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

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2014 WOMEN'S HEALTH CLINICAL REVIEW TEAM

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CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) US MEDICAL ELIGIBILITY CRITERIA (MEDICAL ELIGIBILITY CRITERIA) 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 Medical Eligibility Criteria 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 Medical Eligibility Criteria and SPR should guide clinicians in providing evidence-based contraceptive care in the United States.

The Medical Eligibility Criteria 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 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 Medical Eligibility Criteria 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 Medical Eligibility Criteria 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 Medical Eligibility Criteria:

- 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 Medical Eligibility Criteria 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 Medical Eligibility Criteria 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.

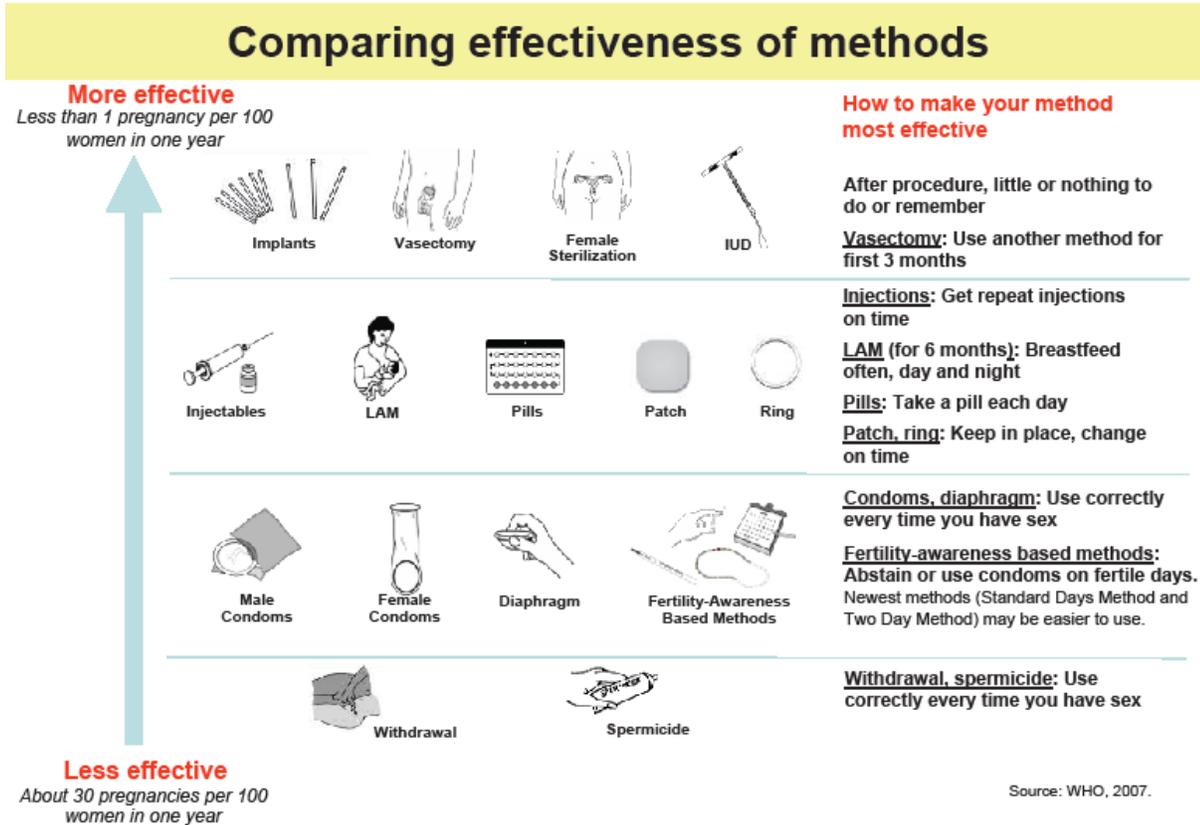
^{§§} With spermicidal cream or jelly.

^{¶¶} 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); Crystelle, 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 Medical Eligibility Criteria, 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:** Lobbok 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 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. Documentation of the preference for deferral should be made in the patient record.

TABLE 1: Exam components

	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
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 cytology alone every 3 years	Prefer co-testing (cytology plus HPV testing) every 5 years Acceptable for 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 (AHRQ and AGA support initiating screening for African American and Native American patients at age 45. Clinicians are encouraged to discuss these recommendations with patients and initiate screening accordingly). 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.

*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.

TABLE 3: STD screening

The following table outlines a risk-based strategy for STD screening. Providers are reminded that screening is to be applied to asymptomatic patients and that additional testing may be appropriate for symptomatic patients. Providers are also encouraged to be aware of their local epidemiology of STDs. Some areas of Georgia have epidemic-level prevalence of disease.

	Females	Males
Chlamydia	<p>Annually all women less than 26 years old</p> <p>For women 26 years old and over, screen annually for those with new partners, multiple partners or partners with other partners</p> <p>Those who have previously tested positive should be screened for reinfection 3 months after treatment or whenever the person presents for care in the 12 months following initial treatment.</p>	<p>Screen those who are in settings with high risk: adolescent clinics, correctional facilities, STD clinics as well as MSM. Screening should be at anatomic site of exposure.</p> <p>Those who have previously tested positive should be screened for reinfection 3 months after treatment or whenever the person presents for care in the 12 months following initial treatment.</p>
Gonorrhea	<p>Annually all women less than 26 years old</p> <p>For women 26 years old and over, screen annually for those with new partners, multiple partners, previous STD or gonorrhea, inconsistent condom use (if at risk), commercial sex work, and drug use.</p> <p>Those who have previously tested positive should be screened for reinfection 3 months after treatment or whenever the person presents for care in the 12 months following initial treatment.</p>	<p>MSM and those with symptoms of infection. Screening should be at anatomic site of exposure.</p> <p>Those who have previously tested positive should be screened for reinfection 3 months after treatment or whenever the person presents for care in the 12 months following initial treatment.</p>

HIV	<p>All patients 13-64 should “routinely” be screened for HIV.</p> <p>Those at high risk should be screened annually. High risk includes: injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test.</p>
Hepatitis C	<p>One time screening for those who were born 1945-1965. Screen also if at high risk for infection.</p>
Syphilis	<p>Populations at risk include MSM, commercial sex workers, persons who exchange sex for drugs, those in adult correctional facilities and those living in communities with high prevalence of syphilis.</p>

PATIENT EDUCATION AND 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>
 - c. **The CDC guidance on Providing Quality Family Planning Services recommends the following immunizations related to reproductive health:**
 - i. **Human Papilloma Virus (HPV):**
 1. **Females aged 11-26 who have not been previously vaccinated should be offered the bivalent or quadrivalent HPV vaccination.**
 2. **Males aged 11-21 who have not been previously vaccinated should be offered the quadrivalent HPV vaccination. Those who are immunocompromised through age 26 should be offered vaccination.**
 - ii. **Hepatitis B: Routine hepatitis B vaccination should be offered to all unvaccinated children and adolescents aged 18 years and younger and all unvaccinated adults who do not have a documented history of hepatitis B infection.**
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. **If the patient is under 18 years of age, then consult legal counsel for possible reporting as child abuse.**

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.

REFERENCES

1. US Preventive Services Task Force. <http://www.uspreventiveservicestaskforce.org/> Accessed May 25, 2013
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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 venous thromboembolism risk (such as age 35 or older previous venous thromboembolism, thrombophilia, immobility, transfusion at delivery, BMI 30 or greater, 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 Standard Nurse 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) Take the first pill on the Sunday following the onset of menses. If the menses starts on Sunday, start that day. Don't wait to start the first pill on the Sunday after menses ends. A Sunday start may allow for women to avoid having cycles on the weekend. Otherwise, there is no benefit to this approach.
 - 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 (greater than 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. **See Quick Start Protocol.**
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. **OPTIONAL for women who desire menstrual suppression: Additional instructions for extended use of OCs**
 - a. **Take one monophasic OC each day (recommend 20 mcg).**
 - b. **Skip the placebo pills (the 7 pills at the end of the month that are a different color) and start the next pill pack.**
 - c. **This means that the woman should take one active pill each day (no placebo pills) until she desires a period. Common extended cycles include bi-cycling (two pill packs in a row followed by one week of placebo pills and the resulting menstrual period), tri-cycling (three pill packs in a row followed by one week of placebo pills and the resulting menstrual period), or continuous (no placebo pills, no menstrual periods).**
 - d. **This will require more pill packs over the course of the year (16 months). Alternatively, a provider can prescribe an extended version of pills (ex. Seasonale, Lybrel) if the woman has coverage and desires menstrual suppression.**
 5. Discuss side effects and danger signs (ACHES).
 6. Discuss effectiveness of combined OCs and back-up methods.
 7. Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit).

<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>

8. Counsel on the use of condoms to reduce the risk of STD/HIV.
9. 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 *US Medical Eligibility for Contraceptive Use* 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.

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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)
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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.

Breakthrough 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)
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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 *US Medical Eligibility for Contraceptive Use* 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 (greater than 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.
10. 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.
11. 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.
12. 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.
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.
15. 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)
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 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 hours 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 that the copper IUD and ulipristal acetate are superior to levonorgestrel for pregnancy prevention in this window.

2. **Due to the time-sensitive nature of use of emergency contraceptive pills, patients may request and/or providers can recommend or provide emergency contraception in advance for use as needed. This may be particularly valuable for women who elect short term or coitally-dependent contraception (contraceptive pills, condoms, contraceptive patch, contraceptive rings, etc.) or for any woman who has a medical condition that puts her at increased risk if she experiences an unintended pregnancy (See Box 2 CDC Medical Eligibility Criteria).**
3. Precautions:
When providing Plan B[®] One-Step, Plan B[®] Two-Step, Next Choice, generic levonorgestrel, or ulipristal acetate, Ella[®]:
 - a. History of hypersensitivity to any component of progestin only pills.
 - b. Undiagnosed vaginal bleeding.
 - c. Known or suspected pregnancy.

OBJECTIVE

1. 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)**
2. Pelvic exam, if indicated.
3. 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

1. 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. **Ulipristal acetate works better than levonorgestrel-only ECP between 72-120 hours and for women who have BMI greater than 30. For women in these situations, clinicians should preferentially offer Ulipristal acetate or Paragard if available due to their higher efficacy.**
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. **Emergency contraception does not protect from pregnancy going forward (except for use of Paragard as EC), and future acts of sex require additional contraception.**
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. **Women who use ulipristal acetate for EC and who begin a hormonal contraception should use a back-up method for two weeks from the time she took ECPs.**
6. 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.
7. Provide counseling on preconception health counseling and future fertility. (Refer to Preconception Health Toolkit)
<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>
8. Advise patient that ECP does not protect against STD/HIV. Counsel on the use of condoms to reduce the risk of STD/HIV.

9. 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, Luteru, 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 over-the-counter 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 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)**

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)
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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.

