New Protocol for Contraceptive Management

Satellite Conference and Live Webcast
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Produced by the Alabama Department of Public Health
Distance Learning and Telehealth Division

Faculty

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Objectives

- Review the New ADPH Family Planning Protocol
- Discuss protocol framework and utility
- Explain the guidelines for specific risk factors, based on clinical scenarios

Protocol Framework

- U.S. Medical Eligibility Criteria (U.S. MEC)
- ADPH Vision
- Goal

Why is evidence-based guidance for contraceptive use needed?

- **To base family planning practices on the best available evidence**
- **To address misconceptions regarding who can safely use contraception**

Why is evidence-based guidance for contraceptive use needed?

- **To remove unnecessary medical barriers**
- **To improve access and quality of care in family planning**

How to use this document: U.S. MEC: Categories

1. No restriction for the use of the contraceptive method for a woman with that condition
2. Advantages of using the method generally outweigh the theoretical or proven risks
3. Theoretical or proven risks of the method usually outweigh the advantages – not usually recommended unless more appropriate methods are not available or acceptable
4. Unacceptable health risk if the contraceptive method is used by a woman with that condition

How to use this document: Abbreviations

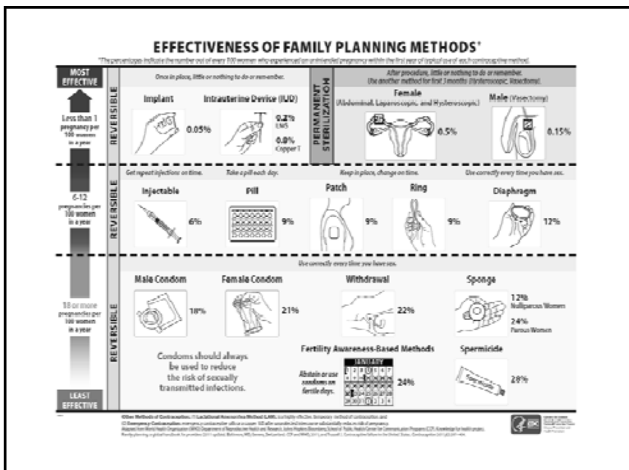
Cu-IUD- Copper
LNG-IUD- Levonorgestrel IUD
Implant- Nexplanon
DMPA- Depo Provera
POP- Progestin-only pill
CHC- Combined hormonal contraception/Pills, Ring, Patch
I/C- Initiation of method/Continuation of method
----- = Method not appropriate for use

How to use this document

- DISCLAIMER: Guidelines based on 1 Risk Factor. A consult is required for categories with an asterisk (*). A consult is also required for patients currently diagnosed with cancer or cancer within the last 5 years. Dispensing Categories:

How to use this document

- 1 = 12 month supply, 2 = 6 month supply, and 3 = 3 month supply, initial patients = 3 month supply unless established on a method. Consult annually after initial unless issue is resolved.



Clinical Scenario: Age

1 Risk Factor	Cu-IUD	LNG-IUD	Implant	DMPA	POP	CHC	CONSULT (*=Consult)	Comments (√=Comments)
Age√								Women who have metabolic bone disease or chronic corticosteroid use (≥6 months duration) require phone consultation with collaborating physician.
Menarche-18yo	2	2	1	2	1	1		Most studies show that women lose bone mineral density during DMPA use and it is unclear if women with long durations of DMPA regain their baseline levels. Any changes in health status including medications may change the appropriateness of DMPA.
19-34	1	1	1	1	1	1		
≥35-49	1	1	1	1	1	1		
≥50-54	1	1	1	4√	2	2		See above comment
≥55	4	4	4	4	4	4		

Clinical Scenario: Multiple Risk Factors

1 Risk Factor	Cu-IUD	LNG-IUD	Implant	DMPA	POP	CHC	CONSULT (*=Consult)	Comments (√=Comments)
Multiple Risk Factors Atherosclerotic Cardiovascular Disease (age, DM, smoking, HTN, low HDL, high LDL, high triglycerides) *Appendix B	1	2	2√	3√	2√	I=3 C=4√	Consult recommendations in Appendix B.	When a woman has multiple major risk factors, any which will substantially increase her risk for cardiovascular disease; the use of CHCs might increase her risk to an unacceptable level. See Appendix B: Multiple Risk Factors.

