone) and norelgestromin (a progestin hormone) to prevent pregnancy.
- **ETIOLOGY** ORTHO EVRA<sup>™</sup> acts by suppressing gonadotropins, similar to combination oral contraceptives. Although the primary mechanism of this action is inhibition of ovulation, other alterations include changes in the cervical mucus which increase the difficulty of sperm entry into the uterus, and changes in the endometrium which reduce the likelihood of implantation.
- **SUBJECTIVE** 1. **Client provides a** detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and the *WHO Medical Eligibility Criteria for Contraceptive Use*.
  - 2. If breastfeeding, has been breastfeeding at least 6 months **postpartum**.
  - 3. If non-breastfeeding, is at least 21 days postpartum.
  - 4. If age 35 or older, and does not smoke.
  - 5. If age 40 or older, and has any co-morbidities (to include the following: BMI of 30 or greater, diabetes, hypertension, smoking), must use other non-estrogen containing methods.
  - 6. If on Antiretroviral Therapy, does not take Ritonavir-boosted protease inhibitors. Refer to *WHO Medical Eligibility Criteria for Contraceptive Use* for clarification of this classification.
  - 7. If on Anticonvulsant Therapy, does not take certain anticonvulsants (e.g., phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine or lamotrigine). Refer to WHO Medical Eligibility Criteria for Contraceptive Use for clarification of this classification.
  - 8. If on Antimicrobial Therapy, does not take a rifamycin derivative. Refer to *WHO Medical Eligibility Criteria for Contraceptive Use* for clarification of this classification.

- 9. Refer to *WHO Medical Eligibility Criteria for Contraceptive* Use for medical conditions that represent an unacceptable health risk for using the patch. Medical conditions include:
  - Hypertension
  - Deep vein thrombosis (DVT) / Pulmonary embolism
  - Known thrombogenic mutations
  - Ischaemic heart disease
  - Stroke
  - Known hyperlipidaemias
  - Valvular heart disease (complicated)
  - Positive (or unknown) antiphospholipid antibodies
  - Migraine headaches without aura and age 35 or older
  - Migraine headaches with aura (at any age)
  - Breast cancer
  - Diabetes nephropathy/retinopathy/neuropathy, other vascular disease or diabetes of greater than 20 years' duration
  - Gall-bladder disease (symptomatic) medically treated, current
  - History of cholestasis past combined OC-related
  - Viral Hepatitis acute or flare (initiation of patch)
  - Cirrhosis severe (decompensated)
  - Liver Tumours benign hepatocullular ademona, malignant (hepatoma)
- OBJECTIVE 1. Physical examination and laboratory tests according to programmatic guidelines.
  - 2. Physical exam deferred up to 3 months. Document reason for deferral on chart. Document on Request for and Consent to Family Planning Services (form 3700) that client agreed to have physical exam delayed.
- **ASSESSMENT** Client has no condition representing an unacceptable health risk if using the patch.

#### PLAN DIAGNOSTIC STUDIES

 Lipid profile beginning by age 45. Rescreen every 5 years or more often depending on test results and risk factors for CVD.
 Women with cardiovascular risk factors may need to be tested at a younger age. The need to perform a lipid profile on women age 20-44 should be based on the client's comprehensive health assessment, which includes the screening of risk factors for CVD. Cardiovascular risk factors include family history of CVD, hypertension, dyslipidemia, diabetes, obesity (BMI), and smoking. An individual's risk of heart disease increases as the number of risk factors increases. Refer to <u>http://www.womenshealth.gov/heart-</u><u>health-stroke/heart-disease-risk-factors</u> for more information on cardiovascular heart disease risk factors. The RN may consult with and/or refer client to the APRN/physician, if needed, to further determine the client's risk for CVD and the need for a lipid profile. The decision to draw a lipid profile will be based on a clinical evaluation that is determined by the RN and/or the APRN/physician. For more information on increased blood cholesterol levels and estrogen-containing contraceptives, refer to Standard Nurse Protocol for Abnormal Lipid Profiles While Using Hormonal Contraceptives.

- 2. Blood glucose beginning by age 45. Consider screening women at an earlier age in the presence of high-risk factors for diabetes. Rescreen every 3 years or more often depending on test results and high risk factors. For Recommended Tests and Immunizations for Women with High-Risk Factors refer to www.womenshealth.gov.
- 3. Screen women for colorectal cancer according to district policy/ procedure for colorectal cancer screening.

# THERAPEUTIC

# PHARMACOLOGIC

 Availability: ORTHO EVRA<sup>™</sup> Patch, box of three patches

# 2. Application:

- a. Remove liner and apply the sticky surface of the patch on clean, dry skin of the lower abdomen, buttocks, upper outer arm, or upper torso (not on the breasts).
- b. Press down firmly on the patch with the palm of the hand for 10 seconds. Make sure that the edges stick well.
- c. Avoid placing patch on the exact same site for 2 consecutive weeks.
- d. Location of patch should not be altered in mid week.

- 3. Initiation:
  - a. Apply the first patch on the first day of menses or on the Sunday following the first day of menses. If client starts on the first day, she does not need a back-up method. If she begins the patch after the first day of her period, the package insert recommends use of back-up method for 7 days.
  - b. Alternatively, client does not need to wait for menstrual period to apply first patch if reasonably certain she is not pregnant (negative pregnancy test ). Use of back-up method for 7 days is recommended with the immediate start approach.
  - c. The first day **the patch is applied** is designated as "Patch-Change Day."
  - d. Remove the patch and apply a new patch on Patch-Change Day on weeks 2 and 3. Apply the new patch to a different area of skin to reduce skin irritation.
  - e. No patch is applied on week 4. Menstrual period will begin during week 4.

# 4. Management of Missed/Forgotten Patches:

# a. <u>1<sup>st</sup> Week</u>

- 1) Apply new patch as soon as possible.
- 2) Record this day of the week as new Patch-Change Day.
- 3) Use back-up method for first 7 days of patch use.
- 4) If new patch was applied 3 or more days late (patch was left off for 10 days or more in a row) and client had unprotected sex in last 120 hours, offer emergency contraception.

# b. $2^{nd} - 3^{rd}$ Week

- 1) 1-2 days late:
  - Apply a new patch as soon as remembered.
  - Keep the same Patch-Change Day.
  - No need for back-up method.
- 2) More than 2 days late:
  - Stop current cycle and start a new 4week cycle by applying a new patch immediately.
  - Record this day of the week as the new Patch-Change Day.

- Use back-up method for first 7 days of patch use.
- c. <u>4<sup>th</sup> Week</u>
  - 1) Remove the patch.
  - 2) Start the next cycle on the usual Patch-Change Day.
  - 3) No need for back-up method.

# CLIENT EDUCATION/COUNSELING

- 1. Counsel **client** according to the seven basic elements of informed consent (BRAIDED Benefits Risks Alternatives Inquiries Decision Explanation Documentation.)
- 2. The absorption of medication is identical when applied on any of the four suggested areas of the body.
- 3. Women who use Ortho Evra are exposed to about 60% more estrogen than if they were taking a typical birth control pill containing 35 micrograms of estrogen. In general, increased estrogen exposure may increase the risk of developing serious blood clots (for instance, in the legs or lungs) that can block blood vessels and cause death or serious disability. However, it is not known whether women using Ortho Evra are at a greater risk of having these serious problems. One study found a doubling of this risk and another study found no increased risks. The manufacturer of Ortho Evra is doing studies on this.
- The transdermal contraceptive patch may be less effective in women with body weight of 198 lbs (90 kg) or higher. May consider back-up method such as condoms if weight is 198 lbs (90 kg) or higher.
- 5. Check the patch every day to make sure it is sticking. Avoid touching the sticky surface.
- 6. Do not apply creams, oils, or cosmetics near the patch site.
- 7. If the patch becomes loose and is still sticky, try to reattach it. If it is not sticky, replace it with a new patch, and then change the new patch on the usual **Patch-C**hange **D**ay.
- 8. Do not attempt to tape down a patch that has become loosened.

- 9. To remove the patch, grasp it by an edge and pull it off. Fold it closed on itself on the adhesive side to seal in the medication. Discard the patch in the garbage; do not flush it into the toilet.
- 10. Remove any stickiness or adhesive that remains on the skin by using baby oil or lotions.
- 11. Counsel on the use of condoms to reduce the risk of STD/HIV.
- 12. The primary side effects of the patch are headache, nausea, application site reactions, and breast discomfort. Women using the patch are more likely to experience breakthrough bleeding and/or spotting during the first 2 months compared with users of a combined OC. Discuss danger signs (ACHES).

# 13. Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit)

- 14. If smoker or tobacco user, refer to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867).
- 15. Emphasize importance of keeping immunizations current; assess client's immunization status and administer vaccines indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If client declines vaccination, document refusal. See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current **immunization** schedules and administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at <a href="http://www.health.state.ga.us/programs/immunization/publication/ns.asp">http://www.health.state.ga.us/programs/immunization/publication/publication/publicatio</a>

# FOLLOW-UP

- 1. Return as scheduled for evaluation or contact clinic if side effects or danger signs develop.
- 2. If **clien**t did not receive a physical exam, have her return within 3 months for an exam and reassessment.
- 3. Established **clients** should return for evaluation at the end of the current supply of patches, or sooner if side effects or danger signs develop. Outside of clinic hours, seek physician or emergency care if danger signs develop.

#### CONSULTATION/REFERRAL

- 1. **Refer client to physician if client** develops any danger signs.
- 2. Seek consultation, as applicable, on serious health concerns expressed by client.
- 3. Advise client to continue treatment with physician if client is under the supervision of physician for a health problem.
- 4. **Seek consultation, as applicable, if client** has abnormal initial laboratory values or development of abnormal values or physical findings that indicate patch should not be continued.
- 5. **Refer** to nutritionist as indicated.

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# STANDARD NURSE PROTOCOL FOR NuvaRing®

- **DEFINITION** The NuvaRing® is a vaginal contraceptive loop made with a flexible polymer, which contains estrogen and progestin.
- **ETIOLOGY** All combination hormonal contraceptives suppress gonadotropins. Although the primary effect of this action is inhibition of ovulation, other alterations include changes in the cervical mucus (which increase the difficulty of sperm entry into the uterus) and the endometrium (which reduce the likelihood of implantation).
- **SUBJECTIVE** 1. **Client provides a** detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and the *WHO Medical Eligibility Criteria for Contraceptive Use*.
  - 2. If breastfeeding, has been breastfeeding at least 6 months **postpartum.**
  - 3. If non-breastfeeding, is at least 21 days postpartum.
  - 4. If age 35 or older, and does not smoke.
  - 5. If age 40 or older, and has any co-morbidities (to include the following: BMI of 30 or greater, diabetes, hypertension, smoking), must use other non-estrogen containing methods.
  - 6. If on Antiretroviral Therapy, does not take Ritonavir-boosted protease inhibitors. Refer to *WHO Medical Eligibility Criteria for Contraceptive Use* for clarification of this classification.
  - 7. If on Anticonvulsant Therapy, does not take certain anticonvulsants (e.g., phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine or lamotrigine). Refer to WHO Medical Eligibility Criteria for Contraceptive Use for clarification of this classification.
  - 8. If on Antimicrobial Therapy, does not take a rifamycin derivative. Refer to *WHO Medical Eligibility Criteria for Contraceptive Use* for clarification of this classification.
  - 9. Refer to WHO Medical Eligibility Criteria for Contraceptive Use for medical conditions that represent an unacceptable health risk for using NuvaRing®. Medical conditions include:

- Hypertension
- Deep vein thrombosis (DVT) / Pulmonary embolism
- Known thrombogenic mutations
- Ischaemic heart disease
- Stroke
- Known hyperlipidaemias
- Valvular heart disease (complicated)
- Positive (or unknown) antiphospholipid antibodies
- Migraine headaches without aura and age 35 or older
- Migraine headaches with aura (at any age)
- Breast cancer
- Diabetes nephropathy/retinopathy/neuropathy, other vascular disease or diabetes of greater than 20 years' duration
- Gall-bladder disease (symptomatic) medically treated, current
- History of cholestasis past combined OC-related
- Viral Hepatitis acute or flare (initiation of patch)
- Cirrhosis severe (decompensated)
- Liver Tumours benign hepatocullular ademona, malignant (hepatoma)
- **OBJECTIVE** 1. Physical examination and laboratory tests according to programmatic guidelines.

OR

- Physical exam deferred up to 3 months. Document reason for deferral on chart. Document on Request for and Consent to Family Planning Services (form 3700) that client agreed to have physical exam delayed.
- **ASSESSMENT** Client has no conditions representing an unacceptable health risk if using the NuvaRing<sup>®</sup>.

# PLAN DIAGNOSTIC STUDIES

 Lipid profile beginning by age 45. Rescreen every 5 years or more often depending on test results and risk factors for CVD. Women with cardiovascular risk factors may need to be tested at a younger age. The need to perform a lipid profile on women age 20-44 should be based on the client's comprehensive health assessment, which includes the screening of risk factors for CVD. Cardiovascular risk factors include family history of CVD, hypertension, dyslipidemia, diabetes, obesity (BMI), and smoking. An individual's risk of heart disease increases as the number of risk factors increases. Refer to <u>http://www.womenshealth.gov/heart-</u> health-stroke/heart-disease-risk-factors for more information on cardiovascular heart disease risk factors. The RN may consult with and/or refer client to the APRN/physician, if needed, to further determine the client's risk for CVD and the need for a lipid profile. The decision to draw a lipid profile will be based on a clinical evaluation that is determined by the RN and/or the APRN/physician. For more information on increased blood cholesterol levels and estrogen-containing contraceptives, refer to Standard Nurse Protocol for Abnormal Lipid Profiles While Using Hormonal Contraceptives.

- 2. Blood glucose beginning by age 45. Consider screening women at an earlier age in the presence of high-risk factors for diabetes. Rescreen every 3 years or more often depending on test results and high risk factors. For Recommended Tests and Immunizations for Women with High-Risk Factors refer to www.womenshealth.gov.
- 3. Screen women for colorectal cancer according to district policy/procedure for colorectal cancer screening.

# THERAPEUTIC

# PHARMACOLOGIC

# 1. Availability:

NuvaRing® is dispensed in box of 3 NuvaRing ® sachets.

# 2. Storage:

Store out of direct sunlight.