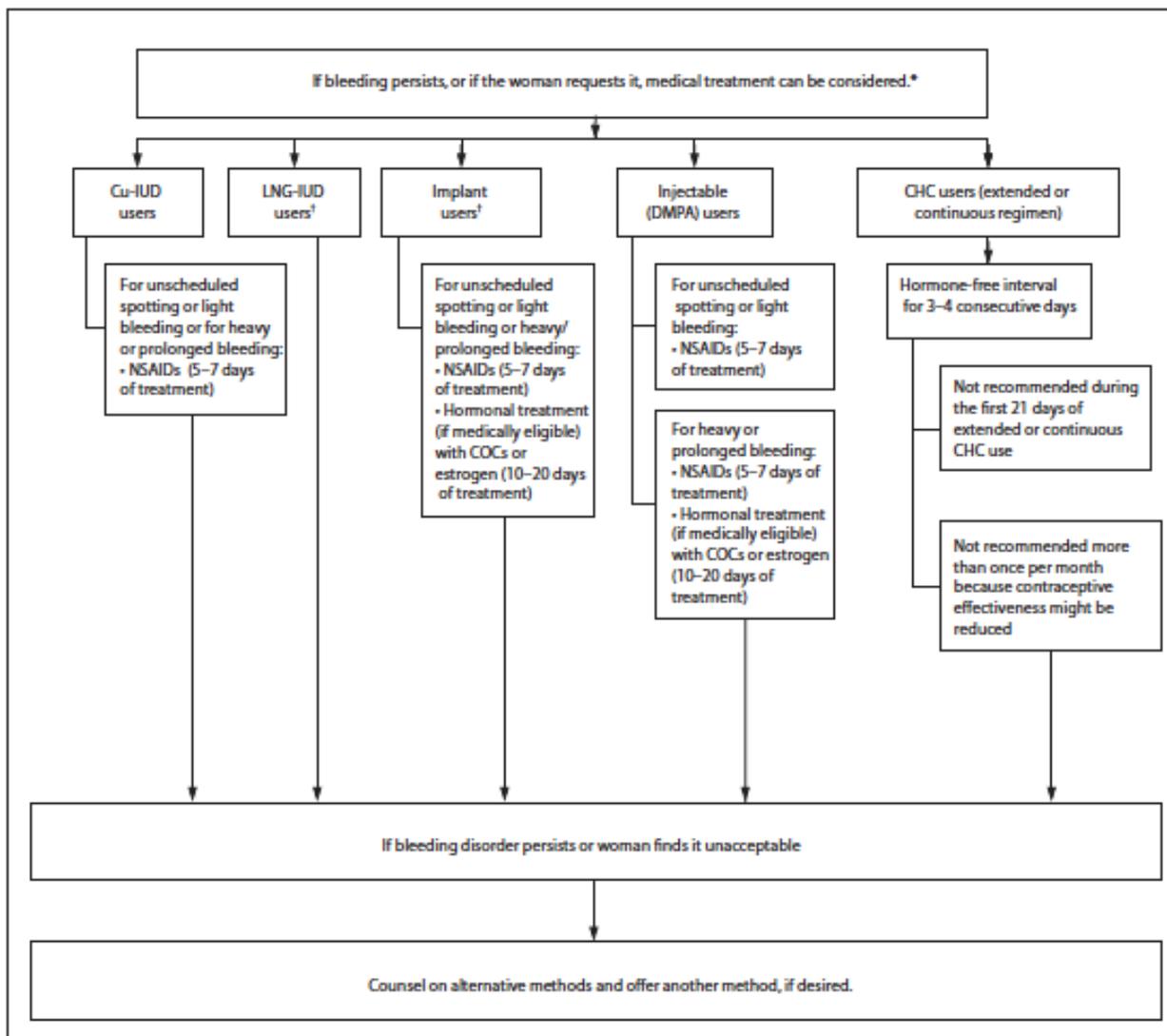
THERAPEUTIC

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.

4. **Refer to APRN or physician for 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)
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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 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 gonadatropin-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 104 mg 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) depo medroxyprogesterone acetate provided the next injection is given within the prescribed dosing period for the IM (150 mg/mL).**
 - d. **Contraceptive coverage will be maintained in switching from depo medroxyprogesterone acetate 104 mg SC to 150 mg IM, provided the next injection is given within the prescribed dosing period for depo medroxyprogesterone acetate 104 mg SC.**

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.”

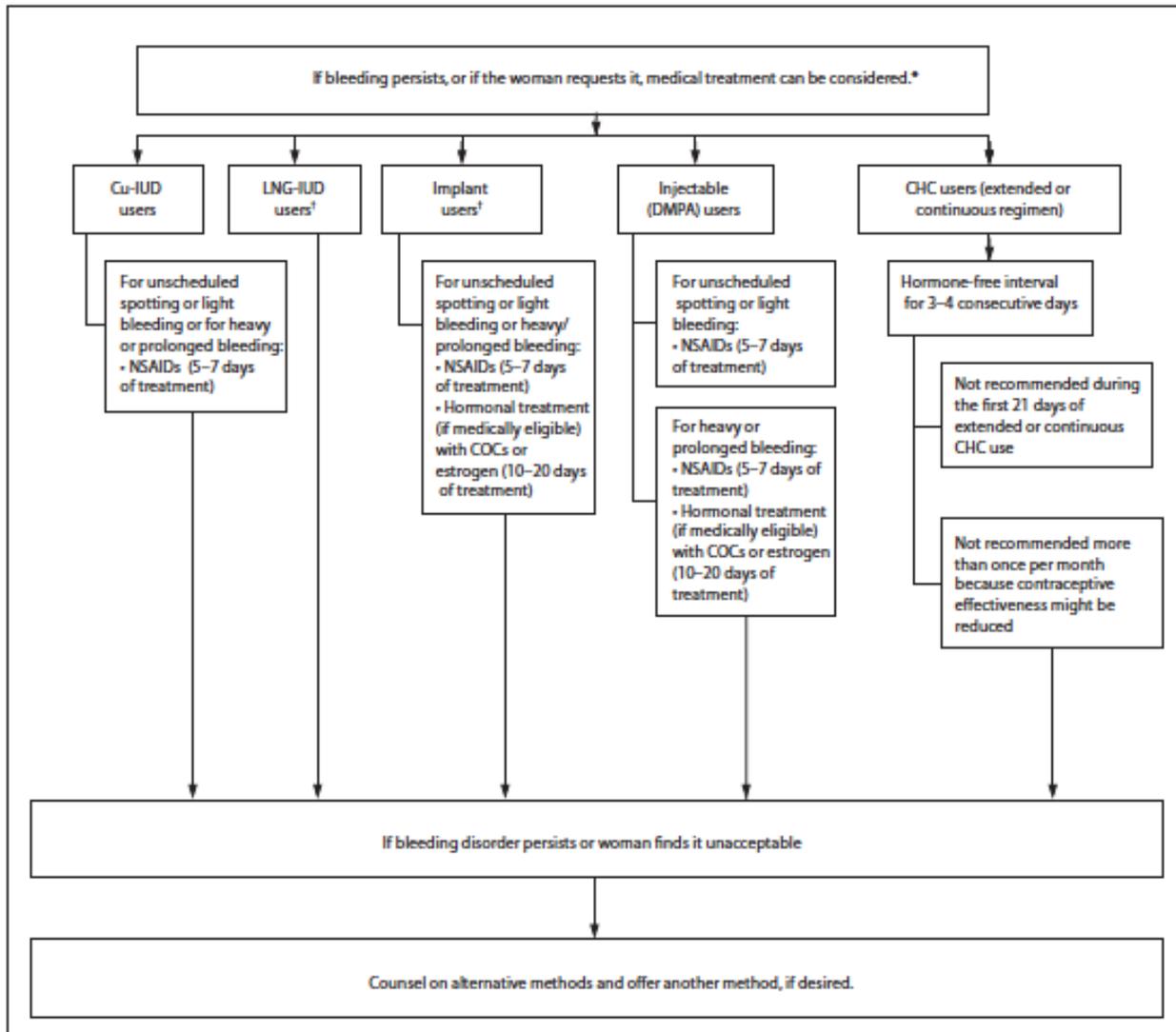
9. Discuss effectiveness of Depo-Provera and back-up methods.
10. Advise patient that Depo-Provera is a long acting contraceptive and not immediately reversible. It takes at least 3 months for fertility to return after last injection. Anovulation may linger after discontinuation. The average delay to 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.

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5. “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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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	DIAGNOSTIC STUDIES Sensitive urine pregnancy test (HCG) only if patient reports symptoms of pregnancy. THERAPEUTIC <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.

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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.
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**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 venous thromboembolism risk (such as age 35 or older, previous venous thromboembolism, 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 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 (greater than 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).
<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>
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 Medical Eligibility Criteria 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.

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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 or older, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI 30 or greater, postpartum hemorrhage, post cesarean delivery, preeclampsia, or smoking). For non-breastfeeding postpartum 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 (greater than 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).
<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>
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 Medical Eligibility Criteria 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)
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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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

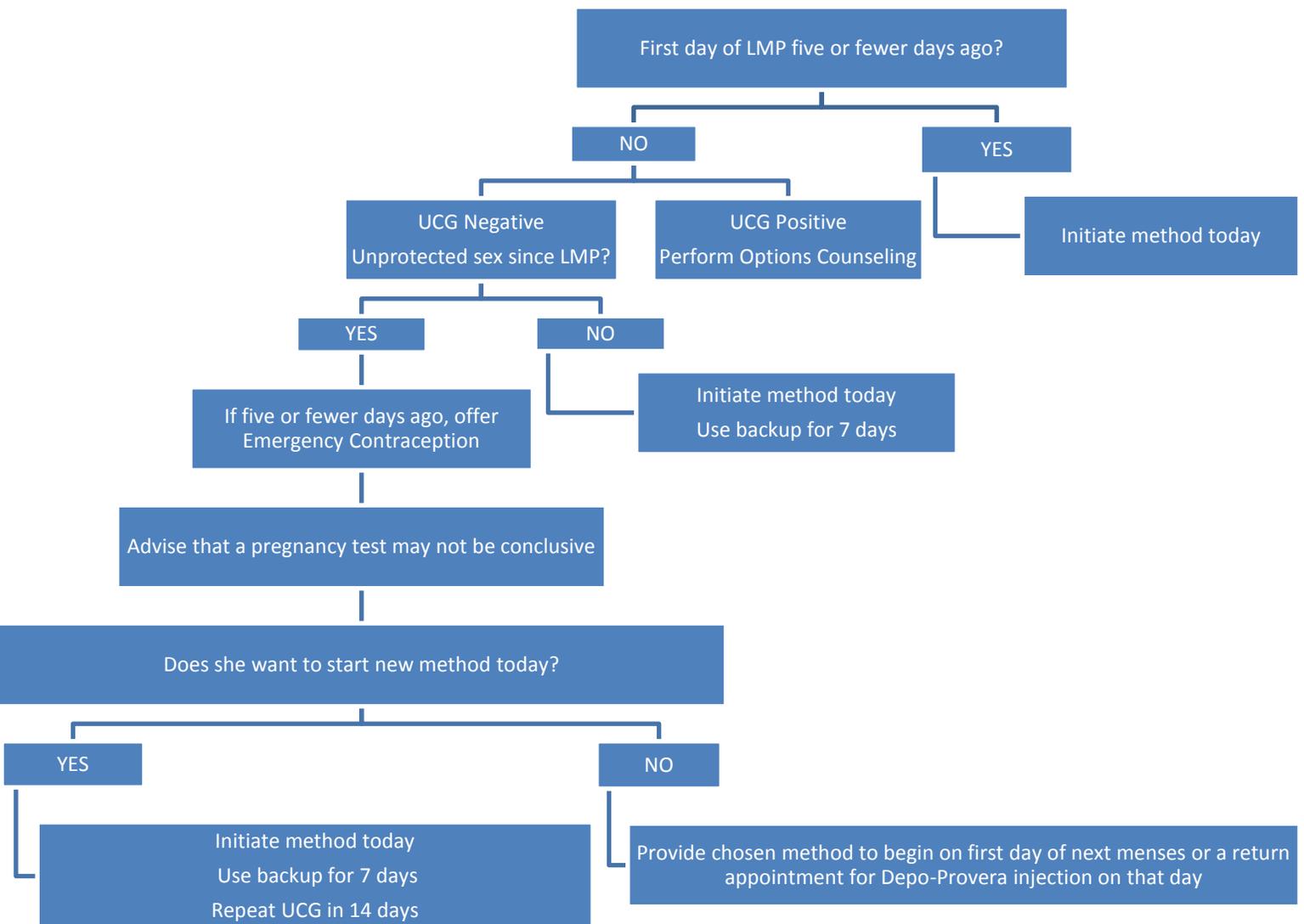
1. Provide method-specific counseling and consent for the method that the patient is initiating.
2. Provide condoms for backup protection (or encourage abstinence) for at least 7 days. Counsel on the continued use of condoms to reduce the risk of STD/HIV.
3. Schedule well-woman care as needed.

