
**STANDARD
NURSE PROTOCOLS
FOR
WOMEN'S HEALTH**

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2014 WOMEN'S HEALTH CLINICAL REVIEW TEAM

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Women's Health Standard Nurse Protocol Approval

In regards to family planning, districts can recommend modifications and/or request adding new protocols to the approved DPH Standard Nurse Protocols for Women's Health by submitting those recommendations and/or requests to the Family Planning program. All recommendations and/or requests must be submitted by the District Health Director (DHD) and/or the district's contracted medical consultant. All modifications made by the District should be submitted to the Family Planning program for review and consultation with the Family Planning Medical Consultant and Public Health Team (an OB/GYN, a DHD, and representatives from laboratory, pharmacy, nursing and legal units) within 30 days post submission of the protocol. Recommendations by the Family Planning Medical Consultant and Public Health Team are based on evidence-based medical practices and alignment with Title X Guidelines and Regulations. All reviewed modified and/or new protocols accepted by the Family Planning Medical Consultant and Public Health Team will be incorporated into the state nursing protocols and considered for implementation statewide if the revision is relevant to all districts.

If the District Health Director and/or district's contracted medical consultant chooses to not implement a particular protocol (in its entirety or specific components of a particular protocol) based on their professional opinion (e.g., situations where the physician is not comfortable with the skill level of the individual nurse) the District Health Director must notify the Georgia Family Planning Program immediately to consult directly with the Family Planning Consultant and Public Health Team to assess the potential Title X implications and adherence to standard medical practices.

The district will not be cited with a deficiency by a program review for using a modified protocol or for using protocols different from those in the approved manual as long as the modified protocol has been submitted, reviewed and accepted by the Family Planning Medical Consultant and Public Health Team or if the modified protocol is in the review process.

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CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) US MEDICAL ELIGIBILITY CRITERIA (MEC) AND SELECTED PRACTICE RECOMMENDATIONS (SPR) FOR CONTRACEPTIVE USE

The CDC US Medical Eligibility Criteria and Selected Practice Recommendations for Contraception Use reflect adaptations of the WHO MEC and SPR to ensure appropriateness for use in the United States. Most of the U.S. guidance does not differ from the WHO guidance. However, several changes have been made, including adaptations of selected WHO recommendations, addition of recommendations for new medical conditions, and removal of recommendations for contraceptive methods not currently available in the United States. Used together, the MEC and SPR should guide clinicians in providing evidence-based contraceptive care in the United States.

The MEC contains recommendations for health-care providers for the safe use of contraceptive methods by women and men with various characteristics and medical conditions. It is intended to assist health-care providers when they counsel women, men, and couples about contraceptive method choice. These recommendations are meant to be a source of clinical guidance; health-care providers should always consider the individual clinical circumstances of each person seeking family planning services.

The SPR contains recommendations which are intended to help health-care providers address issues related to use of contraceptives, such as how to help a woman initiate use of a contraceptive method, which examinations and tests are needed before initiating use of a contraceptive method, what regular follow-up is needed, and how to address problems that often arise during use, including missed pills and side effects such as unscheduled bleeding.

CDC US Medical Eligibility Criteria for Contraceptive Use

The *CDC US Medical Eligibility Criteria for Contraceptive Use, 2010* is available at <http://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf>

This full report provides vital information, not only about what the recommendation is, but also why. Providers should be aware that this guidance is continually updated in response to emerging evidence. For updates, refer to the CDC's website <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm>

Additional resources including iphone/ipad apps, wall charts, wheels and guidance in Spanish can be accessed at that site. Local Title X clinics should make copies of the CDC Medical Eligibility Criteria available to all clinic staff and should encourage its use with each contraceptive clinical encounter

TYPE OF CONTRACEPTIVE		
CONDITION	CATEGORY I=Initiation C=Continuation	CLARIFICATIONS/ EVIDENCE
Condition	Condition classified from 1 to 4 The categories for fertility awareness-based methods and surgical sterilization are described at the beginning of the relevant section.	Clarifications and evidence regarding the classification

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

I=Initiation. This provides guidance for initiating a contraceptive method given the presence of a particular medical condition at the time of initiation.

C=Continuation. This provides guidance about whether to continue a contraceptive method if a particular medical condition has been diagnosed since starting that method of contraception. To illustrate this with an example: **Migraines without aura age 35 or less.** Initiating combined hormonal contraception use in someone with this situation is MEC Category 2. This should be interpreted that it is acceptable to start using a combined hormonal method with this condition. However, for someone age 35 or less who had not previously had migraines without aura, who started to have them while on combined hormonal contraception, continuing the method is MEC Category 3, and one should obtain consultation with an MD.

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. Patient 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 used by the CDC MEC:

COC – Combined oral contraceptive

P/R – Patch/Ring

POP – Progestin-only pill

DMPA – Depot medroxyprogesterone acetate

Implants – Implanon & Nexplanon

Cu IUD – Copper IUD (ParaGard)

LNG IUD – Levonorgestrel IUD (Mirena & Skyla)

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. **District level conditions are often consistent with community-based services and thus the two-tier approach listed in the following table is recommended. Provision of a contraceptive to a woman with a condition that falls into category 3 (for initiation or continuation) should be done only after consultation with the delegating MD.**

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	

The CDC US MEC also highlights the importance of selecting contraceptive methods that have higher efficacy at preventing pregnancy. The following table (Table 1) lists the perfect and typical use failure rates of common contraceptives, as well as the continuation rates at one year. Providers should become familiar with the typical use failure rates, as those are the rates that are experienced by most patients. The CDC US MEC also created a list of conditions that are associated with an increased risk of adverse events in the event of unintended pregnancy (Box 2). For women with

conditions that may make unintended pregnancy an unacceptable health risk, long-acting, highly effective contraceptive methods may be the best choice (Table 1). Women with these conditions should be advised that sole use of barrier methods for contraception and behavior-based methods of contraception may not be the most appropriate choice because of their relatively higher typical-use rates of failure (Table 1).

TABLE 1. Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception and the percentage continuing use at the end of the first year — United States

Method	Women experiencing an unintended pregnancy within the first year of use		Women continuing use at 1 year [§]
	Typical use [*]	Perfect use [†]	
No method [¶]	85%	85%	
Spermicides ^{**}	29%	18%	42%
Withdrawal	27%	4%	43%
Fertility awareness–based methods	25%		51%
Standard Days method ^{††}		5%	
TwoDay method ^{†††}		4%	
Ovulation method ^{††}		3%	
Sponge			
Parous women	32%	20%	46%
Nulliparous women	16%	9%	57%
Diaphragm ^{§§}	16%	6%	57%
Condom ^{¶¶}			
Female (Reality [®])	21%	5%	49%
Male	15%	2%	53%
Combined pill and progestin-only pill	8%	0.3%	68%
Evra patch [®]	8%	0.3%	68%
NuvaRing [®]	8%	0.3%	68%
Depo-Provera [®]	3%	0.3%	56%
Intrauterine device			
ParaGard [®] (copper T)	0.8%	0.6%	78%
Mirena [®] (LNG-IUS)	0.2%	0.2%	80%
Implanon [®]	0.05%	0.05%	84%
Female sterilization	0.5%	0.5%	100%
Male sterilization	0.15%	0.10%	100%
Emergency contraceptive pills ^{***}	Not applicable	Not applicable	Not applicable
Lactational amenorrhea methods ^{†††}	Not applicable	Not applicable	Not applicable

Adapted from Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. Contraceptive technology. 19th revised ed. New York, NY: Ardent Media; 2007.

^{*} Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an unintended pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides, withdrawal, fertility awareness-based methods, the diaphragm, the male condom, the pill, and Depo-Provera are taken from the 1995 National Survey of Family Growth corrected for underreporting of abortion; see the text for the derivation of estimates for the other methods.

[†] Among couples who initiate use of a method (not necessarily for the first time) and who use it *perfectly* (both consistently and correctly), the percentage who experience an unintended pregnancy during the first year if they do not stop use for any other reason. See the text for the derivation of the estimate for each method.

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

[¶] The percentages becoming pregnant in the typical use and perfect use columns are based on data from populations where contraception is not used and from women who cease using contraception to become pregnant. Of these, approximately 89% become pregnant within 1 year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether.

^{**} Foams, creams, gels, vaginal suppositories, and vaginal film.

^{††} The TwoDay and Ovulation methods are based on evaluation of cervical mucus. The Standard Days method avoids intercourse on cycle days 8–19.

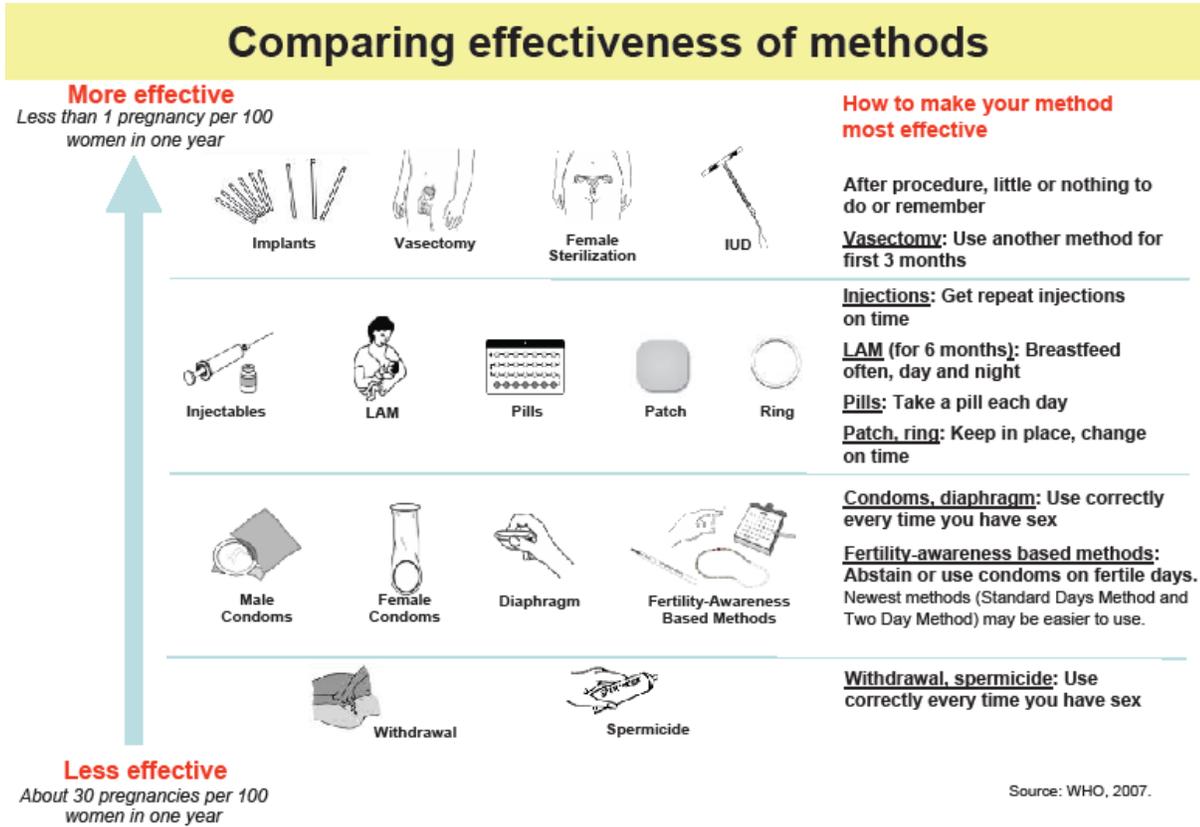
^{§§} With spermicidal cream or jelly.

^{¶¶} Without spermicides.

^{***} Treatment initiated within 72 hours after unprotected intercourse reduces the risk for pregnancy by at least 75%. The treatment schedule is 1 dose within 120 hours after unprotected intercourse and a second dose 12 hours after the first dose. Both doses of Plan B can be taken at the same time. Plan B (1 dose is 1 white pill) is the only dedicated product specifically marketed for emergency contraception. The Food and Drug Administration has in addition declared the following 22 brands of oral contraceptives to be safe and effective for emergency contraception: Ogestrel or Ovral (1 dose is 2 white pills); Levlen or Nordette (1 dose is 4 light-orange pills); Cryselle, Levora, Low-Ogestrel, Lo/Ovral, or Quasence (1 dose is 4 white pills); Tri-Levlen or Triphasil (1 dose is 4 yellow pills); Jolessa, Portia, Seasonale, or Trivora (1 dose is 4 pink pills); Seasonique (1 dose is 4 light blue-green pills); Empresse (1 dose is 4 orange pills); Alesse, Lessina, or Levlite (1 dose is 5 pink pills); Aviane (1 dose is 5 orange pills); and Lutera (1 dose is 5 white pills).

^{†††} Lactational amenorrhea method is a highly effective *temporary* method of contraception. However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeding is reduced, bottle feeds are introduced, or the baby reaches 6 months of age.

Some providers may find the following graphic useful in interpreting the above efficacy data and in counseling patients. In general, provider counseling should follow a hierarchical approach, encouraging the patient to use the most effective contraceptive for which she is eligible and finds acceptable.



BOX 2. Conditions associated with increased risk for adverse health events as a result of unintended pregnancy

Breast cancer

Complicated valvular heart disease

Diabetes: insulin-dependent; with nephropathy/
retinopathy/neuropathy or other vascular disease; or
of >20 years' duration

Endometrial or ovarian cancer

Epilepsy

Hypertension (systolic >160 mm Hg or diastolic
>100 mm Hg)

History of bariatric surgery within the past 2 years

HIV/AIDS

Ischemic heart disease

Malignant gestational trophoblastic disease

Malignant liver tumors (hepatoma) and
hepatocellular carcinoma of the liver

Peripartum cardiomyopathy

Schistosomiasis with fibrosis of the liver

Severe (decompensated) cirrhosis

Sickle cell disease

Solid organ transplantation within the past 2 years

Stroke

Systemic lupus erythematosus

Thrombogenic mutations

Tuberculosis

The CDC's Selected Practice Recommendations for Contraceptive Use were released in June, 2013. They can be found at <http://www.cdc.gov/mmwr/pdf/rr/rr5904.pdf> Like the MEC, the SPR represents an extensive and ongoing review of the literature regarding how to use contraception. Specifically, the SPR provides recommendations on when to initiate contraceptives, which studies are necessary prior to initiation, and makes some suggestions on clinical management scenarios.

Clinicians are encouraged to read the document in its entirety, including the detailed review on the utility of a urine pregnancy test. This set of protocols (in particular, the Quick Start protocol) reflects that using a checklist to be "reasonably certain that a woman is not pregnant" has a very high probability that the woman is not pregnant. See Box 1 below:

BOX 1. How To Be Reasonably Certain that a Woman Is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is ≤ 7 days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is ≤ 7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [$\geq 85\%$] of feeds are breastfeeds),* amenorrheic, and < 6 months postpartum

* **Source:** Labbok M, Perez A, Valdez V, et al. The Lactational Amenorrhea Method (LAM): a postpartum introductory family planning method with policy and program implications. *Adv Contracept* 1994;10:93–109.

The SPR supports immediate initiation for all methods of contraception if you can be reasonably certain that the woman is not pregnant.

When To Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back-up) needed	Examinations or tests needed before initiation [†]
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection [†]
Levonorgestrel-releasing IUD	Anytime	If > 7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection [†]
Implant	Anytime	If > 5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	If > 7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If > 5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If > 5 days after menses started, use back-up method or abstain for 2 days.	None

Abbreviations: BMI = body mass index; HIV = human immunodeficiency virus; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use, 2010.

^{*} Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI (weight [kg]/height [m]²) at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

[†] Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's STD Treatment Guidelines (available at <http://www.cdc.gov/std/treatment>). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3) (Box 2). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

Other key recommendations from the SPR include a detailed discussion of the tests and/or examinations that are needed before initiation of contraceptive methods. For this classification,

Class A: essential and mandatory in all circumstances for safe and effective use of the contraceptive method.

Class B: contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available.

Class C: does not contribute substantially to safe and effective use of the contraceptive method.

TABLE. Examinations and tests needed before initiation of contraceptive methods

Examination or test	Contraceptive method and class							
	Cu-IUD and LNG-IUD	Implant	Injectable	CHC	POP	Condom	Diaphragm or cervical cap	Spermicide
Examination								
Blood pressure	C	C	C	A*	C	C	C	C
Weight (BMI) (weight [kg]/height [m] ²)	—†	—†	—†	—†	—†	C	C	C
Clinical breast examination	C	C	C	C	C	C	C	C
Bimanual examination and cervical inspection	A	C	C	C	C	C	A§	C
Laboratory test								
Glucose	C	C	C	C	C	C	C	C
Lipids	C	C	C	C	C	C	C	C
Liver enzymes	C	C	C	C	C	C	C	C
Hemoglobin	C	C	C	C	C	C	C	C
Thrombogenic mutations	C	C	C	C	C	C	C	C
Cervical cytology (Papanicolaou smear)	C	C	C	C	C	C	C	C
STD screening with laboratory tests	—¶	C	C	C	C	C	C	C
HIV screening with laboratory tests	C	C	C	C	C	C	C	C

Abbreviations: BMI = body mass index; CHC = combined hormonal contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; HIV = human immunodeficiency virus; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pill; STD = sexually transmitted disease; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*.

* In cases in which access to health care might be limited, the blood pressure measurement can be obtained by the woman in a nonclinical setting (e.g., pharmacy or fire station) and self-reported to the provider.

† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

§ A bimanual examination (not cervical inspection) is needed for diaphragm fitting.

¶ Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's *STD Treatment Guidelines* (available at <http://www.cdc.gov/std/treatment>). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

The SPR discusses follow-up suggestions after contraceptive initiation (table below). It also makes recommendations about management of abnormal bleeding during contraceptive use and what to do with a woman who develops PID with an IUD in situ. These are reflected in these protocols.

Routine Follow-Up After Contraceptive Initiation

These recommendations address when routine follow-up is recommended for safe and effective continued use of contraception for healthy women. The recommendations refer to general situations and might vary for different users and

different situations. Specific populations that might benefit from more frequent follow-up visits include adolescents, those with certain medical conditions or characteristics, and those with multiple medical conditions.

TABLE. Routine follow-up after contraceptive initiation

Action	Contraceptive method				
	Cu-IUD or LNG-IUD	Implant	Injectable	CHC	POP
General follow-up					
Advise women to return at any time to discuss side effects or other problems or if they want to change the method. Advise women using IUDs, implants, or injectables when the IUD or implant needs to be removed or when a reinjection is needed. No routine follow-up visit is required.	X	X	X	X	X
Other routine visits					
Assess the woman's satisfaction with her current method and whether she has any concerns about method use.	X	X	X	X	X
Assess any changes in health status, including medications, that would change the method's appropriateness for safe and effective continued use based on U.S. MEC (i.e., category 3 and 4 conditions and characteristics) (Box 2).	X	X	X	X	X
Consider performing an examination to check for the presence of IUD strings.	X	—	—	—	—
Consider assessing weight changes and counseling women who are concerned about weight change perceived to be associated with their contraceptive method.	X	X	X	X	X
Measure blood pressure.	—	—	—	X	—

Abbreviations: CHC = combined hormonal contraceptive; Cu-IUD = copper-containing intrauterine device; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pill; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use, 2010.