**NOTE**: Prior to dispensing to the user, refrigerate at 2-8° C (36-46° F). After dispensing to the user, NuvaRing® can be stored for up to 4 months at room temperature out of direct sunlight. When dispensed to the user, place an expiration date on the label not to exceed either 4 months from the date of dispensing or the expiration date, whichever comes first.

# 3. Insertion:

- a. Remove NuvaRing® from the foil pouch
- b. Hold NuvaRing® between your thumb and index finger, press the sides together while lying down, squatting, or standing with one leg up
- c. Press opposite sides of the ring together, and gently push the folded ring into your vagina. If you feel discomfort after inserting NuvaRing®,

slide it farther in until it feels comfortable. The exact position of NuvaRing® is not important for it to be effective. Once inserted, keep NuvaRing® in place for 3 weeks in a row.

- 4. Initiation:
  - a. Insert NuvaRing® into vagina during the first five days of menstrual cycle, even if still bleeding.
    - 1) If ring inserted on Day 1 of menses, no back-up method is needed.
    - 2) If ring inserted on Day 2-5 of cycle, additional back-up method needed for the first 7 days.
  - b. May insert NuvaRing® into vagina on any cycle day if reasonably certain she is not pregnant (negative pregnancy test). Use a back-up method for 7 days.
  - c. Leave the NuvaRing® in place for 3 weeks. The NuvaRing® may remain in the vagina during sexual intercourse.
  - d. After 3 weeks of use, remove the NuvaRing<sup>®</sup> for 7 days. No NuvaRing<sup>®</sup> is inserted during week 4. During the 7 ring-free days (week 4), withdrawal bleeding will occur.
- 5. **Continuation:** 
  - a. After 7 ring-free days, insert a new NuvaRing® into the vagina to begin the cycle again. Insert the new NuvaRing® on the same day of the week the previous NuvaRing® was inserted, even if the menses is not finished.
- 6. Late Replacement or Removal:
  - a. If the NuvaRing® is out of the vagina for more than 3 hours during weeks 1 or 2, re-insert the ring as soon as possible. Use a back-up method for the next 7 days.
  - b. If the NuvaRing® is out of the vagina for more than 3 hours during week 3, stop the current cycle and discard the ring.
    - Insert a new ring immediately and keep it in place for 3 weeks, starting a new cycle. The client may not experience a withdrawal bleed from her previous cycle. A back-up method must be used until the new ring has been used continuously for 7 days.

OR

- 2) Have a withdrawal bleed and insert a new ring no later than 7 days from when the last ring was removed/ expelled. A backup method must be used until the new ring has been used continuously for 7 days. This option should only be chosen if the ring was used continuously for the preceding seven days.
- c. If client waited more than 7 days before inserting a new NuvaRing®, or kept NuvaRing® in longer than 4 weeks, insert a new NuvaRing® as soon as possible and begin a new 4-week cycle. Consider a pregnancy test and emergency contraception plus a back-up method for the first 7 days after reinsertion of new ring.
- d. Offer emergency contraception if a new ring was inserted 3 or more days late and client had unprotected sexual intercourse in the last 120 hours (5 days).
- 7. Removal & Disposal:
  - a. Remove the NuvaRing® by hooking the index finger under the forward rim or by grasping the rim between the index and middle finger and pulling the ring out.
  - b. Place the used NuvaRing® in the foil pouch and throw it away in a trash container out of the reach of children and pets (do not flush it down the toilet).
- 8. Women switching from estrogen-progestin oral contraceptives to the vaginal ring should insert the ring within 7 days of the last hormonally-active tablet and no later than the day that a new oral contraceptive cycle would have been started; a back-up method of contraception is not needed.

# **CLIENT EDUCATION/COUNSELING**

- 1. Counsel the **client** according to the seven elements of informed consent (BRAIDED Benefits Risks Alternatives Inquiries Decision Explanation Documentation).
- 2. If client is switching from progestin-only pills, insert the first ring on the same day she takes the last pill.

- 3. The NuvaRing® does not require fitting or placement in a specific position, nor the use of spermicidal jelly. It does not need to surround the cervix. If discomfort is felt, the device is probably not placed high enough in the vagina.
- 4. Do not rely upon a diaphragm as a back-up method because NuvaRing® may interfere with the correct placement and position of a diaphragm.
- 5. Keep the foil pouch. After removal of the **NuvaRing**<sup>®</sup> in 3 weeks, dispose of the NuvaRing<sup>®</sup> in the pouch. Do not flush it down the toilet. Keep it out of reach of children and animals.
- 6. The primary side effects of the NuvaRing® are similar to those of combined OC pills. Some women may experience vaginal irritation or infection.
- 7. Discuss side effects and danger signs (ACHES). Also discuss other danger signs including worsening depression, spitting up blood or sudden shortness of breath (could signify a blood clot in the lung).
- 8. NuvaRing® can be accidentally expelled when it has not been inserted properly, while removing a tampon, or when straining to move the bowels. If expelled, rinse ring with cool/lukewarm water and re-insert promptly (within 3 hours from the time it was expelled). If **ring is** lost, insert a new one.
- 9. The NuvaRing® does not need to be removed for intercourse.
- 10. Check for possible pregnancy if:
  - a. Miss a period and the device was out of the vagina for longer than 3 hours.
  - b. Miss a period and waited longer than a week to insert a new device.
  - c. Miss a period and the NuvaRing® was in place more than 4 weeks.
  - d. Followed instructions, but miss 2 periods in a row.
- 11. If scheduled for laboratory tests or major surgery, tell the health care provider that you are using the NuvaRing®.
- 12. Ovulation resumes during the first recovery cycle after discontinuation, suggesting rapid return of fertility.
- 13. Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit)

- 14. NuvaRing® does not protect against HIV infection and other sexually transmitted diseases. Counsel on use of condoms to reduce the risk of STD including HIV.
- 15. Cigarette smoking increases the risk of serious cardiovascular side effects from combination oral contraceptive use and NuvaRing®.
- 16. If smoker or tobacco user, refer to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867).
- 17. Emphasize importance of keeping immunizations current; assess client's immunization status and administer vaccines indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If client declines vaccination, document refusal. See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current **immunization** schedules and administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at <a href="http://www.health.state.ga.us/programs/immunization/publications.asp">http://www.health.state.ga.us/programs/immunization/publications.asp</a>.

# FOLLOW-UP

- 1. Return as scheduled for evaluation or contact clinic if side effects or danger signs develop.
- 2. Established **clients** should return for evaluation at the end of the current supply, or sooner if side effects or danger signs develop. Outside of clinic hours, seek physician or emergency care if danger signs develop.

#### CONSULTATION/REFERRAL

- 1. **Refer client to physician if client** develops any danger signs.
- 2. Seek consultation, as applicable, if client has abnormal initial laboratory values or development of abnormal values or physical findings that indicate the ring should not be continued.
- 3. **Refer** to nutritionist as indicated.
- 4. If **client** is under the supervision of medical provider for a health problem, **advise client to continue treatment with physician**.

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#### STANDARD NURSE PROTOCOL FOR VAGINAL CONTRACEPTIVE DIAPHRAGM

- **DEFINITION** The diaphragm is a dome-shaped rubber cup that is inserted into the vagina before intercourse. It consists of a soft rubber or latex cup that is fitted for size.
- **ETIOLOGY** The dome of the diaphragm covers the cervix. The posterior rim rests in the posterior fornix and the anterior rim fits snugly behind the pubic bone. **The diaphragm acts as a barrier and** prevents sperm from entering. Spermicidal cream or jelly placed in the dome prior to insertion add to its effectiveness by killing any sperm that might slip around the edge of the diaphragm.
- SUBJECTIVE 1. Client provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and the WHO Medical Eligibility Criteria for Contraceptive Use.
  - 2. Refer to WHO Medical Eligibility Criteria for Contraceptive Use for medical conditions that represent an unacceptable health risk for using a diaphragm. Medical conditions include:
    - HIV/AIDS or high risk of HIV infection • Antiretroviral Therapy
    - History of Toxic Shock Syndrome
    - Known allergy or hypersensitivity to latex or natural rubber
  - 3. Client reports no full-term delivery within the past 6-12 weeks.

#### OBJECTIVE

- 1. Physical examination and laboratory tests according to programmatic guidelines.
- 2. Physical exam deferred up to 3 months. Document reason for deferral on chart. Document on Request for and Consent to Family Planning Services (form 3700) that client agreed to have physical exam delayed.
- 3. Pelvic exam shows:
  - a. Adequate vaginal tone to hold the diaphragm in place.
  - b. Absence of uterine prolapse, severe cystocele or rectocele.
  - c. Uterus is not fixed in retroflexed or retroverted position.
  - d. Notch behind the symphysis pubis is adequate to support the rim of the diaphragm.

- 4. **Client** is physically able to insert a diaphragm.
- **ASSESSMENT** Client has no condition representing an unacceptable health risk if using the diaphragm.

#### PLAN DIAGNOSTIC STUDIES

- 1. Blood glucose beginning by age 45. Consider screening women at an earlier age in the presence of high-risk factors for diabetes. Rescreen every 3 years or more often depending on test results and high risk factors. For Recommended Tests and Immunizations for Women with High-Risk Factors refer to www.womenshealth.gov.
- 2. Screen women for colorectal cancer according to district policy/procedure for colorectal cancer screening.

# THERAPEUTIC

### PHARMACOLOGIC

Contraceptive jelly/ cream containing spermicide.

NOTE: Increased use of nonoxynol 9 is associated with risk of vaginal irritation, therefore increased risk of HIV transmission.

#### NON-PHARMACOLOGIC MEASURES

Fit **client** for appropriate size and type of diaphragm. **(See Appendix A)** 

# **CLIENT EDUCATION/COUNSELING**

- 1. Counsel **client** according to the seven basic elements of informed consent (BRAIDED Benefits Risks Alternatives Inquiries Decision Explanation Documentation).
- 2. Insertion, removal and care of diaphragm, with return demonstration.
- 3. Once in position, the diaphragm provides effective contraceptive protection for 6 hours.
4. After intercourse, the diaphragm must be left in place for at least 6 hours, but it should be removed as soon as possible thereafter. Continuous wearing of a contraceptive diaphragm for more than 24 hours is not recommended.

If more than one act of intercourse in 6 hours, do not remove diaphragm. Add additional spermicide before each act of intercourse. Increased use of nonoxynol 9 is associated with risk of vaginal irritation, therefore increased risk of HIV transmission.

- 5. Prevention of toxic shock syndrome
  - a. Do not use diaphragm during menses.
  - b. Do not leave diaphragm in place for more than 24 hours.
  - c. Seek care for danger signs of toxic shock:
    - 1) Temperature of 101° F or higher.
      - 2) Diarrhea.
      - 3) Vomiting.
      - 4) Muscle aches.
      - 5) Rash appearing like sunburn.
- 6. Diaphragm will need to be refitted and replaced with new diaphragm at least every 2 years or:
  - a. After vaginal delivery.
  - b. After gynecologic or lower abdominal surgery.
  - c. After weight loss or gain of over 10 pounds.
  - d. After second trimester abortion.
- 7. Discuss risks that decrease the effectiveness of the diaphragm (eg., petroleum jelly can weaken latex causing tears and leaks).
- 8. Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit)
- 9. Counsel on use of condoms to reduce the risk of STD/HIV.
- 10. If smoker or tobacco user, refer to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867).
- 11. Emphasize importance of keeping immunizations current, assess client's immunization status and administer vaccines indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If client declines vaccination, document refusal. See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current **immunization** schedules and

administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at <u>http://www.health.state.ga.us/programs/immunization/publications.asp</u>.

### FOLLOW-UP

Return to clinic in one month, with diaphragm in place, to assess for proper fit.

### **REFERRAL/CONSULTATION**

- 1. Signs/symptoms of toxic shock syndrome.
- 2. Signs/symptoms of urinary tract infection **or vaginal infection** as appropriate.
- 3. Signs/symptoms of cystocele or rectocele.

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### STANDARD NURSE PROTOCOL FOR BACTERIAL CYSTITIS

- **NOTE**: Females under age 18 must be established Women's Health clients.
- **DEFINITION** Cystitis is a bladder inflammation.
- ETIOLOGY Cystitis is a common lower urinary tract infection that affects the bladder and not the kidneys. Cystitis is usually caused by bacteria (generally e-coli) which travel to the bladder from the urethra. Women are more likely to develop cystitis after sexual intercourse. Bacterial cystitis may be characterized by dysuria, frequency, urgency and low fever.

# SUBJECTIVE 1. Client provides a detailed health history (includes menstrual, sexual, contraception, personal health and family health) that may reveal factors that increase the risk for bacterial cystitis.

- 2. Client may report recent history which includes the following:
  - a. Frequency, burning on urination
  - b. Urgency, with or without incontinence
  - c. Suprapubic pain and/or tenderness
- 3. No symptoms of vaginal infection If indicated, do work-up for possible vaginal infection, chlamydia and gonorrhea
- 4. No recent history of fever, shaking chills, unilateral flank pain, inability to urinate or a sudden decrease in urine volume. No history of kidney disease.
- **OBJECTIVE** 1. Lower abdominal tenderness on palpation.
  - 2. Temperature less than 100°F.
  - 3. Diagnostic criterion: Dipstick urinalysis positive for either white blood cells (WBC) and/or nitrites, hematuria, abnormal urine discoloration or odor.
- **ASSESSMENT** Bacterial cystitis

### PLAN DIAGNOSTIC STUDIES

1. Urine pregnancy test, if any possibility of pregnancy.

- 2. If diagnosis is **questionable**, obtain clean-catch urine for urinalysis and culture and sensitivity.
- 3. If abnormal vaginal discharge or discharge from the urethra, perform wet prep and perform tests for gonorrhea and chlamydia.

### THERAPEUTIC

### PHARMACOLOGIC

 Trimethoprim 160 mg/sulfamethoxazole 800 mg (Bactrim DS, Septra DS, Sulfatrim DS).
 1 tablet PO, with food, every 12 hours for 3 days.

**NOTE:** Do not give if **client** has a history of allergy to the drug components; asthma, kidney or liver disease, folic acid deficiency states, G6-PD deficiency, or any other blood dyscrasia; is taking thiazide diuretics, warfarin (Coumadin), phenytoin (Dilantin), or methotrexate; is pregnant; or, is breastfeeding an infant less than 2 months old, or with or an elevated bilirubin (see Referral/Consultation).