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 <i>Medical Eligibility Criteria for Contraceptive Use</i>.2. Refer to CDC <i>Medical Eligibility Criteria for Contraceptive Use</i> 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).
<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>
 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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8. "Every Woman, Every Time," *A Preconception Care Toolkit for Georgia*, 2010, <<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>> (May 16, 2011)
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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 less than 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 nitro-furantoin 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. **Foods that may decrease absorption include: dietary fiber, soy products, spinach, and eggs. Foods that enhance dietary absorption of iron include broccoli, grapefruit, orange juice, peppers and strawberries.**
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, pancrelipase and **proton pump inhibitors** 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. **Refer any woman at risk for endometrial pathology (ex. 35 years old or older with abnormal bleeding, chronic anovulation, Tamoxifen therapy) to MD for evaluation for possible endometrial sampling.**
6. 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)
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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)
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STANDARD NURSE PROTOCOL FOR SCREENING MAMMOGRAPHY

DEFINITION	A mammogram is an x-ray image of the breast.
ETIOLOGY	Mammography may detect cancer up to three years before a breast mass is palpable. It is the only method of screening for breast cancer proven to decrease mortality. The goal of performing screening mammograms is the early detection of breast cancer, resulting in reduced morbidity and mortality. Various well-respected professional organizations have differing recommendations as to what age to initiate and how often to conduct the screenings. The American Cancer Society recommends annual breast cancer screening by mammography beginning at age 40, continuing as long as the woman is in good health. Kaiser Permanente Care Management Institute recommends screening mammograms be performed every one to two years in women age 40 and above.
SUBJECTIVE	<ol style="list-style-type: none">1. Obtain health history, including family history of cancers.2. Reports no breast symptoms requiring diagnostic evaluation.3. Age 40 or older.
OBJECTIVE	Perform California Method clinical breast exam
ASSESSMENT	Clinical breast exam normal
PLAN	THERAPEUTIC PHARMACOLOGIC NONE NON-PHARMACOLOGIC MEASURES <ol style="list-style-type: none">1. Annual or biennial screening mammogram for women ages 40-49. Women at increased risk for breast cancer should be screened annually.2. Annual screening mammogram for women age 50 and older (annual as defined by the CDC is every 12-18 months). NOTE: It is important to ascertain where and when any prior mammograms or breast ultrasounds were done so that

appropriate comparison exams are available to the interpreting radiologist.

PATIENT EDUCATION/COUNSELING

1. No lotions, deodorants, perfumes or powders should be used on breasts or under arms prior to mammogram. This may cause shadows to appear in the imaging.
2. Educate regarding current screening mammogram recommendations.
3. Any unusual breast changes (i.e., mass, skin changes, nipple discharge, and severe pain) that a patient discovers in the future should be evaluated by a clinician as soon as possible.

FOLLOW-UP:

1. If screening mammogram report is incomplete or abnormal, follow radiologist's recommendation for diagnostic mammography or breast ultrasound. Refer to Ordering Diagnostic Mammograms and Breast Ultrasound nurse protocol.
2. Notify patient of screening mammogram results and document in medical record.

CONSULTATION/REFERRAL

1. Refer to MD as needed for abnormal screening mammogram result.
2. Refer to GA DPH BCCP manual for reimbursement guidelines if screening mammogram is to be funded by this program.

REERENCES

1. Georgia Department of Public Health BCCP Manual, 2014.
2. American College of Radiology ACR Appropriateness Criteria <http://www.acr.org/~media/ACR/Documents/AppCriteria/Diagnostic/BreastCancerScreening.pdf>, 2012 (October 9, 2014)
3. Women'shealth.gov. <http://womenshealth.gov/publications/our-publications/fact-sheet/mammograms.html#j> Content last updated: June 21, 2013. (October 9, 2014)
4. What Is a Mammogram and When Should I Get One? http://www.cdc.gov/cancer/breast/basic_info/mammograms.htm Oct 2013 (October 9, 2014)
5. American Cancer Society Guidelines for the Early Detection of Cancer, 5/3/2014
6. Kaiser Permanente Care Management Institute (KPCMI). Breast cancer screening clinical practice guideline. Oakland (CA): Kaiser Permanente Care Management Institute; 2010 Aug. 142 p. (current)

STANDARD NURSE PROTOCOL FOR ORDERING DIAGNOSTIC MAMMOGRAMS AND BREAST ULTRASOUNDS

DEFINITION	<p>Breast diagnostic procedures may be requested to further evaluate an abnormal finding of the breast, enabling diagnosis. The diagnostic tests that the public health nurse may be asked to order include: diagnostic mammogram and/or breast ultrasound. A diagnostic mammogram may include supplemental views and/or spot compressions and is performed under the immediate supervision of the radiologist.</p> <p>A breast ultrasound uses sound waves to make pictures of the tissues inside the breast and can show all areas of the breast including the area closest to the chest wall, which is hard to study with a mammogram. A breast ultrasound determines whether an area of concern is solid, fluid-filled or a combination of both.</p>
ETIOLOGY	<p>A diagnostic mammogram is appropriate to further assess findings such as a palpable breast mass, persistent focal breast pain, clear (but not necessarily colorless) or bloody nipple discharge and/or skin changes. It is often requested by the radiologist when a screening mammogram requires further investigation. A diagnostic mammogram is also ordered for short-term follow-up of a probable benign finding indicated by a previous BIRADS 3 mammogram interpretation.</p> <p>Breast ultrasounds evaluate palpable masses and areas of concern discovered on mammograms. In the woman under 30 years of age, initially, an ultrasound alone is often preferred to evaluate a breast mass due to the increased breast density in this population.</p>
SUBJECTIVE	<ol style="list-style-type: none">1. Obtain health history, including family history of cancers.2. May report unilateral persistent focal pain, not associated with menstrual cycle.3. May report breast mass or skin changes of breast.4. May have no outward symptoms (if diagnostic testing is requested for further evaluation of incomplete or abnormal screening breast imaging).
OBJECTIVE	<p>Perform California Method clinical breast exam</p>

ASSESSMENT Document condition requiring diagnostic mammogram and/or breast ultrasound (i.e., breast mass, skin changes, BIRADS 0 mammogram report, BIRADS 3-short-term follow-up, unilateral focal breast pain)

PLAN

THERAPEUTIC

PHARMACOLOGIC

NONE

NON-PHARMACOLOGIC MEASURES

1. Follow BCCP New Palpable Breast Mass algorithm included in this protocol.
2. Order as appropriate (indicate right or left breast if unilateral procedure):
 - a. Unilateral or bilateral diagnostic mammogram
 - b. Unilateral or bilateral breast ultrasound
3. If not already enrolled, enroll patient in BCCP if patient is eligible and funding is available.

NOTE: It is important to ascertain where and when any prior mammograms or breast ultrasounds were done so that appropriate comparison exams are available to the interpreting radiologist.

PATIENT EDUCATION/COUNSELING

1. No lotions, deodorants, perfumes or powders should be used on breasts or under arms prior to mammogram. This may cause shadows to appear in the imaging.
2. Educate regarding current screening mammogram recommendations.
3. Any unusual breast changes (i.e., mass, skin changes, nipple discharge, and severe pain) that a patient discovers in the future should be evaluated by a clinical breast exam as soon as possible.

FOLLOW-UP:

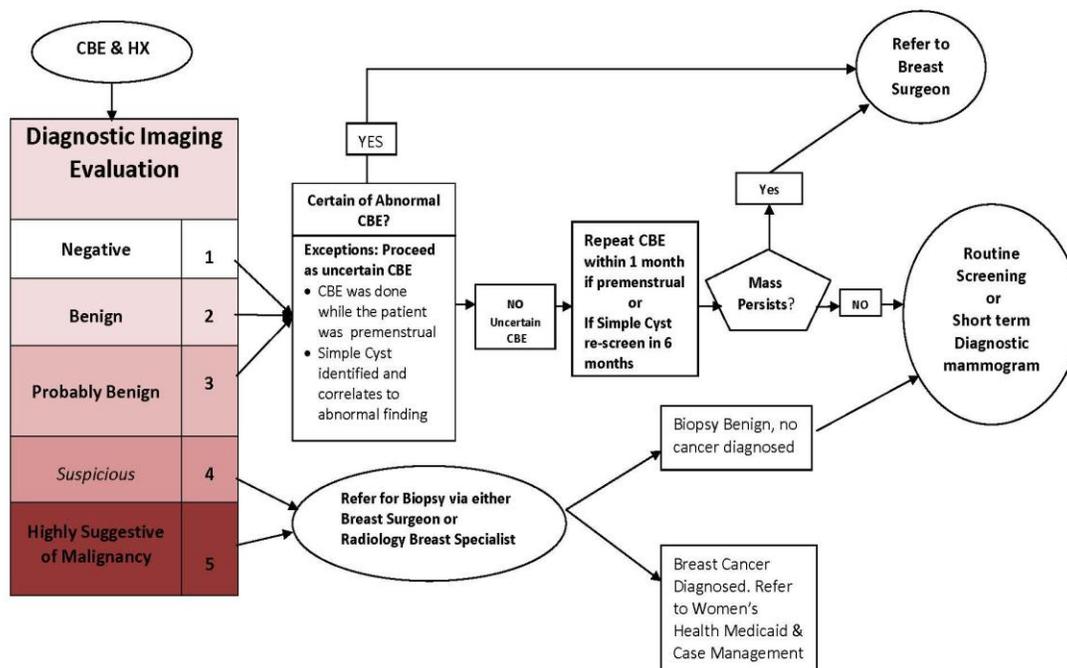
1. For a newly diagnosed breast mass, follow BCCP New Palpable Breast Mass algorithm included in this protocol.