REFERENCES:

1. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," *MMWR* 2010; 59, <http://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf> (March 20, 2013)
2. Centers for Disease Control and Prevention, U.S. Selected Practice Recommendations for Contraceptive Use. *MMWR* 2013; 62

STANDARD NURSE PROTOCOL FOR PREVENTIVE CARE AND HEALTH SCREENING

- DEFINITION** Preventive care and health screening is an important part of providing health care to women. Screening, by its definition, is performed before the onset of symptoms of disease to prevent disease or to identify it in its early stages. Recommendations for preventive care and health screening are generally grouped by age and are determined after identifying major causes of morbidity and mortality for that age group. Attention is directed towards those conditions for which early identification can impact the trajectory of the disease and intervention is possible.
- ETIOLOGY** This protocol discusses the examination, counseling and testing that should be offered as a part of preventive care in a family planning setting. Please note that offering preventive care and health screening is valuable for overall health, but there is no screening that is necessary for the safe provision of contraception. Preventive care and screening, like all aspects of clinical care, change over time. Providers must make efforts to be up-to-date on recommendations. Suggested resources for providers include the US Preventive Services Task Force <http://www.uspreventiveservicestaskforce.org/adultrec.htm> and American College of Obstetricians and Gynecologists www.acog.org. Furthermore, cervical cancer screening and breast cancer screening in Title X clinics in Georgia should be consistent with current Georgia Breast and Cervical Cancer Program Screening Guidelines.
- SUBJECTIVE**
1. Patient's general well-being and health habits (including exercise, nutrition, sexuality, substance use, experiences of intimate partner violence and immunization history).
 2. A family history to include cancer, heart disease, hypertension, high cholesterol, diabetes, autoimmune diseases, mental health disorders and other concerns.
- OBJECTIVE**
- EXAM**
- The following exam components should be performed and documented at the initial visit and annually thereafter. A patient may defer the exam up for three months, per Title X guidelines. Documentation of the preference for deferral should be made in the patient record.

TABLE 1:

	13-18 years	19-39 years	40-64 years
Height	X	X	X
Weight	X	X	X
BMI	X	X	X
Blood pressure	X	X	X
Tanner staging of secondary sexual characteristics	X		
Neck (thyroid and lymph nodes)		X	X
Oral cavity			X
Heart and Lung	X	X	X
Breast exam		X	X
Abdomen	X	X	X
Pelvic exam	As indicated	X (begin at age 21)	X
Rectal exam			X (begin at age 50)
Skin exam		X	X

ASSESSMENT Preventive care and health screening

PLAN **DIAGNOSTIC STUDIES (Please see chart below)**

The following table outlines the diagnostic studies (lab and other) that should be performed at the initial and annual visit by age category.

TABLE 2:

	13-18 years	19-39 years	40-64 years
Urine pregnancy test	As indicated	As indicated	As indicated
Chlamydia	X	X (for those age 25 and under, as indicated thereafter)	As indicated
Gonorrhea	X	X (for those age 25 and under, as indicated thereafter)	As indicated
HIV	If sexually active	X	X
Cervical cancer screening	None	Ages 21-29: Cytology alone every 3 years Age 30 and over: Prefer co-testing (cytology plus HPV) every 5 years Acceptable for	Prefer co-testing (cytology plus HPV testing) every 5 years Acceptable for cytology alone every 3 years

		cytology alone every 3 years	
Urinalysis	As indicated	As indicated	As indicated
Hemoglobin	As indicated	As indicated	As indicated
Wet prep	As indicated	As indicated	As indicated
Lipids*			X (begin at age 45 and every 5 years thereafter)
Fasting glucose**			X (begin at age 45 and every 5 years thereafter)
Mammography			X (every 1-2 years ages 40-49, annually thereafter)
Colon cancer screening			Begin at age 50. Preference for colonoscopy every 10 years. Sigmoidoscopy every 5 years, with high-sensitive fecal occult blood test (3 samples) every 3 years or annual screening with high-sensitive fecal occult blood testing (3 samples) acceptable.

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*For those who are at increased risk for cardiovascular disease, lipid screening may occur after age 20 and every five years thereafter. Increased risk can occur with the following:

- a. BMI greater than 30
- b. Hypertension
- c. Personal history of coronary heart disease
- d. Diabetes
- e. Family history of early onset heart disease (less than 50 years for males and less than 60 years for females)
- f. Tobacco use

**For those with hypertension, screening for type 2 diabetes with a fasting glucose is appropriate.

PATIENT EDUCATION/COUNSELING

1. Obesity: For those with BMI greater than 30, Intensive, multicomponent behavioral interventions for obese adults include the following components:
 - a. Behavioral management activities, such as setting weight-loss goals.
 - b. Improving diet or nutrition and increasing physical activity
 - i. Regular aerobic physical activity at least 30 minutes per day, most days of the week.
 - ii. Refer for diet and nutrition counseling, if available.
 - c. Addressing barriers to change.
 - d. Self-monitoring.
 - e. Strategizing how to maintain lifestyle changes.

2. Nutrition
 - a. Refer to nutritionist or dietician (if available) if patient has poor dietary intake, is overweight or underweight, is anemic or has any chronic disease related to poor nutrition.
 - b. Recommend that all women who are seeking pregnancy or are capable of pregnancy are consuming 400 mcg of folic acid daily for prevention of neural tube defects.
3. Smoking: For women reporting any amount of smoking,
 - a. Refer patient to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867), if smoker or tobacco user.
 - b. Providers may utilize the 5 A framework to tobacco cessation
 - i. **Ask** about tobacco use.
 - ii. **Advise** to quit through clear personalized messages.
 - iii. **Assess** willingness to quit.
 - iv. **Assist** to quit.
 - v. **Arrange** follow-up and support
4. Alcohol use
 - a. May screen using AUDIT, AUDIT-C, CAGE, T-ACE or single question tool.
 - i. Single question tool is “How many times in the past year have you had 5 (for men) or 4 (for women and all adults older than 65 years) or more drinks in a day?”
 - b. Women identified to have a positive screen should be counseled that her level of drinking may be negatively impacting her health and safety and referred to local resources, including Alcoholics Anonymous.
5. Immunizations
 - a. Emphasize importance of keeping immunizations current; assess patient’s immunization status and administer vaccines indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If patient declines vaccination, document refusal.
 - b. 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>
6. Intimate Partner Violence
 - a. Women should be asked about safety within her relationship including physical, emotional and sexual violence and coercion.
 - b. Those who are experiencing partner violence should be referred to local resources.

FOLLOW-UP

As indicated by exam, patient education and counseling.

CONSULTATION/REFERRAL

Women with abnormal screening labs (those that fall outside the lab report's reference range) or findings should be referred to MD for appropriate follow-up (i.e. to a primary care provider for management of laboratory abnormalities), as indicated.

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1. US Preventive Services Task Force. <http://www.uspreventiveservicestaskforce.org/> Accessed May 25, 2013
2. AUDIT-C toolkit. http://old.thenationalcouncil.org/galleries/business-practice%20files/tool_auditc.pdf Accessed May 26, 2013
3. Barbieri, Robert. Your age-based guide to comprehensive well-woman care. *OBGManagement, October 2012 · Vol. 24, No. 10*, Pg 20-33.
4. ACOG Practice Bulletin #131: Screening for Cervical Cancer. <https://access.acog.org/eweb/dynamicpage.aspx?site=congress&webcode=LoginRequired&urlReq=http%3a%2f%2fwww.acog.org%2fResources+And+Publications%2fPractice+Bulletins+List.aspx>
5. Title X Family Planning Program Instructions <http://www.hhs.gov/opa/title-x-family-planning/title-x-policies/program-instructions/> Accessed May 29, 2013
6. Centers for Disease Control and Prevention, U.S. Selected Practice Recommendations for Contraceptive Use. *MMWR* 2013; 62
7. **www.arhp.org**

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STANDARD NURSE PROTOCOL FOR COMBINED ORAL CONTRACEPTIVES

- DEFINITION** Combined oral contraceptives (OCs) 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 **from pill to pill**. Combined OCs are commonly referred to as the "pill(s)."
- ETIOLOGY** Combined OCs work primarily **by preventing ovulation**. The progestin in combined OCs 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. **Estrogen may contribute to the contraceptive effect by decreasing folliculogenesis by suppressing release of FSH, but serves primarily to allow menstrual cycle control. Estrogen and progestins have other effects on the reproductive tract, however, there is no significant evidence that these effects contribute to the contraceptive efficacy of combined OCs.**
- SUBJECTIVE**
1. Patient 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 **CDC US Medical Eligibility Criteria for Contraceptive Use**.
 2. If breastfeeding, is at least **6 weeks** postpartum.
 3. **If non-breastfeeding, must be at least 21 days postpartum without co-morbidities that increase VTE risk (such as age \geq 35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI \geq 30, postpartum hemorrhage, post cesarean delivery, preeclampsia, or smoking). For non-breastfeeding post-partum patient with above co-morbidities, patient *must* be at least 42 days postpartum before initiating combined hormonal contraception.**
 4. If age 35 or older, does not smoke.
 5. If age **35** or older, and has **two or more** co-morbidities (to include the following: BMI of 30 or greater, diabetes, **hyperlipidemia**, **must** use non-estrogen containing methods **as first line**).
 6. If on antiretroviral therapy, does not take ritonavir-boosted protease inhibitors. Refer to **CDC US 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 **CDC US Medical Eligibility Criteria for Contraceptive Use** for clarification of this classification.
8. If on antimicrobial therapy, does not take a rifamycin derivative. Refer to **CDC US Medical Eligibility Criteria for Contraceptive Use** for clarification of this classification.
9. Refer to **CDC US Medical Eligibility Criteria for Contraceptive Use** for medical conditions that represent an unacceptable health risk for taking combined OCs. Medical conditions include:
 - Hypertension
 - Deep vein thrombosis (DVT) / Pulmonary embolism
 - Known thrombogenic mutations
 - Ischemic heart disease
 - Stroke
 - Known hyperlipidemias (**Continuation=3, if developed while on combined method**)
 - Valvular heart disease-complicated (**pulmonary hypertension, risk for atrial fibrillation, history of subacute bacterial endocarditis**)
 - **Lupus with 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 OCs-related
 - Viral Hepatitis – acute or flare (initiation of combined OCs)
 - Cirrhosis – severe (decompensated)
 - Liver Tumors – benign hepatocellular adenoma, malignant (hepatoma)
 - **History of malabsorptive bariatric surgery (Roux-en-Y gastric bypass, biliopancreatic diversion)**
 - **Major surgery with prolonged immobilization**
 - **Solid organ transplant, complicated (graft failure, rejection, cardiac allograft vasculopathy)**

OBJECTIVE

1. Physical examination and laboratory tests according to programmatic guidelines. **See protocol for Preventive Care and Health Screening.**

OR

2. Physical exam deferred up to 3 months. Document reason for deferral on chart. Document on **the patient's medical record** that **patient** agreed to have physical exam delayed.

ASSESSMENT Patient has no condition representing an unacceptable health risk for taking combined OCs.

PLAN

DIAGNOSTIC STUDIES

1. **Blood pressure is below 140/90.**
2. Urine pregnancy test, as indicated

THERAPEUTIC

PHARMACOLOGIC

1. Select a combined OCs based on the hormonal dose, the patient's medical history (clinical picture), preference, past experiences with combined OCs 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 method to begin taking pills. **See Patient Education/Counseling below.**
 3. Provide instructions on selected combined OCs usage to include: pill initiation 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 13-month supply of combined OCs to patient with current physical exam.
- OR**
6. Dispense first 3-month supply of combined OCs to patient with deferred physical exam.
 7. Instruct patient to take one pill orally each day.
 8. Schedule follow-up exam.

PATIENT EDUCATION/COUNSELING

1. Counsel patient according to the seven basic elements of informed consent (BRAIDED - Benefits Risks Alternatives Inquiries Decision Explanation Documentation).
2. Educate patient on the choices for pill initiation:
 - a. Quick Start: This approach **is preferred and** has been shown to be more successful than the other approach for starting pills. **See Quick Start protocol.**
 - 1) The patient 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.
 - 4) Use a back-up method for 7 days if she is not in the first 6 days of her cycle.**
 - 5) If she has taken Ella for emergency contraception, use a back up method for 14 days.**
 - 6) If the patient 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 1st day of her menses.
 - b. First Day Start:
 - 1) Start taking the pills on the first day of menses.
 - 2) No back-up is needed if starting on the first day of menses.**
 - c. Sunday Start
 - 1) Start taking the pills on the first Sunday of menses. **A Sunday start may allow for women to avoid having cycles on the weekend. Otherwise, there is no benefit to this approach.** Don't wait to start the first pill on the Sunday after menses ends.
 - 2) Use a back-up method for 7 days.
 - d. Switching from other methods:
 - 1) **When switching from a non-hormonal method, start combined OCs immediately following the guidelines for the quick start method.**
 - 2) For patients with an IUD, **it may be reasonable to start combined OCs when the appointment for IUD removal is made.**
 - 3) **When switching from a hormonal method that works primarily by inhibiting ovulation, start OCs**

- immediately after stopping the other method with no breaks.**
- 4) If a woman is amenorrheic as a result of history of using Depo Provera injection and is late for reinjection (**> 15 weeks 0 days**), she can start the combined OCs the same day with a 7-day use of back-up method. **Offer** emergency contraception and follow up pregnancy test if she has had recent (**within last 5 days**) unprotected sex.
3. Explain instructions for combined OCs use.
 - a. Take pills at the same time every day **to encourage pill taking to be part of a routine.**
 - b. Use a back-up barrier method (**or abstinence**) for the first 7 days of combined OCs initiation, **as indicated above.**
 - 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) **in advance and instruct women to use it if 2 or more pills were missed** and patient had unprotected sex in the last 5 days.
 4. Discuss side effects and danger signs (ACHES).
 5. Discuss effectiveness of combined OCs 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. Discuss **importance of discussing all medications and herbal supplements with clinician because they can alter the metabolism of hormonal contraception** and cause side effects, and/or decrease effectiveness.

FOLLOW-UP

1. Patient 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 patient did not receive a physical exam, have her return within 3 months for an exam and reassessment.

3. Established patients 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 patient to physician if patient 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 OCs.
 - g. Dizziness, weakness, numbness or depression.
2. Seek consultation, as applicable, on serious health concerns expressed by patient.
3. Advise patient to continue treatment with physician if patient is under the supervision of physician for a health problem.
4. Seek consultation, as applicable, if patient has **health screening** laboratory values or develops abnormal laboratory values and/or physical findings that indicate combined OCs should not be continued.
5. **Seek consultation if the patient develops high blood pressure while on combined hormonal contraception.**
 - a. **Immediately refer patient to the Emergency Room with severe hypertension characterized by systolic pressure 180 mmHg or greater or diastolic pressure 110 mmHg or greater on any occasion. Instruct the patient to stop the combined OCs and discuss non-estrogen containing methods.**
 - b. **For blood pressure 140 mmHg or greater systolic, or 90 mmHg or greater diastolic, on two measurements 6 hours apart, discuss changing method to one that does not contain estrogen (IUD, Implant, progestin-only method).**
 - c. **A diagnosis of hypertension requires two readings more than six hours apart. If the woman has a single elevated reading (using an appropriately sized blood pressure cuff) and desires to continue to use combined hormonal contraception, ask her to return for a repeat blood pressure check in 1-7 days.**
 1. **If she has an elevated blood pressure when she returns, discuss the need to change to a method**

that does not contain estrogen, using the CDC's MEC guidance for women with hypertension. Refer her for primary care management of her blood pressure.

2. If she has a normal blood pressure when she returns, she may continue combined hormonal contraception, but may warrant more frequent blood pressure monitoring.

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
3. M. Zieman, R.A. Hatcher. *Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2012. (Current)
4. "Every Woman, Every Time," *A Preconception Care Toolkit for Georgia*, 2010, <<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>> (March 20, 2013)
5. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," MMWR 2010; 59, <http://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf> (March 20, 2013)
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**STANDARD NURSE PROTOCOL FOR
SPOTTING OR BREAKTHROUGH BLEEDING
WHILE USING COMBINED HORMONAL CONTRACEPTIVES**

DEFINITION	Breakthrough bleeding (BTB) is an abnormal uterine bleeding that occurs between menstrual periods in women using oral contraceptive, but can also occur with other combined hormonal contraception (patch and ring) . 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 OCs, 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 a new hormonal contraceptive and generally resolves by the third or fourth month of use.
SUBJECTIVE	<ol style="list-style-type: none">1. Patient provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history).2. Patient may have a recent history which includes the following:<ul style="list-style-type: none">• started new hormonal contraceptive• missed contraceptive or incorrect usage• inter-menstrual 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 with sexual intercourse• new sex partner• smoking• new medications3. Patient may have history of taking anti-seizure medications (phenobarbital, phenytoin, carbamazepine, lamotrigine, topiramate or promidone), rifampin, or griseofulvin.
OBJECTIVE	Pelvic exam is negative for other causes of bleeding.
ASSESSMENT	Spotting or BTB while taking combined hormonal contraceptive .
PLAN	DIAGNOSTIC STUDIES <ol style="list-style-type: none">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 for information on combined hormonal formulations.

1. For women with persistent irregular bleeding after 2-3 months, **offer** changing to other formulations, although no research indicates any specific OCs is best at eliminating spotting or bleeding.

Break through bleeding and spotting are most commonly seen in very low dose formulations (20 mcg). Offering a switch to a monophasic, 35 mcg pill or to a tri-phasic pill may help these symptoms. Instructions for taking these pills should be one pill orally daily.

OR

2. **For extended-cycle users with at least 21 days of pills, she can stop taking pills for 2 to 3 days to allow a withdrawal bleed to start, then restart the active pills, taking them again for at least 21 days. The length of time between unscheduled bleeding episodes should increase with the duration of use.**
3. **If symptoms persist despite change, consider changing method.**

PATIENT EDUCATION/COUNSELING

1. Reassure new combined hormonal contraceptive users that breakthrough bleeding generally decreases dramatically over the first 3-4 months of initiation.
2. Reinforce proper **administration** of combined hormonal contraceptive, especially **the importance of** taking pills at the same time each day.
3. Counsel on use of alternate contraceptive method if combined hormonal contraceptive 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.
 - a. Refer patient to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867), if smoker or tobacco user.

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 patient has abnormal diagnostic test results.
3. Refer patient to physician for pelvic pathology.

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
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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 **primarily** by thickening and decreasing cervical mucus preventing sperm penetration. **This effect on cervical mucus rapidly resolves, so punctual daily dosing is essential for optimizing contraceptive efficacy. Secondary mechanism of action may include:** 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 **may be used for women who cannot use estrogen according to the CDC MEC guidance and for those who cannot tolerate** estrogen-excess side effects.
- SUBJECTIVE**
1. Patient 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 **CDC Medical Eligibility Criteria for Contraceptive Use**.
 2. **If breastfeeding, she may initiate immediately. However, there is minimal likelihood of ovulating before one month postpartum in a woman who is breastfeeding.**
 3. If on antiretroviral therapy, does not take ritonavir-boosted protease inhibitors. Refer to **CDC 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 **CDC Medical Eligibility Criteria for Contraceptive Use** for clarification of this classification.
 5. If on antimicrobial therapy, does not take a rifamycin derivative. Refer to **CDC Medical Eligibility Criteria for Contraceptive Use** for clarification of this classification.

6. Refer to **CDC Medical Eligibility Criteria for Contraceptive Use** for medical conditions that represent an unacceptable health risk for taking the minipill. Medical conditions include:
 - **Lupus with positive** (or unknown) antiphospholipid antibodies
 - Breast cancer
 - Cirrhosis – severe (decompensated)
 - Liver Tumors – benign hepatocellular adenoma; malignant (hepatoma)

7. Refer to **CDC Medical Eligibility Criteria for Contraceptive Use** for medical conditions that represent an unacceptable health risk if **they develop while taking** the minipill. Women with these conditions may initiate minipills. However, if women who did not have these conditions at the time of initiation develop these conditions after being on minipills, the minipills should not be continued. Medical conditions include:
 - **Ischemic heart disease**
 - **Stroke**
 - **Migraines with aura**

8. May **report** estrogen-excess side effects while taking combined **hormonal** contraceptives, such as headaches, **breast tenderness**, nausea, **chloasma**.