### ÓR

2. Nitrofurantoin (Macrobid®)100 mg, 1 capsule PO with food, every 12 hours for 7 days or Macrodantin 50 mg, 1 tab PO four times a day for 7 days.

**NOTE:** Do not give if **client** has a history of nitro-furantoin allergy, kidney or liver disease, optic neuritis, G6-PD deficiency or anemia; is taking sulfinpyrazone/ Anturane, probenecid, or magnesium-containing antacids; or is breastfeeding an infant less than one month old or with G6-PD deficiency.

### OR

- 3. If allergic or otherwise intolerant of treatments above, is at least 18 years old and not pregnant or breast-feeding,
  - a. Norfloxacin (Noroxin®) 400 mg, 1 tablet PO every 12 hours for 3 days if uncomplicated and due to *E. coli, K. pneumoniae*, or *P. mirabilis*.
  - All other organisms, Norfloxacin 400 mg, 1 tablet PO 2 times a day for 7 10 days.

Take at least 2 hours before or 2 hours after food, milk products, iron or zinc supplements, antacids and/or other medications.

**NOTE**: Do not give if **client** has a history of quinolone antibiotic allergy, tendon rupture, atherosclerotic cardiovascular disease, kidney or liver disease, neurologic disorder or blood dyscrasia; or is taking theophylline, caffeine (e.g., in pain and fever-relieving medications), cyclosporine, warfarin (Coumadin®), probenecid, nitrofurantoin or sucralfate (Carafate®).

- 4. For non-curative symptomatic relief, if **client** is age 12 or older, is not pregnant or breast-feeding, and has no history of liver disease:
  - a. Phenazopyridine Hydrochloride (Pyridium®) 200 mg, 1 tablet PO 3 times a day after meals as needed for 2 days when used concomitantly with an antibacterial agent. OR
  - b. Nonprescription phenazopyridine hydrochloride 95 mg (AzoStandard, Azo-Gesic, Prodium) for less than 2 days. Follow package directions.

Discontinue medication immediately if any yellowish or orange discoloration of skin or eyes is noted. This medication may stain contact lenses.

### NON-PHARMACOLOGIC MEASURES

- 1. Increase fluid intake (cranberry juice might be suggested) and empty bladder frequently.
- 2. Warm sitz baths.

### CLIENT EDUCATION/COUNSELING

- 1. **Stress** the importance of taking the full course of treatment, unless serious side-effects occur.
- 2. **Discuss common** drug-specific instructions and cautions:
  - a. For trimethoprim/sulfamethoxazole: avoid sun exposure, discontinue drug immediately if develop a rash or signs of liver problems. Drink a full glass of water with each dose.
  - b. For nitrofurantoin: discontinue drug if develop peripheral neuropathy, visual problems, diarrhea, or symptoms of liver or lung problems.
  - c. For norfloxacin: avoid sun exposure, discontinue drug if develop diarrhea, tendon symptoms, rash or other allergic symptoms. Drink a full glass of water. May cause dizziness/drowsiness.

- d. Phenazopyridine may cause discoloration of urine and may stain panties. Recommend pantyliners.
- 3. **Discuss** potential risk factors for cystitis and prevention strategies.
- 4. **Advise that** eating or consuming cultured milk products (yogurt, buttermilk) may help prevent vaginal yeast infection while antibiotics are being taken.
- 5. Seek medical care immediately if medication side-effects or systemic symptoms develop.
- 6. Discuss that post-menopausal women may have increased susceptibility for cystitis because of a decrease in vaginal lactobacilli and an increased pH. Cultured milk products (yogurt, buttermilk) which contain live active cultures are good dietary sources of lactobacilli. Look for product containers labeled "lactobacillus acidophilus."

### FOLLOW-UP

- 1. **Client** should call the clinic if cystitis symptoms are not improved within 48 hours of starting therapy.
- 2. If no improvement in 48 hours after starting therapy or if symptoms persist after therapy is complete, either perform complete UA, culture and sensitivity and treat or refer for testing.

### **REFERRAL/CONSULTATION**

- 1. **Refer to physician** if **client** is pregnant.
- 2. Refer to physician if client has any of the following:
  - a. gross hematuria in a specimen uncontaminated by menses
  - b. systemic complaints such as temperature equal to or greater than 100°F, fast pulse, shaking chills or unilateral flank pain
  - c. recurrent cystitis within one month, or more than 3 episodes in one year
  - d. If follow-up urinalysis reveals unexplained (non-menstrual) microhematuria without WBC or nitrite.

### REFERENCES

- 1. Robert Hatcher et al., *Contraceptive Technology,* 19th ed., Ardent Media, Inc., New York, 2007. (Current)
- 2. Constance Uphold and Virginia Graham, *Clinical Guidelines in Family Practice*, 4<sup>th</sup> ed., Barmarrae Books, Inc., Gainesville, FL, 2003. **(Current)**
- 3. "Cystitis acute", *MedlinePlus*, U.S. National Library of Medicine, <www.nlm.nih.gov/medlineplus/ency/article/000526.htm> (May 16, 2011)
- 4. "Lexi-Drugs Online," *Lexi-Comp Database*, Lexi-Comp, Inc., Hudson, Ohio <a href="http://online.lexi.com">http://online.lexi.com</a>> (July 5, 2011)

### NURSE PROTOCOL FOR DYSMENORRHEA (PRIMARY)

- **DEFINITION** Primary dysmenorrhea is painful menstruation without identifiable causes; it is also known as spasmodic dysmenorrhea.
- ETIOLOGY Elevated levels of prostagladins E2 and F in the endometrium cause uterine contractions. This increases intrauterine pressure, creating uterine ischemia and spasmodic pain. The main symptom of dysmenorrhea is pain with menses that is concentrated in the abdomen, pelvic region, or lower back. Symptoms often cooccurring with menstrual pain include nausea, vomiting, diarrhea, headaches, weakness, dizziness or lightheadedness. Differential diagnosis includes: pelvic inflammatory disease, endometriosis, adenomyosis, endometrial hyperplasia, endometrial cancer, leiomyomata, ectopic pregnancy, IUD with partial expulsion.
- SUBJECTIVE1.Client provides a detailed health history (includes menstrual,<br/>sexual, contraception, personal health and family history).<br/>Note history of: parity, menarche, method of contraception, pelvic<br/>inflammatory disease/sexually transmitted diseases, onset of<br/>symptoms/changes over time, family history of dysmenorrhea,<br/>nutritional status.

# 2. Client reports cramping pain in the lower abdomen just before or during menstruation.

- 3. **Client** may report symptoms of congestive (secondary) dysmenorrhea: irritability, depression, nervousness, exhaustion, backache, constipation, bloating, weight gain, breast tenderness, dull ache, and/or onset of symptoms prior to menses.
- 4. **Client** may report symptoms of spasmodic dysmenorrhea: nausea, vomiting, diarrhea, weakness, dizziness, pelvic cramping, abdominal/back/thigh cramping, sweating, pallor, and/or headache.
- **OBJECTIVE** Physical examination usually within normal limits, unless secondary factors are present.
- ASSESSMENT Primary dysmenorrhea

### PLAN DIAGNOSTIC STUDIES

As indicated: Pap smear, gonorrhea/Chlamydia tests, vaginal wet mount, pregnancy test.

### THERAPEUTIC

### PHARMACOLOGIC

- Over the counter analgesics Coated aspirin, Aleve®, Motrin IB®, Nuprin®, acetaminophen (e.g., Tylenol®), per package directions prn.
  - OR
- Ibuprofen 400 mg PO every 4 hours as needed for pain. (Maximum dose 1.2 gm/day)
   OR
- 3. Naproxen 500 mg PO for one dose, then 250 mg PO every 6-8 hours as needed for pain. (Maximum dose 1250 mg/day)

**NOTE:** Do not order if **client** has a history of allergic reaction to aspirin.

4. **May initiate contraceptive method if** method poses no unacceptable health risk: OC, medroxyprogesterone acetate, Ortho Evra Patch, NuvaRing® may decrease symptoms.

### NON-PHARMACOLOGIC

- 1. Topical heat.
- 2. Regular exercise may be helpful.

### CLIENT EDUCATION/COUNSELING

- 1. **Inform client that** primary dysmenorrhea probably does not affect fertility.
- 2. Assess **client's** knowledge of activities that may provide relief.
- 3. Caution **client** if taking prostaglandin inhibitors (Aleve®, Motrin Ibuprofen®, Nuprin®, aspirin)
  - a. Prolonged chronic use may cause kidney problems and GI upset.
  - b. Stop medication and report severe persistent headaches, fever and muscle aches, which may be signs of aseptic meningitis.
- 4. Counsel on the use of condoms to reduce the risk of STD/HIV.

### FOLLOW-UP

Return to clinic if no relief from therapy after 6-8 weeks.

### CONSULTATION/REFERRAL

- 1. **Refer to physician** for differential diagnosis, as indicated.
- 2. Refer to physician if no relief from therapy or **if client develops** severe side effects of medication.

### REFERENCES

- 1. Robert Hatcher et al., Contraceptive Technology, 19th ed., Ardent Media, Inc., New York, 2007. (Current)
- 2. Joellen Hawkins, et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 9th ed., Springer Publishing Co., New York, 2007. (Current)
- 3. Constance Uphold and Mary Graham, *Clinical Guidelines in Family Practice*, 4<sup>th</sup> ed., Barmarrae Books, Inc., Gainesville, FL, 2003. (Current)
- 4. "Lexi-Drugs Online," *Lexi-Comp Database*, Lexi-Comp, Inc., Hudson, Ohio <a href="http://online.lexi.com">http://online.lexi.com</a> (July 5, 2011)

### STANDARD NURSE PROTOCOL FOR IRON-DEFICIENCY ANEMIA IN NON-PREGNANT AND NON-LACTATING WOMEN 18 AND OVER

DEFINITION Anemia is a condition in which the body does not have enough healthy red blood cells. Red blood cells provide oxygen to the body. Iron deficiency anemia develops due to low iron levels.

ETIOLOGY Iron-deficiency anemia, the most common type of anemia, is present in 20% of all premenopausal women in the United States. The primary cause of iron-deficiency anemia in premenopausal women is loss of blood through menstruation. In postmenopausal women, bleeding is usually from the GI tract (chronically bleeding lesions, reflux esophagitis, peptic ulcers, gastric or colorectal adenocarcinomas). Irondeficiency anemia also commonly occurs during pregnancy. Irondeficiency anemia can usually be corrected with iron supplementation.

# SUBJECTIVE 1. Client provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history).

- 2. Client may be asymptomatic if anemia is mild.
- 3. **Client** may report history which includes the following:
  - a. Pallor, fatigue, malaise, and/or anorexia
  - b. History of GI bleeding
  - c. Changes in stool color or bleeding from hemorrhoids
  - d. Excessive blood loss during menses or history of fibroid tumors
  - e. Poor dietary intake of iron rich foods, and pica
  - f. History of drug/medication use, especially aspirin and other nonsteriodal anti-inflammatory drugs
  - g. Nonspecific complaints of headache, poor concentration, and/or palpitations
  - h. Uncomfortable tingling or crawling feeling in the legs (restless leg syndrome)
  - i. Frequent blood donations
- 4. With severe anemia, the **client** may also present with:
  - a. Weakness and faintness
  - b. Increased heart rate
  - c. Shortness of breath
  - d. Dizziness or lightheadedness
  - e. Symptoms of heart failure

- f. Confusion and dementia
- g. Nausea and loss of appetite
- h. Headaches
- i. Bleeding gums
- j. Sore tongue
- 5. No history of major hemoglobinopathies (e.g., sickle cell anemia, sickle C disease, sickle beta thalassemia, hemoglobin c disease).

### **OBJECTIVE** 1. **Client** may have **the following**:

- a. Pallor, best seen in conjunctivae.
- b. Atrophy of the surface or edges of the tongue.
- c. Inflammation/cracking of the lips.
- d. Spoon nails (thin and concave from side to side).
- e. Tachycardia, flow murmur.
- 2. Hemoglobin below 12 gm/dL for a non-smoker and below 12.3 gm/dL for smoker or hematocrit below **35.7%** for non-smoker and below 36.9% for smoker.

#### **ASSESSMENT** Iron-deficiency anemia, presumptive if:

- no suggestion of sickle cell or other hemoglobin variants
- negative stool occult blood x 3, if clinically indicated

### PLAN DIAGNOSTIC STUDIES

Stool occult blood x 3, if clinically indicated or **client** is age 35 years or older.

### THERAPEUTIC

### PHARMACOLOGIC

- 1. Treatment of iron deficiency anemia:
  - a. Ferrous Sulfate 300 mg PO bid up to 300 mg qid or 250 mg (extended release) PO 1-2 times daily. OR
  - b. Ferrous fumarate 150-200 mg elemental iron PO daily in divided doses; 60-100 mg elemental iron PO twice daily, up to 60 mg elemental iron PO qid.
- 2. Prophylaxis of iron deficiency:
  - a. Ferrous Sulfate 300 mg PO daily.
  - b. Ferrous fumarate 60-100 mg elemental iron PO daily.

Note: To avoid GI upset, start with a single daily dose and increase by 1 tablet per day each week or as tolerated until desired daily dose is achieved. Do not give if client has sickle cell or hemoglobin variants.

### **CLIENT EDUCATION/COUNSELING**

- 1. For best absorption, take iron supplements on an empty stomach. If the iron upsets the stomach, take iron with a small amount of food, but not with dairy products, coffee or tea.
- 2. Introduce iron gradually to minimize stomach upset. Take one tablet once a day x 1 week and then increase to twice daily if needed.
- 3. Beverages consumed with meals or supplements have a dramatic effect on iron absorption.
  - a. **Vitamin C** (Orange juice ~ 1 cup) doubles the absorption of iron.
  - b. Tea, coffee or milk can reduce absorption to less than one half and should be consumed in moderation between meals or supplements.
- 4. Antacids, tetracycline, cimetidine and pancrelipase interfere with iron absorption. Do not take iron within 3 hours of taking these medications. Iron affects other medications and a pharmacist or health care provider should be consulted before starting another medication.
- 5. Iron supplements may cause black or dark green bowel movements, diarrhea, or constipation.
- 6. Counsel **client** on other common side effects of iron therapy.
- 7. Too much iron is dangerous. Iron tablets may look like candy and a package of iron tablets can poison a child. Keep iron supplements out of the reach of children.