- 2. If a breast mass is discovered during the premenstrual time of a woman's menstrual cycle, have her return for a recheck of her breast during the week following the end of her menses. If the mass remains present, proceed with diagnostic testing.**
- 3. Continue to follow-up until condition proves benign. If malignancy is identified, follow-up until patient is under oncologic care.**

CONSULTATION/REFERRAL

- 1. Refer to surgeon for evaluation of abnormal clinical findings and further management.**
- 2. Refer women who have bilateral nipple discharge with no evidence of a breast mass to MD for evaluation. The nipple discharge may be due to an underlying medical condition not related to an abnormality of the breast specifically.**
- 3. For unilateral spontaneous nipple discharge refer to the Spontaneous Unilateral Nipple Discharge (Non-Lactating) nurse protocol.**

NEW PALPABLE BREAST MASS



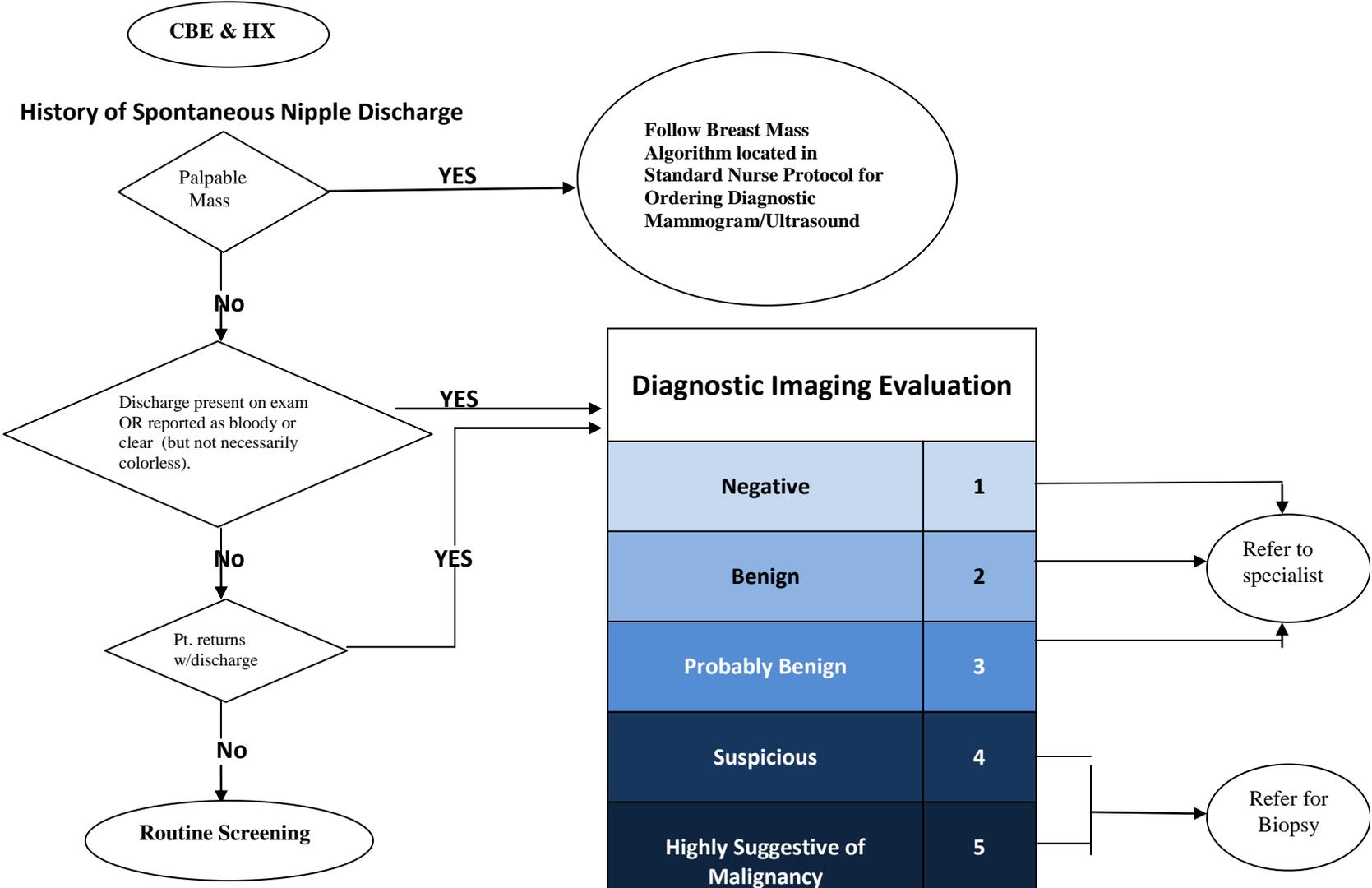
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1. Georgia Department of Public Health BCCP Manual, 2014.
2. American College of Radiology Practice Parameter for the Performance of Screening and Diagnostic Mammography Amended 2014 (Resolution 39) <http://www.acr.org/~media/3484ca30845348359bad4684779d492d.pdf> (October 9, 2014)
3. Women's health.gov. <http://womenshealth.gov/publications/our-publications/fact-sheet/mammograms.html#j> Content last updated: June 21, 2013 (October 9, 2014).
4. American College of Radiology Practice Parameter for the Performance of Breast Ultrasound Examination Amended 2014 (Resolution 39) <http://www.acr.org/~media/52d58307e93e45898b09d4c4d407dd76.pdf> (October 13, 2014)
5. T Richards, A Hunt, S Courtney, and H Umeh Nipple Discharge: A Sign of Breast Cancer? Ann R Coll Surg Engl. Mar 2007; 89(2): 124–126. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1964556/> (October 9, 2014)

STANDARD NURSE PROTOCOL FOR SPONTANEOUS UNILATERAL NIPPLE DISCHARGE (NON-LACTATING)

DEFINITION	Spontaneous unilateral nipple discharge is the presence of discharge flowing from the nipple that does not require manipulation of the nipple to visualize the discharge. Spontaneous leaking from the nipple should be absent within 6 months after cessation of breastfeeding.
ETIOLOGY	Many conditions may cause spontaneous nipple discharge; most of these conditions are benign. These benign conditions include: intraductal papilloma, mammary duct ectasia, fibrocystic changes, endocrine disorders and infection/abscesses. The most common cause for bloody nipple discharge in the absence of a breast mass is intraductal papilloma. Less than 10% of nipple discharge is associated with breast cancer.
SUBJECTIVE	<ol style="list-style-type: none">1. Obtain health history, including family history of cancers.2. Reports discharge from one nipple that flows spontaneously. Discharge may be described as a single or variety of colors (ie: white, clear, yellow, green or bloody).3. Denies known breast mass.
OBJECTIVE	Perform California Method clinical breast exam
ASSESSMENT	Spontaneous unilateral nipple discharge observed OR Spontaneous unilateral nipple discharge reported
PLAN	THERAPEUTIC PHARMACOLOGIC NONE NON-PHARMACOLOGIC MEASURES <ol style="list-style-type: none">1. Follow recommendation from the Spontaneous Unilateral Nipple Discharge (Non-Lactating) algorithm included in this protocol.2. Order bilateral diagnostic mammogram and ultrasound of the breast with discharge.

Spontaneous Unilateral Nipple Discharge (Non-Lactating)



PATIENT EDUCATION/COUNSELING

1. Inform patient that less than 10% of nipple discharge is due to breast cancer, but further diagnostic testing is warranted to rule out breast cancer.
2. No lotions, deodorants, perfumes or powders should be used on breasts or under arms prior to mammogram. This may cause shadows to appear in the imaging.
3. It is important to ascertain where and when any prior mammograms or breast ultrasounds were done so that appropriate comparison exams are available to the interpreting radiologist.
4. Educate regarding current screening mammogram recommendations.
5. Any unusual breast changes (ie: mass, skin changes, nipple discharge, severe pain) that a patient discovers in the future should be evaluated by a clinical breast exam as soon as possible.

FOLLOW-UP:

1. If no discharge is present, follow routine recommendation for breast cancer screening.
2. Instruct the patient not to try to express discharge from her nipples. Explain that expressing discharge tend to increase the amount of discharge.
3. If no unilateral discharge is noted upon exam, and reported discharge is non-bloody, have patient return to clinic for exam if/when unilateral discharge returns.
4. Continue to follow-up until condition proves benign. If malignancy is identified, follow-up until patient is under oncologic care.

CONSULTATION/REFERRAL

1. Refer to surgeon for evaluation after mammogram results are received.
2. Radiologists' requests for galactogram to be reimbursed by BCCP must be pre-approved by a nurse consultant at the state office. A galactogram is not indicated unless the nipple discharge is spontaneous, unilateral, and expressed from a single pore.
3. All breast masses suspicious for cancer must be referred to surgeon for evaluation after thorough imaging evaluation and minimally invasive biopsy if indicated.

REFERENCES

1. http://www.merckmanuals.com/professional/gynecology_and_obstetrics/breast_disorders/nipple_discharge.html Last full review/revision September 2013 by Mary Ann Kosir, MD; Content last modified October 2013.
2. Georgia Department of Public Health BCCP Manual, 2014.

3. Edward Azavedo, MD, PhD, John M Lewin, MD, Bernard D Coombs, MB, ChB, PhD
<http://emedicine.medscape.com/article/347305-overview#a01> Breast Imaging in Nipple Discharge Evaluation, Sep 4, 2013.
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5. ALEXANDER K.C. LEUNG, M.B.B.S. and DANIELE PACAUD, M.D., Diagnosis and Management of Galactorrhea Am Fam Physician. 2004 Aug 1;70(3):543-550.

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.

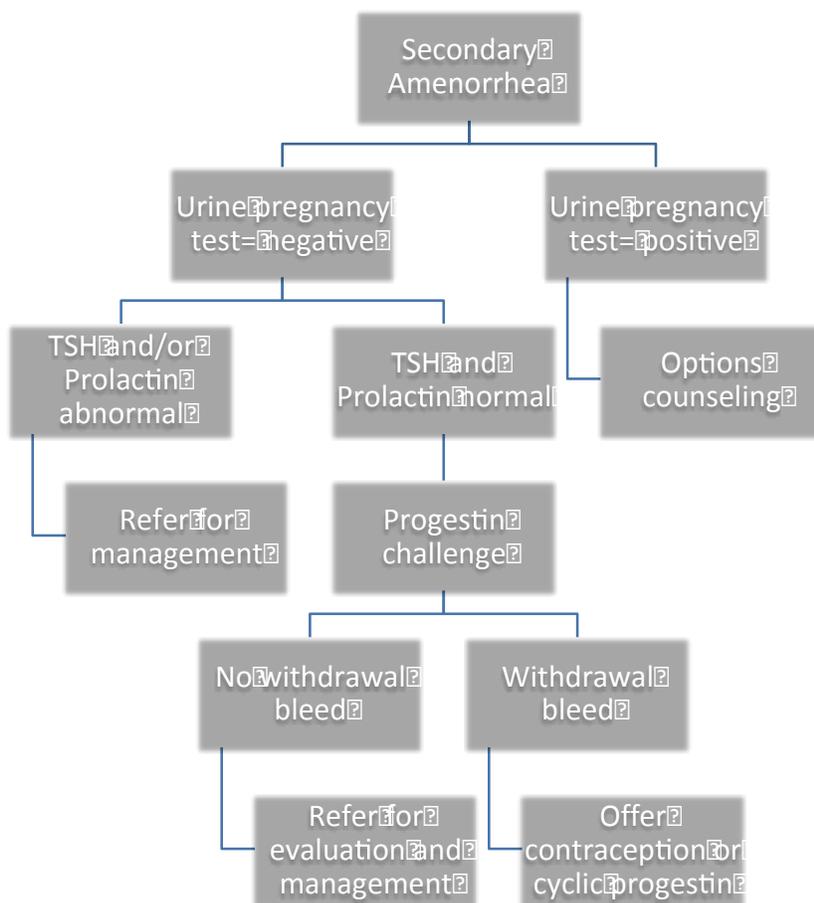
OR

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.,
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(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.