Two or More Risk Factors

	APPENDIX B Combined	Progestin-only
1. Age ≥ 35 years old 2. Smoker 3. Overweight (BMI 27-29) 4. Obese (BMI ≥ 30) 5. Hypertension 6. Diabetes 7. Migraines	**NO COMBINED METHODS** See exceptions below	▪ Any progestin-only method is acceptable unless specified in "Exceptions" section below. ▪ No consult required for NP. See "Exceptions" below for nurses. May provide up to 3 month supply.
EXCEPTIONS		
If any combination of: ▪ Uncontrolled Hypertension consisting of ≥160/≥100; ▪ Diabetes (vascular or ≥ 10 years duration); ▪ Migraines with Aura	**NO COMBINED METHODS**	NP **Phone consult** is required for Implant, otherwise **written consult is indicated to initiate and annually**. May initiate or continue any progestin-only method ▪ May provide up to 3 month supply.
Overweight (BMI 27-29) Migraines (without aura) < 35 y/o	▪ COCs and rings: acceptable method. ▪ *Patch: dispense with caution. ▪ **Utilize discretion to issue up to a 6 month supply except with patch (3 month supply). NP **No consult** required for NP.	▪ Any progestin-only method is acceptable. ▪ **No consult** required for nurse or NP. ▪ May provide up to 6 month supply. NOTE: The standard overweight BMI range is 25-29, although for the purposes of this protocol, the BMI range of 25-26 is not considered a risk factor.
Overweight (BMI 27-29) Controlled Hypertension < 35 y/o Overweight (BMI 27-29) Non-vascular Diabetes< 35 y/o	▪ COCs and rings: acceptable method. ▪ *Patch: dispense with caution. NP **Written consult** required to initiate and annually while on combined method. ▪ Closer monitoring required; three month supply.	
Overweight (BMI 27-29) ≥ 35 years old	NP **Phone consult** required to initiate and annually while on combined method.	
Obese BMI > 30 and ≥ 35 years old	• **NO COMBINED METHODS**	
Overweight (BMI 27-29) Smoker < 35 y/o	• COCs and rings: acceptable method. • *Patch: dispense with caution. • **Utilize discretion to issue up to a 6 month supply • **No consult** required for nurse or NP.	
Obese Smoker < 35 y/o	**BMI 30-34:** ▪ COCs and rings: acceptable method. ▪ *Patch: dispense with caution. ▪ **Utilize discretion to issue up to a 6 month supply except with patch (3 month supply). ▪ **No consult** required for nurse or NP. **BMI > 35: NO COMBINED METHODS**	

Conditions Associated with Increased Risk for Adverse Heath Events as a Result of Pregnancy	
Breast cancer	Hepatocellular adenoma and malignant liver tumors (hepatoma)
Co	
Cys	
Dia reti dis	
Enc	
Epi	2
Hyp > 1	
His	
HIV: not clinically well or not receiving anti-retroviral therapy	Thrombogenic mutations
Ischemic heart disease	Tuberculosis
Gestational trophoblastic disease	

Consider long-acting, highly-effective contraception for these patients

Clinical Scenario: Hypertension

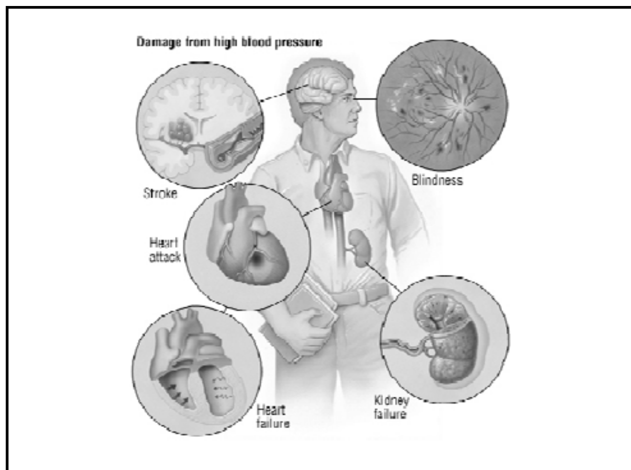
1 Risk Factor	Cu-IUD	LNG-IUD	Implant	DMPA	POP	CHC	CONSULT (*=Consult)	Comments (√=Comments)
Hypertension√								See HTN in abnormal findings.
Controlled BP < 140/90	1	1	1	2	1√	3*	**Written Consult**	If under care of PMD and HTN Controlled. **POPs 6 month supply.**
Stage 1 BP>140/90-159/99	1	1	1	2	1√	----		Referral indicated. **Dispensing 3 month supply POPs.**
Stage 2 BP≥160/100	1	2	2*√	3*	2*√	4	**Written Consult (Phone Consult** with Implant)	Implant insertions and/or removal with HTN - Consult for guidance. Referral Indicated
Alert BP ≥180/110	1√	2*√	2*√	3*√	2*√	4√	**Phone consult**	Same day referral to ER/PMD. **Alert BP dispensing 3 month supply.**
Gestation-HTN	1	1	1	1	1	2		