### FOLLOW-UP

Recheck hemoglobin/hematocrit at the end of 4-6 weeks of initial treatment.

1. If the hemoglobin has increased **by** 1 gm/dL **or more**, or hematocrit by 3% **or more**, continue treatment for 2-3 months to replenish iron stores, **then recheck hemoglobin/hematocrit**.

- 2. If the hemoglobin is not increased **at least** 1 gm/dL or hematocrit by **at least** 3%:
  - a. Assess for compliance with therapy, diet, enteric parasites and other possible anemia-causing conditions.
  - b. Refer to a physician for further evaluation.

### CONSULTATION/REFERRAL

- 1. **Refer to physician if** hemoglobin less than 9 gm/dL or hematocrit less than 27%.
- 2. If after 4-6 weeks, the hemoglobin does not increase at least 1 gm/dL or hematocrit by at least 3%, despite compliance with iron supplementation regimen and the absence of acute illness, refer to physician.
- 3. **Refer any client** with sickle cell anemia or **other** hemoglobin variants **to physician**.
- 4. **Refer client to physician** if there is evidence of other medical problems.

### REFERENCES

- 1. Constance Uphold and Virginia Graham, *Clinical Guidelines in Family Practice*, 4<sup>th</sup> ed., Barmarrae Books, Inc., Gainesville, FL, 2003. (Current)
- 2. CDC, "*Recommendations to Prevent and Control Iron Deficiency in the United States,*" MMWR, Vol. 47, No. RR-3, April 3, 1998. (Current)
- 3. Mayo Clinic, "Iron Deficiency Anemia," <<u>http://mayoclinic.com/health/iron-</u> <u>deficiency-anemia/DS00323</u>> (May 16, 2011)
- 4. "Iron Deficiency Anemia", *MedlinePlus*, U.S. National Library of Medicine, <<u>www.nlm.nih.gov/medlineplus/ency/article/000584.htm</u>> (May 16, 2011)
- 5. Handouts: Iron Deficiency Anemia, National Anemia Action Council, <<u>www.anemia.org/patients/information-handouts/iron-deficiency</u>> (May 16, 2011)
- 6. "Lexi-Drugs Online," *Lexi-Comp Database*, Lexi-Comp, Inc., Hudson, Ohio <a href="http://online.lexi.com">http://online.lexi.com</a>> (July 5, 2011)

#### STANDARD NURSE PROTOCOL FOR LOCAL ESTROGEN THERAPY FOR TREATMENT OF VULVAR/VAGINAL ATROPHY

- DEFINITION Vaginal atrophy is thinning and inflammation of the vaginal walls due to a decline in estrogen. This condition is also called atrophic vaginitis or urogenital atrophy.
- **ETIOLOGY** Vaginal atrophy is caused by a decrease in estrogen production. Symptoms of urogenital atrophy are seen in almost half of untreated menopausal women as well as in 10-25% of women receiving conventional doses of systemic hormone therapy (HT). The vagina as well as the urethra and trigone of the bladder are estrogen-dependent tissues. When circulating estrogen levels drop because of transient or permanent ovarian failure (including menopause) or because of antiestrogenic medications, these tissues atrophy.

# SUBJECTIVE 1. Client provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history).

- 2. **Client** may **report history which includes:** 
  - a. vaginal irritation
  - b. pruritis
  - c. vaginal dryness or itching
  - d. dyspareunia (pain during sex)
  - e. light bleeding after intercourse
  - f. dysuria
  - g. **urinary** incontinence
  - h. **menopausal symptoms** (hot flushes/flashes, insomnia, and night sweats)

### **OBJECTIVE** Physical exam findings of urogenital atrophy including the following:

- 1. Pale, thin friable vaginal epithelium
- 2. Loss of vaginal rugae and elasticity
- 3. Sparse pubic hair
- 4. Dryness of labial skin and loss of turgor
- 5. Introital petechiae or fissure
- 6. Erythematous urethral meatus
- 7. Eversion of urethral mucosa, urethral caruncle

### ASSESSMENT Vulvovaginal atrophy associated with menopause. According to product package insert, no contraindications to using vaginal estrogen.

**NOTE:** contraindications for vaginal estrogen products are the same as for systemically administered estrogen.

### PLAN DIAGNOSTIC STUDIES

- 1. Consider FSH and/or thyroid studies if menopause is in question.
- 2. Wet prep, urine dip stick, STD tests as indicated to rule out vaginitis and cystitis.
- 3. Pap smear and mammogram according to Georgia Breast and Cervical Cancer Screening Program guidelines.
- 4. Fasting lipid profile and glucose.
- 5. Additional screening tests for age as indicated.

### THERAPEUTIC

### PHARMACOLOGIC

1. For relief of atrophic vaginitis:

Premarin vaginal cream (or equivalent), 0.5-2 gm daily intravaginally for 3 weeks and one week off. Lower doses may be effective. Medication should be discontinued as promptly as possible.

- a. **Client** should use lowest dose possible to relieve symptoms.
- b. Treatment with vaginal cream longer than 6-12 months requires ultrasonic monitoring of endometrial thickness with biopsy when indicated as estrogen cream is absorbed systemically.
- c. Latex condom, diaphragm and cervical cap may be weakened by vaginal cream.
- 2. For ASCUS Pap smear with evidence of atrophy: Premarin vaginal cream (or equivalent), 0.5-2 gm daily intravaginally for 3 weeks. Lower doses may be effective. Medication should be discontinued as promptly as possible.

### CLIENT EDUCATION/COUNSELING

1. Counsel **client** according to seven basic elements of informed consent (BRAIDED – Benefits Risks Alternatives Inquiries Decision Explanation Documentation).

- 2. Vaginal estrogen cream provides the quickest response and subsequent relief of symptoms of atrophic vaginitis.
- 3. Vaginal moisturizers such as Replens, applied on a regular basis, have been shown to be beneficial for local vaginal symptoms.
- 4. Vaginal estrogen cream may weaken latex condoms, diaphragms and cervical caps, therefore reducing their effectiveness.
- 5. Regular sexual activity has been shown to help maintain vaginal health.
- 6. Counsel on good health practices, including diet, intake of calcium and vitamin D, weight-bearing exercises and increase in physical activity, breast and cervical cancer screening, safer sex and STD/HIV risk reduction and testing.
- 7. If smoker or tobacco user, refer to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867).

### FOLLOW UP

- 1. As needed for specific problems.
- 2. Evaluate response to therapy in 3 months or sooner.
- 3. Annual physical exam, Pap smears and mammograms according to BCCP guidelines.

### **REFERRAL/CONSULTATION**

- 1. For any questions regarding management.
- 2. For ultrasound of endometrium and biopsy and **as** indicated if treatment with vaginal cream is longer than 6-12 months.
- 3. Emphasize importance of keeping immunizations current; assess client's immunization status and administer vaccines indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If client declines vaccination, document refusal. See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current **immunization** schedules and administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at <a href="http://www.health.state.ga.us/programs/immunization/publications.asp">http://www.health.state.ga.us/programs/immunization/publications.asp</a>.

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- 1. Robert Hatcher et al., *Contraceptive Technology,* 19th ed., Ardent Media, Inc., New York, 2007. (Current)
- 2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 9th ed., Springer Publishing Co., New York, 2007. (Current)
- 3. "Premarin Vaginal Cream," *Physician Prescribing Information*, Wyeth Pharmaceuticals, Inc., **2010**, <<u>http://labeling.pfizer.com/showlabeling.aspx?id=132</u>> (May 16, 2011)
- 4. Aetna IntiHealth, "Vaginal Atrophy (Atrophic Vaginitis)," March 2009, <<u>www.intelihealth.com/IH/ihtIH/:/9339/9504.html</u>> (May 16, 2011)
- 5. Kraft, Sy, "What is Atrophic Vaginitis (Vaginal Atrophy)? What Causes Atrophic Vaginitis?" *Medical News Today,* 20 May 2010, <a href="http://www.medicalnewstoday.com/articles/189406.php">http://www.medicalnewstoday.com/articles/189406.php</a> (May 16, 2011)
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  <a href="http://www.mayoclinic.com/health/menopause/DS00119">http://www.mayoclinic.com/health/menopause/DS00119</a> (May 16, 2011)
- 7. Nanette Santoro, "Women want to know: Predicting the final menses," Sexuality, Reproductive, & Menopause, May 2007, Vol. 5, No. 2, p. 6-10. <a href="http://www.srm-ejournal.com/article.asp?AID=7103&UID">http://www.srm-ejournal.com/article.asp?AID=7103&UID</a> (May 16, 2011)

### STANDARD APRN PROTOCOLS

### STANDARD APRN PROTOCOL FOR AMENORRHEA (PRIMARY AND SECONDARY)

### **DEFINITION** Amenorrhea is defined as the absence of menses. Primary amenorrhea is defined as no menstrual period by the age of 15, lack of any secondary sexual characteristics by age 13, or no menses within 5 years after the development of breasts, pubic or axillary hair.

Secondary amenorrhea is defined as absence of menstrual periods for a length of time equivalent to a total of at least three of the previous cycle intervals or six-twelve months of amenorrhea in a woman who normally experiences irregular menses.

### ETIOLOGY

- 1. Gonadal failure.
- 2. Congenital absence of uterus and vagina.
- 3. Constitutional delay.

### Secondary:

Primary:

- 1. Pregnancy; breastfeeding.
- 2. Pituitary disease or tumor; disruption of hypothalamic- pituitary axis.
- 3. Menopause.
- 4. Too little body fat (about 22% required for menses).
- 5. Excessive exercise (e.g., long-distance running, ballet dancing, gymnastics, figure skating, etc.).
- 6. Rapid weight loss.
- 7. Cessation of menstruation following use of OC or medroxyprogesterone acetate.
- 8. Recent change in lifestyle (e.g., increased stress).
- 9. Thyroid disease.
- 10. Polycystic ovary disease.
- 11. Anorexia nervosa or other eating disorders.
- 12. Premature ovarian failure, ovarian dysgenesis, infection, hemorrhage, necrosis, neoplasm.
- 13. Asherman's Syndrome.
- 14. Cervical stenosis.
- 15. Medications including psychotropics.
- 16. Chronic illness.
- 17. Tuberculosis.

## SUBJECTIVE 1. Client provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history).

2. **Client** reports absence of menses (as defined above).

- 3. **Client may have a** history which includes the following:
  - a. Changes in skin/hair, vision/hearing or voice
  - b. Palpitations
  - c. Breast size changes or galactorrhea
  - d. Vasomotor symptoms
  - e. Changes in weight, dietary habits
  - f. Cold or heat intolerance
  - g. Known medical problems
  - h. Stress
  - i. Exercise patterns (changes or rigorous)
  - j. Recent pregnancy
  - k. Genital tract procedures
- **OBJECTIVE** 1. May be obese or underweight for height.
  - 2. May note on physical examination:
    - a. Skin/hair changes dry skin or warm, moist skin, excessive sweating, palmar erythema, acne, hirsutism, **balding**, purple abdominal striae, absence of pubic or axillary hair.
    - b. Facial plethora, moon facies, exophthalmos, ocular signs, visual fields defect, impaired auditory acuity, abnormal thyroid size and consistency, fine silky scalp hair or alopecia pattern.
    - c. Tachycardia.
    - d. Breast tissue atrophy, galactorrhea.
    - e. "Buffalo" hump of back.
    - f. On pelvic exam:
      - 1. External Vulvar atrophy, clitoromegaly.
      - 2. Internal Atrophic vaginal mucosa, change in cervical mucous or imperforate hymen.
      - 3. Bimanual Softening of cervix or cervical uterine junction, cervical stenosis, uterine or ovarian atrophy or enlargement.
- **ASSESSMENT** Primary amenorrhea.

OR

Secondary amenorrhea with or without galactorrhea.

### PLAN DIAGNOSTIC STUDIES

1. Pregnancy test.

- 2. For secondary amenorrhea only:
  - a. <u>Amenorrhea with galactorrhea:</u>
    - 1) Amenorrhea with galactorrhea, and not breastfeeding:
      - a) Draw fasting prolactin level(s) prior to breast exam or 1 week after exam and no nipple stimulation for 1 week in addition to thyroidstimulating hormone (TSH) test (for underlying hypothyroidism).
         OR
      - b) May refer to physician for diagnostic testing.
    - 2) Amenorrhea with galactorrhea and normal prolactin level/ TSH values and negative pregnancy test:
      - a) Perform Progestin challenge test. OR
      - b) May refer to physician for diagnostic testing.
  - b. Amenorrhea without galactorrhea:
    - 1) May refer to physician for diagnostic testing. OR
    - 2) Draw TSH test (for underlying hypothyroidism).
    - 3) Consider follicle-stimulating hormone (FSH) and luteinizing hormone (LH) test if applicable.
    - 4) Amenorrhea without galactorrhea and normal TSH and negative pregnancy test: Perform Progestin challenge test.

### THERAPEUTIC

### PHARMACOLOGIC

### Progestin challenge test

Medroxyprogesterone **Acetate** 5-10 mg 1 tab PO daily for 5-10 days.

1. If bleeding occurs with progestin challenge test (usually within 2-7 days)

### AND

- a. Client desires contraception and OC do not pose an unacceptable health risk, begin any FDA approved 35 mcg or less OC. (See Appendix A) OR
- b. **Client** does not desire contraception, give medroxyprogesterone acetate, 10 mg PO daily, for

the first 10 days of every month, for 3 consecutive months.

2. If no bleeding occurs with progestin challenge test, repeat pregnancy test.

### CLIENT EDUCATION/COUNSELING

- 1. Give menstrual calendar and counsel on its use.
- 2. Inform that bleeding usually occurs within 2 weeks after treatment (frequently 2-7 days).
- 3. Discuss what can be expected during future evaluation. Explain that accurate diagnosis may take time.
- 4. Review female anatomy and menstrual cycle to help her understand the testing being done.
- 5. Discuss contraception, as indicated.
- 6. Explain that post-pill amenorrhea or resumption of normal menses may take up to 6 months.

### FOLLOW-UP

Return in two weeks if no withdrawal bleeding has occurred after medroxyprogesterone acetate or no withdrawal bleeding with OC.