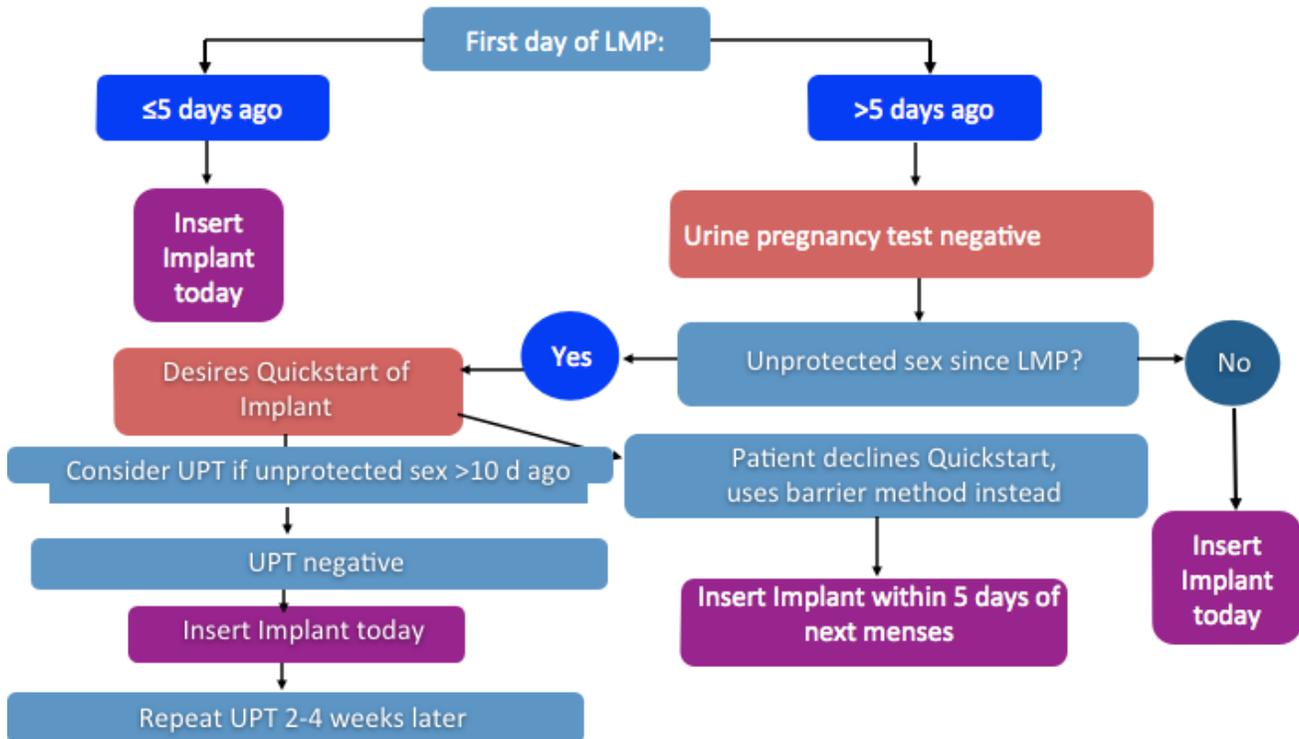
- SUBJECTIVE**
1. Desires an implant for long-term contraception.
 2. Has detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information 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 more than 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).
<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>
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 –

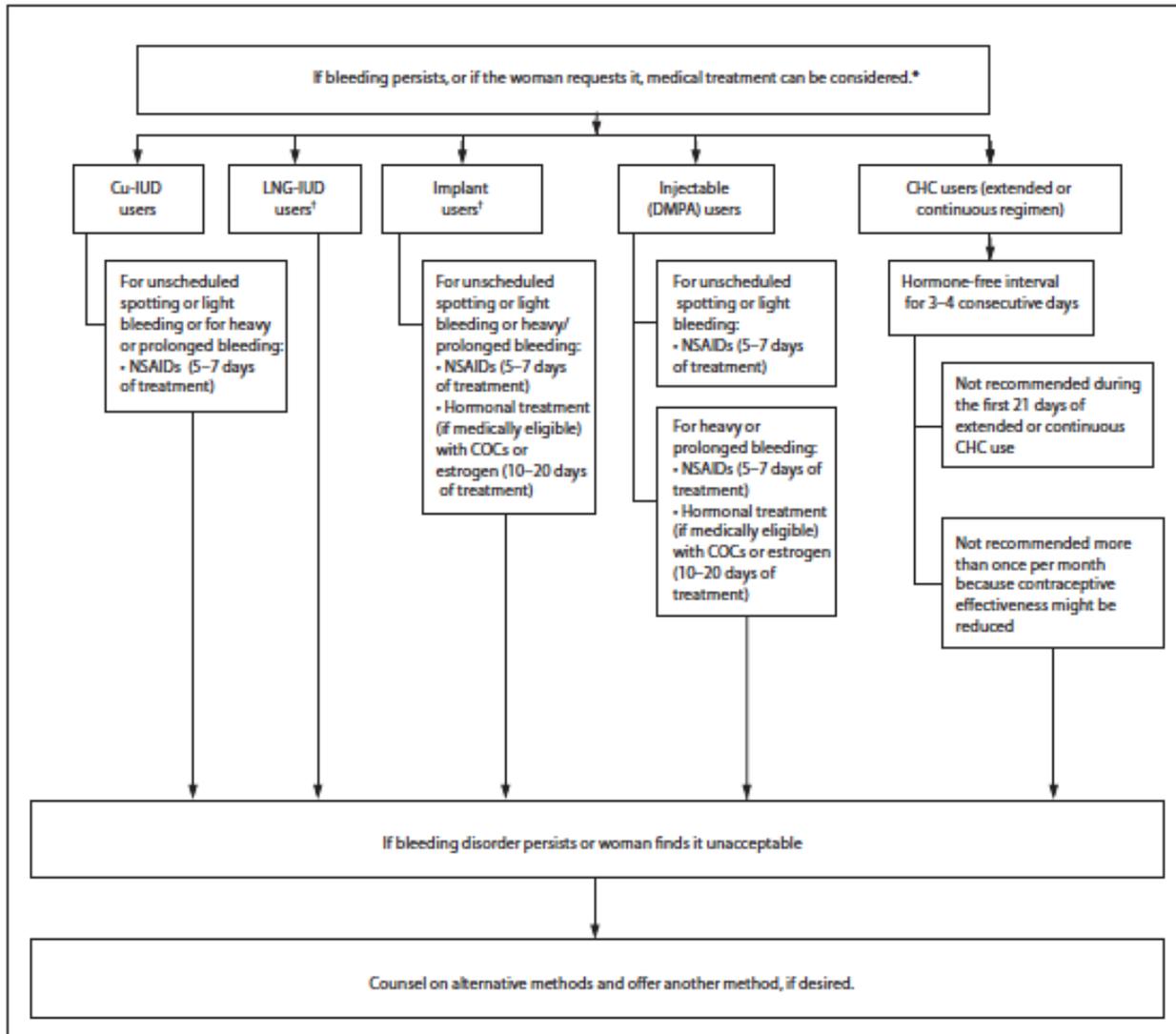
Consult/referral. None of the following has been proven to be effective at treatment of bothersome bleeding while using the implant. Often continuation of use of the implant is the best treatment, but for some women the bleeding profile may not improve. If a woman is interested in continuing the implant 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)
OR
- 4) 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

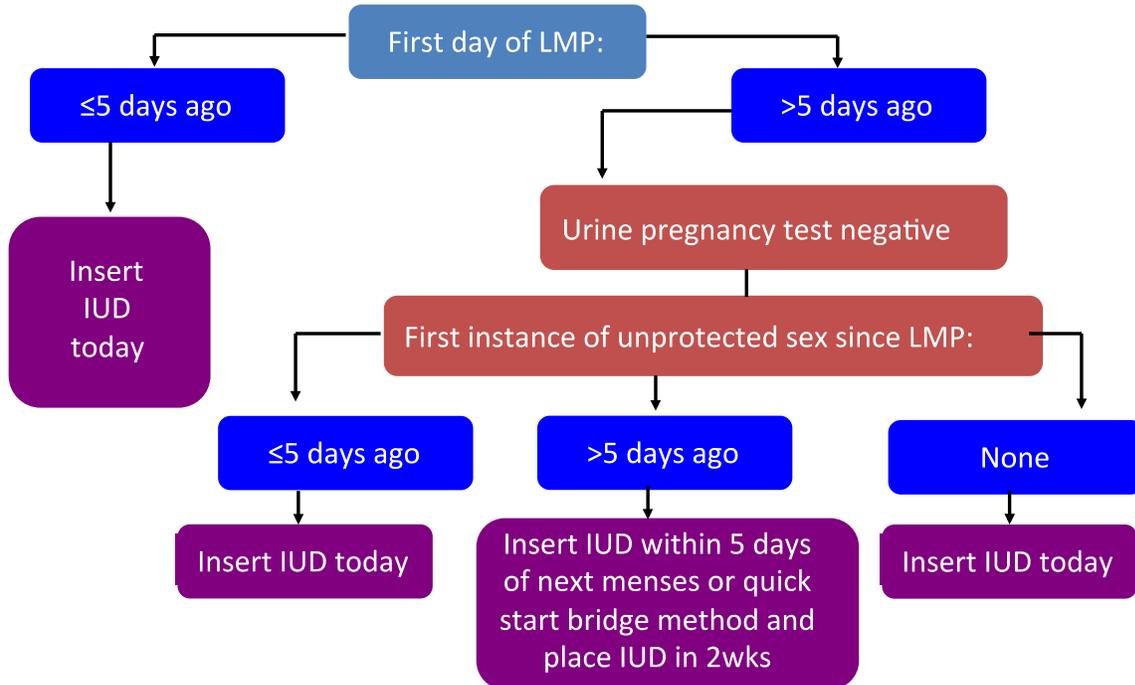
- DEFINITION** The Copper T380A (ParaGard®) intrauterine device, is a copper-bearing contraceptive device that prevents pregnancy for at least 10 years. It prevents pregnancy by immobilizing sperm, inhibiting fertilization and preventing implantation due to local inflammatory responses and endometrial 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. Medical Eligibility Criteria 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. Medical Eligibility Criteria 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)
<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>
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.