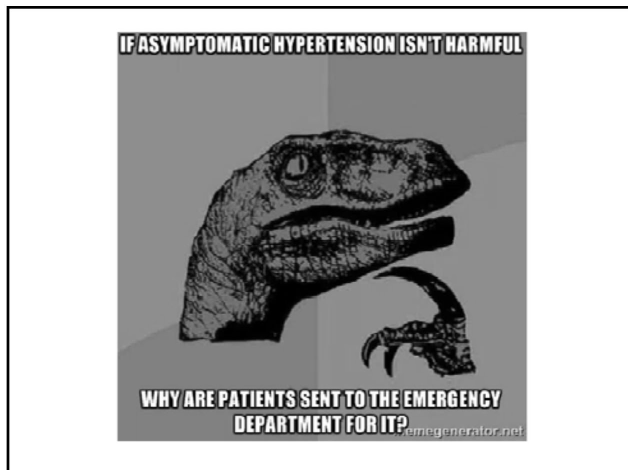
Hypertension: Deferring Exam due to HTN

- Asymptomatic vs. Symptomatic HTN- Dizziness, flushed face, frequent headaches, fatigue, epistaxis (nosebleed), nervousness, blurred vision/loss of vision, excessive perspiration, palpitations, weakness, polyuria, cramping in legs with walking.

Hypertension: Deferring Exam due to HTN

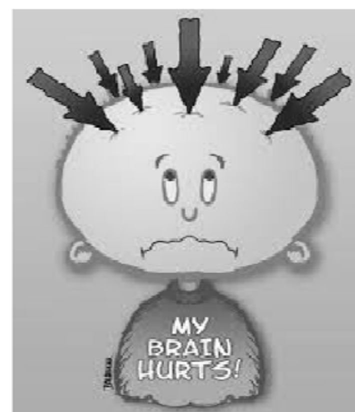
- Obtain recheck BP and if asymptomatic perform exam. Follow protocol for contraceptive management.





Clinical Scenario: Diabetes

1 Risk Factor	Cu-IUD	LNG-IUD	Implant	DMPA	POP	CHC	CONSULT (*=Consult)	Comments (√=Comments)
Diabetes								
History of Gestational Diabetes	1	1	1	1	1	1		
Un-complicated Diabetes	1	2	2	2	2√	2*√	Written Consult to initiate and annually.	CHC 3 month supply. If under PMD care, POPs up to 6 month supply.
Complicated Diabetes or ≥10 Years Duration	1	2*	2*	3*	2*√	----	Written Consult to initiate and annually.	POPs 3 month supply. If under PMD care, POPs up to 6 month supply.



Clinical Scenario: Headaches

1 Risk Factor	Cu-IUD	LNG-IUD	Implant	DMPA	POP	CHC	CONSULT (*=Consult)	Comments (√=Comments)
Headaches√								Accurate diagnosis of headaches vs. migraines and aura is needed.
Non-migraine	1	1	1	1	1	1		
Migraine w/o aura, includes menstrual migraine	1	1	1	1	1√	2√		POPs 6 month supply. For multiple risks factors: see Appendix B. COC use threefold increased risk for ischemic stroke.
Migraine w/ aura	1	1*	1*	1*	1*	4√	Written Consult	COC use threefold increased risk for ischemic stroke.

Clinical Scenario: Headaches

Topiramate (Topamax)

- **Certain anticonvulsants lower COC, POP, and Implant effectiveness increasing the likelihood of pregnancy.**

Clinical Scenario: Headaches

- Providing education on the use of a back up method is imperative.
- Topamax has also been associated with birth defects such as cleft lip/palate.