### CONSULTATION/REFERRAL

- 1. If **client** has primary amenorrhea.
- 2. Positive pregnancy test, refer for prenatal care.
- 3. Amenorrhea with galactorrhea and abnormal test results.
- 4. If client does not have a withdrawal bleed after progestin challenge test and negative pregnancy test, refer for further evaluation.
- 5. **Client** fails to have spontaneous menses within 3 months after treatment.
- 6. Suspected eating disorders, or polycystic ovarian syndrome.
- 7. If **client** has abnormal laboratory test(s).

- 8. Client has neurological symptoms such as headache or abnormal neurological exam.
- 9. May refer for diagnostic testing (i.e., prolactin level, TSH, FSH, LH).

### REFERENCES

- 1. Robert Hatcher et al., Contraceptive Technology, 19th ed., Ardent Media, Inc., New York, 2007. (Current)
- 2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecological Settings*, 9th ed., Springer Publishing Co., New York, 2007. (Current)
- 3. Leon Speroff and Marc Fritz, *Gynecologic Endocrinology and Infertility*, **8th** ed., Lippincott, Williams and Wilkins, Philadelphia, PA, **2010. (Current)**
- 4. Provera® (medroxyprogesterone acetate tablet), *Physician Prescribing Information,* <<u>http://media.pfizer.com/files/products/uspi\_provera.pdf</u>> (May 16, 2011)

### STANDARD APRN PROTOCOL FOR CONTRACEPTIVE IMPLANT INSERTION: IMPLANON

<u>NOTE:</u> All clinicians performing insertions and/or removals of IMPLANON must complete the IMPLANON Clinical Training Program, a required comprehensive hands-on workshop. Only clinicians who complete the program will be able to order the product. You must be an advanced practice clinician or a physician in order to attend the required training.

For training information, call 1-877-IMPLANON (1-877-467-5266).

- **DEFINITION** Implanon<sup>®</sup> is a small, thin, implantable hormonal contraceptive that is effective for up to three years. The subdermal contraceptive implant (Implanon<sup>®</sup>) is an etonogestrel-impregnated 4 cm plastic rod. It is placed under the skin of the upper arm. Implanon does not contain estrogen. It prevents pregnancy primarily by inhibiting ovulation. Other contraceptive effects include thickening cervical mucus and thinning the endometrial lining. The implant must be removed at the end of the third year of use and may be replaced with a new implant if continued contraception is desired.
- **SUBJECTIVE** 1. Desires an implant for long-term contraception.
  - 2. Has detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and to the WHO Medical Eligibility Criteria for Contraceptive Use.
- OBJECTIVE 1. Physical examination and laboratory tests according to programmatic guidelines.
  - 2. Physical exam deferred up to 3 months. Document reason for deferral on chart. Document on Request for and Consent to Family Planning Services (form 3700) that client agreed to have physical exam delayed.
  - 3. **Pregnancy must be excluded before inserting IMPLANON.**
  - **ASSESSMENT** Client has no condition representing an unacceptable risk if using Implanon.

### PLAN DIAGNOSTIC STUDIES

1. Pregnancy test if indicated to rule out pregnancy before inserting Implanon.

- 2. The lipid profile may be obtained at the clinician's discretion if needed. The decision to draw a lipid profile will be determined by the RN and/or the APRN/physician, which is based on a clinical evaluation of the individual client. The RN may consult with and/or refer client to the APRN/physician, if needed, to further determine the client's risk for CVD and the need for a lipid profile.
- 3. Blood glucose beginning by age 45. Consider screening women at an earlier age in the presence of high-risk factors for diabetes. Rescreen every 3 years or more often depending on test results and high-risk factors. For Recommended Tests and Immunizations for Women with High-Risk Factors refer to www.womenshealth.gov.
- 4. Screen women for colorectal cancer according to district policy/procedure for colorectal cancer screening.

### PHARMACOLOGIC

- 1. Local anesthesia with 2 mL of 1% lidocaine should be injected under the skin and along the insertion track.
- 2. Insert Implanon per manufacturer's directions. May be inserted any time in the cycle as long as pregnancy has been ruled out and manufacturer's instructions regarding back-up contraception are followed.

**NOTE:** Before insertion, the **client** must read and sign the consent form provided by the manufacturer in addition to the program's method specific consent form.

### NON-PHARMACOLOGIC MEASURES

- 1. Take precautions to avert a vasovagal reaction (syncope/ fainting). Allow the **client** to lie still several minutes after insertion. Ask about pain or feeling faint. If the **client** says she feels like she can sit up, have her sit up slowly while being supported. If no problems in 1-2 minutes, allow her to stand.
- 2. Treat signs of vasovagal reaction (pallor/cyanosis, pinchedface look, dilated pupils, weak and rapid pulse, rapid shallow breathing, hypotension) according to the Emergency Guidelines, **Policies and Procedures** section of this manual.

3. Ice to insertion area for discomfort.

### **CLIENT EDUCATION/COUNSELING**

- 1. Counsel **client** according to seven basic elements of informed consent (BRAIDED Benefits Risks Alternatives Inquiries Decision Explanation Documentation).
- 2. In addition to the manufacturer's consent form, the packaging also includes a User Card. The User Card should be filled out and given to the **client** after Implanon insertion so she will have a record of the location of Implanon and when Implanon should be removed.
- 3. Teach **client** how to check for Implanon.
  - a. The implant should be palpated by both the clinician and **client** before **client** goes home to ensure proper placement.
  - b. The **client** may confirm placement at any time by palpating her inner upper arm.
  - c. If **client** cannot feel the implant, she should use another method of contraception (e.g., condoms or abstinence) and return to the clinic.
- 4. Review warning signs and symptoms of possible insertion site problems: redness, swelling, or purulent discharge at insertion site.
- 5. Counsel client on common side effects: menstrual changes or bleeding irregularities (spotting, light bleeding, prolonged bleeding or no bleeding), emotional lability, weight gain, headache, acne, depression.
- 6. Further counsel client regarding unpredictable bleeding irregularities, so that they know what to expect. Women who use Implanon are likely to have changes in their vaginal bleeding patterns, especially during the first three months of use, which are often unpredictable. These may include changes in bleeding frequency or duration, or amenorrhea. Amenorrhea and oligomenorrhea are common.
- 7. Take over-the-counter ibuprofen or acetaminophen and/or apply ice to insertion area for discomfort.
- 8. **Provide counseling on preconception health counseling and** future fertility. (Refer to Preconception Health Toolkit)

- 9. Use condoms to reduce the risk of STD, including HIV.
- 10. Outside of clinic hours, seek physician or emergency care if warning signs develop.
- 11. Implanon is approved for use for 3 years.
- 12. If smoker or tobacco user, refer to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867).
- 13. Emphasize importance of keeping immunizations current; assess client's immunization status and administer vaccines indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If client declines vaccination, document refusal. See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current **immunization** schedules and administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at http://health.state.ga.us/programs/immunization/publications.asp.

### **FOLLOW-UP**

- 1. Return as scheduled for evaluation or contact clinic if side effects or danger signs develop.
- 2. If **client** did not receive a physical exam, have her return within 3 months for an exam and reassessment.
- 3. After an Implanon has been in place for 3 years, check with manufacturer regarding possible approval for a longer time.

### CONSULTATION/REFERRAL

- 1. Difficult Implanon insertion or removal.
- 2. Suspected ectopic pregnancy.
- 3. Other complications related to implant use.

### REFERENCES

- 1. Robert Hatcher et al., *Contraceptive Technology,* 19th ed., Ardent Media, Inc., New York, 2007. (Current)
- World Health Organization (WHO), Medical Eligibility Criteria for Contraceptive Use, 4<sup>th</sup> ed., 2009,
   <a href="http://whglibdoc.who.int/publications/2010/9789241563888">http://whglibdoc.who.int/publications/2010/9789241563888</a> eng.pdf> (May 16,

<<u>http://whqlibdoc.who.int/publications/2010/9789241563888\_eng.pdf</u>> (May 16, 2011)

- 3. "General Screenings and Immunizations for Women," Office on Women's Health, <<u>http://www.womenshealth.gov/prevention/general</u>> (May 16, 2011)
- 4. "Every Woman, Every Time," A Preconception Care Toolkit for Georgia, 2010, <<u>http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm</u>> (May 16, 2011)
- 5. "Implanon," Schering-Plough, 2009 <<u>http://www.implanon-usa.com</u>> (May 16, 2011)
- 6. Implanon® Patient Labeling Schering-Plough, 2009, <<u>http://www.spfiles.com/piimplanon.pd.pdf</u>> (May 16, 2011)
- 7. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," MMWR 2010; 59, <<u>http://www.cdc.gov/mmwr</u>> (June 6, 2011)
- 8. "Get clinical training, " IMPLANON, 2011 <<u>http://www.implanon-usa.com/en/HCP/get-clinical-training/index.asp</u>> (August 23, 2011)

### STANDARD APRN PROTOCOL FOR IMPLANON® REMOVAL

<u>NOTE:</u> All clinicians performing insertions and/or removals of IMPLANON must complete the IMPLANON Clinical Training Program, a required comprehensive hands-on workshop. Only clinicians who complete the program will be able to order the product. You must be an advanced practice clinician or a physician in order to attend the required training.

For training information, call 1-877-IMPLANON (1-877-467-5266).

- **DEFINITION** Removal of Implanon® at the **client**'s request, due to clinical findings such as pregnancy or side effects, or per guidelines that Implanon® must be removed after 3 years.
- **SUBJECTIVE** 1. **Client** desires Implanon® removal.
  - 2. May be pregnant.
  - 3. Complains of severe side effects.
  - 4. Three years may have elapsed since insertion.
- **OBJECTIVE** 1. Positive pregnancy test.
  - 2. Clinical findings of severe side effects or a contraindication for continuing with Implanon®.
- **ASSESSMENT** Removal of Implanon® is desired or recommended.

### PLAN DIAGNOSTIC STUDIES

Implant palpable under skin and exact position localized. If implant is not palpable, do not attempt to begin removal process. Implant must be localized with ultrasound using a high frequency linear array transducer (10 megahertz or greater) or MRI. Only remove a non-palpable implant once the location of the implant has been established. If imaging methods fail, call the manufacturer, Organon, at 1-877-467-5266 for further instructions.

### THERAPEUTIC

Per manufacturer's instructions, remove the Implanon® capsule through a very small incision over the tip that is closest to the elbow.

- 1. Per manufacturer's removal instructions:
  - a. Inject local anesthetic under the distal tip of the implant.
  - b. Make a 2-3 mm incision just above the tip of the rod.
  - c. Gently push the tip of the implant through the incision and grasp with a hemostat or forceps for removal.
  - d. Place bandage over incision.
- 2. If implant is not palpable but has been localized by ultrasound and is found to be deeply inserted, referral to a specialist with expertise in deep removals is highly recommended. This specialist should have a good understanding of the vessels and nerves of the arm. Any adverse events associated with removal should be reported to Organon at 1-877-467-5266.

### **CLIENT EDUCATION/COUNSELING**

- 1. Provide **client** with instructions for care. Take over-the-counter ibuprofen or acetaminophen for discomfort if needed.
- 2. Discuss alternative contraceptive method, if desired.
- 3. Menses may be delayed or irregular for a month or more after removal.
- 4. If smoker or tobacco user, refer to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867).
- 5. Emphasize importance of keeping immunizations current; assess client's immunization status and administer vaccines indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If client declines vaccination, document the refusal. See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current **immunization** schedules and administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at <a href="http://health.state.ga.us/programs/immunization/publications.asp">http://health.state.ga.us/programs/immunization/publications.asp</a>.

### FOLLOW-UP

- 1. May follow-up in 1-2 weeks for incision check, if indicated.
- 2. Return, as needed, for contraception or annual exam.

### CONSULTATION/REFERRAL

1. Difficult/failed removal.

- 2. Successful removal, **client** pregnant.
- 3. Persistent side effects.

### REFERENCES

- 1. Robert Hatcher et al., *Contraceptive Technology,* 19th ed., Ardent Media, Inc., New York, 2007. (Current)
- World Health Organization (WHO), Medical Eligibility Criteria for Contraceptive Use, 4<sup>th</sup> ed., 2009,
   <a href="http://whqlibdoc.who.int/publications/2010/9789241563888">http://whqlibdoc.who.int/publications/2010/9789241563888</a> eng.pdf
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- 3. "General Screenings and Immunization for Women," Office on Women's Health, < <u>http://www.womenshealth.gov/prevention/general/</u>> (May 16, 2011)
- 4. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," MMWR 2010; 59, <<u>http://www.cdc.gov/mmwr</u>> (June 6, 2011)
- 5. "Implanon," Schering-Plough, 2009 <<u>http://www.implanon-usa.com</u>> (May 16, 2011)
- 6. Implanon® Patient Labeling Schering-Plough, 2009, <<u>http://www.spfiles.com/piimplanon.pd.pdf</u>> (May 16, 2011)
- 7. "Get clinical training, " IMPLANON, 2011 <<u>http://www.implanon-usa.com/en/HCP/get-clinical-training/index.asp</u>> (August 23, 2011)

### STANDARD APRN PROTOCOL FOR IUD INSERTION: COPPER T380A

- **DEFINITION** The Copper T380A (ParaGard<sup>®</sup>) intrauterine device, is a copper-bearing contraceptive device **that prevents pregnancy for up to 10 years.** It prevents pregnancy by immobilizing sperm, inhibiting fertilization and preventing implantation due to local inflammatory responses and endometrial effects.
- **SUBJECTIVE** 1. Desires an IUD for **long-term contraception**.
  - 2. Not at high risk for sexually transmitted infections.
  - 3. Has detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and to the WHO Medical Eligibility Criteria for Contraceptive Use.

### **OBJECTIVE** 1. Normal pelvic exam at the time of insertion.

# 2. Annual physical exam is current according to Title X Guidelines.

- 3. Negative pregnancy test at the time of insertion.
- 4. Laboratory tests:
  - a. Cervical Cytology rules out cervical cancer.
  - b. Negative gonorrhea and chlamydia tests within last 60 days.
  - c. Wet mount if indicated.
  - d. Hemoglobin or hematocrit within the last 60 days.
- **ASSESSMENT** Client has no condition representing an unacceptable risk if using a Copper T380A.

### PLAN DIAGNOSTIC STUDIES

 Blood glucose beginning by age 45. Consider screening women at an earlier age in the presence of high-risk factors for diabetes. Rescreen every 3 years or more often depending on test results and high risk factors. For Recommended Tests and Immunizations for Women with High-Risk Factors refer to www.womenshealth.gov. 2. Screen women for colorectal cancer according to district policy/procedure for colorectal cancer screening.