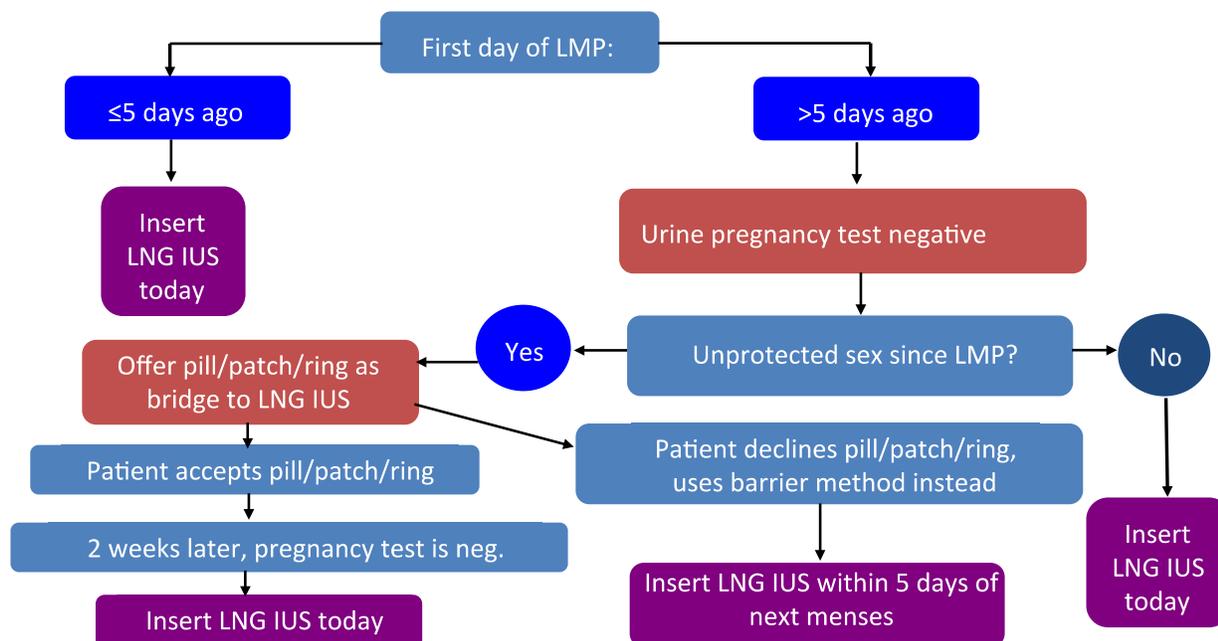
OR

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. Medical Eligibility Criteria 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. Medical Eligibility Criteria 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 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)
<http://www.fpm.emory.edu/Preventive/projects/GAPCCToolkit.htm>
 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: CONTRACEPTIVES

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Women's Health Products

CONTRACEPTIVE CATEGORY	PRODUCT NAME	NDC	Progestin	mg	Estrogen	mcg	Mfr
MonoPhasic 50mcg							
MonoPhasic	OGESTREL TAB	52544084828	Norgestrel	0.5	E.estradiol	50	Watson
MonoPhasic	NECON TAB 1MG/50MCG	52544024531	Norethindrone	1	Mestranol	50	Watson
MonoPhasic	NORINYL 1+50 TAB WALLETTTE	52544026531	Norethindrone	1	Mestranol	50	Watson
MonoPhasic	ZOVIA TAB 1/50-28	52544038428	Ethinodiol D-Ethinyl	1	Estradiol	50	Watson
MonoPhasic 35mcg							
MonoPhasic LoDose	KELNOR TAB 1/35	00555906458	Ethinodiol D-Ethinyl	1	Estradiol	35	Teva
MonoPhasic LoDose	ZOVIA TAB 1/35-28	52544038328	Ethinodiol D-Ethinyl	1	Estradiol	35	Watson
MonoPhasic LoDose	GILDAGIA TB.4MG/.035MGQ/P3X28	00603359049	Norethindrone	0.4	E.estradiol	35	Qualitest
MonoPhasic LoDose	VYFEMLA TAB .4MG/.35MG LUPI 3	68180087513	Norethindrone	0.4	E.estradiol	35	Lupin Pharma
MonoPhasic LoDose	OVCON-35 TAB 0.035/0.4	00430058045	Norethindrone	0.4	E.estradiol	35	Warner Chilcott
MonoPhasic LoDose	BRIELLYN TB 0.4/0.35	68462031629	Norethindrone	0.4	E.estradiol	35	Glenmark Generics
MonoPhasic LoDose	ZENCHENT TB 0.035/0.4	52544095328	Norethindrone	0.4	E.estradiol	35	Watson
MonoPhasic LoDose	BALZIVA TAB 0.035/0.4	00555903458	Norethindrone	0.4	E.estradiol	35	Teva
MonoPhasic LoDose	GILDAGIA TB.4MG/.035MGQ/P6X28	00603359017	Norethindrone	0.4	E.estradiol	35	Qualitest
MonoPhasic LoDose	PHILITH TB 0.4/0.035	16714034704	Norethindrone	0.4	E.estradiol	35	NorthStar Rx LLC
MonoPhasic LoDose	BREVICON TAB 0.5/35	52544025428	Norethindrone	0.5	E.estradiol	35	Watson
MonoPhasic LoDose	NORTREL TAB 0.5/35	00555900867	Norethindrone	0.5	E.estradiol	35	Teva
MonoPhasic LoDose	WERA TAB 0.5/0.035MG 3X28NSTR@	16714037003	Norethindrone	0.5	E.estradiol	35	NorthStar Rx LLC
MonoPhasic LoDose	MODICON TAB DIALPAK 0.5/35	50458017115	Norethindrone	0.5	E.estradiol	35	JOM Ortho
MonoPhasic LoDose	NECON TAB 0.5/35	52544055028	Norethindrone	0.5	E.estradiol	35	Watson
MonoPhasic LoDose	NORTREL TAB 1/35	00555900942	Norethindrone	1	E.estradiol	35	Teva
MonoPhasic LoDose	ALYACEN 1/35 1MG/0.035	68462039429	Norethindrone	1	E.estradiol	35	Glenmark Generics

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CONTRACEPTIVE CATEGORY	PRODUCT NAME	NDC	Progestin	mg	Estrogen	mcg	Mfr
MonoPhasic LoDose	PIRMELLA TB 1/0.35MG LUPI 3X28	68180089313	Norethindrone	1	E.estradiol	35	Lupin Pharma
MonoPhasic LoDose	CYCLAFEM 1/35/TB1/0.035	00603752149	Norethindrone	1	E.estradiol	35	Qualitest
MonoPhasic LoDose	CYCLAFEM 1/35TB1/0.035	00603752117	Norethindrone	1	E.estradiol	35	Qualitest
MonoPhasic LoDose	DASETTA 1/35TB1/0.035	16714034804	Norethindrone	1	E.estradiol	35	NorthStar Rx LLC
MonoPhasic LoDose	NECON TAB 1/35	52544055228	Norethindrone	1	E.estradiol	35	Watson
MonoPhasic LoDose	NORINYL 1+35 TAB WALLETTTE	52544025928	Norethindrone	1	E.estradiol	35	Watson
MonoPhasic LoDose	NORTREL TAB 1/35	00555901058	Norethindrone	1	E.estradiol	35	Teva
MonoPhasic LoDose	ORTHO NOVUM 1/35 DIALPAK	50458017615	Norethindrone	1	E.estradiol	35	JOM Ortho
MonoPhasic LoDose	NORGEST/EE 0.25/0.035	68462030929	Norgestimate	0.25	E.estradiol	35	Glenmark Generics
MonoPhasic LoDose	ESTARYLLA 35MC/.25MG SAN UD84	00781405815	Norgestimate	0.25	E.estradiol	35	Sandoz
MonoPhasic LoDose	MONONESSA 0.25/0.035	52544024728	Norgestimate	0.25	E.estradiol	35	Watson
MonoPhasic LoDose	MONO-LN T.25MG/.035MG6X28NSTR@	16714036004	Norgestimate	0.25	E.estradiol	35	NorthStar Rx LLC
MonoPhasic LoDose	ORTHO-CYCLEN TAB	50458019715	Norgestimate	0.25	E.estradiol	35	JOM Ortho
MonoPhasic LoDose	PREVIFEM 0.25/0.035TB Q/P	00603764217	Norgestimate	0.25	E.estradiol	35	Qualitest
MonoPhasic LoDose	SPRINTEC 0.25/0.035	00555901658	Norgestimate	0.25	E.estradiol	35	Teva
MonoPhasic LoDose	ZENCHENT TAB 0.4MG AMN 3X28@	65162034784	Norethindrone	0.4	E.estradiol/Iron	35	Amneal
MonoPhasic LoDose	FEMCON FE 0.4mg/35mcg Chewable w/Iron	00430048214	Norethindrone	0.4	E.estradiol/Iron	35	Warner Chilcott
MonoPhasic LoDose	WYMZYA FE TB0.4/35MCG LUP5X28@	68180089813	Norethindrone	0.4	E.estradiol/Iron	35	Lupin Pharma
MonoPhasic 30mcg							
MonoPhasic LoDose	EMOQUETTE TB 0.15/0.03Q/P	00603754049	Desogestrel	0.15	E.estradiol	30	Qualitest
MonoPhasic LoDose	ENSKYCE TAB 0.15MG LUPI 3X28	68180088213	Desogestrel	0.15	E.estradiol	30	Lupin Pharma
MonoPhasic LoDose	EMOQUETTE TB 0.15/0.03Q/P	00603754017	Desogestrel	0.15	E.estradiol	30	Qualitest
MonoPhasic LoDose	DESOGEST TAB 0.15MG 6X28 NSTR@	16714036704	Desogestrel	0.15	E.estradiol	30	NorthStar Rx LLC
MonoPhasic LoDose	APRI TAB 0.15/0.03MG	00555904358	Desogestrel	0.15	E.estradiol	30	Teva
MonoPhasic LoDose	DESOGEN TAB 0.15/0.03MG	00052026106	Desogestrel	0.15	E.estradiol	30	Schering/Merck
MonoPhasic LoDose	ORTHO-CEPT TAB 0.15/0.03MG	50458019615	Desogestrel	0.15	E.estradiol	30	JOM Ortho
MonoPhasic LoDose	YASMIN TAB	5041904203	Drospirenone	0.03	E.estradiol	30	Bayer HC
MonoPhasic LoDose	ZARAH TB 3MG/0.03MG	52544098131	Drospirenone	0.03	E.estradiol	30	Watson
MonoPhasic LoDose	DROSPIR/ETH TB 3/.03MG	68180090213	Drospirenone	0.03	E.estradiol	30	Lupin Pharma
MonoPhasic LoDose	SYEDA TAB 3/0.03MG	00781565815	Drospirenone	0.03	E.estradiol	30	Sandoz
MonoPhasic LoDose	OCELLA TB 3/0.03MG	00555913167	Drospirenone	0.03	E.estradiol	30	Teva
MonoPhasic LoDose	ALTAVERA TAB 3X28 UD 0.15/0.03MG	00781558315	Levonorgestrel	0.15	E.estradiol	30	Sandoz