9. May want lowest-dose oral contraceptive available.

OBJECTIVE

1. Physical examination and laboratory tests according to programmatic guidelines. **See protocol for Preventive Care and Health Screening.**
OR
2. Physical exam deferred up to 3 months. Document reason for deferral on chart. Document on **the medical record** that patient agreed to have physical exam delayed.

ASSESSMENT

Patient has no condition representing an unacceptable health risk if taking minipills.

PLAN

DIAGNOSTIC STUDIES

1. **Pregnancy test, if indicated, is negative.**

THERAPEUTIC

PHARMACOLOGIC

1. Order any FDA approved progestin-only OC. (See Appendix A)
2. **Determine appropriate pill initiation method to begin taking pills. See Patient Education/Counseling below.**
3. **Provide instructions on selected progestin-only pill usage to include: pill initiation 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 13-pack supply of minipill to patient with current physical exam.**
- OR
6. **Dispense first 3-month supply of minipill to patient with deferred physical exam.**
7. **Instruct patient to take one pill daily by mouth at the same time of day.**
8. **Schedule follow-up exam.**

PATIENT EDUCATION/COUNSELING

1. Counsel **patient** according to seven basic elements of informed consent (BRAIDED - Benefits Risks Alternatives Inquiries Decision Explanation Documentation).
2. **Educate patient on the choices for pill initiation:**
 - a. **Quick Start: This approach is preferred and has been shown to be more successful than the other approaches for starting pills (e.g., taking the first pill on the first day of the next menses or taking the first pill on the first Sunday after the next menses). See Quick Start protocol.**
 - 1) **The patient 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.**
 - 4) **Use a back-up method for 2 days.**

- 5) If the patient 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 1st day of her menses.
 - b. **First Day Start:**
 - 1) Start taking the pills on the first day of menses.
 - 2) No back-up is needed if starting on the first day of menses.
 - c. **Sunday Start**
 - 1) Start taking the pills on the first Sunday of menses. A Sunday start may allow for women to avoid having cycles on the weekend. Otherwise, there is no benefit to this approach. Don't wait to start the first pill on the Sunday after menses ends.
 - 2) Use a back-up method for 2 days.
 - d. **Switching from other methods:**
 - 1) When switching from a non-hormonal method, start progestin only pills immediately following the guidelines for the quick start method.
 - 2) For patients with an IUD, it may be reasonable to start minipills when the appointment for IUD removal is made.
 - 3) When switching from a hormonal method that works primarily by inhibiting ovulation, start minipills immediately after stopping the other method with no breaks.
 - 4) If a woman is amenorrheic as a result of history of using Depo Provera injection and is late for reinjection (> 15 weeks 0 days), she can start the minipills the same day with a 2-day use of back-up method. Offer emergency contraception and follow up pregnancy test if she has had recent (within last 5 days) unprotected sex.
9. Explain instructions for minipill use.
- a. 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.

- b. 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.
 - c. Advise patient to refer to the pill package insert for missed pill(s) instructions.
 - d. Offer Plan B or emergency contraceptive pills (ECP) **in advance to be used** if pill was missed or taken late and patient had unprotected sex in the past **120** hours. ECP reduce the risk of pregnancy. (See Nurse Protocol of Emergency Contraceptive Pills.) Restart the pill no later than the day after emergency contraception was used.
10. Discuss effectiveness of minipill and back-up methods.
 - a. There appear to be no significant metabolic effects and there is an immediate return to fertility upon discontinuation of the minipill.
 - b. The minipill may cause irregular bleeding or amenorrhea.
11. **Discuss** 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.
12. Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit).
13. Counsel on the use of condoms to reduce the risk of STD/HIV.
14. Discuss **importance of discussing all medications and herbal supplements with clinician because they can alter the metabolism of hormonal contraception** and cause side effects, and/or decrease effectiveness.

FOLLOW- UP

1. **Patient** 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 **patient** did not receive a physical exam, have her return within 3 months for an exam and reassessment.

3. Established **patients** 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 patient to physician if patient develops danger signs.
2. Seek consultation, as applicable, if patient has abnormal **health screening** laboratory values or develops abnormal laboratory values and/or physical findings that indicate the minipill should not be continued.
3. Refer to physician if patient 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.

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
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STANDARD NURSE PROTOCOL FOR EMERGENCY CONTRACEPTIVE PILLS (ECP)

DEFINITION

Emergency Contraception is a contraceptive method used to prevent pregnancy. **Progestin-only** Emergency Contraceptive Pills (ECP) are increased doses of levonorgestrel taken after sexual intercourse to prevent pregnancy. ECP are ineffective if a woman is already pregnant. **Ulipristal acetate is the newest branded emergency contraceptive. It is a selective progestin receptor modulator. It also works to delay ovulation. It is only available by prescription, but has superior efficacy in preventing pregnancy compared to progestin-only ECP between 72-120 after sex and also in women who are obese. The copper IUD is the most effective method of emergency contraception and should be offered to women who need emergency contraception and who desire contraception going forward. It can be placed up to 5 days after unprotected sex and left in place up to at least 10 years, with studies suggesting up to 12 years efficacy. See Copper IUD protocol for details on placement.**

As of April 2013, a court ruling indicated levonorgestrel based ECP must be made available over-the-counter. They are still available by prescription, and this may be an important clinical practice to continue because of cost concerns. Ulipristal acetate and the Copper IUD are available only by prescription.

High doses of combined hormonal contraception may also be used as emergency contraception. This is called the Yuzpe method. Information about how to prescribe this is listed later in this protocol for information, but the Yuzpe method should not be used in settings where other ECP are an option. Not only does the Yuzpe method have a lower efficacy for pregnancy prevention, it is also associated with more side effects.

ETIOLOGY

ECP work by delaying or preventing ovulation. ECP are most effective if given within 72 hours of unprotected intercourse, **but are effective up to 120 hours**. 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 **pregnancy** once implantation has occurred. The effectiveness of treatment depends on when in the woman's menstrual cycle the emergency contraception is used **and how soon after sex it is taken**.

There **are no** medical contraindications to the use of ECP **except known pregnancy and allergy to the medicine**. 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. Patient 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).

For women who are interested in ongoing contraception, the copper IUD provides the most effective emergency contraception and highly effective long acting reversible contraception. It should be discussed with all women requesting emergency contraception.

NOTE: Progestin only Emergency Contraception is most effective if given within 72 hours of unprotected intercourse. The sooner ECP are initiated, the more effective the treatment. **If the patient is more than 72 hours from unprotected intercourse, educate the woman the copper IUD and ulipristal acetate are superior to levonorgestrel for pregnancy prevention in this window.**

2. Precautions:
When providing Plan B[®] One-Step, Plan B[®] Two-Step, Next Choice, **generic levonorgestrel, or ulipristal acetate, Ella[®]**:
- History of hypersensitivity to any component of progestin only pills.
 - Undiagnosed vaginal bleeding.
 - Known or suspected pregnancy.

OBJECTIVE

- A pregnancy test is not needed before providing ECP, but may be performed if the patient reports more than one act of unprotected intercourse since last menstrual period (LMP)**
- Pelvic exam, if indicated.
- Current and local availability of Plan B[®] One-Step, Plan B[®] Two-Step, Next Choice, generic levonorgestrel, or ulipristal acetate:**

ASSESSMENT Patient requests emergency contraception: no contraindications.

PLAN **THERAPEUTIC**

PHARMACOLOGIC

- Plan B[®] One-Step - one single dose of 1.5 mg levonorgestrel taken orally (1 white pill – 1.5 mg each) as soon as possible within **120** hours after unprotected intercourse.

2. **Plan B® Two-Step, Next Choice and generic levonorgestrel – are packaged as two doses of 0.75 mg with package instructions to take these doses 12 hours apart. (While it is appropriate to separate the doses in the Yuzpe method due to high side effects, this is not necessary for progestin-only ECP). It works better, and is easier for the patient to take both pills orally at once as soon as possible. NOTE: Antiemetics not needed with progestin only ECP.**
3. **If the patient is a candidate for ulipristal acetate, one tablet of 30 mg ulipristal acetate to be taken orally as soon as possible.**
4. **If patient wants to initiate an ongoing method, initiate the method according to manufacturer's directions at the next menstrual cycle, or begin the method the day after ECP treatment is complete, Depo-Provera can be initiated on the same day as ECP. Encourage use of a back-up method for 7 days and repeat urine pregnancy testing in 2 weeks.**
5. **Offer STD screening if sexual encounter also placed her at risk of contracting STDs. If she has been raped, refer to local authorities and clinical setting where an exam can be performed for collecting evidence (if your clinic does not do this). Provision of the ECP should not be delayed for this referral.**
6. **Refer patient to NP for copper IUD placement if she is interested in copper IUD as emergency contraception.**

PATIENT EDUCATION/COUNSELING

1. **Provide the patient with exact directions for taking medication. This will include taking one dose (combining doses, if necessary, for those that suggest separating progestin only ECP over 12 hours) of the levonorgestrel based ECP or ulipristal acetate as soon as possible.**
2. Strongly encourage **patient** to choose an acceptable, ongoing method of birth control.
3. **Inform patient 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 **patient** to return to clinic for pregnancy test.

4. **If she initiates an ongoing method immediately after ECP, her next cycle may also be delayed. In this setting, offer a urine pregnancy test in 2 weeks.**
5. **The risks of nausea and emesis are greatest with combined hormonal contraception (Yuzpe method). This is not the first line approach to providing emergency contraception. However, if a patient has no other options, discuss the risk 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, **patient** may need additional medication.
 - c. If **patient** vomits within **two** hours after either dose, take an additional dose.
 - d. If **patient** vomits more than two hours after taking the pills, additional pills are not recommended.
6. Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit)
7. **Advise patient 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.

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 ongoing birth control method if not provided at visit.

CONSULTATION/REFERRAL

1. **Refer patient to physician immediately for severe nausea/emesis or symptoms concerning for an ectopic pregnancy.**

Table 1: Oral Contraceptives approved for EC in the United States 9				
Branda	Manufacturer	Pills per Dose	Ethinyl Estradiol per Dose (mcg)	Levonorgestrel per Dose (mg) ^b
Dedicated emergency contraception (take one dose)				
Plan B One-Step TM	Teva	1 white pill	0	1.5
Next Choice [®]	Watson	2 peach pills	0	1.5
ella [®]	Watson	1 white pill	0	0 ^c
Combined progestin and estrogen pills (take two does 12 hours apart) ^d				
Aviane TM	Teva	5 orange pills	100	0.50
Cryselle TM	Teva	4 white pills	120	0.60
Enpresse TM	Teva	4 orange pills	120	0.50
Jolessa TM	Teva	4 pink pills	120	0.60
Lessina [®]	Teva	5 pink pills	100	0.50
Levora TM	Watson	4 white pills	120	0.60
Lo/Ovral [®]	Akrimax	4 white pills	120	0.60
LoSeasonique [®]	Teva	5 orange pills	100	0.50
Low-Ogestrel [®]	Watson	4 white pills	120	0.60
Lutera TM	Watson	5 white pills	100	0.50
Lybrel [®]	Wyeth	6 yellow pills	120	0.54
Nordette [®]	Teva	4 light-orange pills	120	0.60
Ogestrel [®]	Watcon	2 white pills	100	0.50
Portia [®]	Teva	4 pink pills	120	0.60
Quasense [®]	Watson	4 white pills	120	0.60
Seasonale [®]	Teva	4 pink pills	120	0.60
Seasonique [®]	Teva	4 light-blue-green pills	120	0.60
Sronyx TM	Watson	5 white pills	100	0.50
Trivora [®]	Watson	4 pink pills	120	0.50

Notes:

- a. **Plan B One-Step, Next Choice, and Ella are the only dedicated products specifically marketed for emergency contraception in the United States. Aviane, Cryselle, Enpresse, Jolessa, Lessina, Levora, Lo/Ovral, LoSeasonique, Low-Ogestrel, Luter, Lybrel, Nordette, Ogestrel, Portia, Quasense, Seasonale, Seasonique, Sronyx and Trivora have been declared safe and effective for use as ECPs by the United States Food and Drug Administration. Outside the United States, more than 100 emergency contraceptive products are specifically packaged, labeled, and marketed. Levonorgestrel-only ECPs are available either over-the-counter or from a pharmacist without having to see a clinician in 60 countries. Plan B One-Step and Next Choice are available over-the counter to women and men aged 17 and older in the United States. A prescription is required for Ella for women of all ages.**
- b. **The label for Plan B One-Step indicates to take the pill within 72 hours after unprotected intercourse. Research has shown that that all of the brands listed here are effective when used within 120 hours after unprotected sex. The label for Next Choice says to take one pill within 72 hours after unprotected intercourse and another pill 12 hours later. Research has shown that both pills can be taken at the same time with no decrease in efficacy or increase in side effects and that they are effective when used within 120 hours after unprotected sex.**
- c. **30 mg ulipristal acetate within 120 hours after unprotected sex.**
- d. **The progestin in Cryselle, Lo/Ovral, Low-Ogestrel and Ogestrel is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each tablet is twice the amount of levonorgestrel.**

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
3. M. Ziemann, R.A. Hatcher. *Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2012. (Current)

4. "Every Woman, Every Time," *A Preconception Care Toolkit for Georgia*, 2010, <<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>> (March 20, 2013)
5. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," MMWR 2010; 59, <http://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf> (March 20, 2013)
6. Association of Reproductive Health Professionals, Emergency Contraception: Clinical Update < <https://www.arhp.org/Publications-and-Resources/Clinical-Proceedings/EC/Methods>> (Accessed April 12, 2013)
7. Centers for Disease Control and Prevention, U.S. Selected Practice Recommendations for Contraceptive Use. MMWR 2013; 62
8. "Lexi-Comp Online," Lexi-Comp, Inc., <<http://online.lexi.com>> (August 6, 2013)

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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	<p>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. NOTE: The Levonorgestrel IUD helps reduce menses and dysmenorrhea in many women.</p> <p>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.</p>
SUBJECTIVE	<ol style="list-style-type: none">1. Patient provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history).2. Patient reports painful menses and gives history of current IUD.3. Patient may have a recent history which includes the following:<ul style="list-style-type: none">• heavy or late menses• PID/STD• vaginal infection/discharge• recent sexual partner change or multiple sexual partners• pain with IUD in past4. Patient provides IUD type, insertion date, and date of last string check.
OBJECTIVE	<ol style="list-style-type: none">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. Urine pregnancy test.
2. Hemoglobin/hematocrit, if indicated.
3. Gonorrhea and chlamydia tests; vaginal wet mount, if indicated.

THERAPEUTIC

PHARMACOLOGIC

Prostaglandin inhibitors/nonsteroidal anti-inflammatory drugs such as:

1. Ibuprofen 400 mg **to 800 mg PO every 6-8 hours** as needed for pain.
(Maximum daily dose **3200 mg/day based on patient response and tolerance**)
OR
2. Naproxen 500 mg PO for one dose, then 250 mg PO every 6-8 hours as needed for pain. (**Day 1 maximum daily dose 1250 mg/day, subsequent daily dose maximum of 1000 mg/day**)
OR
3. Over-the-counter-strength products (e.g., Advil, Nuprin, Aleve, Motrin IB, coated aspirin, or acetaminophen) per package directions prn.
4. **For optimal relief, encourage starting these medicines 24-48 hours before menses begin and continue through the first two days of the cycle.**

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 **patient** desires and replaced with progestin-releasing IUD.

PATIENT 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.
4. **If providing an NSAID, remind patient not to take additional NSAIDs over-the-counter.**

FOLLOW-UP

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

CONSULTATION/REFERRAL

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

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
3. M. Ziemann, R.A. Hatcher. *Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2012. (Current)
4. "Every Woman, Every Time," *A Preconception Care Toolkit for Georgia*, 2010, <<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>> (March 20, 2013)
5. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," MMWR 2010; 59, <http://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf> (March 20, 2013)
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STANDARD NURSE PROTOCOL FOR COPPER IUD-RELATED MENORRHAGIA

DEFINITION	Menorrhagia refers 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	<p>Presence of IUD in utero. Bleeding problems constitute one of the more common IUD complications. Women using the copper-releasing IUD (Cooper T380A) usually have heavier menses. Excessive bleeding with the Cooper T380A can be treated with non-steroidal 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.</p> <p>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.</p>
SUBJECTIVE	<ol style="list-style-type: none">1. Patient provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history).2. Patient reports prolonged or excessive menstrual bleeding and gives history of current IUD.3. Patient may have a recent history which includes the following:<ul style="list-style-type: none">• decrease in appetite• dizziness, weakness or tiredness• pale skin color
OBJECTIVE	<ol style="list-style-type: none">1. External exam usually within normal limits.2. Internal exam may be within normal limits; or may note partially-expelled 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. Urine pregnancy test.
3. Gonorrhea and chlamydia tests; vaginal wet mounts, if indicated.

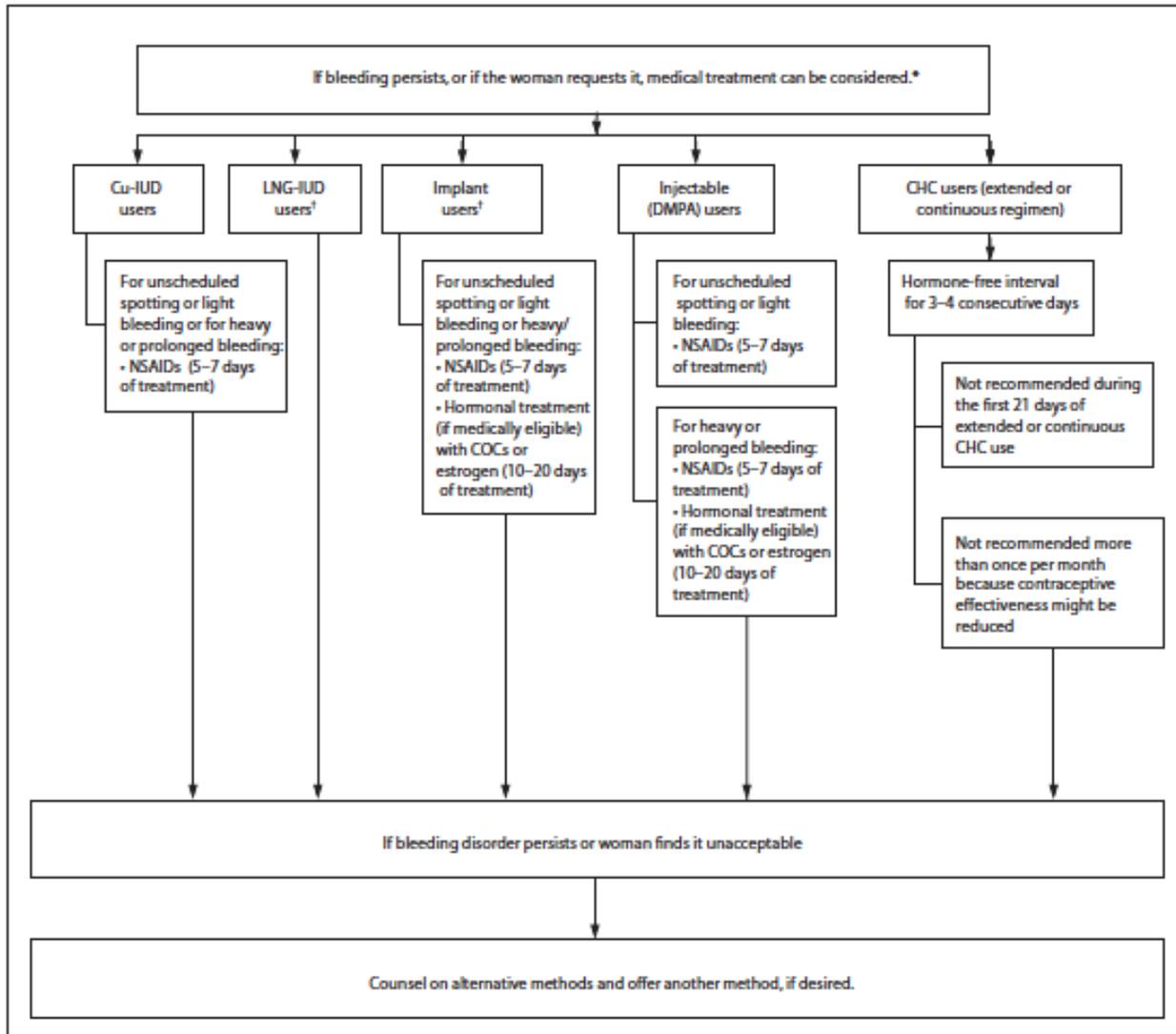
THERAPEUTIC

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 (or **if the patient also has dysmenorrhea begin 24-48 hours prior to the onset**) and continue for 3-4 days.
 - a. Ibuprofen 400 mg PO every 4 hours as needed for pain. (Maximum dose 1.2 gm/day)
OR
 - b. 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.
3. **Some providers have had success with hormonal contraception; it may be reasonable to offer 1-3 months of combined hormonal contraception (pill, patch, ring) if the patient has no contraindications to it.**

Table 1. Management of Women with Bleeding Irregularities, from the CDC’s US Selected Practice Recommendations, 2013

Management of Women with Bleeding Irregularities While Using Contraception



Abbreviations: CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; LNG-IUD = levonorgestrel-releasing intrauterine device; NSAIDs = nonsteroidal antiinflammatory drugs.

