Women's Care for the Internist: Focus on Today's Contraceptive Options

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Objectives

- Describe the various options for contraception management for women including their benefits and common side effects
- Contrast between selection of combined methods and progestin only hormonal methods
- Understand how to use the CDC medical eligibility criteria to guide contraceptive selection for patients

Contraception Options

Current Contraceptive Options

Most effective

Prevents
pregnancy
>99% of the
time

Male/Female Sterilization IUD/IUS Implants Very effective

Prevents
pregnancy
~91-99% of
the time

Pills
Injectables
Patch
Ring

Moderately effective

Prevents pregnancy ~81-90% of the time

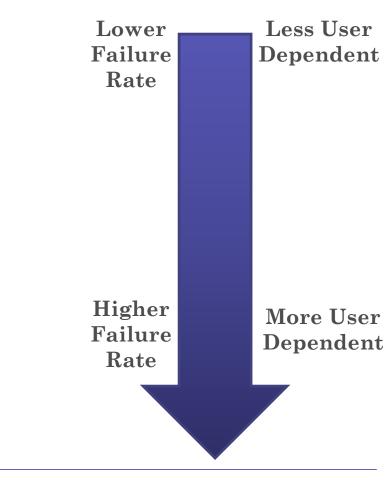
Male/Female Condom Sponge Diaphragm Effective

Prevents
pregnancy
up to 80% of
the time

Fertility
awareness
Cervical cap
Spermicide

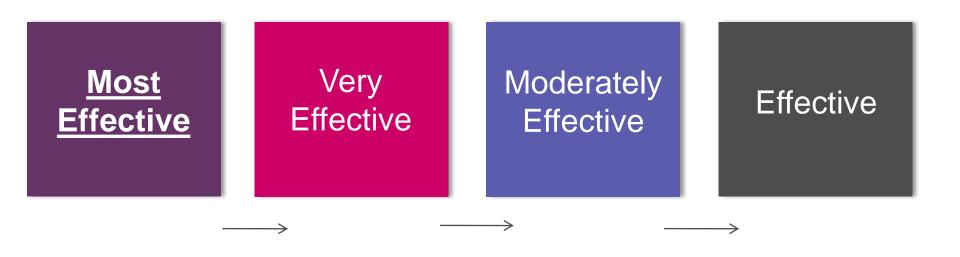
FAILURE RATES W/IN 1ST YEAR TYPICAL USE

Contraceptive Method Levonorgestrel intrauterine	Percentage of Women Experiencing an Unintended Pregnancy 0.1%
system Female sterilization	0.5%
Copper-T IUD	0.8%
Injection	3%
Oral contraceptive	8%
Vaginal ring	8%
Patch	8%
Condom	15%
Diaphragm	16%
Fertility awareness	25%
Spermicide	29%
No method	85%



Trussell J. In: Contraceptive Technology. 18th rev ed. 2004:773-845.

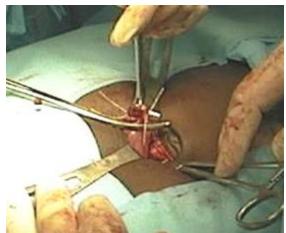
Current Contraceptive Options



Most effective

Female Sterilization

- Traditional Routes:
 - Abdominal (postpartum)
 - Laparoscopic (interval)
- Cumulative 10-year failure rates:
 - 0.8% 2.5%
 - High likelihood of ectopic with failure
- Sterilization Regret
 - Younger than 30: 20%
 - Greater than 30: 6%





Female Sterilization



- Transcervical Sterilization (Essure®)
 - Micro-inserts placed into proximal fallopian tubes
 - Requires back-up contraception
 - Confirmatory HSG performed 3 months later
 - Concerns
 - Several patient reports of pain
 - Misplaced devices
 - Inadequate f/up and unintended pregnancies
 - FDA Black box warning