### PHARMACOLOGIC

- 1. May give an over-the-counter (OTC) nonsteroidal antiinflammatory agent 30-60 minutes before the procedure to reduce discomfort.
- 2. Insert Copper T380A per manufacturer's directions. May be inserted any time in the cycle as long as pregnancy has been ruled out.

**NOTE:** Before insertion, the client must read and sign the consent form if provided by the manufacturer in addition to the program's method specific consent form.

 If hemoglobin below 12.0 gm/dL for non-smoker or below 12.3 gm/dL for smoker or hematocrit below 35.7% for nonsmoker or below 36% for smoker, treat according to appropriate nurse protocol for age for iron deficiency anemia.

### NON-PHARMACOLOGIC MEASURES

- Take precautions to avert a vasovagal reaction (syncope/ fainting) caused by uterine manipulation and sounding. After IUD insertion, allow the **client** to lie still for at least 30 seconds (while explaining how to check for strings). Ask about pain or cramping. If the **client** says she feels okay, have her sit up slowly while being supported. If no problems in 30 seconds, allow her to stand.
- 2. Treat signs of vasovagal reaction (pallor/cyanosis, pinchedface look, dilated pupils, weak and rapid pulse, rapid shallow breathing, hypotension) according to the Emergency Guidelines, **Policies and Procedures** section of this manual.

### CLIENT EDUCATION/COUNSELING

- 1. Counsel client according to seven basic elements of informed consent (BRAIDED Benefits Risks Alternatives Inquiries Decision Explanation Documentation).
- 2. Teach **client** how to check for IUD strings.
  - a. The IUD can be expelled without being noticed.

- b. Check for the strings frequently during the first months, then after each menses and any time there is abnormal cramping while menstruating.
- c. Inspect tampons on removal for IUD.
- d. If **client** cannot feel the strings, or if the plastic part is felt, use another method of contraception and return to the clinic.
- e. Most likely cause of IUD failure is expulsion with risk highest during the first year, particularly within the first 3 months after insertion.
- 3. Review warning signs and symptoms of possible problem: abdominal pain, **vaginal** discharge, **pain with intercourse**, missing string, **pregnancy symptoms**, heavy bleeding.
- 4. There is a small increased risk of PID, which is most likely to occur within the first 2-3 weeks after insertion.
- 5. Menstrual irregularities (spotting, light bleeding) are common in the first 3-6 months after insertion.
- 6. Take over-the-counter ibuprofen or naproxen sodium **per package directions if needed for discomfort**.
- 7. Should strongly consider changing to another contraceptive method if behavior puts client at risk for PID (multiple partners, partner with multiple partners).

# 8. **Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit)**

- 9. Use condoms to reduce the risk of STD, including HIV.
- 10. Outside of clinic hours, seek physician or emergency care if warning signs develop.
- 11. The T380A is approved for use for 10 years.
- 12. If smoker or tobacco user, refer to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867).
- 13. Emphasize importance of keeping immunizations current; assess client's immunization status and administer vaccines indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If client declines vaccination, document the refusal. See the Georgia Immunization Program Manual, Recommended Schedule and

Guidelines, for current immunization schedules and administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at

http://www.health.state.ga.us/programs/immunization/publications.asp.

### FOLLOW-UP

- 1. Re-examine and evaluate the **client** shortly after the first postinsertion menses, but no later than three months afterwards.
- 2. If **client** had a low hemoglobin or hematocrit, recheck after completion of at least 4–6 weeks of iron therapy:
  - a. If hemoglobin drops more than 2 gm/dL or hematocrit drops 6% or more, strongly consider removal and treat according to appropriate nurse protocol for age for iron deficiency anemia. If hemoglobin is less than 9 gm/dL or hematocrit less than 27%, strongly consider removal and treat according to protocol.
  - b. If IUD removed for the above reasons:
    - 1) Repeat hemoglobin/hematocrit in 1-2 months.
    - 2) Provide an alternate method of contraception.
- 3. If evidence of pelvic inflammatory disease, see Nurse Protocol for Pelvic Inflammatory Disease (PID). IUD removal is not necessary unless no improvement after 2-3 days of antibiotic treatment.
- 4. If pregnancy occurs, counsel **client** that IUD should be removed at time of diagnosis whether pregnancy is continued or terminated.
- 5. After a T380A has been in place for 10 years, check with manufacturer regarding possible approval for a longer time.

### CONSULTATION/REFERRAL

- 1. Difficult IUD insertion or removal.
- 2. Suspected **uterine or** ectopic pregnancy.
- 3. To MD for IUD removal if pregnant.
- 4. Other complications related to IUD use.
- 5. Presence of actinomyces on Pap smear report and evidence of pelvic infection.
#### 6. To MD for further evaluation if presence of actinomyces on Pap smear report and client requests insertion/reinsertion of IUD.

# REFERENCES

- 1. Robert Hatcher et al., *Contraceptive Technology,* 19th ed., Ardent Media, Inc., New York, 2007. (Current)
- 2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 9th ed., Springer Publishing Co., New York, 2007. (Current)
- 3. "ParaGard," *Physician Prescribing Information*, Duramed Pharmaceuticals, Inc., 2006, <a href="http://www.drugs.com/pro/paragard.html">http://www.drugs.com/pro/paragard.html</a> (May 16, 2011)
- 4. World Health Organization (WHO), Medical Eligibility Criteria for Contraceptive Use, 4<sup>th</sup> ed., 2009,
   <a href="http://whqlibdoc.who.int/publications/2010/9789241563888">http://whqlibdoc.who.int/publications/2010/9789241563888</a> eng.pdf
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- 5. "General Screenings and Immunizations for Women," Office on Women's Health, <<u>http://www.womenshealth.gov/prevention/general</u>> (May 16, 2011)
- 6. "Every Woman, Every Time," A Preconception Care Toolkit for Georgia, 2010, <<u>http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm</u>> (May 16, 2011)
- 7. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," MMWR 2010; 59, <<u>http://www.cdc.gov/mmwr</u>> (June 6, 2011)

#### STANDARD APRN PROTOCOL FOR IUD INSERTION: MIRENA® LNG Intrauterine System

**DEFINITION** The levonorgestrel-releasing intrauterine system (brand name Mirena®) system consists of a small T-shaped frame with a steroid reservoir that contains levonorgestrel, a potent progestin found in many combination oral contraceptives, progestin-only pills, and implants.

The LNG intrauterine system releases a low dose of levonorgestrel (20 mcg per day) into the uterine cavity for at least five years, a system similar to that of levonorgestrel implants or levonorgestrel-containing mini-pills. As with these methods, thickening the cervical mucus and inhibition of ovulation, sperm motility and function are considered the primary means of preventing pregnancy. A weak foreign-body effect is also noted which could decrease implantation.

- **SUBJECTIVE** 1. Desires an IUD for long-term contraception.
  - 2. History is negative for pelvic inflammatory disease unless there has been a subsequent intrauterine pregnancy.
  - 3. Has detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and to the WHO Medical Eligibility Criteria for Contraceptive Use.
- **OBJECTIVE** 1. Normal pelvic exam at the time of insertion.

# 2. Annual physical exam is current according to Title X Guidelines.

- 3. Negative pregnancy test at the time of insertion.
- 4. Laboratory tests:
  - a. Cervical Cytology rules out cervical cancer.
  - b. Negative gonorrhea and chlamydia tests within the last 60 days.
  - c. Wet mount if indicated.
  - d. Hemoglobin or hematocrit within the last 60 days.

# **ASSESSMENT** Client has no condition representing an unacceptable risk if using the Mirena.

## PLAN DIAGNOSTIC STUDIES

- 1. The lipid profile may be obtained at the clinician's discretion if needed. The decision to draw a lipid profile will be determined by the RN and/or the APRN/physician, which is based on a clinical evaluation of the individual client. The RN may consult with and/or refer client to the APRN/physician, if needed, to further determine the client's risk for CVD and the need for a lipid profile.
- 2. Blood glucose beginning by age 45. Consider screening women at an earlier age in the presence of high-risk factors for diabetes. Rescreen every 3 years or more often depending on test results and high risk factors. For Recommended Tests and Immunizations for Women with High-Risk Factors refer to <u>www.womenshealth.gov</u>.
- 3. Screen women for colorectal cancer according to district policy/ procedure for colorectal cancer screening.

# THERAPEUTIC

## PHARMACOLOGIC

- 1. May give an over-the-counter (OTC) nonsteroidal antiinflammatory agent 30-60 minutes before the procedure to reduce discomfort.
- 2. If pregnancy test is negative, may insert Mirena into the uterine cavity within 7 days of onset of menstruation. The Mirena releases 20 mcg levonorgestrel/day over 5 years. The Mirena may be removed and replaced with a new unit at anytime during the menstrual cycle. Do not leave any one system in place for greater than 5 years.

## NON-PHARMACOLOGIC MEASURES

 Take precautions to avert a vasovagal reaction (syncope/ fainting) caused by uterine manipulation and sounding. After IUD insertion, allow the **client** to lie still for at least 30 seconds (while explaining how to check for strings). Ask about pain or cramping. If the **client** says she feels okay, have her sit up slowly while being supported. If no problems in 30 seconds, allow her to stand. 2. Treat signs of vasovagal reaction (pallor/cyanosis, pinchedface look, dilated pupils, weak and rapid pulse, rapid shallow breathing, hypotension) according to the Emergency Guidelines, **Policies and Procedures** section of this manual.

## CLIENT EDUCATION/COUNSELING

- 1. Counsel **client** according to seven basic elements of informed consent (BRAIDED Benefits Risks Alternatives Inquiries Decision Explanation Documentation).
- 2. Teach **client** to check for IUD strings.
  - a. The IUD can be expelled without being noticed.
  - b. Check for the strings frequently during the first months, then after each menses and any time there is abnormal cramping while menstruating.
  - c. Inspect tampons on removal for IUD removal.
  - d. If **client** cannot feel the strings, or if the plastic part is felt, use another method of contraception and return to the clinic.
- 3. Review warning signs and symptoms of possible problem: vaginal discharge, abdominal pain, pain with intercourse, missing string, pregnancy symptoms, or heavy bleeding.
- 4. Take over-the-counter ibuprofen or naproxen sodium **per package directions as needed for discomfort.**
- 5. Should consider changing to another contraceptive method if behavior puts client at risk for PID (i.e., multiple partners, partners with multiple partners).
- 6. Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit)
- 7. Use condoms to reduce the risk of STD/HIV.
- 8. Discuss altered menstrual bleeding patterns:
  - a. 1 to 4 months: may have frequent spotting.
  - b. 1 to 6 months: reduced duration and amount of bleeding.
  - c. Overall 90% reduction in menstrual bleeding.
  - d. After 12 months, about 20% of women have no bleeding.
  - e. The **client** should keep a menstrual record and report a sudden change in menses or suspected pregnancy immediately.
  - f. Give **client** copy of Mirena post-insertion instructions.

- 9. The Mirena system reduces dysmenorrhea and leads to a significant reduction in the amount and length of bleeding.
- 10. After the system is removed, menstruation returns within 30 days. Fertility rapidly returns to normal.
- 11. Outside of clinic hours, seek physician or emergency care if warning signs develop.
- 12. As with other progestin-only methods, persistent ovarian follicles can occur. They do not require treatment or removal of the Mirena, and they usually resolve spontaneously. However, regular follow-up by ultrasound is recommended until cysts disappear.
- 13. The Mirena is effective for five years.
- 14. If smoker or tobacco user, refer to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867).
- 15. Emphasize importance of keeping immunizations current; assess client's immunization status and administer vaccines indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If client declines vaccination, document the refusal. See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current **immunization** schedules and administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at <a href="http://www.health.state.ga.us/programs/immunization/publications.asp">http://www.health.state.ga.us/programs/immunization/publications.asp</a>.

## FOLLOW-UP

- 1. Re-examine and evaluate the **client** shortly after the first postinsertion menses, but no later than three months afterwards.
- 2. If evidence of pelvic inflammatory disease, see Nurse Protocol for Pelvic Inflammatory Disease. IUD removal not necessary unless no improvement after 2-3 days of antibiotic treatment.
- 3. If pregnancy occurs, advise **client** IUD should be removed at time of diagnosis whether pregnancy is continued or terminated.

#### CONSULTATION/REFERRAL

1. Difficult IUD insertion or removal.

- 2. Suspected **uterine or** ectopic pregnancy.
- 3. To MD for IUD removal if pregnant.
- 4. Other complications related to IUD use.
- 5. Presence of actinomyces on Pap smear report and evidence of pelvic infection.
- 6. To MD for further evaluation if presence of actinomyces on Pap smear report and client requests insertion/reinsertion of IUD.

## REFERENCES

- 1. Robert Hatcher et al., *Contraceptive Technology,* 19th ed., Ardent Media, Inc., New York, 2007. (Current)
- 2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 9th ed., Springer Publishing Co., New York, 2007. (Current)
- 3. "Mirena (levonorgestrel-releasing intrauterine system)," *Physician Prescribing Information*, Bayer HealthCare Pharmaceuticals, Inc., 2009, <<u>http://berlex.bayerhealthcare.com/html/products/pi/Mirena\_Pl.pdf</u>> (May 16, 2011)
- 4. World Health Organization (WHO), *Medical Eligibility Criteria for Contraceptive Use*, 4<sup>th</sup> ed., 2009,

<<u>http://whqlibdoc.who.int/publications/2010/9789241563888\_eng.pdf</u>> (May 16, 2011)

- 5. "General Screenings and Immunizations for Women," Office on Women's Health, <<u>http://www.womenshealth.gov/prevention/general</u>> (May 16, 2011)
- "Every Woman, Every Time," A Preconception Care Toolkit for Georgia, 2010, <<u>http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm</u>> (May 16, 2011)
- 7. Zieman M, Hatcher RA et al. *A Pocket Guide to Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2010. (Current)
- 8. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," MMWR 2010; 59, <<u>http://www.cdc.gov/mmwr</u>> (June 6, 2011)
- 9. "Lexi-Drugs Online," *Lexi-Comp Database*, Lexi-Comp, Inc., Hudson, Ohio <a href="http://online.lexi.com">http://online.lexi.com</a>> (July 5, 2011)

## STANDARD APRN PROTOCOL FOR LOST IUD STRINGS

- DEFINITION Inability to visibly locate IUD (intrauterine device) strings or inability to feel the IUD strings.
- **ETIOLOGY** Lost IUD strings may be the result of expulsion of the IUD, retraction of the strings into the uterine cavity, perforation of the IUD through the cervix or uterine wall, or use of an IUD (from another country) that never had a string attached. In some rare instances, clinicians have intentionally cut strings off or cut the strings short.
- **SUBJECTIVE** Client may report that she cannot feel IUD strings on self-exam.
- **OBJECTIVE** No IUD strings visible upon careful examination of the vagina and cervical opening, and inability to feel the strings.
- **ASSESSMENT** IUD strings not visible.