* If clinically warranted, evaluate for underlying condition. Treat the condition or refer for care.

† Heavy or prolonged bleeding, either unscheduled or menstrual, is uncommon.

NON-PHARMACOLOGIC MEASURES

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

2. **Consult with APRN or physician to discuss possible need for removal if:**
 - 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) **significantly** improves menorrhagia. Refer to **CDC Medical Eligibility Criteria for Contraceptive Use** for medical conditions that represent an unacceptable health risk for the selected contraceptive method.

PATIENT EDUCATION/COUNSELING

1. Counsel patient on the importance of iron rich foods in the daily diet of menstruating women.

2. Discuss signs of possible pelvic infection and excessive bleeding.

FOLLOW-UP

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

CONSULTATION/REFERRAL

1. Immediately refer patient to physician if suspect ectopic pregnancy.

2. Refer patient to physician if menorrhagia continues for 1-2 menstrual periods after pharmacologic measures started.

3. Refer patient to **APRN or** physician if no improvement in anemia after 4 weeks of iron supplemental therapy.

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
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**STANDARD NURSE PROTOCOL FOR
MEDROXYPROGESTERONE ACETATE (Depo-Provera)
(Injectable Contraceptive)**

- DEFINITION** Medroxyprogesterone acetate is a progestin-only (estrogen-free) long acting reversible hormonal contraceptive birth control 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 follicular-stimulating hormone (FSH) and luteinizing hormone (LH) and by eliminating the LH surge. The pituitary gland remains responsive to gonadotropin-releasing hormone, which suggests that the site of action of medroxyprogesterone acetate is the hypothalamus.
- SUBJECTIVE**
1. **Patient** desires Depo-Provera as choice of contraception.
 2. **Patient** 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 **CDC Medical Eligibility Criteria for Contraceptive Use**.
 3. Refer to **CDC Medical Eligibility Criteria for Contraceptive Use** for medical conditions that represent an unacceptable health risk for taking Depo-Provera. Medical conditions include:
 - a. Multiple risk factors for arterial cardiovascular disease (examples of risk factors include, **but are not limited to, the following: age over 35**, smoking, diabetes, **high cholesterol, obesity** and hypertension). **Women with multiple risk factors for arterial cardiovascular disease should be encouraged to consider long-acting reversible contraceptives. For women with three or more risk factors, consult with the delegating physician prior to initiating Depo-Provera.**
 - b. Elevated blood pressure levels (systolic equal to or greater than 160 mmHg or diastolic equal to or greater than 100 mmHg., **patients with well controlled hypertension or those who have blood pressures less than 160/100 are candidates for Depo-Provera**)
 - c. Vascular disease
 - d. Deep vein thrombosis (DVT) / Pulmonary embolism - acute
 - e. Ischemic heart disease
 - f. Stroke
 - g. Positive (or unknown) antiphospholipid antibodies
 - h. Severe thrombocytopenia (**at the time of initiation**)
 - i. Unexplained vaginal bleeding (**suspicious, before evaluation**)

- j. Breast cancer
- k. Diabetes – nephropathy/retinopathy/neuropathy, **other vascular disease or diabetes of greater than 20 years' duration**
- l. Cirrhosis – severe (decompensated)
- m. Liver Tumors – benign hepatocellular adenoma; malignant (hepatoma)

4. Refer to CDC *Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk if they develop while taking the Depo-Provera. Women with these conditions may initiate Depo-Provera. However, if women who did not have these conditions at the time of initiation develop these conditions after being on Depo-Provera, the Depo-Provera should not be continued. Medical conditions include:
- Migraines with aura

OBJECTIVE

1. Physical examination and laboratory tests according to programmatic guidelines. **See protocol for Preventative Care and Health Screening.**
OR
2. Physical exam deferred up to 3 months. Document reason for deferral on chart. Document on **the medical record** that patient agreed to have physical exam delayed.

ASSESSMENT

Patient has no condition representing an unacceptable **health** risk if using Depo-Provera.

PLAN

DIAGNOSTIC STUDIES

1. Pregnancy test, if indicated, is negative.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Allergic reactions may occur. Encourage patient 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 **IM or SC**
IM: 1 mL vials or prefilled syringes containing 150 mg/1mL.
SC: 104mg/0.65mL

2. Storage:

Depo-Provera **IM** 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).

Depo-Provera SC is to be stored at room temperature 20° to 25°C (68° to 77° F). Shake vigorously prior to administration.

3. Administration:

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

Depo-Provera 104mg SC, administer by SC injection in the anterior thigh or abdomen; avoid boney areas and the umbilicus. Administer over 5-7 seconds. Do not rub the injection area (refer to package insert).

4. Initiation:

- a. **Quick Start:** This approach is preferred and has been shown to be more successful than the other approach for starting hormonal contraception. See Quick Start protocol.
 1. The patient receives Depo-Provera the day of her clinic visit, as long as she is not pregnant.
 2. If she needs emergency contraception: Provide emergency contraception.
 3. Use a back-up method for 7 days.
- b. **During cycle:**
 1. Provide Depo-Provera within 5 days of first day of menses.
 2. No back-up is needed if starting within the first 5 days of menses.
- c. **Switching from other methods:**
 1. For patients with an IUD, it may be reasonable to start the Depo-Provera when the appointment for IUD removal is made.
 2. When switching from a hormonal method that works primarily by inhibiting

ovulation, give the Depo-Provera immediately after stopping the other method with no breaks.

5. Continuation:
 - a. The manufacturer recommends re-injection of Depo-Provera IM between 11 and 13 weeks after a previous injection.
SC between 12 and 14 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 patient is not having any unacceptable symptoms or problems, she may receive re-injection.
 - c. **Contraceptive coverage will be maintained in switching from IM (150 mg/mL) to subcutaneous (104 mg per 0.65 mL) medroxyprogesterone provided the next injection is given within the prescribed dosing period for the IM (150 mg/mL).**

6. **Managing Late Injections:**
 - a. **Refer to late for Depo-Provera protocol. If greater than 15 weeks from last shot and patient desires to continue with Depo-Provera, treat as re-initiation.**

PATIENT EDUCATION/COUNSELING

1. Counsel patient 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 patient to use back-up contraception during the first week after the injection if injections are late.
3. **Discuss danger signs and other warning signs including repeated painful headaches, heavy bleeding, severe depression, 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 (**as noted below in follow-up**).

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 that amenorrhea is common on Depo-Provera and is not harmful. Approximately 50% of women are amenorrheic after one year of use, and this increases to 80% by 5 years.**
7. **Review the FDA black box warning and WHO and CDC recommendations on Depo-Provera and bone mineral density.** Counsel **patient** 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. **Advise patient after 2 years of continuous DMAP use, re-evaluation regarding bone health, risk and continuation of DMPA for contraception is appropriate.** Women and their providers should continually reassess contraceptive medical eligibility over time, but for healthy women 18-45 years old, the duration of use for DMPA need not be limited.
8. Please see details below.

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.”

The WHO **and many others have** 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.”*

Most studies have found that women lose bone mineral density while using Depo-Provera , but regain bone mineral density after discontinuing Depo-Provera. **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. 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.

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 patients with significant risk factors for osteoporosis.

WHO further recommended:

“Among adolescents (menarche to age 17) 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 long-term 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.”

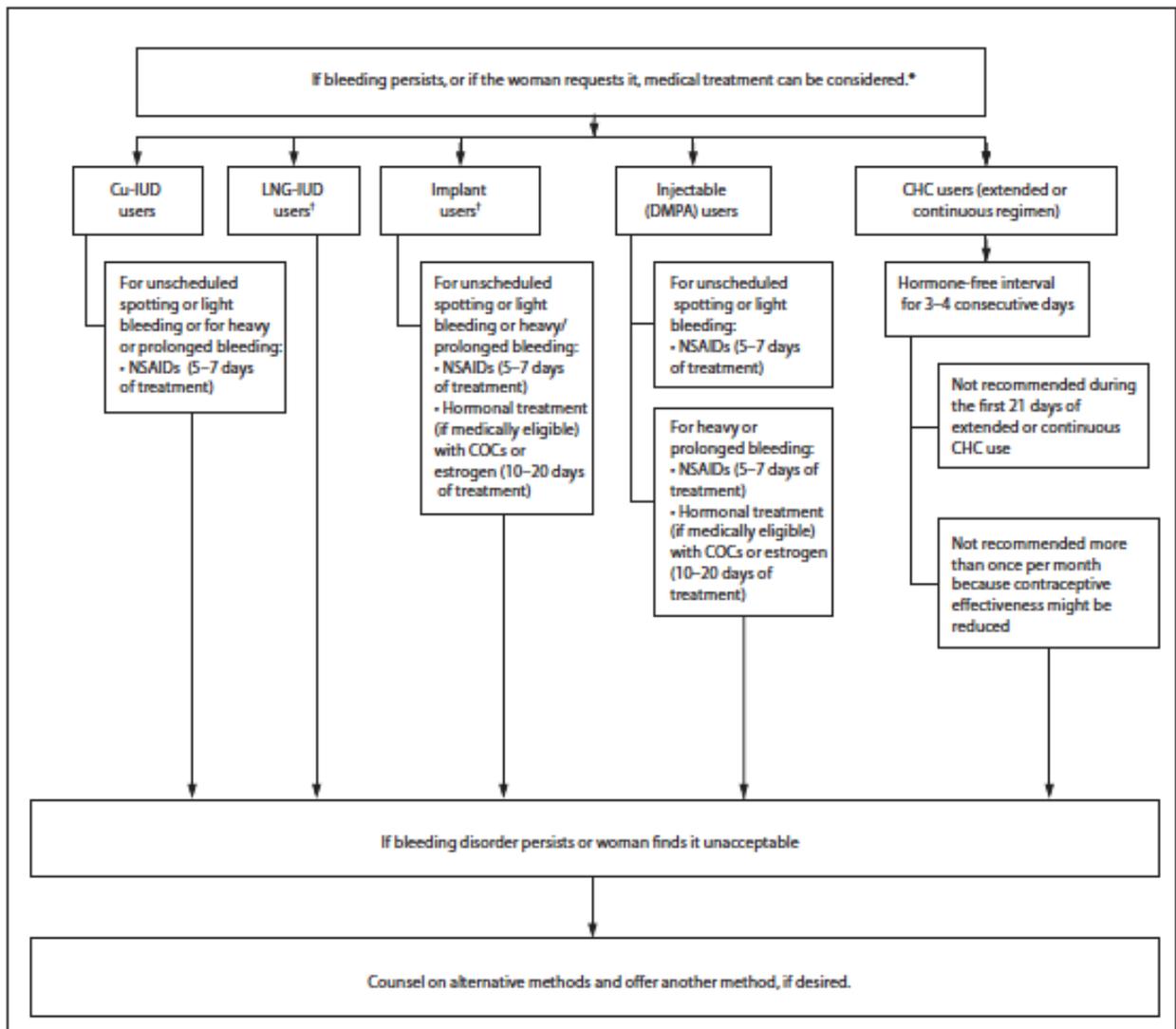
9. Discuss effectiveness of Depo-Provera and back-up methods.
10. Advise patient that Depo-Provera is a long acting contraceptive and not **immediately** reversible. **It takes at least 3 months for fertility to return after last injection. Anovulation may linger after discontinuation.** The average 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.
11. There is no apparent increased risk for breast cancer.
12. 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.
13. Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit - <http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>>)
14. Counsel on the use of condoms to reduce the risk of STD/HIV. Medroxyprogesterone acetate offers no protection from STD/HIV.

FOLLOW-UP

1. Return for re-injection of Depo-Provera **IM** between 11 and 13 weeks after previous injection **and SC between 12 and 14 weeks after previous injection.**
2. 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)
 - b. **See table below**

Table. 1 Management of Bleeding Irregularities, from CDC’s US Selected Practice Recommendations.

Management of Women with Bleeding Irregularities While Using Contraception



Abbreviations: CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; LNG-IUD = levonorgestrel-releasing intrauterine device; NSAIDs = nonsteroidal antiinflammatory drugs.

* If clinically warranted, evaluate for underlying condition. Treat the condition or refer for care.

† Heavy or prolonged bleeding, either unscheduled or menstrual, is uncommon.

CONSULTATION/REFERRAL

1. Outside of clinic hours, seek physician or emergency care if warning signs develop.
2. Refer patient to physician if patient develops any danger signs.

3. Refer patient to physician for development of prolonged side effects (e.g. irregular bleeding) or contraindicating conditions.
4. Management of chronic coexisting medical problems. Advise patient to continue treatment with physician if patient is under the supervision of physician for a health problem.
5. Refer to nutritionist, if applicable **and available**, for calcium deficiency or weight gain related to poor nutrition.

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. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
3. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
4. M. Ziemann, R.A. Hatcher. *Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2012. (Current)
5. "Every Woman, Every Time," *A Preconception Care Toolkit for Georgia*, 2010, <<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>> (March 20, 2013)
6. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," *MMWR* 2010; 59, <http://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf> (March 20, 2013)
7. ACOG Committee Opinion #415: Depot Medroxyprogesterone Acetate and Bone Effects, September 2008. <<http://www.acog.org/~media/Committee%20Opinions/Committee%20on%20Adolescent%20Health%20Care/co415.pdf?dmc=1&ts=20130414T2012416388>> (Accessed April 14, 2013)
8. Centers for Disease Control and Prevention, U.S. Selected Practice Recommendations for Contraceptive Use. *MMWR* 2013; 62
9. "Lexi-Comp Online," Lexi-Comp, Inc., <http://lexicomponline.com/lco/action/doc/retrieve/docid/patch_f/7233#_administration-and-storage-issues> (August 8, 2013)

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**STANDARD NURSE PROTOCOL FOR
LATE RE-INJECTIONS FOR MEDROXYPROGESTERONE ACETATE (DEPO-PROVERA)**

DEFINITION	Patient presents for re-injection of Depo-Provera IM after 13 weeks from previous injection or SC after 14 weeks from previous injection, but before 15 weeks from last injection.
ETIOLOGY	<p>Depo-Provera (the progestin-only contraceptive) is a safe and effective method of contraception for women who:</p> <ul style="list-style-type: none">• desire estrogen-free contraception• prefer a private method, or• prefer a method that requires activity only every three months. <p>Depo-Provera can be safely initiated anytime in the cycle as long as the patient is not pregnant (Please see full Depo-Provera nurse protocol for details regarding its use). Each Depo-Provera IM injection is effective for 13 weeks and SC is effective for 14 weeks per manufacturer's instructions. Pregnancy rates are similar for patients who return for repeat injections between 13-17 weeks after the previous injection (less than 1%). As a result, the World Health Organization recommends a 4-week grace period for women who present late for their Depo-Provera shot. However, the recently released US Selected Practice Recommendations for Contraceptive Use suggest that in the US the grace period be 2 weeks rather than four because the differences in the populations studied.</p>
SUBJECTIVE	Greater than 13 weeks since last Depo-Provera injection IM OR Greater than 14 weeks since last Depo-Provera injection SC
OBJECTIVE	Recent menstrual and coital history, urine pregnancy test as needed.
ASSESSMENT	Greater than 13 weeks for IM or greater than 14 weeks for SC and less than 15 weeks since last Depo-Provera injection
PLAN	<p>DIAGNOSTIC STUDIES</p> <p>Sensitive urine pregnancy test (HCG) only if patient reports symptoms of pregnancy.</p> <p>THERAPEUTIC</p> <ol style="list-style-type: none">1. If pregnancy test is positive, immediately refer patient for options counseling.2. Patients who return up to and including 15 weeks 0 days from their last injection of Depo-Provera who report no symptoms of

- pregnancy may receive a repeat injection of Depo-Provera without requiring a pregnancy test. Clinicians may follow the Depo-Provera nurse protocol as if she was on time for her injection.
3. Patients who return after 15 weeks 0 days for a repeat injection of Depo-Provera, require a pregnancy test. Patients who fall into this category should be considered a “restart” and follow the full Depo-Provera nurse protocol, which encourages Quick Start. Offer emergency contraception if the patient has had unprotected intercourse in the last 120 hours.

PATIENT EDUCATION/COUNSELING

1. Ensure proper method-specific counseling and consent have been completed, and provide additional education about Depo-Provera to the patient, as needed.
2. Provide condoms for backup protection for at least 7 days. Counsel on the continued use of condoms to reduce the risk of STD/HIV.
3. Schedule well-woman care as needed.

FOLLOW-UP

For patients who wish to continue Depo-Provera, follow-up appointments should be scheduled for 12-13 weeks for next injection.

CONSULTATION/REFERRAL

1. Symptoms of pregnancy.
2. Signs or symptoms of allergic reaction (rash, difficulty breathing, redness and swelling at injection site, etc.).
3. Signs or symptoms of infection (fever, severe pain, redness or swelling at injection site, etc.)
4. Intolerable bleeding pattern.