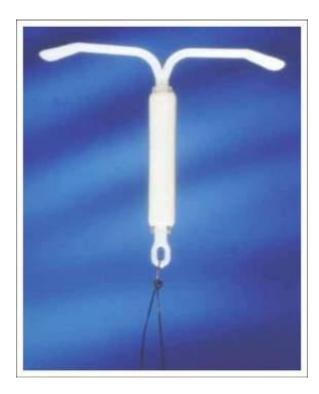
Male Sterilization



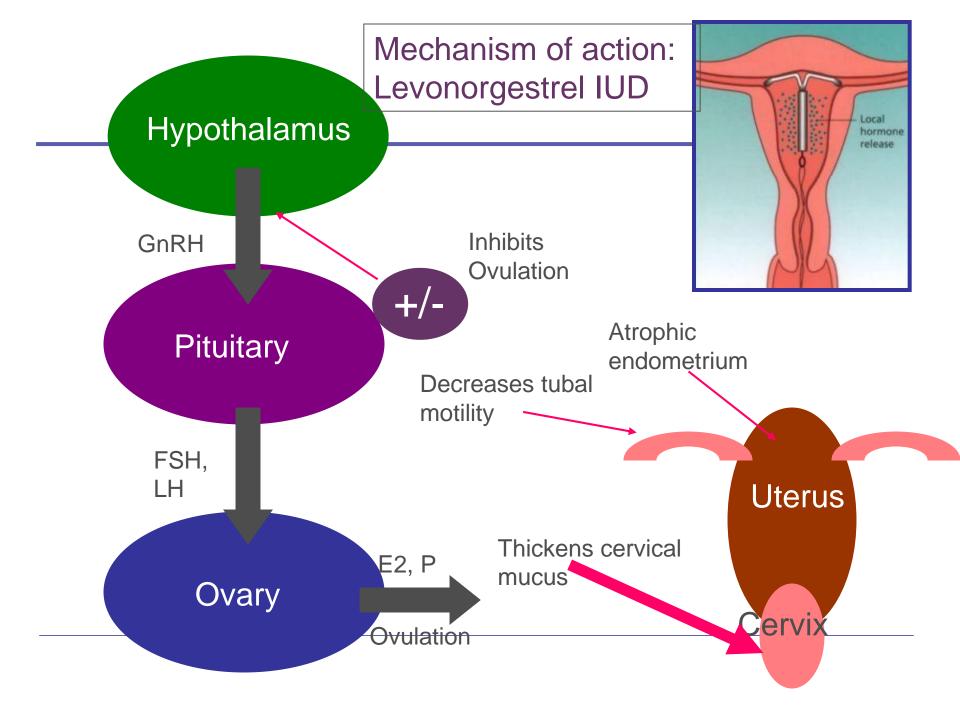
- Worldwide 13% of married/in-union women rely on vasectomy
- Scalpel\ No-scalpel technique
 - Interrupts the vas deferens
 - Outpatient procedure
 - <1% failure
 - Confirmatory sperm counts
- Sexual function unaffected

Most effective

Levonorgestrel Intrauterine System (LNG IUS)



- Brand name: Mirena
- Generic name: Liletta
- = 20 mcg levonorgestrel/day
- Approved for 5 years' use
- Failure Rates:
 - 1-yr perfect use= 0.1%
 - 1-yr typical use= 0.1%
 - Cumulative (5-yr)= 0.7%



Does the levonorgestrel containing IUD prevent fertilization?

Sperm_ blocked by cervical mucus.

LNG IUD Considerations

Menstrual changes

- Irregular bleeding/ Daily spotting (first 6 months)
- Hypomenorrhea at one year: 50%
- Amenorrhea at one year: 20%
- Bacterial Vaginosis more likely with irregular bleeding

Pelvic pain

- Can happen, especially in nulliparous women
- Usually resolves with time
- Consider partial expulsion/intraabdominal IUD

Acne

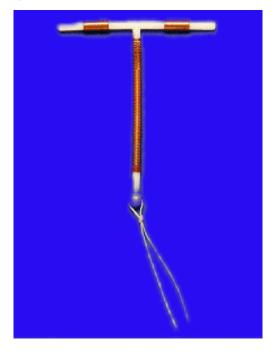
Minority of patients secondary to LNG effect, resolves with time