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CONTRACEPTIVE CATEGORY	PRODUCT NAME	NDC	Progestin	mg	Estrogen	mcg	Mfr
MonoPhasic LoDose	KURVELO TAB .15MG/.3MG LUPI 3	68180084413	Levonorgestrel	0.15	E.estradiol	30	Lupin Pharma
MonoPhasic LoDose	LEVON/ETH EST.15/.03MG MYL 84	00378655053	Levonorgestrel	0.15	E.estradiol	30	Mylan
MonoPhasic LoDose	MARLISSA TAB 0.15mg/0.03mg	68462038829	Levonorgestrel	0.15	E.estradiol	30	Glenmark Generics
MonoPhasic LoDose	LEVORA TAB 0.15/30	52544027928	Levonorgestrel	0.15	E.estradiol	30	Watson
MonoPhasic LoDose	PORTIA TB 0.150/.03MG	00555902058	Levonorgestrel	0.15	E.estradiol	30	Teva
MonoPhasic LoDose	JUNEL TB 1.5MG/30MCG	00555902742	Nor. Acetate	1.5	E.estradiol	30	Teva
MonoPhasic LoDose	GILDESS TAB 1.5/0.03 Q/P 3X21@	00603760648	Nor. Acetate	1.5	E.estradiol	30	Qualitest
MonoPhasic LoDose	LOESTRIN 21 TAB 1.5/30	51285008297	Nor. Acetate	1.5	E.estradiol	30	Teva
MonoPhasic LoDose	GILDESS TAB 1.5/0.03 Q/P 6X21@	00603760615	Nor. Acetate	1.5	E.estradiol	30	Qualitest
MonoPhasic LoDose	MICROG 1.5/0.030MG BP	52544095121	Nor. Acetate	1.5	E.estradiol	30	Watson
MonoPhasic LoDose	LOESTRIN FE TAB 1.5/30	51285008498	Nor. Acetate	1.5	E.estradiol/Iron	30	Teva
MonoPhasic LoDose	LOESTRIN FE TAB 1.5/30	51285008370	Nor. Acetate	1.5	E.estradiol/Iron	30	Teva
MonoPhasic LoDose	GILDESS FE 1.5/0.03	00603760817	Nor. Acetate	1.5	E.estradiol/Iron	30	Qualitest
MonoPhasic LoDose	JUNEL FE 1.5MG/30MCG	00555902858	Nor. Acetate	1.5	E.estradiol/Iron	30	Teva
MonoPhasic LoDose	LARIN FE TB 1.5/30	16714040504	Nor. Acetate	1.5	E.estradiol/Iron	30	NorthStar Rx LLC
MonoPhasic LoDose	MICROG FE 1.5MG/30MCG	52544063128	Nor. Acetate	1.5	E.estradiol/Iron	30	Watson
MonoPhasic LoDose	ELINEST TB 0.3/0.03MG6X28NSTR@	16714036504	Norgestrel	0.3	E.estradiol	30	NorthStar Rx LLC
MonoPhasic LoDose	CRYSSELLE TB 0.3/.03MG	00555904958	Norgestrel	0.3	E.estradiol	30	Teva/Barr
MonoPhasic LoDose	LOW-OGESTREL TAB	52544084728	Norgestrel	0.3	E.estradiol	30	Watson
MonoPhasic LoDose	RECLIPSEN TB 0.15/0.03MG	52544095428	Desogestrel	0.15	E.estradiol	30	Watson
MonoPhasic 20mcg							
MonoPhasic LoDose	VESTURA 3MG/0.02MG	52544098231	Drospirenone	3.0	E.estradiol	20	Watson
MonoPhasic LoDose	YAZ TAB	50419040503	Drospirenone	3.0	E.estradiol	20	Bayer HC
MonoPhasic LoDose	LORYNA 3/0.02 UD	00781565615	Drospirenone	3.0	E.estradiol	20	Sandoz
MonoPhasic LoDose	GIANVI TB 3/0.02MG BP	00093542358	Drospirenone	3.0	E.estradiol	20	Teva
MonoPhasic Ultra LoDose	LESSINA TAB 0.1/0.02MG	00555901467	Levonorgestrel	0.1	E.estradiol	20	Teva
MonoPhasic Ultra LoDose	ORSYTHIA TAB 0.1/0.02 Q/P	00603763449	Levonorgestrel	0.1	E.estradiol	20	Qualitest
MonoPhasic Ultra LoDose	LEVONO+ES TB.1MG/.02MGLUP3X28@	68180085413	Levonorgestrel	0.1	E.estradiol	20	Lupin Pharma
MonoPhasic Ultra LoDose	LEVON/ETH TB 0.1/.02MG MYL 84@	00378728753	Levonorgestrel	0.1	E.estradiol	20	Mylan

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CONTRACEPTIVE CATEGORY	PRODUCT NAME	NDC	Progestin	mg	Estrogen	mcg	Mfr
MonoPhasic Ultra LoDose	FALMINA TAB0.1/0.02MG3X28NSTR@	16714035903	Levonorgestrel	0.1	E.estradiol	20	NorthStar Rx LLC
MonoPhasic Ultra LoDose	AVIANE TAB 0.1/0.02MG	00555904558	Levonorgestrel	0.1	E.estradiol	20	Teva
MonoPhasic Ultra LoDose	ORSYTHIA TAB 0.1/0.02 Q/P	00603763417	Levonorgestrel	0.1	E.estradiol	20	Qualitest
MonoPhasic Ultra LoDose	FALMINA TAB0.1/0.02MG6X28NSTR@	16714035904	Levonorgestrel	0.1	E.estradiol	20	NorthStar Rx LLC
MonoPhasic Ultra LoDose	LUTERA TB 0.1/0.02MG	52544094928	Levonorgestrel	0.1	E.estradiol	20	Watson
MonoPhasic Ultra LoDose	SRONYX TAB 0.1/0.02MG	52544096728	Levonorgestrel	0.1	E.estradiol	20	Watson
MonoPhasic Ultra LoDose	LOESTRIN FE TAB 1/20	51285008198	Nor. Acetate	1	E.estradiol/FE Fum	20	Teva
MonoPhasic Ultra LoDose	LOESTRIN FE TAB 1/20	51285008070	Nor. Acetate	1	E.estradiol/FE Fum	20	Teva
MonoPhasic Ultra LoDose	JUNEL FE 1MG/20MCG	00555902658	Nor. Acetate	1	E.estradiol/FE Fum	20	Teva
MonoPhasic Ultra LoDose	GILDESS FE 1/0.2MG TB	00603760917	Nor. Acetate	1	E.estradiol/FE Fum	20	Qualitest
MonoPhasic Ultra LoDose	LARIN FE 1/20 1/02MG 6X28NSTR@	16714040604	Nor. Acetate	1	E.estradiol/FE Fum	20	NorthStar Rx LLC
MonoPhasic Ultra LoDose	MICROG FE 1.0MG/20MCG	52544063028	Nor. Acetate	1	E.estradiol/FE Fum	20	Watson
MonoPhasic Ultra LoDose	JUNEL TAB 1MG/20MCG	00555902542	Nor. Acetate	1	E.estradiol	20	Teva
MonoPhasic Ultra LoDose	GILDESS TAB 1/0.02MG Q/P 3X21@	00603760748	Nor. Acetate	1	E.estradiol	20	Qualitest
MonoPhasic Ultra LoDose	LARIN 1MG/0.02MG NSTR 3X21@	16714040803	Nor. Acetate	1	E.estradiol	20	NorthStar Rx LLC
MonoPhasic Ultra LoDose	LOESTRIN 21 TAB 1/20	51285007997	Nor. Acetate	1	E.estradiol	20	Teva
MonoPhasic Ultra LoDose	GILDESS TAB 1/0.02MG Q/P 6X21@	00603760715	Nor. Acetate	1	E.estradiol	20	Qualitest
MonoPhasic Ultra LoDose	MICROGESTIN 1/0.020MG BP	52544095021	Nor. Acetate	1	E.estradiol	20	Watson
Biphasic							
Biphasic	VIORELE TAB 0.15/.02-.01mg	68462031829	Desogestrel	0.15/ 0.0	E.estradiol	20/10	Glenmark Generics
Biphasic	KARIVA TAB 0.15/.02-.01mg	00555905058	Desogestrel	0.15/ 0.0	E.estradiol	20/10	Teva
Biphasic	AZURETTE TAB 0.15/.02-.01mg	52544094028	Desogestrel	0.15/ 0.0	E.estradiol	20/10	Watson
Biphasic	PIMTREA .15MG/.02MG 6X28 NSTR@	16714040404	Desogestrel	0.15/ 0.0	E.estradiol	20/10	NorthStar Rx LLC
Biphasic	MIRCETTE 28-DAY CYCLE PK	51285011458	Desogestrel	0.15/ 0.0	E.estradiol	20/10	Teva
Biphasic	NECON TAB 10/11	52544055428	Norethindrone	0.5/1.0	E.estradiol	35	Watson
TriPhasic							
TriPhasic	ESTROSTEP FE S/F A/F TAB	00430057045	Nor. Acetate	1	E.estradiol	20/30/35	Warner Chilcott