#### PLAN DIAGNOSTIC STUDIES

Sensitive urine pregnancy test (HCG).

#### THERAPEUTIC

- 1. If pregnancy test is positive, immediately refer client to physician.
- 2. If pregnancy is ruled out by HCG and exam:
  - a. Prepare cervix as with insertion.
  - Gently rotate cytobrush inside cervical canal to snag IUD string. If unsuccessful, attempt to retrieve the IUD string using curved forceps, alligator forceps, or IUD retriever. Use tenaculum if necessary to steady the cervix.
    - If strings located and **client** wants removal, remove the IUD with gentle, steady traction. Provide another method of contraception if appropriate.
    - 2) If dislodgement or abnormal placement suspected, remove IUD. Provide alternative contraceptive methods.
    - 3) Consider giving doxycycline 100 mg bid for 7-10 days if aggressive probing for string retrieval or IUD removal difficult.

- 3. If unsuccessful in locating strings:
  - a. Refer for pelvic ultrasound or if necessary, abdominal x-rays.
  - b. If the IUD is identified as properly positioned in the uterus, no action is necessary; reassure the **client.**
  - c. If ultrasound identifies the IUD, but unable to identify in uterus, refer to MD. Advise alternative method of contraception.

# CLIENT EDUCATION/COUNSELING

- 1. If the IUD is removed, advise the **client** to use another method of contraception.
- 2. Check for IUD strings after each menstrual period.
- 3. If smoker or tobacco user, refer to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867).

## FOLLOW-UP

Return to clinic as needed for contraception or yearly exam.

## CONSULTATION/REFERRAL

- 1. Immediately refer client to physician, if pregnancy test is positive.
- 2. Consult with a physician for any questions regarding management (see APRN Protocol for IUD Removal).

## REFERENCES

- 1. Robert Hatcher et al., *Contraceptive Technology,* 19th ed., Ardent Media, Inc., New York, 2007. (Current)
- 2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 9th ed., Springer Publishing Co., New York, 2007. (Current)
- 3. Leon Speroff and Phillip Darney, A Clinical Guide for Contraception, 5<sup>th</sup> ed., Lippincott, Williams and Wilkins, Baltimore, MD, **2010.** (Current)

#### STANDARD APRN PROTOCOL FOR IUD REMOVAL/COMPLICATIONS AND ACTIONS

- **DEFINITION** Removal of an IUD by the clinician at the **client's** request, due to clinical findings such as pregnancy, infection or partial expulsion, or per recommended time frame for the device. It is important to comply with a woman's wishes if she wants to have her IUD removed.
- **SUBJECTIVE** 1. **Client** may request IUD removal for any reason.
  - 2. **Client** may report a condition that precludes IUD use, such as suspected or confirmed pregnancy, or no longer in a stable, mutually monogamous relationship.
  - 3. **Client** may complain of dysmenorrhea, dyspareunia, menorrhagia, aching, abdominal pains, and tenderness on ambulation, malaise, and chills/fever.
  - 4. History of use of the Copper T380A for 10 years or Mirena for 5 years.
- **OBJECTIVE** May have findings on pelvic exam or laboratory tests that require IUD removal such as: partial expulsion, enlargement of uterus, positive pregnancy test, other pelvic infection/disease.
- **ASSESSMENT** Indications for removal of IUD.

#### PLAN DIAGNOSTIC STUDIES

If indicated:

- 1. Sensitive urine pregnancy test.
- 2. Wet mount of vaginal secretions.
- 3. Gonorrhea and chlamydia tests.

**THERAPEUTIC** (by APRN or MD)

**NOTE:** Easier removal may be possible at the time of menses or at midcycle.

1. If **client** is not pregnant, remove IUD slowly, applying gentle, steady traction to string with sponge forceps.

- 2. If **client** is not pregnant and the IUD cannot be removed with gentle traction, use a tenaculum to steady the cervix and straighten the anteversion or retroversion.
- 3. If the **client** is not pregnant and the strings are not visible, probe for them in the cervical canal with a cytobrush or cotton tipped applicator, narrow (e.g., alligator-type) forceps or IUD retriever. See Nurse Protocol for Lost IUD Strings.
- 4. If client is pregnant, client should be counseled on the possibility of disruption of pregnancy and miscarriage with removal of IUD, risk and benefits. After counseling, refer client to physician for removal of IUD.

## **CLIENT EDUCATION/COUNSELING**

- 1. Choose a non-hormonal method of contraception for two menstrual cycles if the **client** desires pregnancy or any method if the **client** does not desire pregnancy.
- 2. Delay pregnancy for 2-3 months, to allow uterus to regain normal endometrium.
- 3. There are no known major long-term side effects after removal of an IUD.
- 4. In pregnant **client**, advise her that she is at increased risk of preterm labor and spontaneous abortion if IUD is left in place. However, reassure her that the fetus is not at increased risk for birth defects with IUD in place. Advise **client** that at time of removal she is also at risk for spontaneous abortion, although spontaneous abortion risk is less with removal than if IUD were left in place.

# 5. Provide counseling on preconception health counseling and future fertility. (Refer to PCH Toolkit)

- 6. If smoker or tobacco user, refer to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867).
- 7. Emphasize importance of keeping immunizations current; assess client's immunization status and administer vaccines indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If client declines vaccination, document refusal. See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current **immunization** schedules and

administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at <u>http://www.health.state.ga.us/programs/immunization/publications.asp</u>.

### FOLLOW-UP

Return to clinic as needed, for contraception or yearly exam.

#### **CONSULTATION/REFERRAL**

Refer or consult with physician if:

- 1. Difficult/failed removal.
- 2. Successful removal, **client** pregnant.
- 3. Unable to visualize and/or probe for strings.

#### TABLE OF IUD COMPLICATIONS AND ACTIONS

	CONDITION	ACTION
1.	Pain from tenaculum application to the cervix.	<ol> <li>May consider application of topical anesthesia such as Lidocaine gel, etc.</li> </ol>
2.	Pain with sounding of the uterus during insertion.	<ol> <li>Sound slowly and gently consider smaller sound. If severe, check alignment of uterine cavity.</li> </ol>
3.	Cramping/pain immediately after insertion, for a day or so thereafter, or with each menses: a. if severe b. if mild	3. a. Consider IUD removal by APRN b. See Nurse Protocol IUD Related Dysmenorrhea
4.	<ul><li>Pain at time of insertion, persistent and increasing, and signs of abdominal tenderness:</li><li>a. if strings are present</li><li>b. if strings are absent</li></ul>	<ul><li>4.</li><li>a. Presume partial perforation has occurred; remove IUD and treat for pelvic infection.</li><li>b. Consider possibility of perforation. Refer client to physician.</li></ul>
5.	Partial expulsion of an IUD	5. Remove IUD. Pregnancy test as indicated.
6.	Pelvic inflammatory disease	<ol> <li>See Nurse Protocol for Pelvic Inflammatory Disease.</li> </ol>
7.	Spontaneous abortion	7. Refer to physician.
8.	Uterine Pregnancy or Ectopic pregnancy	8. Refer to physician.

#### REFERENCES

- 1. Robert Hatcher et al., *Contraceptive Technology,* 19th ed., Ardent Media, Inc., New York, 2007. (Current)
- 2. Leon Speroff and Phillip Darney, A Clinical Guide for Contraception, 5<sup>th</sup> ed., Lippincott Williams and Wilkins, Baltimore, **2010. (Current)**
- 3. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 9th ed., Springer Publishing Co., New York, 2007. (Current)
- 4. *"Every Woman, Every Time," A Preconception Care Toolkit for Georgia*, 2010, <<u>http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm</u>> (May 16, 2011)

# APPENDIX A

Contraceptiv	es
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	Contraceptives											
Monophasic Oral Contraceptives												
Name	Cycle Count	Progestin	mg	Estrogen	mcg	Same Formula						
Necon 1/50M	28 Pills	Norethindrone	1	Mestranol	50	Norinyl 1/50, Ortho-Novum 1/50						
Norinyl 1/50	28 Pills	Norethindrone	1	Mestranol	50	Ortho Novum, Necon 1/50,						
Zovia 1/50	28 Pills	Ethy. Diacetate	1	E.estradiol	50	None						
Ogestrel	28 Pills	Norgestrel	0.5	E.estradiol	50	None						
Ovcon 50	28 Pills	Norethindrone	1	E.estradiol	50	None						

#### Monophasic Oral Contraceptives (Low Dose)

Name	Cycle Count	Progestin	mg	Estrogen	mcg	Same Formula
Zovia 1/35	28 Pills	Ethy. Diacetate	1	E.estradiol	35	Kelnor
Kelnor 1/35	28 Pills	Ethy. Diacetate	1	E.estradiol	35	Zovia
Necon 1/35	28 Pills	Norethindrone	1	E.estradiol	35	Ortho Novum 1/35, Norinyl 1/35, Nortrel 1/35
Norinyl 1/35	28 Pills	Norethindrone	1	E.estradiol	35	Necon 1/35, Norinyl 1/35, Ortho-Novum 1/35
Nortrel 1/35	21 Pills	Norethindrone	1	E.estradiol	35	Ortho Novum 1/35, Necon 1/35, Norinyl 1/35
Nortrel 1/35	28 Pills	Norethindrone	1	E.estradiol	35	Ortho Novum 1/35, Necon 1/35, Norinyl 1/35
Ortho-Novum 1/35	28 Pills	Norethindrone	1	E.estradiol	35	Necon 1/35, Norinyl 1/35, Nortrel 1/35
Brevicon 0.5/35	28 Pills	Norethindrone	0.5	E.estradiol	35	Modican, Necon .5/35, Nortrel .5/35
Modicon 0.5/35	28 Pills	Norethindrone	0.5	E.estradiol	35	Brevicon, Necon 0.5/35, Nortrel .5/35
Necon 0.5/35	28 Pills	Norethindrone	0.5	E.estradiol	35	Brevicon, Modicon, Nortrel .5/35
Nortrel 0.5/35	28 Pills	Norethindrone	0.5	E.estradiol	35	Brevicon, Modicon, Necon .5/35
ZenChent 52544-0953-28	28 Pills	Norethindrone	0.4	E.estradiol	35	Ovcon 35, Balziva
Balziva	28 Pills	Norethindrone	0.4	E.estradiol	35	Ovcon 35, Zenchent
Ovcon 35	28 Pills	Norethindrone	0.4	E.estradiol	35	ZenChent, Balziva
Mono Nessa	28 Pills	Norgestimate	0.25	E.estradiol	35	Ortho-Cyclen, Sprintec, Previfem
Ortho-Cyclen	28 Pills	Norgestimate	0.25	E.estradiol	35	Mono Nessa, Sprintec, Previfem
Ortho-Cyclen	29 Pills	Norgestimate	0.25	E.estradiol	35	Mono Nessa, Sprintec, Previfem
Previfem	28 Pills	Norgestimate	0.25	E.estradiol	35	Mono Nessa, Ortho-Cyclen, Sprintec
Sprintec	28 Pills	Norgestimate	0.25	E.estradiol	35	Mono Nessa, Ortho-Cyclen, Previfem
Apri28	28 Pills	Desogestrel	0.15	E.estradiol	30	Desogen, Ortho-Cept, Reclipsen, Solia
Desogen	28 Pills	Desogestrel	0.15	E.estradiol	30	Apri, Ortho-Cept, Reclipsen, Solia
Ortho-Cept	28 Pills	Desogestrel	0.15	E.estradiol	30	Apri, Desogen, Reclipsen, Solia
Reclipsen	28 Pills	Desogestrel	0.15	E.estradiol	30	Desogen, Ortho-Cept, Apri, Solia
Solia	28 Pills	Desogestrel	0.15	E.estradiol	30	Desogen, Ortho-Cept, Apri, Reclipsen
Yasmin	28 Pills	Drospirenone	3	E.estradiol	30	Ocella, Zarah
Zarah	28 Pills	Drospirenone	3	E.estradiol	30	Ocella, Yasmin
Ocella	28 Pills	Drospirenone	3	E.estradiol	30	Yasmin, Zarah
Levora	28 Pills	Levonorgestrel	0.15	E.estradiol	30	Portia, Levlen, Nordette
Nordette	28 Pills	Levonorgestrel	0.15	E.estradiol	30	Portia, Levora, Levlen
Portia-28	28 Pills	Levonorgestrel	0.15	E.estradiol	30	Levlen, Levora, Nordette
Junel 1.5/30	21 Pills	Nor. Acetate	1.5	E.estradiol	30	Microgestin 1.5/30, Loestrin 1.5/30
Loestrin 1.5/30	21 Pills	Nor. Acetate	1.5	E.estradiol	30	Microgestin 1.5/30, Junel 1.5/30
Microgestin 1.5/30	21 Pills	Nor. Acetate	1.5	E.estradiol	30	Loestrin 1.5/30, Junel 1.5/30
Junel Fe 1.5/30	28 Pills	Nor. Acetate	1.5	E.estradiol	30	Loestrin Fe 1.5/30, Microgestin Fe 1.5/30
Loestrin Fe 1.5/30	28 Pills	Nor. Acetate	1.5	E.estradiol	30	Microgestin 1.5/30, Junel Fe 1.5/30
Microgestin Fe 1.5/30	28 Pills	Nor. Acetate	1.5	E.estradiol	30	Loestrin Fe 1.5/30, Junel Fe 1.5/30
Cryselle	28 Pills	Norgestrel	0.3	E.estradiol	30	Lo/Ovral, Low-Ogestrel
Lo/Ovral	28 Pills	Norgestrel	0.3	E.estradiol	30	Cryselle, Low-Ogestrel
Low-Ogestrel	28 Pills	Norgestrel	0.3	E.estradiol	30	Cryselle, Lo/Ovral
Generess FE 0.8/25 mcg Chewable w/Iron	28 Pills	Norethindrone	0.8	E.estradiol	25	Ovcon FE
Zeosa FE 0.4mg/35mg Chewable w/Iron	28 Pills	Norethindrone	0.4	E.estradiol	35	Ovcon FE
Femcon FE 0.4mg/35mg Chewable w/Iron	28 Pills	Norethindrone	0.4	E.estradiol	35	Ovcon FE