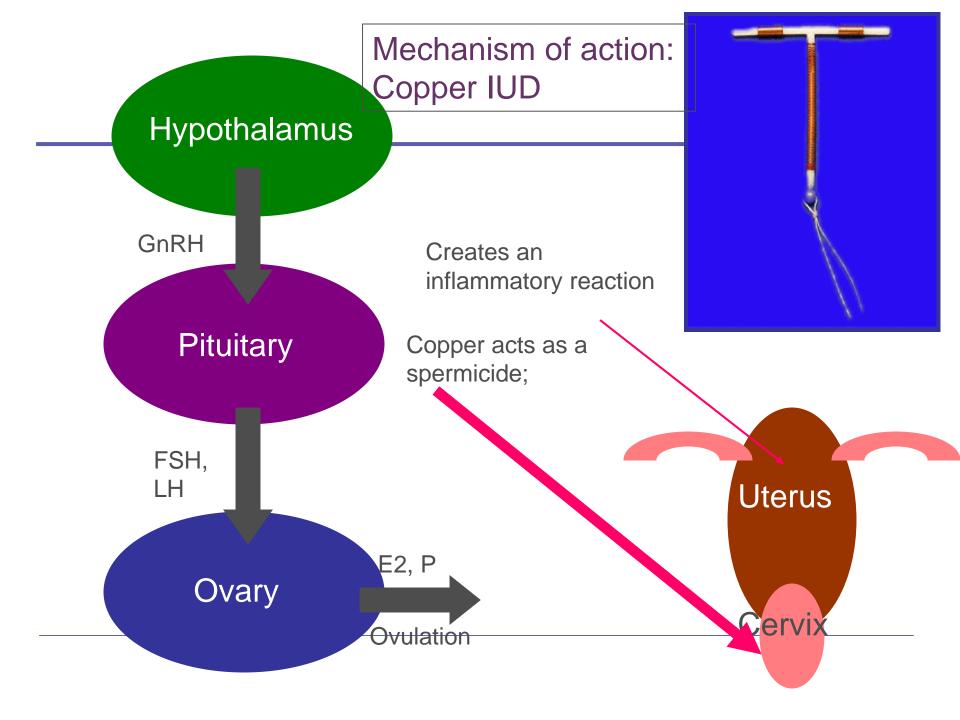
Noncontraceptive indications

- Heavy menstrual bleeding (on-label)
- Dysmennorhea
- Endometriosis
- Adenomyosis
- Endometrial hyperplasia/cancer

Copper-T IUD

- Brand name: Paragard®
- Polyethylene device w/380 mm³ copper
- Approved for 10 years' use
- Failure rates
 - 1-yr perfect= 0.6%
 - 1-yr typical= 0.8%
- Continuation at 1 year= 80% use



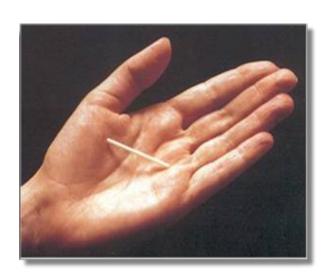


Copper IUD Considerations

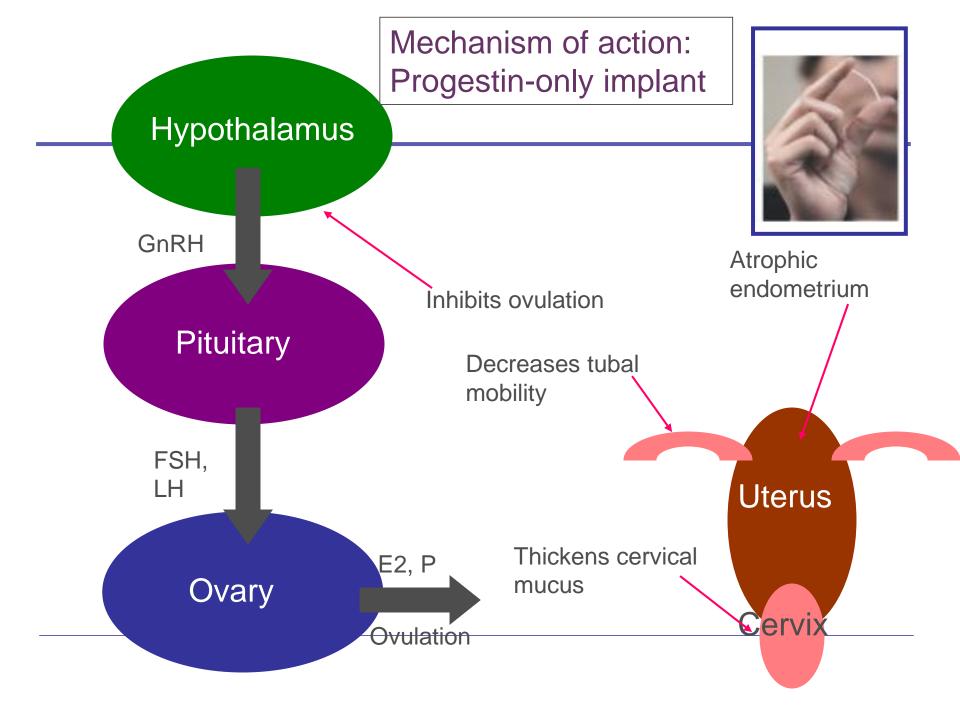
- Menstrual Changes
 - Average blood loss may increase by 50%
 - Dysmennorhea (20%)
 - Removal rates of 11.9% in first year
 - Treat with scheduled NSAIDs starting 2 days prior to onset of menses