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CONTRACEPTIVE CATEGORY	PRODUCT NAME	NDC	Progestin	mg	Estrogen	mcg	Mfr
TriPhasic	TILIA FE TAB 3/ 7/ 9/ 7	52544014331	Nor. Acetate	1	E.estradiol	20/30/35	Watson
TriPhasic	TRI-LEGEST FE TAB	00555903270	Nor. Acetate	1	E.estradiol	20/30/35	Teva
TriPhasic	CAZIAN TAB	52544095931	Desogestrel	0.1/0.125/0.15	E.estradiol	25	Watson
TriPhasic	CYCLESSA TAB	00052028306	Desogestrel	0.1/0.125/0.15	E.estradiol	25	Schering/ Merck
TriPhasic	VELIVET TAB	00555905167	Desogestrel	0.1/0.125/0.15	E.estradiol	25	Teva
TriPhasic	MYZILRA TAB Q/P 3X28	00603762549	Levonorgestrel	0.05/0.075/0.125	E.estradiol	30	Qualitest
TriPhasic	ENPRESSE TB 0.05/0.03 6/5/10	00555904758	Levonorgestrel	0.05/0.075/0.125	E.estradiol	30	Teva
TriPhasic	MYZILRA TB 0.05/0.03/0.075/0.04:0.125/0.03 TriPhasic	00603762517	Levonorgestrel	0.05/0.075/0.125	E.estradiol	30	Qualitest
TriPhasic	LEVONEST TAB 6X28 NSTR@	16714034004	Levonorgestrel	0.05/0.075/0.125	E.estradiol	30	NorthStar Rx LLC
TriPhasic	TRIVORA TAB 6/5/10	52544029128	Levonorgestrel	0.05/0.075/0.125	E.estradiol	30	Watson
TriPhasic	CYCLAFEM 7/7/70.5/0.035	00603752549	Norethindrone	0.5/0.75/1.0	E.estradiol	35	Qualitest
TriPhasic	ALYACEN 7/7/7 TAB	68462055629	Norethindrone	0.5/0.75/1.0	E.estradiol	35	Glenmark Generics
TriPhasic	NECON 7/7/7 TAB	52544093628	Norethindrone	0.5/0.75/1.0	E.estradiol	35	Watson
TriPhasic	NORTREL TAB 7/7/7	00555901258	Norethindrone	0.5/0.75/1.0	E.estradiol	35	Teva
TriPhasic	DASETTA 7/7/7	16714034604	Norethindrone	0.5/0.75/1.0	E.estradiol	35	NorthStar Rx LLC
TriPhasic	CYCLAFEM 7/7/70.5/0.035	00603752517	Norethindrone	0.5/0.75/1.0	E.estradiol	35	Qualitest
TriPhasic	ORTHO NOVUM 7/7/7	50458017815	Norethindrone	0.5/0.75/1.0	E.estradiol	37	JOM Ortho
TriPhasic	ARANELLE TAB 7/9/5	00555906667	Norethindrone	0.5/1.0/0.5	E.estradiol	35	Teva
TriPhasic	LEENA TAB 7/9/5	52544021928	Norethindrone	0.5/1.0/0.5	E.estradiol	35	Watson
TriPhasic	TRI-NORINYL TAB WALLETTE 7/9/5	52544027428	Norethindrone	0.5/1.0/0.5	E.estradiol	35	Watson
TriPhasic Lo	ORTHO TRI-CYCLEN LO TAB	50458025115	Norgestimate	0.18/0.215/0.25	E.estradiol	25	JOM Ortho
TriPhasic	NORG-ETH ESTR0.18/0.03	68462056529	Norgestimate	0.18/0.215/0.25	E.estradiol	35	Glenmark Generics
TriPhasic	TRI-EST 35+180/215/250 3X28SAN	00781406015	Norgestimate	0.18/0.215/0.25	E.estradiol	35	Sandoz
TriPhasic	ORTHO TRI-CYCLEN	50458019115	Norgestimate	0.18/0.215/0.25	E.estradiol	35	JOM Ortho
TriPhasic	TRINESSA TAB 0.18/0.215/0.25	52544024828	Norgestimate	0.18/0.215/0.25	E.estradiol	35	Watson
TriPhasic	TRI-PREVIF 0.18/0.35MGQ/P	00603766317	Norgestimate	0.18/0.215/0.25	E.estradiol	35	Qualitest
TriPhasic	TRI-SPRINTEC TAB 0.18/0.215/0.25	00555901858	Norgestimate	0.18/0.215/0.25	E.estradiol	35	Teva
TriPhasic	TRI-LN TB.18MG/.035MG6X28NSTR@	16714036304	Norgestimate	0.18/0.215/0.25	E.estradiol	35	NorthStar Rx LLC

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CONTRACEPTIVE CATEGORY	PRODUCT NAME	NDC	Progestin	mg	Estrogen	mcg	Mfr
QuadPhasic							
QuadPhasic	NATAZIA TAB	50419040903	Dienogestrel	2 and 3	Estradiol Valerate	1, 2, and 3	Bayer HC
Combinations							
Combinations	SAFYRAL TAB 3mg / 0.03 mg B vitamin 451mcg	50419040303	Drospirenone	3mg	E.estradiol w/Levomefolate Calcium 451 mcg	0.03	Bayer HC
Combinations	BEYAZ TAB (drsp®) 3 mg/20mcgth a B vitamin,451 mcg	50419040703	Drospirenone	3mg	E.estradiol w/Levomefolate Calcium 451 mcg	0.03	Bayer HC
Extended Cycle							
Extended Cycle	QUARTETTE (TM) TRADE 91	51285043165	Levonorgestrel	0.15	E.estradiol	2, 2.5, 3, & 1	Teva
Extended Cycle	AMETHIA TB 0.15/0.03MG	52544026829	Levonorgestrel	0.15	E.estradiol	30	Watson
Extended Cycle	CAMRESE TAB 2X91	00093313482	Levonorgestrel	0.15	E.estradiol	30	Teva
Extended Cycle	DAYSEE TB.15MG/.03MG 2X91	68180084613	Levonorgestrel	0.15	E.estradiol	30	Lupin Pharma
Extended Cycle	SEASONIQUE EC TAB 2X91	51285008787	Levonorgestrel	0.15	E.estradiol	30	Teva
Extended Cycle	LEVONORG+ESTR TAB LUPI 3X91	68180084313	Levonorgestrel	0.15	E.estradiol	30	Lupin Pharma
Extended Cycle	INTROVAL TB 0.15/0.03UD	00781558436	Levonorgestrel	0.15	E.estradiol	30	Sandoz
Extended Cycle	JOLESSA 91DAY OC PK	00555912366	Levonorgestrel	0.15	E.estradiol	30	Teva
Extended Cycle	QUASENSE TB 0.15/0.03	52544096691	Levonorgestrel	0.15	E.estradiol	30	Watson
Extended Cycle	LOSEASONIQUE TAB 0.1-0.02MG 2X91	51285009287	Levonorgestrel	0.1-0.02	E.estradiol	20:10	Teva
Extended Cycle	CAMRESE LO TAB 2X91	00093614882	Levonorgestrel	0.1-0.02	E. Estradiol	20:10	Teva
Extended Cycle	LEVONORG+ESTR TAB LUPI 2X91 @	68180084813	Levonorgestrel	0.1-0.02	E. Estradiol	20:10	Lupin Pharma
Extended Cycle	AMETHIA LO 0.1/0.02/0.01MG	52544022829	Levonorgestrel	0.1-0.02	E.estradiol	20:10	Watson
Extended Cycle	LOMEDIA 24 FE TAB AMN 3X28	65162031684	Nor. Acetate	1.0 (+75mg FF)	E.estradiol	20	Amneal
Extended Cycle	LOESTRIN 24 FE TAB	00430053014	Nor. Acetate	1.0 (+75mg FF)	E.estradiol	20	Warner Chilcott
Extended Cycle	AMETHYST TAB 90/20MCG	52544029528	Levonorgestrel	0.9	E.estradiol	20	Watson

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Progestins							
Progestins	HEATHER TAB 0.35MG	68462030329	Norethindrone	0.35	None		Glenmark Generics
Progestins	NORETHINDR TAB 0.35MG	68462030529	Norethindrone	0.35	None		Glenmark Generics
Progestins	NORETHINDR 0.35MG TAB	00378727253	Norethindrone	0.35	None		Mylan
Progestins	NORETHIN TAB 0.35MG MYL 3X28@	00378729253	Norethindrone	0.35	None		Mylan
Progestins	NORETHINDR TAB 0.35MG	68180087613	Norethindrone	0.35	None		Lupin Pharma
Progestins	CAMILA TAB 0.35MG	00555071558	Norethindrone	0.35	None		Teva
Progestins	ERRIN TAB 0.35MG	00555034458	Norethindrone	0.35	None		Teva
Progestins	NORETHIN TAB 0.35MG 6X28NSTR@	16714007304	Norethindrone	0.35	None		NorthStar Rx LLC
Progestins	NORETHIN TAB 0.35MG 6X28 NSTR@	16714041304	Norethindrone	0.35	None		NorthStar Rx LLC
Progestins	JOLIVETTE TAB 0.35MG	52544089228	Norethindrone	0.35	None		Watson
Progestins	ORTHO MICRONOR TB DIALPAK	50458019416	Norethindrone	0.35	None		JOM Ortho
Progestins	NOR-Q.D. TAB 0.35MG	52544023528	Norethindrone	0.35	None		Watson
Progestins	NORA-BE TAB 0.35MG	52544062928	Norethindrone	0.35	None		Watson
Emergency							
Emergency	PLAN B ONE-STEP 1.5mg (single tablet dose) Clinic PK	51285096319	Levonorgestrel	1.5	None		Teva
Emergency	PLAN B ONE-STEP 1.5mg (single tablet dose) Tradepack	51285094288	Levonorgestrel	1.5	None		Teva
Emergency	PLAN B ONE-STEP 1.5mg (single tablet dose) Tradepack - OTC	51285094388	Levonorgestrel	1.5	None		Teva
Emergency	PLAN B ONE-STEP 1.5mg (single tablet dose) - OTC Clinic PK	51285014619	Levonorgestrel	1.5	None		Teva
Emergency	PLAN B ONE-STEP 1.5mg (single tablet dose) non-clam shell - OTC	51285016288	Levonorgestrel	1.5	None		Teva
Emergency	MY WAY TAB 1.5MG GAVI 1@	43386062230	Levonorgestrel	1.5	None		Gavis Pharmaceutical
Emergency	NEXT CHOICE TAB 1.5MG	52544028754	Levonorgestrel	1.5	None		Watson
Emergency	LEVONORG TAB 0.75MG PERR 2@	45802084054	Levonorgestrel	0.75	None		Perrigo
Emergency	Ella		Ulipristal Acetate	30			Afaxys
Injectable DMPA							
Injectable DMPA	Medroxyprogesterone Depo-SubQ Pro 104 PFS	00009470913	Progesterone	104	None		Pfizer
Injectable DMPA	Medroxyprogesterone 150 MG/ML PFS	59762453802	Progesterone	150	None		Greenstone

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Injectable DMPA	DEPO-PROVERA SYRDSP 150MG/ML 1	00009737607	Progesterone	150	None		Pfizer
Injectable DMPA	DEPO-PROVERA SYRDSP 150MG/ML 1	00009737611	Progesterone	150	None		Pfizer
Injectable DMPA	Medroxyprogesterone 150 MG/ML Vial	59762453701	Progesterone	150	None		Greenstone
Injectable DMPA	Depo-Provera 150 MG/ML Vial	00009074630	Progesterone	150	None		Pfizer
Injectable DMPA	Medroxyprogesterone 150 MG/ML Vial	00703680101	Progesterone	150	None		Teva
Injectable DMPA	Medroxyprogesterone 150 MG/ML Vial	59762453702	Progesterone	150	None		Greenstone
Injectable DMPA	Depo-Provera 150 MG/ML Vial	00009074635	Progesterone	150	None		Pfizer
Injectable DMPA	Medroxyprogesterone 150 MG/ML Vial	00703680104	Progesterone	150	None		Teva
IUD's							
IUD's	Paragard T 380A Intrauterine Copper Device - 10 year	51285020401					Teva - ICS/Paragard
IUD's	Mirena IUS DS - 5 year device	50419042101	Levonorgestrel	52		20/day	Bayer
IUD's	Skyla - 3 year device	50419042201	Levonorgestrel	13.5			Bayer
IUD's	Implanon	00052027201	Etonogestrel	68			Merck
IUD's	Nexplanon	00052433001	Etonogestrel	68			Merck
IUD's	Nexplanon	00052027401	Etonogestrel	68			Merck
RING							
Vaginal Ring	NuvaRing	00052027303	Etonogestrel	0.12/day	E.estradiol	0.015/day	Schering/ Merck

Department of Public Health, Office of Pharmacy, September 24, 2014