#### Monophasic Oral Contraceptives (Ultra-Low Dose)

Name	Cycle Count	Progestin	mg	Estrogen	mcg	Same Formula
Aviane-28	28 Pills	Levonorgestrel	0.1	E.estradiol	20	Levlite, Lessina, Lutera, Sronyx
Lessina-28	28 Pills	Levonorgestrel	0.1	E.estradiol	20	Levlite, Aviane, Lutera, Sronyx
Lutera-28	28 Pills	Levonorgestrel	0.1	E.estradiol	20	Aviane, Lessina, Levlite, Sronyx
Sronyx	28 Pills	Levonorgestrel	0.1	E.estradiol	20	Aviane, Lessina, Levlite, Lutera
Junel Fe 1/20	28 Pills	Nor. Acetate	1	E.estradiol	20	Loestrin Fe 1/20, Microgestin Fe 1/20
Mircrogestin Fe 1/20	28 Pills	Nor. Acetate	1	E.estradiol	20	Junel Fe, Loestrin Fe 1/20
Junel 1/20	21 Pills	Nor. Acetate	1	E.estradiol	20	Loestrin 1/20, Microgestin 1/20
Loestrin 1/20	21 Pills	Nor. Acetate	1	E.estradiol	20	Junel 1/20, Microgestin 1/20
Microgestin 1/20	21 Pills	Nor. Acetate	1	E.estradiol	20	Loestrin 1/20, Junel 1/20

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#### Contraceptives

Biphasic Oral Contracept	iphasic Oral Contraceptives											
	Cycle											
Name	Count	Progestin	mg	Estrogen	mcg	Same Formula						
Kariva	28 Pills	Desogestrel	0.15/ 0.0	E.estradiol	20/10	Mircette, Azurette						
Azurette	28 Pills	Desogestrel	0.15/ 0.0	E.estradiol	20/10	Mircette, Kariva						
Mircette	28 Pills	Desogestrel	0.15/ 0.0	E.estradiol	20/10	Kariva, Azurette						
Necon 10/11	28 Pills	Norethindrone	0.5/1.0	E.estradiol	35	None						

#### **Multiphasic Oral Contraceptives**

	Cycle					
Name	Count	Progestin	mg	Estrogen	mcg	Same Formula
Estrostep FE	28 Pills	Nor. Acetate	1	E.estradiol	20/30/35	Tilia, Tri-Legest
Tilia FE 3/ 7/ 9/ 7	28 Pills	Nor. Acetate	1	E.estradiol	20/30/35	Estrostep FE, Tri-Legest
Tri-Legest FE	28 Pills	Nor. Acetate	1	E.estradiol	20/30/35	Estrostep FE, Tilia
Cesia	28 Pills	Desogestrel	0.1/0.125/0.15	E.estradiol	25	Cyclessa, Velivet, Caziant
Caziant	28 Pills	Desogestrel	0.1/0.125/0.15	E.estradiol	25	Velivet, Cesia, Cyclessa
Cyclessa	28 Pills	Desogestrel	0.1/0.125/0.15	E.estradiol	25	Velivet, Cesia, Caziant
Velivet	28 Pills	Desogestrel	0.1/0.125/0.15	E.estradiol	25	Cyclessa, Cesia, Caziant
Enpresse-28 6/5/10	28 Pills	Levonorgestrel	0.05/0.075/0.125	E.estradiol	30	Trivora
Trivora-28 6/5/10	28 Pills	Levonorgestrel	0.05/0.075/0.125	E.estradiol	30	Empresse
Necon 7/7/7	28 Pills	Norethindrone	0.5/0.75/1.0	E.estradiol	35	Ortho-Novum 7/7/7, Nortrel 7/7/7
Nortrel 7/7/7	28 Pills	Norethindrone	0.5/0.75/1.0	E.estradiol	35	Ortho-Novum 7/7/7, Necon 7/7/7
Ortho-Novum 7/7/7	28 Pills	Norethindrone	0.5/0.75/1.0	E.estradiol	37	Nortrel 7/7/7, Necon 7/7/7
Aranelle 7/9/5	28 Pills	Norethindrone	0.5/1.0/0.5	E.estradiol	35	Leena, Tri-Norinyl
Leena 7/9/5	28 Pills	Norethindrone	0.5/1.0/0.5	E.estradiol	35	Aranelle, Tri-Norinyl
Tri-Norinyl 7/9/5	28 Pills	Norethindrone	0.5/1.0/0.5	E.estradiol	35	Aranelle, Leena
Ortho Tri-Cyclen Lo	28 Pills	Norgestimate	0.18/0.215/0.25	E.estradiol	25	Tri-Lo Sprintec
Ortho Tri-Cyclen Lo	28 Pills	Norgestimate	0.18/0.215/0.25	E.estradiol	25	Tri-Lo Sprintec
Tri-Lo Sprintec	28 Pills	Norgestimate	0.18/0.215/0.25	E.estradiol	25	Tri-Cyclen Lo
Ortho Tri-Cyclen	28 Pills	Norgestimate	0.18/0.215/0.25	E.estradiol	35	Tri-Sprintec, Tri-Nessa, Tri-Previfem
Tri-Nessa	28 Pills	Norgestimate	0.18/0.215/0.25	E.estradiol	35	Ortho Tri-Cyclen, Tri-Sprintec, Tri-Previfem
Tri-Previfem	28 Pills	Norgestimate	0.18/0.215/0.25	E.estradiol	35	Ortho Tri-Cyclen, Tri-Sprintec, Tri-Nessa
Tri-Sprintec	28 Pills	Norgestimate	0.18/0.215/0.25	E.estradiol	35	Ortho Tri Cyclen, Tri-Nessa, Tri-Previfem

#### **Quadphasic Oral Contraceptives**

	Cycle					
Name	Count	Progestin	mg	Estrogen	mcg	Same Formula
Natazia	28 Pills	Dienogest	2 and 3	<b>Estradial Valerate</b>	1, 2, and 3	None

#### Extended Cycle Contraceptives

	Cycle					
Name	Count	Progestin	mg	Estrogen	mcg	Same Formula
Jolessa	91 Pills	Levonorgestrel	0.15	E.estradiol	30	Seasonale, Quasense
Quasense	91 Pills	Levonorgestrel	0.15	E.estradiol	30	Seasonale, Jolessa
Seasonale	91 Pills	Levonorgestrel	0.15	E.estradiol	30	Jolessa, Quasense
Seasonique	91 Pills	Levonorgestrel	0.15	E.estradiol	30	None
Lo Seasonique	91 Pills	Levonorgestrel	0.1-0.02	E.estradiol	30	None
Loestrin 24	28 Pills	Nor. Acetate	1.0 (+75mg FF)	E.estradiol	20	None
Yaz	28 Pills	Drospirenone	3	E.estradiol	20	None
Lybrel 90mcg	28 Pills	Levonorgestrel	0.9	E.estradiol	20	None

#### **Progestin Only Contraceptives**

Name	Cycle Count	Dragatin		Fotrogen		Same Formula
Name	Count	Progestin	mg	Estrogen	mcg	Same Formula
Camila	28 Pills	Norethindrone	0.35	None		Micronor, Nor QD, Errin, Jolivette, Nora-BE
Errin	28 Pills	Norethindrone	0.35	None		Nor-QD, Camila, Micronor, Jolivette, Nora-BE
Jolivette	28 Pills	Norethindrone	0.35	None		Nor-QD, Camila, Micronor, Errin, Nora-BE
Ortho-Micronor	28 Pills	Norethindrone	0.35	None		Nor-QD, Camila, Errin, Jolivette, Nora-BE
Nor-QD	28 Pills	Norethindrone	0.35	None		Micronor, Camila, Errin, Jolivette, Nora-BE
Nora-BE	28 Pills	Norethindrone	0.35	None		Nor-QD, Camila, Errin, Jolivette, Micronor

#### Vaginal Ring Contraceptives

Name	Cycle Count	Progestin	mg	Estrogen	mcg	Same Formula
NuvaRing	3 Rings	Etonogestrel	0.12/day	E.estradiol	0.015/day	None

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njectable DMPA Contraceptives	Contracep	11763				
lame	PKG Count	Progestin	mg	Estrogen	mcg	Same Formula
ledroxyprogesterone / Depo-Provera	1	Progesterone	150	None		Depo-Provera
ransdermal (patch) Contraceptives						
lame	Cycle Count	Progestin	mg	Estrogen	mcg	Same Formula
Ortho Evra	1 Week	Norelgestromin	0.15/day	E.estradiol	0.02/day	None
ntrauterine (IUD) Contraceptives						
		Method of				
lame	Count	Delivery	mg	Estrogen	mcg	Same Formula
Paragard T 380A Intrauterine Copper Device - 10 year device	1	Spermicide			00/1	None
/lirena IUS DS - 5 year device	1	Levonorgestrel			20/day	None
mplant Contraceptives	1					,
law a	Count	Method of		Fatragen		Same Formula
lame	Count	Delivery	<b>mg</b> 68	Estrogen	mcg	None
nplanon	I	Etonogestrel	00			None
mergency Contraceptives lame		Progestin			men	Same Formula
	Cycle Count		<b>mg</b> 0.75	Estrogen	mcg	NextChoice
lan B One-Step EXT CHOICE™	2 Pills	Levonorgestrel	0.75	None None		Plan B
IIIa ULIPRISTAL ACETATE 30 MG	1 Pill	Levonorgestrel	30	None		None
			00	NONE		
permicidals - Foam, Film, Gels, Suppositories	Method of				Same	1
ame	Delivery	mg	Estrogen	mcg	Formula	
CF Vaginal Contraceptive Foam	Nonoxynol-9		- gen	-3	Delfen	1
CF Vaginal Contraceptive Film	Nonoxynol-9				None	
elfen Contraceptive Foam w/applicator	Nonoxynol-9				VCF	1
arriers - Diaphragms/ Caps / Condoms						-
	Method of					
ame	Delivery	mg	Estrogen	mcg	Mfr	Same Formul
IAPHRAGM COILSPRING 100MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
IAPHRAGM COILSPRING 105MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
APHRAGM COILSPRING 50MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM COILSPRING 55MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM COILSPRING 60MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM COILSPRING 65MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM COILSPRING 70MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM COILSPRING 75MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM COILSPRING 80MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM COILSPRING 85MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
NAPHRAGM COILSPRING 90MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM COILSPRING 95MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
IAPHRAGM FLATSPRING 55MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
NAPHRAGM FLATSPRING 60MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
IAPHRAGM FLATSPRING 65MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
IAPHRAGM FLATSPRING 70MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
IAPHRAGM FLATSPRING 75MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
IAPHRAGM FLATSPRING 80MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
IAPHRAGM FLATSPRING 85MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
NAPHRAGM FLATSPRING 90MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
IAPHRAGM FLATSPRING 95MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
RTHO ALL-FLEX DIAPHRAGM 65M LATEX-FREE	Non-Systemic				Ortho	None
RTHO ALL-FLEX DIAPHRAGM 70M LATEX-FREE	Non-Systemic				Ortho	None
RTHO ALL-FLEX DIAPHRAGM 75M LATEX-FREE	Non-Systemic				Ortho	None
RTHO ALL-FLEX DIAPHRAGM 80M LATEX-FREE	Non-Systemic				Ortho	None
	Non-Systemic				Ortho	None
RTHO ALL-FLEX FITTING SET					Ortho	None
RTHO ALL-FLEX FITTING SET RTHO-DIAPHRAGM ALLFLEX 55MM W/ORTHO-GYNOL	Non-Systemic					
RTHO ALL-FLEX FITTING SET RTHO-DIAPHRAGM ALLFLEX 55MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 60MM W/ORTHO-GYNOL	Non-Systemic Non-Systemic				Ortho	None
RTHO ALL-FLEX FITTING SET RTHO-DIAPHRAGM ALLFLEX 55MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 60MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 65MM W/ORTHO-GYNOL	Non-Systemic Non-Systemic Non-Systemic				Ortho	None
RTHO ALL-FLEX FITTING SET RTHO-DIAPHRAGM ALLFLEX 55MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 60MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 65MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 70MM W/ORTHO-GYNOL	Non-SystemicNon-SystemicNon-SystemicNon-Systemic				Ortho Ortho	None None
RTHO ALL-FLEX FITTING SET RTHO-DIAPHRAGM ALLFLEX 55MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 60MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 65MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 70MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 75MM W/ORTHO-GYNOL	Non-Systemic Non-Systemic Non-Systemic Non-Systemic Non-Systemic				Ortho Ortho Ortho	None None None
RTHO ALL-FLEX FITTING SET RTHO-DIAPHRAGM ALLFLEX 55MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 60MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 65MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 70MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 75MM W/ORTHO-GYNOL RTHO-DIAPHRAGM ALLFLEX 80MM W/ORTHO-GYNOL	Non-Systemic Non-Systemic Non-Systemic Non-Systemic Non-Systemic Non-Systemic				Ortho Ortho Ortho Ortho	None None None None
ORTHO ALL-FLEX FITTING SET ORTHO-DIAPHRAGM ALLFLEX 55MM W/ORTHO-GYNOL ORTHO-DIAPHRAGM ALLFLEX 60MM W/ORTHO-GYNOL ORTHO-DIAPHRAGM ALLFLEX 65MM W/ORTHO-GYNOL ORTHO-DIAPHRAGM ALLFLEX 70MM W/ORTHO-GYNOL ORTHO-DIAPHRAGM ALLFLEX 80MM W/ORTHO-GYNOL ORTHO-DIAPHRAGM ALLFLEX 85MM W/ORTHO-GYNOL ORTHO-DIAPHRAGM ALLFLEX 85MM W/ORTHO-GYNOL ORTHO-DIAPHRAGM ALLFLEX 80MM W/ORTHO-GYNOL	Non-Systemic Non-Systemic Non-Systemic Non-Systemic Non-Systemic				Ortho Ortho Ortho	None None None

Department of Public Health, Office of Pharmacy, September 14, 2011