Implant

- Brand name: Nexplanon (Formerly Implanon)®
- Single rod contains etonogestrel
- Effective for 3 years
- Failure Rates
 - 1-yr perfect use= 0%
 - 1-yr typical use failure rate= 0.05%



- Obese women excluded in initial studies
 - Further investigations demonstrate serum concentrations remain high enough to inhibit ovulation in overweight and obese women



Implant Counseling Consideration: Bleeding patterns

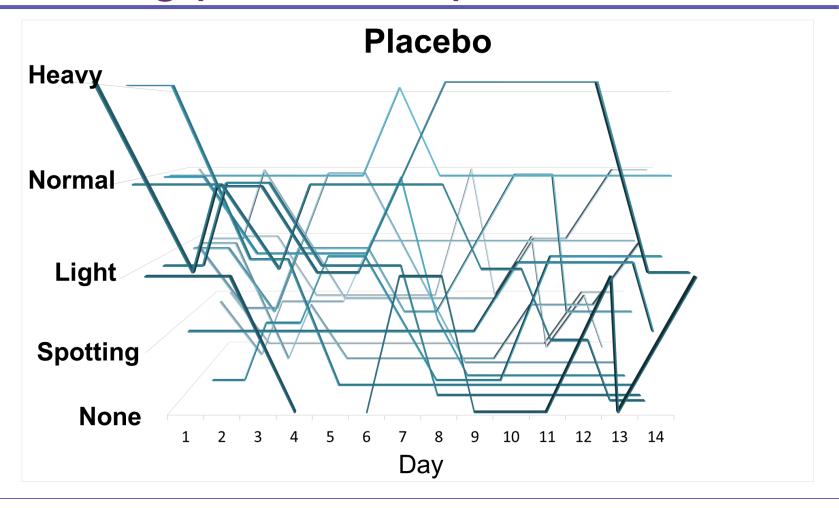
- Not related to other progestin method experiences
- 4,431 evaluable reference periods

Bleeding pattern	Percen	t of cycles
Amenorrhea	21%	
Infrequent bleeding	33%	Impossible to predict!!!
Frequent bleeding	6%	
Prolonged bleeding	17%	
	'	

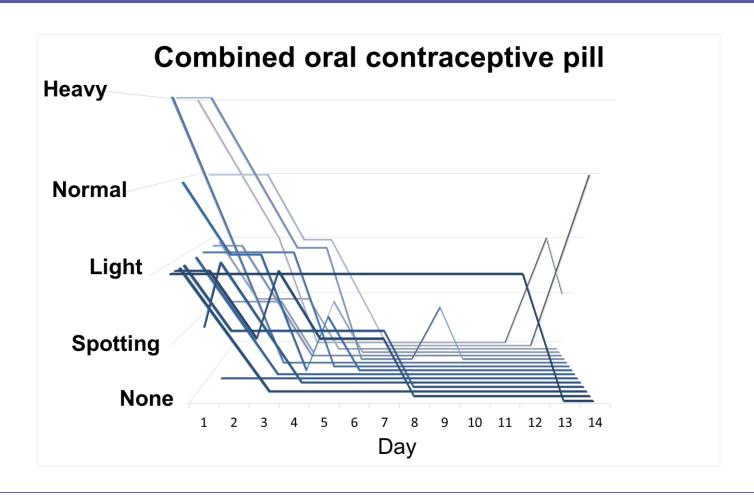
Implant continuation

- Continuation at 1 year= 88%
- Continuation at 2 years= 82% (53-90%)
- Most common reason for removal= "bothersome bleeding"
 - 11.3% in clinical trials
 - Typically prolonged, frequent episodes
 - "Tipping point" for removal