REFERENCES

1. Hatcher RA, et al. Contraceptive Technology, 20th revised Edition, Ardent Media, Inc, New York, NY: 2011.
2. World Health organization, Selected Practice Recommendations, 2nd edition, WHO: 2005
3. Nelson AL, Katz T. Initiation and continuation rates seen in 2-year experience with same day injections of Depo-Provera. *Contraception* 2007; 75:84-7.
4. Steiner MJ, Kwok C, Stanback J, et al. Injectable contraception: what should the longest interval be for reinjections? *Contraception* 2008; 77:410-14.
5. Centers for Disease Control and Prevention. U.S. Selected Practice Recommendations for Contraceptive Use. *MMWR* 2013;62

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

- DEFINITION** ORTHO EVRA™ is a transdermal patch applied to the skin that releases ethinyl estradiol (an estrogen hormone) and norelgestromin (a progestin hormone) to prevent pregnancy.
- ETIOLOGY** **The contraceptive patch works like combined oral contraceptives. They work primarily by preventing ovulation.** The progestin in 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. **Estrogen may contribute to the contraceptive effect by decreasing folliculogenesis by suppressing release of FSH, but serves primarily to allow menstrual cycle control. Estrogen and progestins have other effects on the reproductive tract, however, there is no significant evidence that these effects contribute to the contraceptive efficacy of combined hormonal contraception.**
- SUBJECTIVE**
1. Patient 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 **CDC Medical Eligibility Criteria for Contraceptive Use**.
 2. If breastfeeding, is at least 6 **weeks** postpartum.
 3. **If non-breastfeeding, must be at least 21 days postpartum without co-morbidities that increase VTE risk (such as age ≥ 35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI ≥ 30, postpartum hemorrhage, post cesarean delivery, preeclampsia, or smoking). For non-breastfeeding post-partum patient with above co-morbidities, patient *must* be at least 42 days postpartum before initiating combined hormonal contraception.**
 4. If age 35 or older, does not smoke
 5. If age 35 or older, and has **two or more** co-morbidities (to include the following: BMI of 30 or greater, diabetes, **hyperlipidemia**, **must** use non-estrogen containing methods **as first line**).
 6. If on antiretroviral therapy, does not take ritonavir-boosted protease inhibitors. Refer to **CDC US 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 **CDC US Medical Eligibility Criteria for Contraceptive Use** for clarification of this classification.
8. If on antimicrobial therapy, does not take a rifamycin derivative. Refer to **CDC US Medical Eligibility Criteria for Contraceptive Use** for clarification of this classification.
9. Refer to **CDC US 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
 - Ischemic heart disease
 - Stroke
 - Known hyperlipidemias (**Continuation=3, if developed while on combined method**)
 - Valvular heart disease-complicated (**pulmonary hypertension, risk for atrial fibrillation, history of subacute bacterial endocarditis**)
 - **Lupus with 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 hormonal contraceptive-related
 - Viral Hepatitis – acute or flare (at the time of initiation of combined hormonal patch)
 - Cirrhosis – severe (decompensated)
 - Liver Tumors – benign hepatocellular adenoma, malignant (hepatoma)
 - **Major surgery with prolonged immobilization**
 - **Solid organ transplant, complicated (graft failure, rejection, cardiac allograft vasculopathy)**

OBJECTIVE

1. Physical examination and laboratory tests according to programmatic guidelines. **See protocol for Preventative Care and Health Screening.**

OR

2. Physical exam deferred up to 3 months. Document reason for deferral on chart. Document on **the medical record** that patient agreed to have physical exam delayed.

ASSESSMENT Patient has no condition representing an unacceptable health risk if using the patch.

PLAN

DIAGNOSTIC STUDIES

1. **Blood pressure is below 140/90.**
2. **Urine pregnancy test, as indicated**

THERAPEUTIC

PHARMACOLOGIC

1. Availability: ORTHO EVRA™ Patch, box of three patches
2. Determine appropriate initiation approach to begin taking patch. **See Patient Education/Counseling below.**
3. Provide instructions on contraceptive patch usage to include: initiation method, patch routines, and patch problems.
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.
 - a. The absorption of medication is identical when applied on any of the four suggested areas of the body.
 - b. 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.
 - c. 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. Dispense up to a **one year supply (12 boxes with 3 patches per box)** to patient with current physical exam.

6. Dispense first 3-month supply of patches to patient with deferred physical exam.
7. Schedule follow-up exam.

PATIENT EDUCATION/COUNSELING

1. Counsel patient according to the seven basic elements of informed consent (BRAIDED - Benefits Risks Alternatives Inquiries Decision Explanation Documentation).
2. Educate patient on the choices for patch initiation:

Quick Start: This approach **is preferred and** has been shown to be more successful than the other approach for starting hormonal contraception. **See Quick Start protocol.**

- 1) The patient places the patch 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 patch no later than the next day.
- 4) Use a back-up method for 7 days.
- 5) If the patient is worried about an undetectable early pregnancy:
 - a) She may choose to start the patch that day and return for a urine pregnancy test in 2 weeks
 - OR
 - b) She may choose to wait until the 1st day of her menses.

First Day Start:

- 1) Place the patch on the first day of menses.
- 2) **No back-up is needed if starting on the first day of menses.**

Sunday Start

- 1) Place the patch on the first Sunday of menses. **A Sunday start may allow for women to avoid having cycles on the weekend. Otherwise, there is no benefit to this approach.** Don't wait to start the patch on the Sunday after menses ends.
- 2) Use a back-up method for 7 days.

Switching from other methods:

- 1) **When switching from a non-hormonal method**, start the patch immediately following the guidelines for the quick start method.
 - 2) For patients with an IUD, **it may be reasonable to** start the patch when the appointment for IUD removal is made.
 - 3) **When switching from a hormonal method that works primarily by inhibiting ovulation, start the patch immediately after stopping the other method with no breaks.**
 - 4) If a woman is amenorrheic (ex. as a result of history of using Depo Provera injection and is late for reinjection (> **15 weeks 0 days**)) she can start the patch the same day with a 7-day use of back-up method. **Offer** emergency contraception and follow up pregnancy test if she has had recent unprotected sex.
3. Explain instructions for patch use.
- a. The first day the patch is applied is designated as “Patch-Change Day.”
 - i. 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.
 - ii. No patch is applied on week 4. Menstrual period will begin during week 4.
 - b. 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).
 - i. Press down firmly on the patch with the palm of the hand for 10 seconds. Make sure that the edges stick well.
 - ii. Avoid placing patch on the exact same site for 2 consecutive weeks.
 - iii. Location of patch should not be altered in mid week.
 - iv. Check the patch every day to make sure it is sticking. Avoid touching the sticky surface.
 - c. Do not apply creams, oils, or cosmetics near the patch site.
 - d. 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-Change Day.
 - e. Do not attempt to tape down a patch that has become loosened.
 - f. 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.

-
- g. Remove any stickiness or adhesive that remains on the skin by using baby oil or lotions.
- h. Management of Missed/Forgotten Patches:
- 1st Week
- 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 patient had unprotected sex in last 120 hours, offer emergency contraception.
- 2nd – 3rd 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 4-week 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.
- 4th Week
- 1) Remove the patch.
 - 2) Start the next cycle on the usual Patch-Change Day.
 - 3) No need for back-up method.
4. 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 side effects and danger signs (ACHES).
5. Discuss effectiveness of patch 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. Discuss **importance of discussing all medications and herbal supplements with clinician because they can alter the metabolism of hormonal contraception** and cause side effects, and/or decrease effectiveness.

FOLLOW-UP

1. Return as scheduled for evaluation or contact clinic if side effects or danger signs develop.
2. If patient did not receive a physical exam, have her return within 3 months for an exam and reassessment.
3. Established patients 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 patient to physician if patient develops any danger signs.
2. Seek consultation, as applicable, on serious health concerns expressed by patient.
3. Advise patient to continue treatment with physician if patient is under the supervision of physician for a health problem.
4. Seek consultation, as applicable, if patient has abnormal initial laboratory values or development of abnormal values or physical findings that indicate patch should not be continued.
5. **Seek consultation if the patient develops high blood pressure while on combined hormonal contraception.**
 - a. **Immediately refer patient 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. Instruct the patient to stop the patch and discuss non-estrogen containing methods.**
 - b. **For blood pressure 140 mmHg or greater systolic, or 90 mmHg or greater diastolic, on two measurements 6 hours apart, discuss changing method to one that does not contain estrogen (IUD, Implant, progestin-only method).**
 - c. **A diagnosis of hypertension requires two readings more than six hours apart. If the woman has a single elevated reading (using an appropriately**

sized blood pressure cuff) and desires to continue to use combined hormonal contraception, ask her to return for a repeat blood pressure check in 1-7 days.

1. If she has an elevated blood pressure when she returns, discuss the need to change to a method that does not contain estrogen, using the CDC's MEC guidance for women with hypertension. Refer her for primary care management of her blood pressure.
2. If she has a normal blood pressure when she returns, she may continue combined hormonal contraception, but may warrant more frequent blood pressure monitoring.

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
3. M. Ziemann, R.A. Hatcher. *Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2012. (Current)
4. "Every Woman, Every Time," *A Preconception Care Toolkit for Georgia*, 2010, <<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>> (March 20, 2013)
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STANDARD NURSE PROTOCOL FOR NuvaRing®

- DEFINITION** The NuvaRing® is a vaginal contraceptive **ring** made with a flexible polymer, which contains estrogen and progestin. **It contains ethinyl estradiol and etonogestrel that is absorbed through the vaginal mucosa.**
- ETIOLOGY** **The contraceptive ring works like combined oral contraceptives. They work primarily by preventing ovulation.** The progestin in 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. **Estrogen may contribute to the contraceptive effect by decreasing folliculogenesis by suppressing release of FSH, but serves primarily to allow menstrual cycle control. Estrogen and progestins have other effects on the reproductive tract, however, there is no significant evidence that these effects contribute to the contraceptive efficacy of combined hormonal contraception.**
- SUBJECTIVE**
1. Patient 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 **CDC Medical Eligibility Criteria for Contraceptive Use**.
 2. If breastfeeding, is at least 6 **weeks** postpartum.
 3. **If non-breastfeeding, must be at least 21 days postpartum without co-morbidities that increase VTE risk (such as age ≥ 35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI ≥ 30, postpartum hemorrhage, post cesarean delivery, preeclampsia, or smoking). For non-breastfeeding post-partum patient with above co-morbidities, patient *must* be at least 42 days postpartum before initiating combined hormonal contraception.**
 4. If age 35 or older, does not smoke
 5. If age 35 or older, and has **two or more** co-morbidities (to include the following: BMI of 30 or greater, diabetes, **hyperlipidemia**), **must** use non-estrogen containing methods **as first line**.
 6. If on antiretroviral therapy, does not take ritonavir-boosted protease inhibitors. Refer to **CDC US 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 **CDC US Medical Eligibility Criteria for Contraceptive Use** for clarification of this classification.
8. If on antimicrobial therapy, does not take a rifamycin derivative. Refer to **CDC US Medical Eligibility Criteria for Contraceptive Use** for clarification of this classification.
9. Refer to **CDC US 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
 - Ischemic heart disease
 - Stroke
 - Known hyperlipidemias (**Continuation=3, if developed while on combined method**)
 - Valvular heart disease-complicated (**pulmonary hypertension, risk for atrial fibrillation, history of subacute bacterial endocarditis**)
 - **Lupus with 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 hormonal contraceptive-related
 - Viral Hepatitis – acute or flare (at the time of the initiation of combined hormonal ring)
 - Cirrhosis – severe (decompensated)
 - Liver Tumors – benign hepatocellular adenoma, malignant (hepatoma)
 - **Major surgery with prolonged immobilization**
 - **Solid organ transplant, complicated (graft failure, rejection, cardiac allograft vasculopathy)**

OBJECTIVE

1. Physical examination and laboratory tests according to programmatic guidelines. **See protocol for Preventative Care and Health Screening.**

OR

2. Physical exam deferred up to 3 months. Document reason for deferral on chart. Document on **the medical record** that patient agreed to have physical exam delayed.

ASSESSMENT Patient has no conditions representing an unacceptable health risk if using the NuvaRing®.

PLAN **DIAGNOSTIC STUDIES**

1. **Blood pressure is below 140/90.**
2. **Urine pregnancy test, as indicated**

THERAPEUTIC

PHARMACOLOGIC

1. Availability: **NuvaRing®**.
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. Determine appropriate initiation approach to begin the ring.
See Patient Education/Counseling below.
4. Provide instructions on contraceptive ring usage to include: initiation method, ring routines, and ring problems.
5. 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.
6. Dispense up to a **four-month supply** to patient with current physical exam. **OR**
7. Dispense first 3-month supply of rings to patient with deferred physical exam.
8. Schedule follow-up exam.

PATIENT EDUCATION/COUNSELING

1. Counsel patient according to the seven basic elements of informed consent (BRAIDED - Benefits Risks Alternatives Inquiries Decision Explanation Documentation).

2. Educate patient on the choices for ring initiation:

Quick Start: This approach **is preferred and** has been shown to be more successful than the other approach for starting hormonal contraception. **See Quick Start protocol.**

- 1) The patient **may place the** ring 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 ring no later than the next day.
- 4) Use a back-up method for 7 days.
- 5) If the patient is worried about an undetectable early pregnancy:
 - a) She may choose to start the ring that day and return for a urine pregnancy test in 2 weeks
OR
 - b) She may choose to wait until the 1st day of her menses.

First Day Start:

- 1) Place the ring on the first day of menses.
- 2) **No back-up is needed if starting on the first day of menses.**

Sunday Start

- 1) Place the ring on the first Sunday of menses. **A Sunday start may allow for women to avoid having cycles on the weekend. Otherwise, there is no benefit to this approach.** Don't wait to start the ring on the Sunday after menses ends.
- 2) Use a back-up method for 7 days.

Switching from other methods:

- 1) **When switching from a non-hormonal method, start the ring immediately following the guidelines for the quick start method.**
- 2) For patients with an IUD, it may be reasonable start the ring when the appointment for IUD removal is made.
- 3) **When switching from a hormonal method that works primarily by inhibiting ovulation, start the ring immediately after stopping the other method with no breaks.**
- 4) If a woman is amenorrheic (ex. as a result of history of using Depo Provera injection and is late for reinjection (> **15 weeks 0 days**)) she can start the ring the same day with a 7-day use of back-up method. **Offer**

emergency contraception and follow up pregnancy test if she has had recent unprotected sex.

3. Explain instructions for ring use.
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.
 - d. 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.
 - e. The NuvaRing® does not need to be removed for intercourse.
4. 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.
5. Late Replacement or Removal:
 - a. 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).
 - b. **During the first or second week**, if the NuvaRing® is out of the vagina for more than 3 hours, rinse and re-insert the ring as soon as possible. Use a back-up method for the next 7 days. **If ring is lost, insert a new one. Offer emergency contraception if patient had unprotected intercourse in the last 120 hours (5 days).**
 - c. **During the third week**, if the NuvaRing is out of the vagina for more than 3 hours, she can 1) insert a new ring immediately to begin a new 3-week cycle OR 2) If the ring was used continuously for the preceding 7 days, choose to

- have a withdrawal bleed and insert a new ring no later than 7 days from the last ring removed/expelled. For either option, use a back up method until the new ring has been used continuously for 7 days.**
- d. If patient waited more than 7 days before inserting a new NuvaRing®, **pregnancy must be ruled out prior to restarting therapy.** Consider emergency contraception (if recent intercourse) plus a back-up method for the first 7 days after reinsertion of new ring. **Restart therapy by inserting a new NuvaRing® as soon as possible and begin a new 4-week cycle.**
 - e. **If a new ring was inserted 3 or more days late or the NuvaRing® was in place longer than 4 weeks, pregnancy must be ruled out prior to restarting therapy. Use an additional contraceptive method until new ring has been in place for at least 7 days. Offer emergency contraception if patient had unprotected sexual intercourse in the last 120 hours (5 days).**
6. 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).
 7. The primary side effects of the NuvaRing® are similar to those of combined OC pills. Some women may experience vaginal irritation or infection. The main risks are the same as other combined hormonal contraceptives. Discuss side effects and danger signs (ACHES).
 8. Discuss effectiveness of ring and back-up methods.
 - a. Do not rely upon a diaphragm as a back-up method because NuvaRing® may interfere with the correct placement and position of a diaphragm.
 9. Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit).
 10. Counsel on the use of condoms to reduce the risk of STD/HIV.

11. Discuss **importance of discussing all medications and herbal supplements with clinician because they can alter the metabolism of hormonal contraception** and cause side effects, and/or decrease effectiveness.

FOLLOW-UP

1. Return as scheduled for evaluation or contact clinic if side effects or danger signs develop.
2. If patient did not receive a physical exam, have her return within 3 months for an exam and reassessment.
3. Established patients should return for evaluation at the end of the current supply of rings, 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 patient to physician if patient develops any danger signs.
2. Seek consultation, as applicable, on serious health concerns expressed by patient.
3. Advise patient to continue treatment with physician if patient is under the supervision of physician for a health problem.
4. Seek consultation, as applicable, if patient has abnormal initial laboratory values or development of abnormal values or physical findings that indicate the ring should not be continued.
5. **Seek consultation if the patient develops high blood pressure while on combined hormonal contraception.**
 - a. **Immediately refer patient 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. Instruct the patient to stop the ring and discuss non-estrogen containing methods.**
 - b. **For blood pressure 140 mmHg or greater systolic, or 90 mmHg or greater diastolic, on two measurements 6 hours apart, discuss changing method to one that does not contain estrogen (IUD, Implant, progestin-only method).**
 - c. **A diagnosis of hypertension requires two readings more than six hours apart. If the woman has a single elevated reading (using an appropriately sized blood pressure**

cuff) and desires to continue to use combined hormonal contraception, ask her to return for a repeat blood pressure check in 1-7 days.

- i. If she has an elevated blood pressure when she returns, discuss the need to change to a method that does not contain estrogen, using the CDC's MEC guidance for women with hypertension. Refer her for primary care management of her blood pressure.
- ii. If she has a normal blood pressure when she returns, she may continue combined hormonal contraception, but may warrant more frequent blood pressure monitoring.

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
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3. M. Ziemann, R.A. Hatcher. *Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2012. (Current)
4. "Every Woman, Every Time," *A Preconception Care Toolkit for Georgia*, 2010, <<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>> (March 20, 2013)
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7. "Lexi-Comp Online," Lexi-Comp, Inc., <http://lexicomponline.com/lco/action/doc/retrieve/docid/patch_f/6883#doa> (August 16, 2013)

STANDARD NURSE PROTOCOL FOR QUICK START OF HORMONAL CONTRACEPTION

DEFINITION	Quick Start is a contraceptive initiation method that encourages initiating hormonal contraception on the day of the clinical visit.
ETIOLOGY	<p>This protocol discusses Quick Start as an initiation method for combined hormonal contraception (OC, Vaginal Ring, Contraceptive Patch) and Progestin-only Pills and Depo-Provera. For subdermal contraceptive implants and intrauterine devices, please see those individual nurse protocols for device initiation guidance.</p> <p>Requiring a patient to return for contraceptive initiation or to remember when to start her method at some point in the future opens opportunity not only for failure to initiate the method but also to become pregnant while waiting to do so. Quick Start can streamline patient education regarding initiation. It can make instructions easier to give and to understand. For Depo-Provera, it can increase access by 81%.</p> <p>A sensitive urine pregnancy test is positive when the hormone human chorionic gonadotropin (HCG) is present in sufficient quantities in the body. This will generally be positive by 14 days after an act of intercourse. Thus, a pregnancy test done on any given day would not reliably identify pregnancies from more recent intercourse. Initiation of hormonal contraception during this two week window does not alter whether or not previous intercourse will result in pregnancy that is not yet detectable. There is a low rate of pregnancy for those who initiate hormonal contraceptives while not on their menses (~3%). In general when inadvertently used early in pregnancy, combined hormonal and progestin only contraceptive methods do not harm a pregnancy.</p>
SUBJECTIVE	Patient has not been using hormonal contraception and is interested in starting hormonal contraception. Patient does not have any contraindication to using the selected hormonal contraceptive (as per the individual Standard Nurse Protocol and the CDC Medical Eligibility Criteria).
OBJECTIVE	<p>Medical, menstrual and coital history and urine pregnancy test as needed.</p> <p>Clinicians can be reasonably certain a woman is not pregnant by her history if she has no signs or symptoms of pregnancy and she meets any of the following:</p> <ul style="list-style-type: none">• Has not had intercourse since her last normal menstrual period• Has been consistently and correctly using a reliable method of contraception• Is within the first seven days of a normal menstrual period• Is within four weeks postpartum (non-lactating)

- Is within seven days of a miscarriage or abortion
- Is fully breastfeeding, is amenorrheic and is less than six months postpartum

ASSESSMENT Patient desires hormonal contraception, is not currently pregnant and desires Quick Start initiation.