Clinical Scenario: Headaches

- Determine Type of Headache
- Migraine Characteristics
  - Onset
  - Location
  - Frequency

Clinical Scenario: Headaches

- Duration
- Exacerbating & alleviating factors
- Symptoms
- Triggers

Clinical Scenario: Migraines without Aura

- Nausea
- Vomiting
- Photophobia – sensitivity light; flickering lights
- Phonophobia – sensitivity to sound

Clinical Scenario: Migraines without Aura

- **Visual blurring; generalized spots/flashing**
- **Movement makes headache worse**

Clinical Scenario: Migraines with Aura

- **Unilateral numbness, weakness**
- **A "pins and needles" sensation, tingling on one side of body (paresthesia); hand, arm, face, partial paralysis**

Clinical Scenario: Migraines with Aura

- **Visual disturbance in one or both eyes – zig zag lines that float across field of vision (scintillations), temporary blindness or blind spots (scotomas), peripheral vision loss, tunnel vision, temporary blindness**

Clinical Scenario: Migraines with Aura

- **Difficulty speaking**
- **Olfactory hallucinations (smelling odors not present)**

The most important significance of migraines with aura is that often times they can mimic STROKE!

Clinical Scenario: Thyroid

1 Risk Factor	Cu-IUD	LNG-IUD	Implant	DMPA	POP	CHC	CONSULT (*=Consult)	Comments (√=Comments)
Thyroid disorders Simple Goiter/ Hyperthyroid / Hypothyroid Thyroid Cancer= Phone Consult	1	1	1	1	1√	1√	Written Consult Assess for severity or symptomatic Hyper/Hypo Thyroidism.	If symptomatic and not under the care of PMD, obtain thyroid profile, if results abnormal, phone consult and refer. If followed by outside provider, no lab needed. If thyroid storm symptomology, phone consult and refer. For dispensing – 6 month supply okay when under car of physician. If asymptomatic and not under care of physician obtain thyroid profile, dispensing – 3 months , if results are abnormal consult and refer.

Clinical Scenario: Hepatitis

1 Risk Factor	Cu-IUD	LNG-IUD	Implant	DMPA	POP	CHC	CONSULT (*=Consult)	Comments (√=Comments)
Hepatitis (Viral) Acute or Symptomatic Liver Disease	----	----	----	----	---	----	Phone Consult	Discontinue method, obtain LFTs and refer. Acute s/sx: jaundice, sclera icterus, abdominal varicosities, ascites, and enlarged liver.
Carrier/ Chronic	1	1	1	1	1√	1√		If patient is asymptomatic, LFTs are not required. May initiate up to a 6 month supply.

Clinical Scenario: Anemias

1 Risk Factor	Cu-IUD	LNG-IUD	Implant	DMPA	POP	CHC	CONSULT (*=Consult)	Comments (√=Comments)
Anemias √								See Abnormal Findings
Thalassemia	2	1	1	1	1	1		
Sickle Cell Disease	2	1	1	1√	1	2*	Phone Consult indicated for CHC due to increased coagulation activity.	DMPA method preferred. DMPA may prevent painful sickling crises (in which red blood cells clog blood vessels).
Iron-Deficiency√	2	1	1	1	1	1		All Anemias need referral if unexplained and undiagnosed Hemoglobin <10. Increased Risk Colon Cancer >45 year old African American patients, FIT testing indicated, see FIT protocol.

Clinical Scenario: VHD

1 Risk Factor	Cu-IUD	LNG-IUD	Implant	DMPA	POP	CHC	CONSULT (*=Consult)	Comments (√=Comments)
Valvular Heart Disease (VHD) √								Assessment of heart rate is indicated
Complicated (Symptomatic) √	1	1*	1*	1*	1*	4	Phone Consult	Complicated diseases in this category includes pulmonary HTN, risk for atrial fibrillation, history of subacute bacterial endocarditis. s/sx(s) may include one or more of the following: chest pain, shortness of breath, exertional symptoms, cyanosis, tachycardia.
Uncomplicated (Asymptomatic) √	1	1	1	1	1	2		Uncomplicated VHD includes MVP, mitral insufficiency, regurgitation, or murmur that is asymptomatic with no evidence of shortness of breath, cyanosis, chest pain.