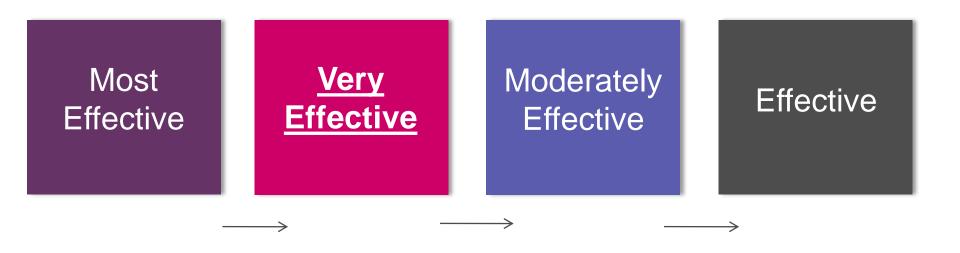
Bleeding pattern on placebo



Bleeding pattern on OCP



Current Contraceptive Options

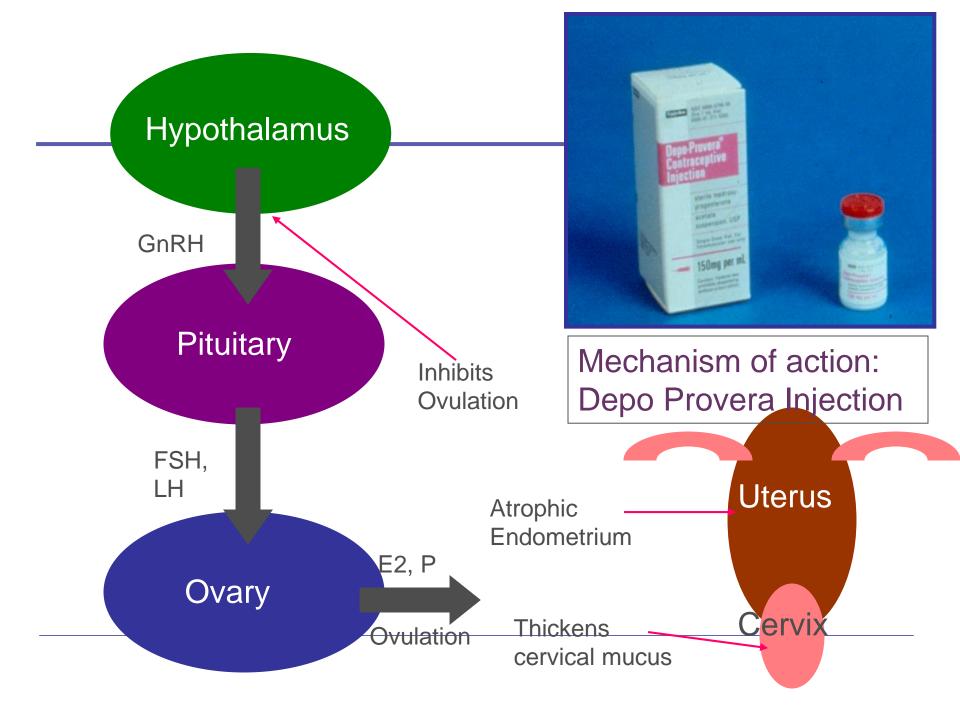


Very effective

Injectable



- Depot Medroxyprogesterone Acetate
- Brand name: Depo-Provera[®]
- Intramuscular or subcutaneous injection every 3 months
- Failure Rates:
 - 1-yr perfect use= 0.3%
 - 1-yr typical use= 3%
- Continuation rate at 1 year= 24-45%¹



DMPA Considerations

- Menstrual Changes
 - Irregular bleeding is common initially
 - Amenorrhea is normal:
 - 50% at 1 year, 80% at 5 years
- Upon discontinuation:
 - Menses may not return for months
 - Return to fertility may be delayed by 10-18 months
- Weight gain
 - On average 5.4 pounds in first year
 - 20% of users susceptible