PLAN

DIAGNOSTIC STUDIES

Sensitive urine pregnancy test (UCG) as indicated.

THERAPEUTIC (See flow chart below)

1. If pregnancy test is positive, immediately refer patient for options counseling.
2. Patients whose last menstrual period started within the past five days can initiate hormonal contraception starting immediately.
3. Patients who have not had unprotected intercourse since the first day of their last period may initiate hormonal contraception starting immediately (regardless of the number of days that have passed since their LMP).
4. If the patient has had unprotected intercourse since LMP and her pregnancy test is negative, she can begin (Quick Start) hormonal contraception immediately.
 - a. Offer initiation of hormonal contraception immediately with the following counseling.
 - i. Starting hormonal contraception today can be easier for patients and can increase access.
 - ii. Hormonal contraception will not prevent a pregnancy from sex that has already occurred.
 - iii. Some studies have found an increased risk of low-birth weight infant for pregnancies that have been exposed to contraception.
 - iv. The likelihood of pregnancy in previous studies of Quick Start in situations like these was 3%.
 - v. If she wants to begin hormonal contraception (OC, Contraceptive Ring, Contraceptive Patch, Depo-Provera) that day, initiate it. Encourage condoms or abstinence for 7 days. Repeat UCG in 14 days
 - b. If she declines initiation of hormonal contraception on that day, provide the method to begin on the first day of her next menstrual cycle or provide an appointment for her to receive a Depo-Provera shot at that time.
 - c. If she has had unprotected sex in the last 120 hours, offer emergency contraception (emergency contraceptive pills or Paragard IUD).

PATIENT EDUCATION/COUNSELING

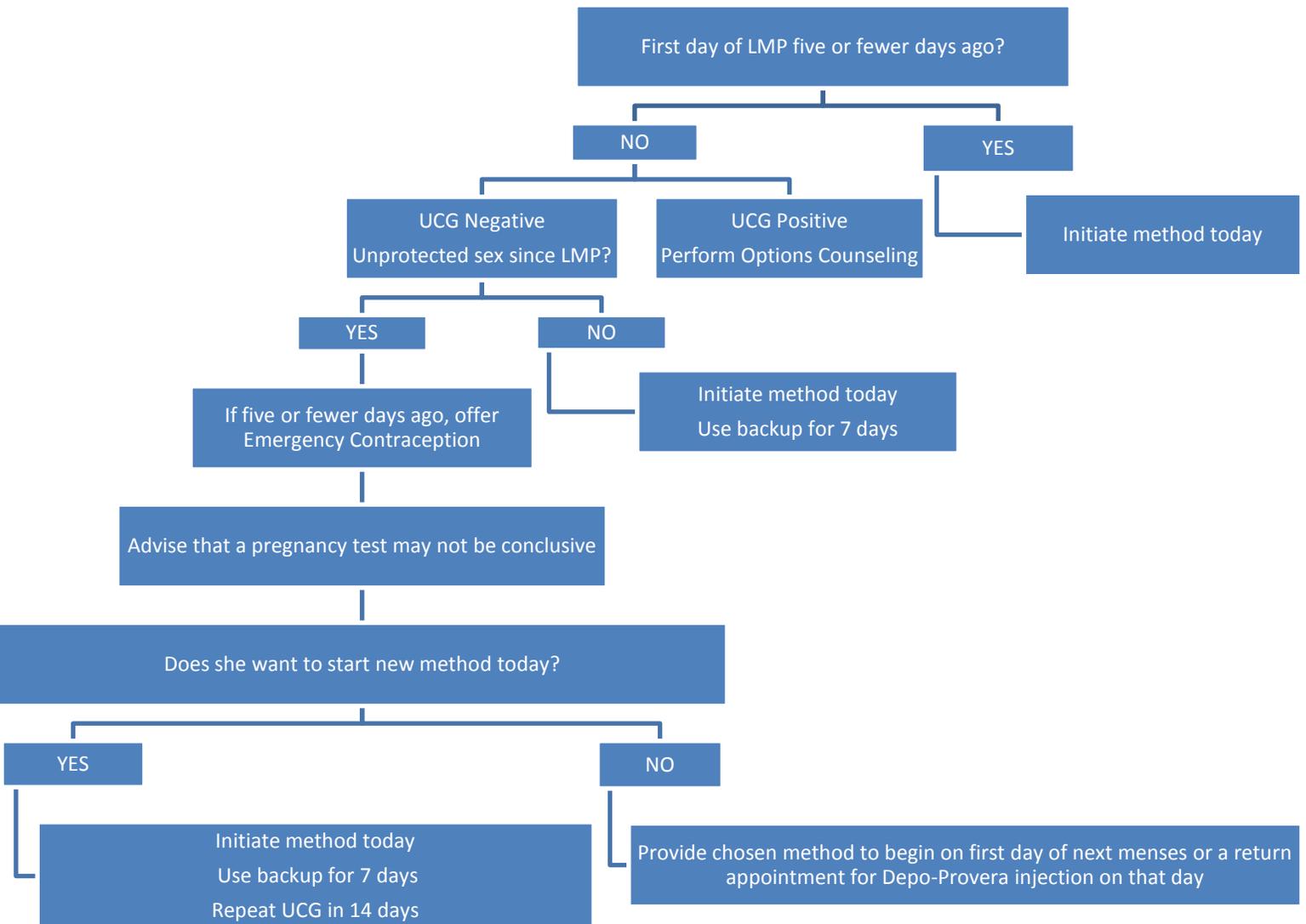
1. Provide method-specific counseling and consent for the method that the patient is initiating.
2. Provide condoms for backup protection (or encourage abstinence) for at least 7 days. Counsel on the continued use of condoms to reduce the risk of STD/HIV.
3. Schedule well-woman care as needed.

FOLLOW-UP

1. Routine follow-up for those who are initiating contraception during the first five days of her cycle or for those who have not had sex since LMP.
2. For those who have had unprotected sex since their last menstrual period, a urine pregnancy test should be repeated in 2 weeks.

CONSULTATION/REFERRAL

1. Symptoms of pregnancy



REFERENCES

1. Hatcher RA, et al. Contraceptive Technology, 20th revised Edition, Ardent Media, Inc, New York, NY: 2011.
2. World Health organization, Selected Practice Recommendations, 2nd edition , WHO: 2005
3. Nelson AL, Katz T. Initiation and continuation rates seen in 2-year experience with same day injections of DEPO-PROVERA. Contraception 2007; 75:84-7.

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	<ol style="list-style-type: none">1. Patient 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 CDC Medical Eligibility Criteria for Contraceptive Use.2. Refer to CDC Medical Eligibility Criteria for Contraceptive Use for medical conditions that represent an unacceptable health risk for using a diaphragm. Medical conditions include:<ul style="list-style-type: none">• HIV/AIDS or high risk of HIV infection<ul style="list-style-type: none">○ Antiretroviral Therapy• History of Toxic Shock Syndrome• Known allergy or hypersensitivity to latex or natural rubber3. Patient reports no full-term delivery within the past 6 weeks.
OBJECTIVE	<ol style="list-style-type: none">1. Physical examination and laboratory tests according to programmatic guidelines. OR2. Physical exam deferred up to 3 months. Document reason for deferral on chart. Document on the medical record that patient agreed to have physical exam delayed.3. Pelvic exam shows:<ol style="list-style-type: none">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. Patient is physically able to insert a diaphragm.
ASSESSMENT	Patient has no condition representing an unacceptable health risk if using the diaphragm.

PLAN

DIAGNOSTIC STUDIES

1. None

THERAPEUTIC

PHARMACOLOGIC

Use diaphragm with contraceptive jelly/ cream containing spermicide.

For patients with latex allergies, provide latex-free diaphragm (e.g. Ortho All-Flex).

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

NON-PHARMACOLOGIC MEASURES

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

PATIENT EDUCATION/COUNSELING

1. Counsel **patient** 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, **vaginal medications**, 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.

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 **patients**.

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 **grade** fever.

SUBJECTIVE

1. Patient 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. Patient 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 **indicated**.
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. **For those <26 years old, follow guidelines for screening for STDs as these infections may be present without vaginal discharge.**

THERAPEUTIC

PHARMACOLOGIC

1. 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 **patient** 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, 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).

OR

2. **Nitrofurantoin monohydrate macrocrystals, 100 mg twice daily for 5 days (with meals)**

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

3. For non-curative symptomatic relief, if **patient** 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, Prodiem) 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.

PATIENT EDUCATION/COUNSELING

1. Stress the importance of **completing** 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. Phenazopyridine may cause discoloration of urine and may stain **underwear**. **Suggest** pantyliners.
3. Discuss potential risk factors for cystitis and prevention strategies.
 - a. Empty bladder frequently
 - b. Urinate after sex
 - c. Wipe from front to back
 - d. Do not douche
 - e. If using vaginal spermicides, consider switching to a different contraceptive method
4. Seek medical care immediately if medication side-effects or systemic symptoms develop.
5. Discuss that post-menopausal women may have increased susceptibility for cystitis because of a decrease in vaginal lactobacilli and an increased pH.

FOLLOW-UP

1. **Patient** should call the clinic if cystitis symptoms are not improved within 48 hours of starting therapy **or if symptoms of severe systemic illness begin**.
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 **patient** is pregnant.
2. Refer to physician if patient 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

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NURSE PROTOCOL FOR DYSMENORRHEA (PRIMARY)

DEFINITION	Primary dysmenorrhea is painful menstruation without identifiable causes.
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 co-occurring 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.
SUBJECTIVE	<ol style="list-style-type: none">1. Patient provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history). Note history of: parity, menarche, method of contraception, pelvic inflammatory disease/sexually transmitted diseases, onset of symptoms/changes over time, family history of dysmenorrhea, nutritional status.2. Patient reports cramping pain in the lower abdomen just before or during menstruation.3. Patient 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. Patient 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

1. Over the counter analgesics – Coated aspirin, Aleve®, Motrin IB®, Nuprin®, acetaminophen (e.g., Tylenol®), per package directions prn.
OR
2. Ibuprofen 400 mg **to 800 mg PO every 6-8 hours** as needed for pain. (Maximum daily dose **3200 mg/day based on patient response and tolerance**)
OR
3. Naproxen 500 mg PO for one dose, then 250 mg PO every 6-8 hours as needed for pain. (**Day 1 maximum daily dose 1250 mg/day, subsequent daily dose maximum of 1000 mg/day**)

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

For optimal relief, encourage starting these medicines 24-48 hours before menses begin and continue through the first two days of the cycle.

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

NON-PHARMACOLOGIC

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

PATIENT EDUCATION/COUNSELING

1. **Inform patient that** primary dysmenorrhea probably does not affect fertility.
2. Assess **patient's** knowledge of activities that may provide relief.
3. Caution **patient** if taking prostaglandin inhibitors (Aleve®, Motrin Ibuprofen®, Nuprin®, aspirin)
 - a. Prolonged chronic use may cause kidney problems and GI upset.
 - b. **Discuss that one should not simultaneously use several different NSAIDs at the same time.**

- c. Stop medication and report severe persistent headaches, fever and muscle aches, which may be signs of aseptic meningitis.

FOLLOW-UP

Return to clinic if no relief from therapy **after two menstrual cycles**.

CONSULTATION/REFERRAL

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

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins, et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)

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STANDARD NURSE PROTOCOL FOR IRON-DEFICIENCY ANEMIA IN NON-PREGNANT WOMEN

- 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). Iron-deficiency anemia also commonly occurs during pregnancy. Iron-deficiency anemia can usually be corrected with iron supplementation.
- SUBJECTIVE**
1. Patient provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history).
 2. Patient may be asymptomatic if anemia is mild.
 3. **Patient** 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 nonsteroidal 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 **patient** 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. **Patient 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.

ASSESSMENT

Symptoms of anemia.

- a. **Anemia in pre-menopausal women is most commonly iron deficiency, and may be due to increased loss with menses, low iron consumption and depleted stores from pregnancies.**

PLAN

DIAGNOSTIC STUDIES

1. Hemoglobin below 11.8 gm/dL for non-pregnant women.

THERAPEUTIC

PHARMACOLOGIC

1. Treatment of (**presumed**) iron deficiency anemia:
 - a. **Ferrous Sulfate 325 mg PO bid.**
 - OR
 - b. **Ferrous fumarate 325 mg PO daily or bid. Ferrous fumarate has more elemental iron in it than ferrous sulfate.**

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 patient has sickle cell or hemoglobin variants.

2. Efforts should be directed towards treatment of the underlying reason for the anemia (ex. Menorrhagia, low consumption, etc.)

PATIENT 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 **patient** 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 at the end of 4-6 weeks of initial treatment.

1. If the hemoglobin has increased by 1 gm/dL or more, continue treatment for 2-3 months to replenish iron stores, then recheck hemoglobin.
2. If the hemoglobin is not increased at least 1 gm/dL:
 - 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.
2. If after 4-6 weeks, the hemoglobin does not increase at least 1 gm/dL despite compliance with iron supplementation regimen and the absence of acute illness, refer to physician.
3. Refer any patient with sickle cell anemia or other hemoglobin variants to physician.
4. Refer patient to physician if there is evidence of other medical problems, **including concerns for GI bleeding (black or tarry stools, patient history with symptoms of reflux or ulcer).**
5. **All post-menopausal women with anemia should be referred to physician for evaluation.**

REFERENCES

1. CDC, "*Recommendations to Prevent and Control Iron Deficiency in the United States*," MMWR, Vol. 47, No. RR-3, April 3, 1998. (Current)
2. Mayo Clinic, "Iron Deficiency Anemia," <<http://mayoclinic.com/health/iron-deficiency-anemia/DS00323>> (April 12, 2013)
3. US Preventative Services Task Force, Clinical Screening Guidelines. <<http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/index.html>> (April 12, 2013)
4. Facts and Comparisons eAnswers, <<http://online.factsandcomparisons.com/MonoDisp.aspx?monoID=fandc-hcp13674&quick=367137%7c5&search=367137%7c5&isstemmed=True&fromTop=true#firstMatch>>(August 16, 2013)

STANDARD APRN PROTOCOLS

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STANDARD APRN PROTOCOL FOR SECONDARY AMENORRHEA

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 **greater than 3 months in a woman who was previously menstruating.**

ETIOLOGY

Primary:

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

Secondary:

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 **insufficiency**, ovarian dysgenesis, infection, hemorrhage, necrosis, neoplasm.
13. Cushing Disease
14. Asherman's Syndrome.
15. Cervical stenosis.
16. Medications including psychotropics.
17. Chronic illness.
18. Tuberculosis.

SUBJECTIVE

1. **Patient** provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history).
2. **Patient** reports absence of menses (as defined above).
3. **Patient** 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, **risk for 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.
 - a. 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.
 - b. Tachycardia.
 - c. Breast tissue atrophy, galactorrhea.
 - d. "Buffalo" hump of back.
 - e. 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.

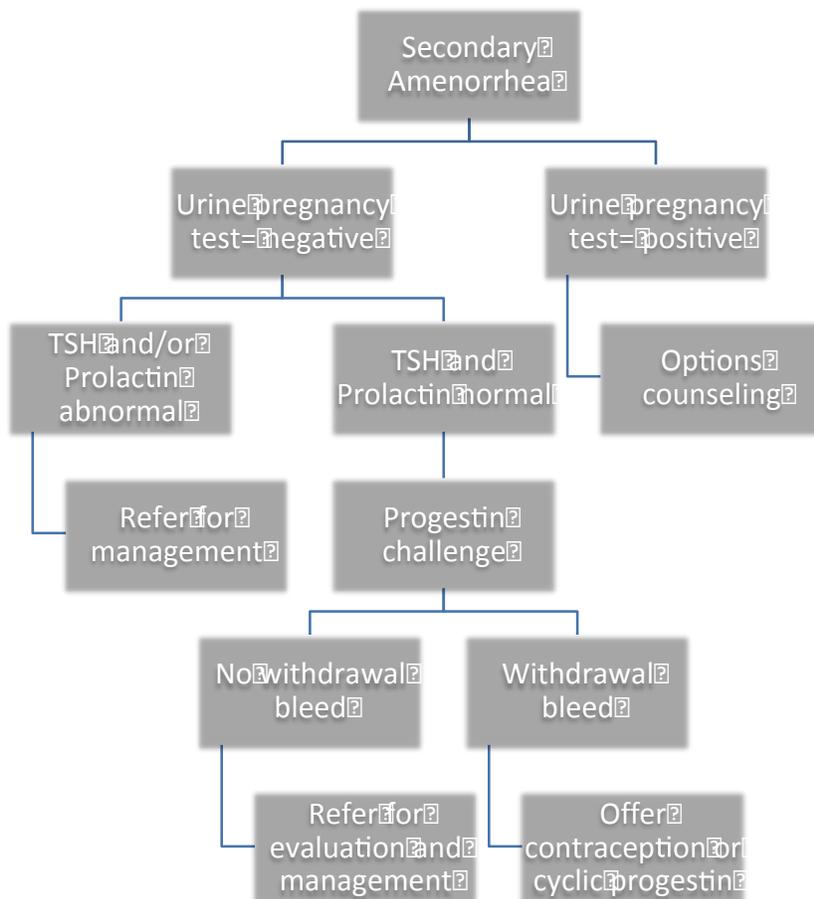
OR

Secondary amenorrhea with or without galactorrhea.

PLAN

DIAGNOSTIC STUDIES

1. Pregnancy test for either primary or secondary amenorrhea.
2. **For primary amenorrhea, refer these patients for further evaluation.**
3. **For secondary amenorrhea, consider TSH and prolactin followed by a progestin challenge test as suggested in Table below. Clinicians may also refer these patients for further evaluation.**



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. **Patient desires contraception begin any desired contraceptive for which she meets the CDC Medical Eligibility Criteria. If she desires cyclic menses, encourage a combined hormonal contraceptive (pill, patch or ring). (See Appendix A)**

OR

- b. **Patient** does not desire contraception, give medroxyprogesterone acetate, 10 mg PO daily, for the first 10 days of every month, for 3 consecutive months. **If she does not have spontaneous menses thereafter, refer.**
2. If no bleeding occurs with progestin challenge test, repeat pregnancy test, **if negative, refer patient for management and/or further evaluation.**

PATIENT 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.

FOLLOW-UP

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

CONSULTATION/REFERRAL

1. If **patient** has primary amenorrhea.
2. Positive pregnancy test, **perform options counseling and refer as indicated.**
3. If patient does not have a withdrawal bleed after progestin challenge test and negative pregnancy test, refer for further evaluation.
4. **Patient** fails to have spontaneous menses within 3 months after treatment.
5. Suspected eating disorders, or polycystic ovarian syndrome.
6. If **patient** has abnormal laboratory test(s).