Summary

- Age
- Two of More Risk Factors
- Hypertension
- Diabetes
- Migraines
- Anemia
- Hepatitis
- Thyroid
- Valvular Heart Disease

Appendices

- Appendix A: Low Risk Patients with Breast Masses
- Appendix B: Recommendations based on Multiple Risk Factors
- Appendix C: Seizures/Anticonvulsant Therapy

Appendices

- Appendix D: Polycystic Ovarian Syndrome (PCOS)
- Appendix E: Indications for Extended Use of Hormonal Methods
- Appendix F: Antiretroviral Therapy (ARV) List

Appendices

- Appendix G: How to be Reasonably Certain that a Woman is Not Pregnant
- Appendix H: Identifying Migraine Headaches Tool/Forms

Consultation

- Nurse ⇨ Collaborating Physician by phone
- F/U Email
  - Consult & Patient visit dates
  - County & CHR #

Consultation

- Age, Gravidity, Para, LMP, Vital Signs (BP, HR, Wt, BMI)
- hCG
- Reason for consult
- Plan of Care discussed with collaborating physician

Consultation

- Nurse's phone number
- Carbon copy (cc) the NP
- Place a copy of the email in the patient's chart under the consult tab
- ***Completed within 72 hours

How to be Reasonably Certain that a Woman is Not Pregnant

- $\leq$ 7 days after the start of normal menses
- Has not had sexual intercourse since the start of last normal menses

How to be Reasonably Certain that a Woman is Not Pregnant

- Has been correctly and consistently using a reliable method of contraception
- $\leq$ 7 days after spontaneous or induced abortion
- Within 4 weeks postpartum

How to be Reasonably Certain that a Woman is Not Pregnant

- Fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [$\geq$ 85%] of feeds are breastfeeds), amenorrheic, and < 6 months postpartum

How to Rule Out Pregnancy

- Abstinence or no unprotected intercourse during past 2 weeks and negative pregnancy test
- Unprotected intercourse during the past 2 weeks or unreliable historian, negative pregnancy test, patient uses condoms or abstains x 2 weeks, returns for and has negative pregnancy test

How to Rule Out Pregnancy

- For first trimester abortion and postpartum patients up to 28 days post delivery, a pregnancy test is not indicated since the hCG levels may remain detectable up to 3-4 weeks, potentially causing a false positive result

How to Rule Out Pregnancy

- Ruling out pregnancy is based on a reliable history at the time of the visit of no intercourse or no unprotected intercourse
- If unprotected intercourse has occurred, provide barrier x 2 weeks, then rule out pregnancy prior to initiating contraceptives

How to Rule Out Pregnancy

- Counsel patient appropriately regarding when to initiate method if not on the same day of service

How to Rule Out Pregnancy

NOTE: In some situations, obtaining a pregnancy test may be at the discretion of the NP. Pregnancy testing is not indicated ≤ 7 days after spontaneous or elective abortion.

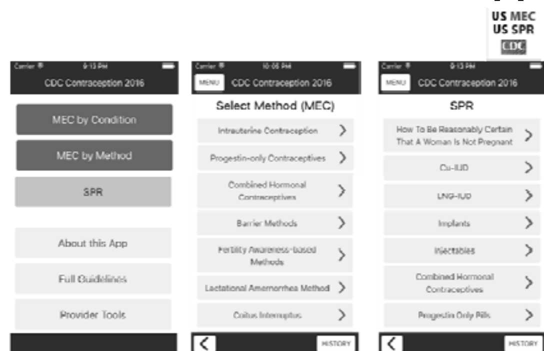
When to Start

- **Within 7 days of onset of menses (including first day start), even if she has not finished bleeding. Have patient use backup method for one week. If later than 7 days, rule out pregnancy.**

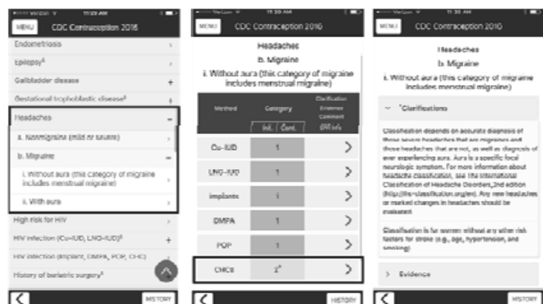
When to Start

- **For the non-breastfeeding, postpartum patient, the ring or combined oral contraception may be initiated no sooner than 6 weeks post delivery due to elevated risk of thrombosis in the early postpartum period.**

2016 U.S. MEC and SPR App



Using the U.S. MEC App



Summary tables and charts

- MEC summary table in English, Spanish

Summary tables and charts

- SPR quick reference charts
  - When to start contraceptive methods and routine follow up
  - What to do for late, missed or delayed combined hormonal contraception

Summary tables and charts

- Management of IUD when PID is found
- Management of women with bleeding irregularities while using contraception

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