Very effective

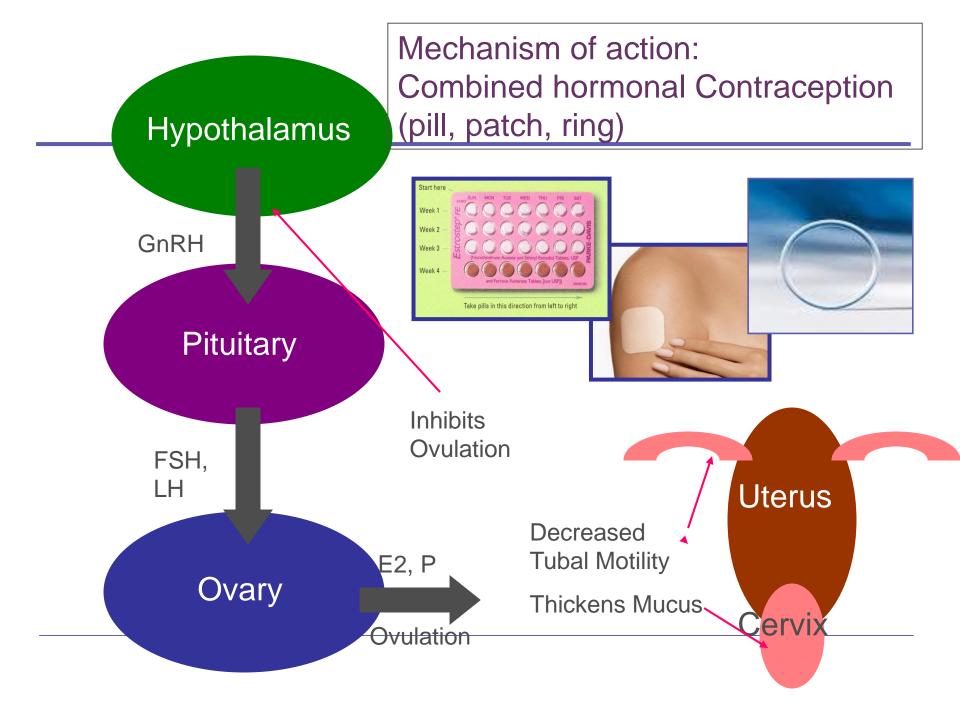
Combined Hormonal Contraceptives

- 1. Oral Contraceptive Pills (daily)
 - 2. Transdermal Patch (weekly)
 - 3. Transvaginal Ring (monthly)
 - 1-yr perfect use failure rate= 0.3%
 - 1-yr typical use failure rate= 8.0%





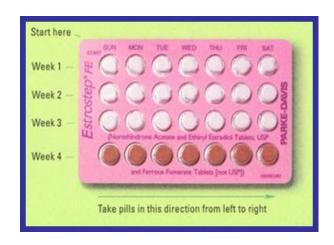






OCP Side effects

- KNOWN:
 - Nausea (PM dosing)
 - Breast tenderness (time)
- UNKNOWN:
 - Libido
 - Weight gain



Very effective

Transdermal Patch



- Brand name: OrthoEvra®
- Weekly
- Worn on trunk, arm, buttock
- Low risk of thromboembolism
- Complaints:
 - skin irritation of adhesive
 - hypo/hyperpigmentation

Very effective

Vaginal Ring





- Brand name: NuvaRing[®]
- Insert intravaginally (monthly)
- Intercourse: leave in, or take out for no longer than 3 hours
- Complaints:
 - Vaginal discharge
 - Sensation during intercourse
- Lowest hormonal profile