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

REFERENCES

1. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecological Settings*, 10th ed., Springer Publishing Co., New York, 2011. (Current)
2. Master-Hunter and Hieman. Amenorrhea: Evaluation and Treatment. *American Family Physicians*. April 15, 2006, Volume 73, Number 8, Pg 1374-1382.
3. "Lexi-Comp Online," Lexi-Comp, Inc.,
<http://lexicomponline.com/lco/action/doc/retrieve/docid/patch_f/7233#f_dosages >
(August 19, 2013)

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STANDARD APRN PROTOCOL FOR CONTRACEPTIVE IMPLANT INSERTION

NOTE: All clinicians performing insertions and/or removals of **the contraceptive implant** must complete the **manufacturer's (Merck)** 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 those who completed training for Implanon, a web-based training can be completed for certification in Nexplanon placement. For those who have never been certified to place the contraceptive implant, in-person training is required. The training is free and can be arranged by calling 1-877-467-5266.**

DEFINITION Nexplanon[®] is a small, thin, implantable hormonal contraceptive that is effective for up to three years. The subdermal contraceptive implant is an etonogestrel-impregnated 4 cm plastic rod. It is placed under the skin of the upper arm. It 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. **Nexplanon[®] is identical to its predecessor, Implanon[®], except that it is radio-opaque and the inserter has been changed.**

SUBJECTIVE

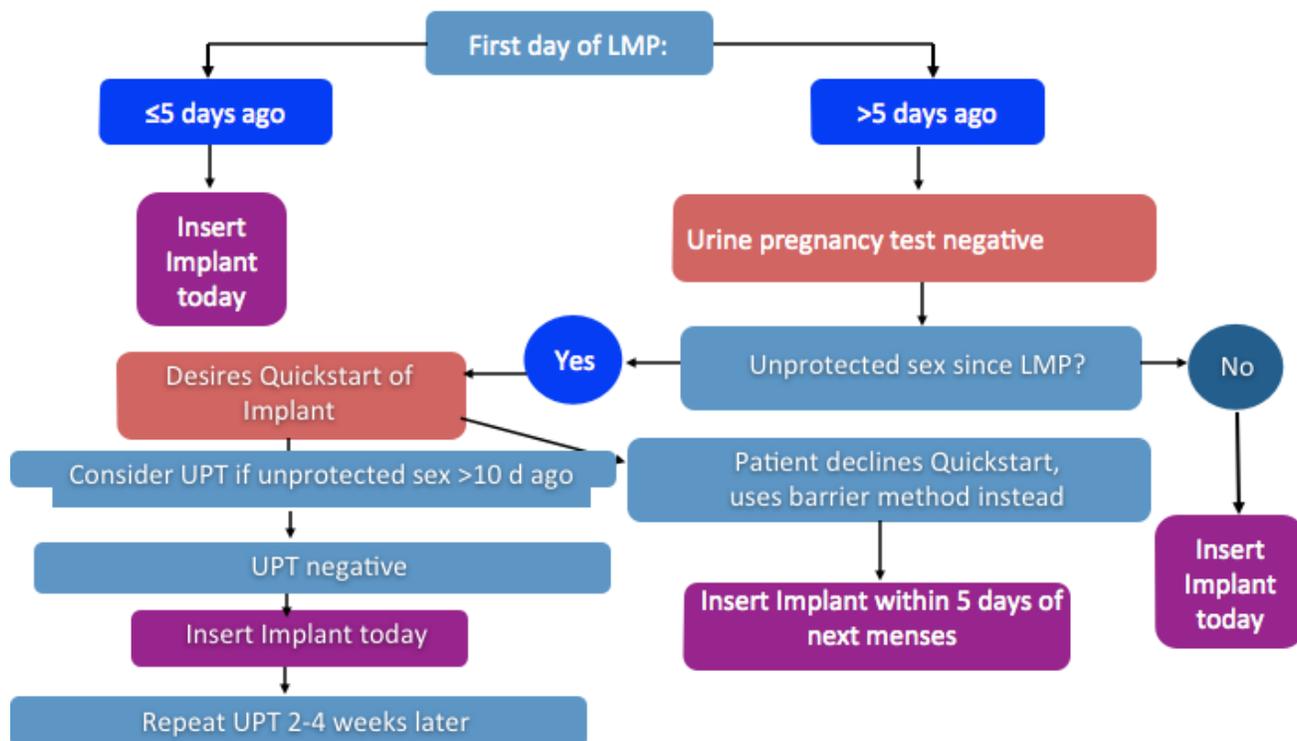
1. Desires an implant for long-term contraception.
2. Has detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and to the **CDC Medical Eligibility Criteria for Contraceptive Use**.
3. **If breastfeeding, she may initiate immediately. However, there is minimal likelihood of ovulating before one month postpartum in a woman who is breastfeeding.**
4. **Refer to CDC *Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk for using the contraceptive implant. Medical conditions include:**
 - **Lupus with positive (or unknown) antiphospholipid antibodies**
 - **Breast cancer**
 - **Cirrhosis – severe (decompensated)**
 - **Liver Tumors – benign hepatocellular adenoma; malignant (hepatoma)**
 - **Unexplained vaginal bleeding, suspicious for serious underlying condition, before evaluation.**

5. Refer to CDC *Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk if they develop while using the contraceptive implant. Women with these conditions may initiate the implant. However, if women who did not have these conditions at the time of initiation develop these conditions after using the implant, the implant should not be continued. Medical conditions include:
 - Migraines with aura
 - Ischemic heart disease
 - Stroke
6. May report estrogen-excess side effects while taking combined hormonal contraceptives, such as headaches, breast tenderness, weight gain, nausea and thus prefer a method that does not contain estrogen.

OBJECTIVE

1. Physical examination and laboratory tests according to programmatic guidelines. **See protocol for Preventative Care and Health Screening.**
OR
2. Physical exam deferred up to 3 months. Document reason for deferral on chart. Document on **the medical record** that patient agreed to have physical exam delayed.
3. Pregnancy must be excluded before inserting **the contraceptive implant**.
4. **Follow the algorithm below for initiation. If switching from a hormonal method, may do so at any time when the patient has been consistently using the method.**
5. Please note, from the CDCs Selected Practice Recommendations, Quick Starting the Implant is acceptable. "In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting the implant likely exceed any risk; therefore, starting the implant should be considered at any time, with a follow-up pregnancy test in 2–4 weeks."

Timing of Insertion for Implant



ASSESSMENT Patient has no condition representing an unacceptable risk if using the contraceptive implant.

PLAN

DIAGNOSTIC STUDIES

1. Pregnancy test if indicated to rule out pregnancy.

PHARMACOLOGIC

1. Local anesthesia with **2-3** mL of 1% lidocaine should be injected under the skin and along the insertion track.
2. Insert the contraceptive implant 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.
3. Before insertion, the **patient** must read and sign the consent form provided by the manufacturer in addition to the program's method specific consent form.

4. **The provider should fill out the Contraceptive Implant Placement procedure note as indicated.**

NON-PHARMACOLOGIC MEASURES

1. Take precautions to avert a vasovagal reaction (syncope/fainting). Allow the **patient** to lie still several minutes after insertion. Ask about pain or feeling faint. If the **patient** 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, pinched-face 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.

PATIENT EDUCATION/COUNSELING

1. Counsel **patient** 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 **patient** after the **contraceptive implant** insertion so she will have a record of the location of **implant** and when it should be removed.
3. Teach **patient** how to check for **the implant**.
 - a. The implant should be palpated by both the clinician and **patient** before **patient** goes home to ensure proper placement.
 - b. The **patient** may confirm placement at any time by palpating her inner upper arm.
 - c. If **patient** 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. **Encourage patient to keep insertion site bandaged for the next 3-5 days.**

5. Counsel patient 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 patient regarding unpredictable bleeding irregularities, so that they know what to expect. Women who use **contraceptive implant** 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. **If inserted >5 days from LMP and patient not currently on hormonal contraception, recommend back-up or abstinence for 7 days.**
9. Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit)
10. Use condoms to reduce the risk of STD, including HIV.
11. Discuss **importance of discussing all medications and herbal supplements with clinician because they can alter the metabolism of hormonal contraception** and cause side effects, and/or decrease effectiveness.
12. The contraceptive implant is approved for use for 3 years.

FOLLOW-UP

1. Return as scheduled for evaluation or contact clinic if side effects or danger signs develop.
2. Outside of clinic hours, seek physician or emergency care if warning signs develop.
3. If **patient** did not receive a physical exam, have her return within 3 months for an exam and reassessment.
 - a. After an **implant** has been in place for 3 years, check with manufacturer regarding possible approval for a longer time.
 - b. **Treatment of side effects: Heavy bleeding –**

Consult/referral. None of the following has been proven to be effective at treatment of bothersome bleeding while using the implant. Often continuation of use of the implant is the best treatment, but for some women the bleeding profile may not improve. If a woman is interested in continuing the implant and would like to try one of the following, it may be reasonable. If she desires removal, this request should be accommodated.

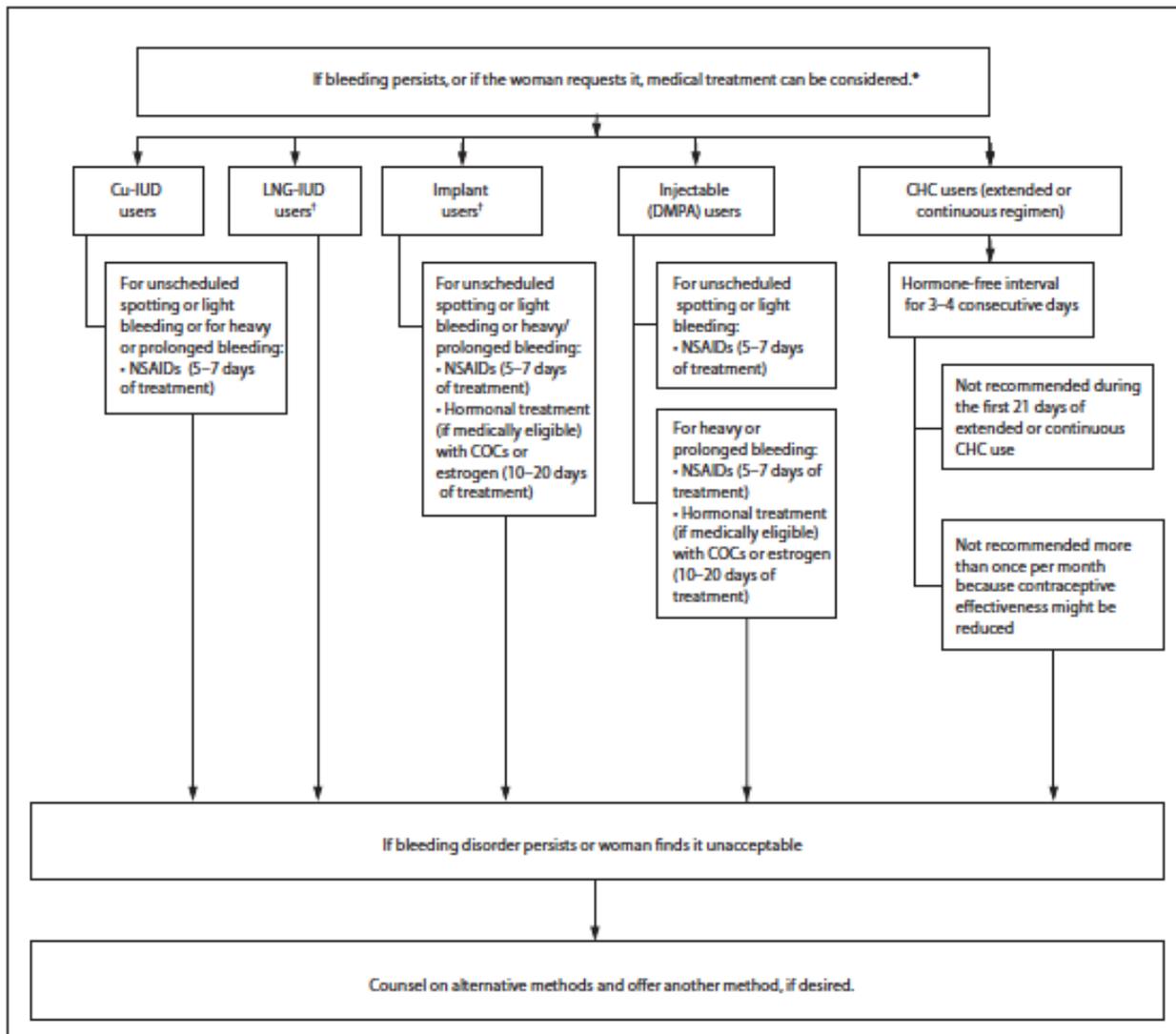
For bleeding irregularities, rule out infection or cervical lesions. Please see table below from the CDC's Selected Practice Recommendations.

May give:

- 1) **A combined low-dose oral contraceptive for 1-3 cycles.**
- 2) **OR**
- 3) **Ibuprofen 400 mg PO every 4 to 6 hours as necessary. (Maximum dose 1.2 gm/day)**
- 4) **OR**
- 5) **If patient not allergic to sulfa drugs, can provide for Celecoxib 200mg daily for 5 days with food**

Table 1. Summary table of from the CDCs Selected Practice Recommendations for Contraceptive Use, 2013

Management of Women with Bleeding Irregularities While Using Contraception



Abbreviations: CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; LNG-IUD = levonorgestrel-releasing intrauterine device; NSAIDs = nonsteroidal antiinflammatory drugs.

* If clinically warranted, evaluate for underlying condition. Treat the condition or refer for care.

† Heavy or prolonged bleeding, either unscheduled or menstrual, is uncommon.

CONSULTATION/REFERRAL

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

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
3. M. Ziemann, R.A. Hatcher. *Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2012. (Current)
4. “Every Woman, Every Time,” *A Preconception Care Toolkit for Georgia*, 2010, <<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>> (March 20, 2013)
5. CDC, “U.S. Medical Eligibility Criteria for Contraceptive Use, 2010,” *MMWR* 2010; 59, <http://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf> (March 20, 2013)
6. The Nexplanon “Learn about it” site. < <http://www.nexplanon-usa.com/en/hcp/learn-about-it/insertion-and-removal/dosage-and-administration/index.asp>> (April 13, 2013)
7. Centers for Disease Control and Prevention, “U.S. Selected Practice Recommendations for Contraceptive Use.” *MMWR*, 2013: 62.
8. “Lexi-Comp Online,” Lexi-Comp, Inc., <<http://online.lexi.com/lco/action/interact>> (August 19, 2013)

STANDARD APRN PROTOCOL FOR CONTRACEPTIVE IMPLANT REMOVAL

NOTE: All clinicians performing insertions and/or removals of **the contraceptive implant** must complete the **manufacturer's (Merck)** 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 those who completed training for Implanon, a web-based training can be completed for certification in Nexplanon placement. There is no difference in removal between these devices. For those who have never been certified to place the contraceptive implant, in-person training is required. The training is free and can be arranged by calling 1-877-467-5266.**

DEFINITION Removal of the **contraceptive implant** at the **patient's** request, due to clinical findings such as pregnancy or side effects, or per guidelines that the **implant** must be removed after 3 years.

SUBJECTIVE

1. **Patient** desires **contraceptive implant** 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 the **implant**.

ASSESSMENT Removal of **the contraceptive implant** 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. **Nexplanon can be localized with x-ray.**

Implanon 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, **Merck**, at 1-877-467-5266 for further instructions.

THERAPEUTIC

Per manufacturer's instructions, remove **the contraceptive implant** 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 **Merck** at 1-877-467-5266.
3. The **provider should fill out the Contraceptive Implant Removal procedure note as indicated.**

PATIENT EDUCATION/COUNSELING

1. Provide **patient** 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.

FOLLOW-UP

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

CONSULTATION/REFERRAL

1. Difficult/failed removal.
2. Successful removal, **patient** pregnant.
3. Persistent side effects.

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
3. M. Ziemann, R.A. Hatcher. *Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2012. (Current)
4. "Every Woman, Every Time," *A Preconception Care Toolkit for Georgia*, 2010, <<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>> (March 20, 2013)
5. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," MMWR 2010; 59, <http://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf> (March 20, 2013)
6. The Nexplanon "Learn about it" site. < <http://www.nexplanon-usa.com/en/hcp/learn-about-it/insertion-and-removal/dosage-and-administration/index.asp>> (April 13, 2013)

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STANDARD APRN PROTOCOL FOR IUD INSERTION: COPPER T380A

DEFINITION

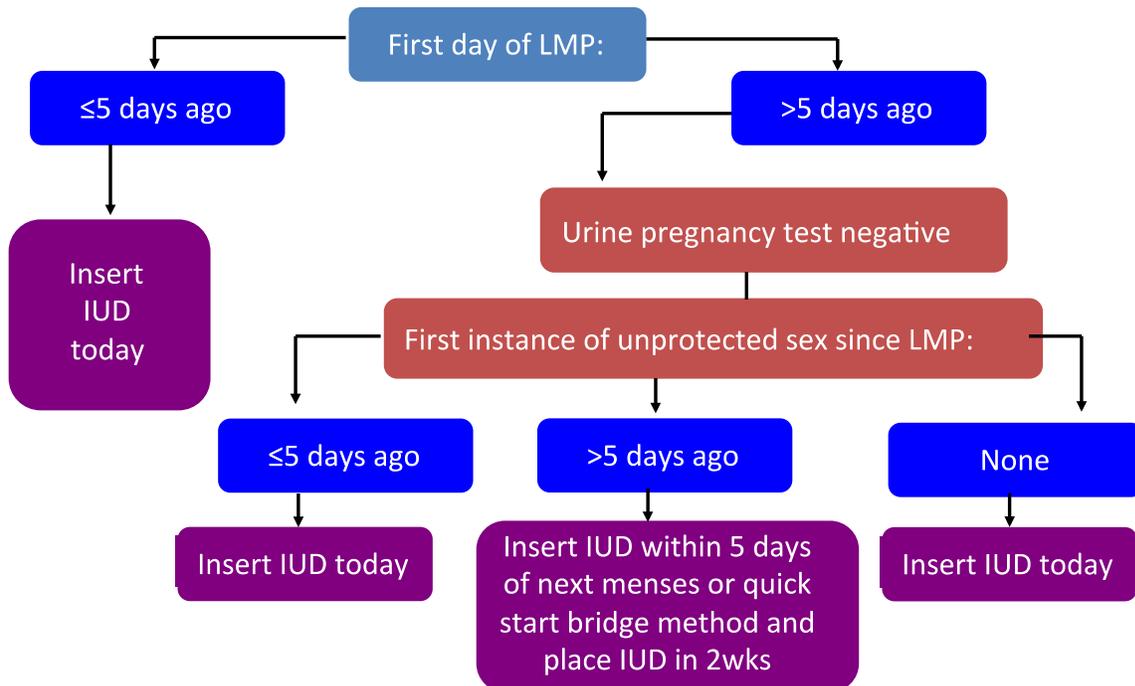
The Copper T380A (ParaGard®) intrauterine device, is a copper-bearing contraceptive device **that prevents pregnancy for at least 10 years**. It prevents pregnancy by immobilizing sperm, inhibiting fertilization and preventing implantation due to local inflammatory responses and endometrial effects. **The copper IUD can also be used for emergency contraception. It is the most effective method of emergency contraception within 5 days of unprotected sex. For women who are seeking ongoing highly effective contraception, use of the copper IUD as emergency contraception may be ideal.**

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 **CDC Medical Eligibility Criteria for Contraceptive Use**. Conditions that present and unacceptable health risk for use of the copper IUD include:
 - **Unexplained vaginal bleeding, suspicious for serious underlying condition, before evaluation.**
 - **Postpartum metritis**
 - **Immediately post septic abortion**
 - **Current PID or within the past 3 months**
 - **Current purulent cervicitis or chlamydial infection or gonorrhea**
 - **AIDS**
 - **Uterine anomalies that distort the endometrial cavity**
 - **Cervical or endometrial cancer waiting to be treated**
 - **Gestational trophoblastic disease**
 - **Severe thrombocytopenia**
 - **Postpartum puerperal sepsis**
 - **Pelvic tuberculosis**
 - **Complicated solid organ transplantation: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy**
4. **May desire hormone-free contraception**
5. **May desire the most effective emergency contraceptive possible.**

- OBJECTIVE**
1. Physical examination and laboratory tests according to programmatic guidelines. **See protocol for Preventative Care and Health Screening.**
OR
 2. Physical exam must be completed
 3. **No pelvic exam findings that are contraindications to placement** at the time of insertion.
 4. **Follow the algorithm below for initiation. If switching from a hormonal method, may do so at any time when the patient has been consistently using the method.**

Timing of Insertion for Copper T IUD



ASSESSMENT Patient has no condition representing an unacceptable risk if using a Copper T380A.