Beneficial effects of estrogen

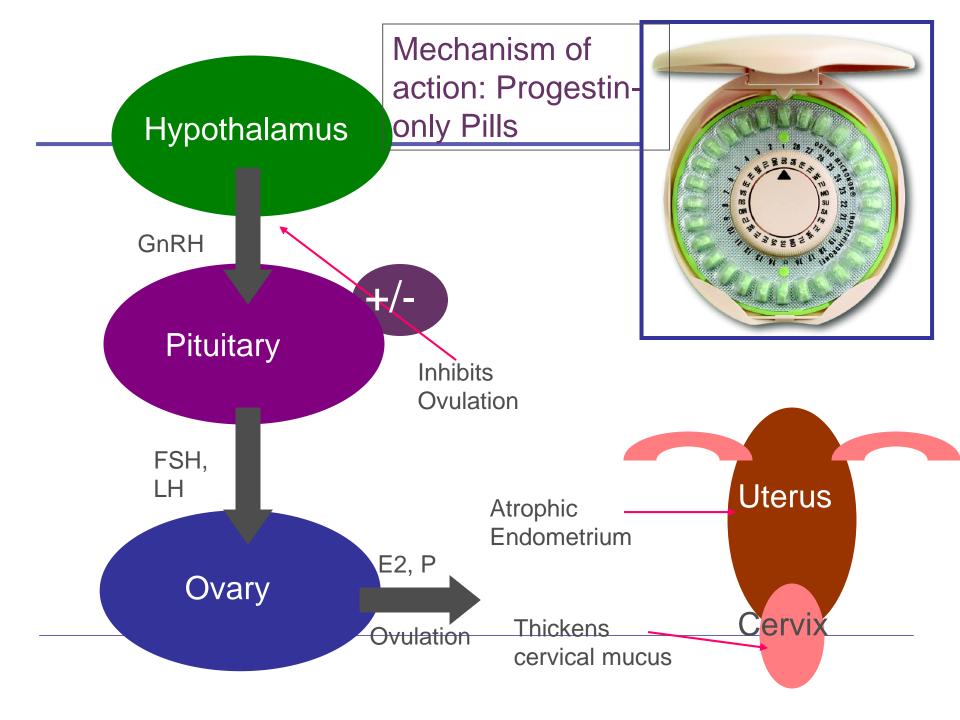
- Contraceptive benefit
 - Helps stabilize uterine lining- less breakthrough bleeding
 - Added suppression of FSH- less follicle development
- Noncontraceptive benefits
 - Reduces SHBG→ less male effects (i.e. acne)
 - Reduces ovarian cancer, endometrial, colon cancer risks

Very effective

Progestin-Only Oral Contraceptives

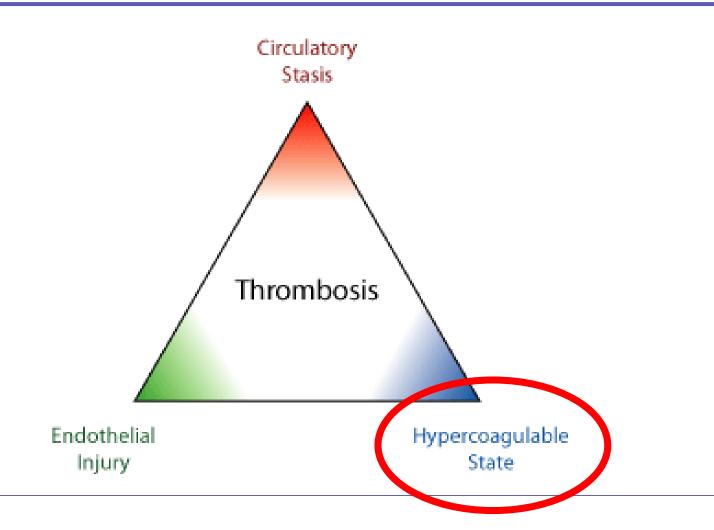


- Called the "mini-pill"
- Two formulations: norethindrone & norgestrel
- Option for lactating women
- No placebo pills
- Less forgiving
 - 3 hr delay → requires back-up x 48 hrs, consider EC
 - Miss one pill → use EC and back-up x 1 week



Estrogen vs. Progestin

Thromboembolism



Physiologic risks of estrogen

- Estrogen increases clotting factors II, VII, X, XII, factor VIII and fibrinogen.
- Shift towards thrombus formation and prevention of clot dissolution.
- Leads to greater risk of venous and arterial clot formation (more venous).
- Higher estrogen more production of clotting factors

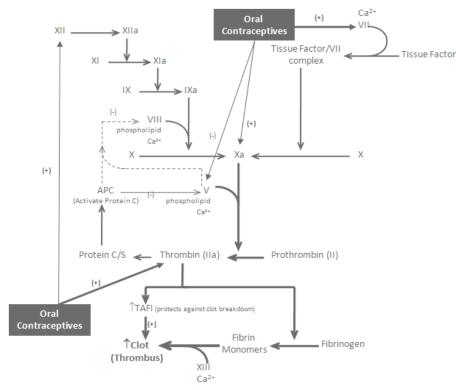
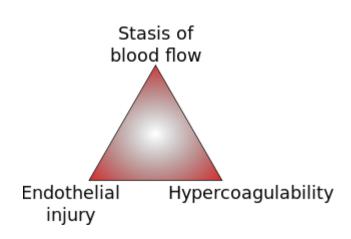


Figure 1. Coagulation cascade of a patient taking estrogen containing oral contraceptives. ©2009 Pharmacology Weekly, Inc.