PLAN **DIAGNOSTIC STUDIES**

1. Negative pregnancy test at the time of insertion.
2. Laboratory tests:

- a. Negative gonorrhea and chlamydia tests, **if indicated. Tests may be performed on the day of placement, and the woman can return for treatment (if necessary). Clarification on this comes from the CDC's Selected Practice Recommendations:** Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's *STD Treatment Guidelines* (available at <http://www.cdc.gov/std/treatment>). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3). For these women, IUD insertion should be delayed until appropriate testing and treatment occur.
- b. Wet mount, if indicated. **NOTE: Trichomonas, yeast and BV are not contraindications to IUD placement. Clinicians may diagnose, treat, and place an IUD on the same day.**

PHARMACOLOGIC

1. May **encourage** an over-the-counter (OTC) non-steroidal anti-inflammatory 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 patient must read and sign the consent form if provided by the manufacturer in addition to the program's method specific consent form.
3. The **provider should fill out the IUD Placement procedure note as indicated.**

NON-PHARMACOLOGIC MEASURES

1. Take precautions to avert a vasovagal reaction (syncope/fainting) caused by uterine manipulation and sounding. After IUD insertion, allow the **patient** to lie still for at least 30 seconds (while explaining how to check for strings). Ask about pain or cramping. If the **patient** 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, pinched-face look, dilated pupils, weak and rapid pulse, rapid shallow breathing, hypotension) according to the Emergency Guidelines, Policies and Procedures section of this manual.

PATIENT EDUCATION/COUNSELING

1. Counsel patient according to seven basic elements of informed consent (BRAIDED – Benefits Risks Alternatives Inquiries Decision Explanation Documentation).
2. **Discuss** checking for IUD strings.
 - a. The IUD can be expelled without being noticed, **and the package insert suggests that women check for the strings monthly. However, checking for the strings has not been shown to add to optimal use of the IUD. If a patient feels reassured by checking the strings, she may do so. However, she should not be instructed that this practice is necessary.**
 - b. **If the patient does check for her strings routinely and cannot feel the strings, or if the plastic part is felt, use another method of contraception and return to the clinic.**
 - c. 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. **Patient should be instructed to return for signs and symptoms of infection.**
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 **adding condoms for STD protection if patient is at risk for STDs** (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. The T380A is approved for use for 10 years, **however clinical data affirms its effectiveness for 12 years, and probably longer. This information can be used when counseling patients who have used their Paragard for 10 years. If they would like to continue using it, evidence indicates that it still provides excellent contraception through 12 years. If she would like to have it removed, this should be honored.**

FOLLOW-UP

1. Outside of clinic hours, seek physician or emergency care if warning signs develop.
2. Re-examine and evaluate the **patient** shortly after the first post-insertion menses, but no later than three months afterwards.
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 **patient** 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 **with** evidence of pelvic infection.

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
3. M. Ziemann, R.A. Hatcher. *Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2012. (Current)
4. "Every Woman, Every Time," *A Preconception Care Toolkit for Georgia*, 2010, <<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>> (March 20, 2013)
5. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," MMWR 2010; 59, <http://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf> (March 20, 2013)
6. Centers for Disease Control and Prevention, U.S. Selected Practice Recommendations for Contraceptive Use. MMWR 2013; 62

**STANDARD APRN PROTOCOL FOR
IUD INSERTION: Levonorgestrel Releasing Intrauterine System®**

DEFINITION

The levonorgestrel-releasing intrauterine system (**Mirena® and a new product Skyla® is on the market. It has a smaller diameter and lower dose of levonorgestrel, but is otherwise quite similar**) 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 into the uterine cavity, 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. **Unlike the copper IUD, the levonorgestrel IUD is not approved for use as emergency contraception.**

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 **CDC Medical Eligibility Criteria for Contraceptive Use**. Conditions that present and unacceptable health risk for use of the levonorgestrel IUD include:
 - **Unexplained vaginal bleeding, suspicious for serious underlying condition, before evaluation.**
 - **Postpartum metritis**
 - **Immediately post septic abortion**
 - **Current PID or within the past 3 months**
 - **Current purulent cervicitis or chlamydial or gonorrhea infection**
 - **AIDS**
 - **Uterine anomalies that distort the endometrial cavity**
 - **Cervical or endometrial cancer waiting to be treated**
 - **Gestational trophoblastic disease**
 - **Lupus with positive or unknown antiphospholipid antibodies**
 - **Breast cancer**
 - **Cirrhosis – severe (decompensated)**
 - **Liver Tumors – benign hepatocellular adenoma; malignant (hepatoma)**
 - **Pelvic tuberculosis**

- **Complicated solid organ transplantation: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy**

Refer to CDC *Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk if they develop while using the contraceptive implant.

Women with these conditions may initiate the implant.

However, if women who did not have these conditions at the time of initiation develop these conditions after using the implant, the implant should not be continued. Medical conditions include:

- Migraines with aura
- Ischemic heart disease
- Stroke

4. May desire lighter periods or no periods at all

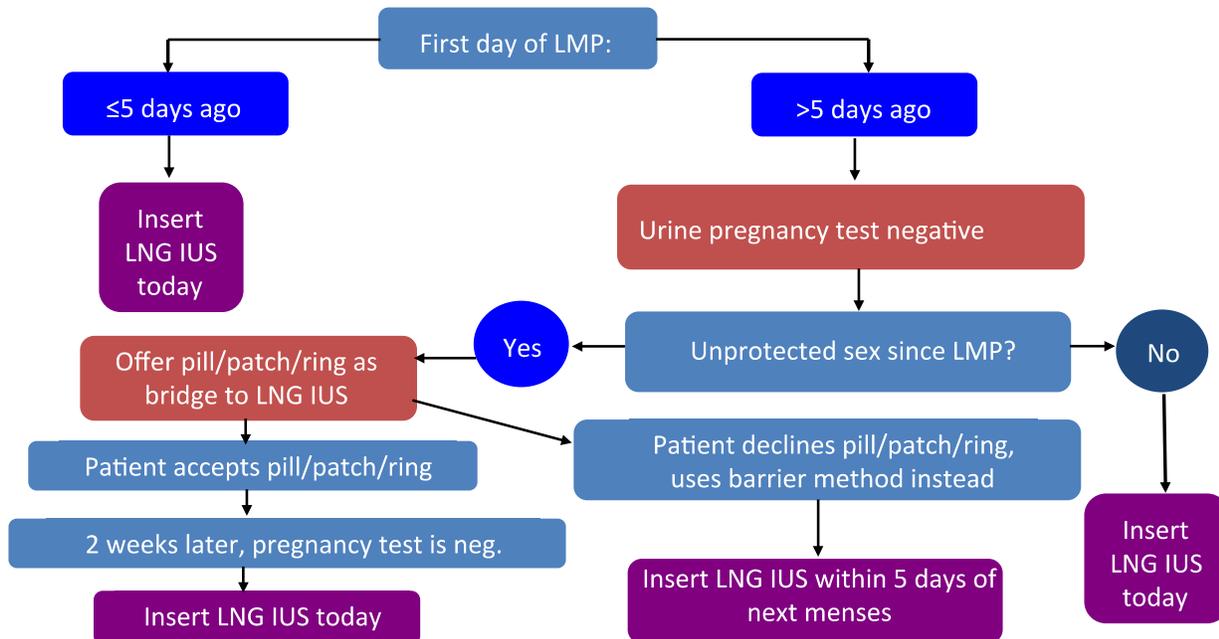
OBJECTIVE

1. Physical examination and laboratory tests according to programmatic guidelines. **See protocol for Preventative Care and Health Screening.**

OR

2. Physical exam **must be completed**
3. Normal pelvic exam at the time of insertion.
4. **Follow the algorithm below for initiation. If switching from a hormonal method, may do so at any time when the patient has been consistently using the method.**

Timing of Insertion for LNG IUS



Hatcher RA et al. *A Pocket Guide to Managing Contraception*. 2005.

ASSESSMENT **Patient** has no condition representing an unacceptable risk if using a levonorgestrel IUD.

PLAN **DIAGNOSTIC STUDIES**

1. Negative pregnancy test at the time of insertion.
2. Laboratory tests:
 - a. Negative gonorrhea and chlamydia tests, **if indicated**.
Tests may be performed on the day of placement, and the woman can return for treatment (if necessary).
Clarification on this comes from the CDC's Selected Practice Recommendations: Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's *STD Treatment Guidelines* (available at <http://www.cdc.gov/std/treatment>). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with purulent cervicitis or current

chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3). For these women, IUD insertion should be delayed until appropriate testing and treatment occur.

- b. Wet mount, if indicated. **NOTE: Trichomonas, yeast and BV are not contraindications to IUD placement. Clinicians may diagnose, treat, and place an IUD on the same day.**

PHARMACOLOGIC

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

Mirena® releases 20mcg per day and is approved for use for 5 years

Skyla® releases 14 mcg per day and is approved for use for 3 years

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

3. The **provider should fill out the IUD Placement procedure note as indicated.**

NON-PHARMACOLOGIC MEASURES

1. Take precautions to avert a vasovagal reaction (syncope/fainting) caused by uterine manipulation and sounding. After IUD insertion, allow the **patient** to lie still for at least 30 seconds (while explaining how to check for strings). Ask about pain or cramping. If the **patient** 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, pinched-face look, dilated pupils, weak and rapid pulse, rapid shallow breathing, hypotension) according to the

Emergency Guidelines, Policies and Procedures section of this manual.

PATIENT EDUCATION/COUNSELING

1. Counsel patient according to seven basic elements of informed consent (BRAIDED – Benefits Risks Alternatives Inquiries Decision Explanation Documentation).
2. **Discuss** checking for IUD strings.
 - a. The IUD can be expelled without being noticed, **and the package insert suggests that women check for the strings monthly. However, checking for the strings has not been shown to add to optimal use of the IUD. If a patient feels reassured by checking the strings, she may do so. However, she should not be instructed that this practice is necessary.**
 - b. **If the patient does check for her strings routinely and cannot feel the strings, or if the plastic part is felt, use another method of contraception and return to the clinic.**
 - c. **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. **Patient should be instructed to return for signs and symptoms of infection.**
5. Discuss common side effects:
 - a. 1 to 4 months: may have frequent spotting.
 - b. After 3- 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 **patient** should keep a menstrual record and report a sudden change in menses or suspected pregnancy immediately.
 - f. The Mirena system **is the only one approved by FDA to reduce dysmenorrhea and leads to a significant reduction in the amount and length of bleeding.**
 - g. As with other progestin-only methods, persistent ovarian follicles can occur. They do not require treatment or removal of the **LNG system**, and they usually resolve

- spontaneously. However, regular follow-up by ultrasound is recommended until cysts disappear.
- h. Give **patient** copy of **LNG system** post-insertion instructions.
6. Take over-the-counter ibuprofen or naproxen **sodium per package directions if needed for discomfort.**
 7. Should strongly consider **adding condoms for STD protection if patient is** at risk for **STDs** (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. The **Mirena** is approved for use for 5 years, **however clinical data affirms its effectiveness for up to 7 years. This information can be used when counseling patients who have used their IUD for 5 years. If they would like to continue using it, evidence indicates that it still provides excellent contraception through 7 years. If she would like to have it removed, this should be honored.**

FOLLOW-UP

1. Outside of clinic hours, seek physician or emergency care if warning signs develop.
2. Re-examine and evaluate the **patient** shortly after the first post-insertion menses, but no later than three months afterwards.
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 **patient** that IUD should be removed at time of diagnosis whether pregnancy is continued or terminated.
5. After a Mirena has been in place for 5 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 **with** evidence of pelvic infection.

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
3. M. Ziemann, R.A. Hatcher. *Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2012. (Current)
4. "Every Woman, Every Time," *A Preconception Care Toolkit for Georgia*, 2010, <<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>> (March 20, 2013)
5. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," *MMWR* 2010; 59, <http://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf> (March 20, 2013)
6. Centers for Disease Control and Prevention, U.S. Selected Practice Recommendations for Contraceptive Use. *MMWR* 2013; 62

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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	Patient 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 patient to physician. 2. If pregnancy is ruled out by HCG and exam: a. Prepare cervix as with insertion using betadine. b. If the patient is not pregnant and the strings are not visible, attempt to retrieve the IUD string using cytobrush, curved forceps, alligator forceps, or IUD retriever. Use tenaculum if necessary to steady the cervix 3. If unsuccessful in locating strings: a. Refer for pelvic ultrasound or if necessary, abdominal x-rays. Advise alternative method of contraception while trying to locate IUD. b. If the IUD is identified as properly positioned in the uterus, no action is necessary; reassure the patient. c. If ultrasound identifies the IUD, but unable to identify in uterus, refer to MD.

PATIENT EDUCATION/COUNSELING

1. If the IUD is removed, advise the **patient** to use another method of contraception.

FOLLOW-UP

Return to clinic as needed for contraception or **preventative care**.

CONSULTATION/REFERRAL

1. Immediately refer patient 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*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
3. M. Ziemann, R.A. Hatcher. *Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2012. (Current)

STANDARD APRN PROTOCOL FOR IUD REMOVAL/COMPLICATIONS AND ACTIONS

DEFINITION Removal of an IUD by the clinician at the **patient's** request, due to clinical findings such as pregnancy 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. **Patient** may request IUD removal for any reason.
 2. **Patient** may report a condition that precludes IUD use, such as suspected or confirmed pregnancy **or partial expulsion**.
 3. **Patient** 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.
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 **patient** is not pregnant, remove IUD slowly, applying gentle, steady traction to string with sponge forceps.
2. If **patient** 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 **patient** is not pregnant and the strings are not visible, attempt to retrieve the IUD string using cytobrush, curved forceps, alligator forceps, or IUD retriever. Use tenaculum if necessary to steady the cervix.
4. If patient is pregnant, patient should be counseled **that removal is recommended. Removal is associated with a slight risk of pregnancy loss at the time of removal, but the risk of infection, miscarriage and preterm birth are more serious if left in situ.** After counseling, refer patient to physician for removal of IUD.

PATIENT EDUCATION/COUNSELING

1. Choose any method if the **patient** does not desire pregnancy.
2. **If the patient is seeking pregnancy, return to fertility is rapid. Initiate folic acid supplementation.**
3. There are no known major long-term side effects after removal of an IUD.
4. Provide counseling on preconception health counseling and future fertility. (Refer to PCH Toolkit)

FOLLOW-UP

Return to clinic as needed, for contraception or **preventative care.**

CONSULTATION/REFERRAL

Refer or consult with physician if:

1. Difficult/failed removal.
2. **Patient** 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.	1. May consider application of topical anesthesia such as Lidocaine gel, etc.
2. Pain with sounding of the uterus during insertion.	2. Sound slowly and gently consider smaller sound. If severe, check alignment of uterine cavity.
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. Pain at time of insertion, persistent and increasing, and signs of abdominal tenderness: a. if strings are present b. if strings are absent	4. a. Presume partial perforation has occurred; remove IUD and treat for pelvic infection. b. Consider possibility of perforation. Refer patient to physician.
5. Partial expulsion of an IUD	5. Remove IUD. Pregnancy test as indicated.
6. Pelvic inflammatory disease	6. See Nurse Protocol for Pelvic Inflammatory Disease.
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*, 20th ed., Ardent Media, Inc., New York, 2011. (Current)
2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings*, 10th ed., Springer Publishing Co., New York, 2012. (Current)
3. M. Ziemann, R.A. Hatcher. *Managing Contraception*. Tiger, Georgia: Bridging the Gap Foundation, 2012. (Current)
4. "Every Woman, Every Time," *A Preconception Care Toolkit for Georgia*, 2010, <<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>> (March 20, 2013)
5. CDC, "U.S. Medical Eligibility Criteria for Contraceptive Use, 2010," MMWR 2010; 59, <http://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf> (March 20, 2013)

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APPENDIX A

Department of Public Health
Nurse Protocols for Registered Professional Nurses
2014

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	Modicon, 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
Apri.-28	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
Microgestin 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 Contraceptives

Name	Cycle 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

Name	Cycle 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
Empresse-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

Name	Cycle Count	Progestin	mg	Estrogen	mcg	Same Formula
Natazia	28 Pills	Dienogest	2 and 3	Estradiol Valerate	1, 2, and 3	None

Extended Cycle Contraceptives

Name	Cycle 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	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

Contraceptives						
Injectable DMPA Contraceptives						
Name	PKG Count	Progestin	mg	Estrogen	mcg	Same Formula
Medroxyprogesterone / Depo-Provera	1	Progesterone	150	None		Depo-Provera
Transdermal (patch) Contraceptives						
Name	Cycle Count	Progestin	mg	Estrogen	mcg	Same Formula
Ortho Evra	1 Week	Norelgestromin	0.15/day	E.estradiol	0.02/day	None
Intrauterine (IUD) Contraceptives						
Name	Count	Method of Delivery	mg	Estrogen	mcg	Same Formula
Paragard T 380A Intrauterine Copper Device - 10 year device	1	Spermicide				None
Mirena IUS DS - 5 year device	1	Levonorgestrel			20/day	None
Implant Contraceptives						
Name	Count	Method of Delivery	mg	Estrogen	mcg	Same Formula
Implanon	1	Etonogestrel	68			None
Emergency Contraceptives						
Name	Cycle Count	Progestin	mg	Estrogen	mcg	Same Formula
Plan B One-Step	1 Pill	Levonorgestrel	0.75	None		NextChoice
NEXT CHOICE™	2 Pills	Levonorgestrel	0.75	None		Plan B
Ella ULIPRISTAL ACETATE 30 MG	1 Pill		30	None		None
Spermicidals - Foam, Film, Gels, Suppositories						
Name	Method of Delivery	mg	Estrogen	mcg	Same Formula	
VCF Vaginal Contraceptive Foam	Nonoxynol-9				Delfen	
VCF Vaginal Contraceptive Film	Nonoxynol-9				None	
Delfen Contraceptive Foam w/applicator	Nonoxynol-9				VCF	
Barriers - Diaphragms/ Caps / Condoms						
Name	Method of Delivery	mg	Estrogen	mcg	Mfr	Same Formula
DIAPHRAGM COILSPRING 100MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM COILSPRING 105MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM 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
DIAPHRAGM COILSPRING 90MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM COILSPRING 95MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM FLATSPRING 55MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM FLATSPRING 60MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM FLATSPRING 65MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM FLATSPRING 70MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM FLATSPRING 75MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM FLATSPRING 80MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM FLATSPRING 85MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM FLATSPRING 90MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
DIAPHRAGM FLATSPRING 95MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
ORTHO ALL-FLEX DIAPHRAGM 65M LATEX-FREE	Non-Systemic				Ortho	None
ORTHO ALL-FLEX DIAPHRAGM 70M LATEX-FREE	Non-Systemic				Ortho	None
ORTHO ALL-FLEX DIAPHRAGM 75M LATEX-FREE	Non-Systemic				Ortho	None
ORTHO ALL-FLEX DIAPHRAGM 80M LATEX-FREE	Non-Systemic				Ortho	None
ORTHO ALL-FLEX FITTING SET	Non-Systemic				Ortho	None
ORTHO-DIAPHRAGM ALLFLEX 55MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
ORTHO-DIAPHRAGM ALLFLEX 60MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
ORTHO-DIAPHRAGM ALLFLEX 65MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
ORTHO-DIAPHRAGM ALLFLEX 70MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
ORTHO-DIAPHRAGM ALLFLEX 75MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
ORTHO-DIAPHRAGM ALLFLEX 80MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
ORTHO-DIAPHRAGM ALLFLEX 85MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
ORTHO-DIAPHRAGM ALLFLEX 90MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None
ORTHO-DIAPHRAGM ALLFLEX 95MM W/ORTHO-GYNOL	Non-Systemic				Ortho	None