Selection of candidates for CHC

- Risk of venous thrombosis
- Risk of arterial thrombosis
- Other risk factors:
 - Major surgery with prolonged immobilization
- Organ specific
 - Active liver/gallbladder problems
- Hormone specific (breast cancer)



Risks in perspective

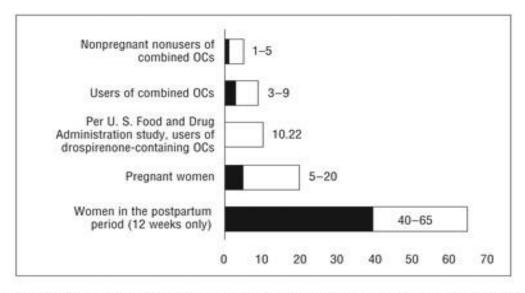


Fig. 1. Likelihood of developing a blood clot (number of women with a blood clot per 10,000 women-years). Abbreviation: OC indicates oral contraceptives. Adapted from Food and Drug Administration. FDA drug safety communication: updated information about the risk of blood clots in women taking birth control pills containing drospirenone. Silver Spring (MD): FDA; 2012. Available at: http://www.fda.gov/DrugS/DrugSafety/ucm299305. Retrieved July 5, 2012. Additional information from Food and Drug Administration. Combined hormonal contraceptives (CHCs) and the risk of cardiovascular disease endpoints. Silver Spring (MD): FDA; 2011. Available at: http://www.fda.gov/downloads/Drugs/DrugSafety/UCM277384.pdf. Retrieved July 5, 2012.

Which Contraceptive Methods are Safe for my Patient?

US Medical Eligibility Criteria for Contraceptive Use





www.cdc.gov/mmwr

Recommendations and Reports

June 18, 2010 / Vol. 59 / No. RR-4

U.S. Medical Eligibility Criteria for Contraceptive Use, 2010

Adapted from the World Health Organization
Medical Eligibility Criteria for Contraceptive Use, 4th edition

US MEC: Categories

1	No restriction for the use of the contraceptive method for a woman with that medical 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 – or that there are no other methods that are available or acceptable to the women with that medical condition
4	Unacceptable health risk if the contraceptive method is used by a woman with that medical condition



Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2010



Key

- No restriction (method can be used)
- Advantages generally outweigh theoretical or proven risks
- Theoretical or proven risks usually outweigh the advantages
 Unacceptable health risk (method not to be used)

This summary sheet only contains a subset of the recommendations from the US MHC. For complete guidance, see: www.cdc.gov/reproductivehealth/usmec

Most contraceptive methods do not protect against sexually transmitted infections (STIs). Consistent and correct use of the male talex condom reduces the risk of STIs and HIV.

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abnormalities	b) Other abnormalities					2	2
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1	b) Sickle cell disease:	2	1	1	1	1	2
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I	b) Benign breast disease	1	1	1	1	1	1
	c) Parally history of cancer	1	1	1	1	1	1
1	d) Resul cancer:						$\overline{}$
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1	ii) past and no evidence of current disease for 5 years	3	3	3	3	3	1
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incase and	b) I month or more postnarium	2*	19	19	19		
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	b) Sevent (decomprosated)	4	3	3	3	3	i
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/Pulmonary	DVTPE						
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	b) Acute DVI7PII	4	2	2	2	2	2
	 c) DVT/PE and established on anticoagulant therapy for at least 3 months 						
	i) higher risk for mearment DVT/PX	4*	2	2	2	2	2
	 kwer risk for mearant DVT/PE 	3*	2	2	2	2	2
	d) Pamily history (first-degra: relatives)	2	- 1	1	- 1	- 1	1
I	c) Major surgery						
	(i) with prolonged	4	2	2	2	2	1
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Warnings for CHC

CDC MEC Medical Condition	CHC
Heavy smoker > 35	4
<4-6 weeks postpartum	3
Uncontrolled HTN	4
H/o DVT or PE	3-4
Migraine with aura	4
Diabetes with vascular disease	3-4
Severe Cirrhosis	4
Hx Bariatric Sx- malabsorptive	3
Mod/ Severe Peripartum Cardiomyopathy	4
Inflammatory bowel disease	2-3

Safety with progestin-only methods

CDC MEC Medical Condition	CHC	Progestin -only
Heavy smoker > 35		1
<4-6 weeks postpartum		2
Uncontrolled HTN		2-3
H/o DVT or PE		2
Migraine with aura		2-3
Diabetes with vascular disease		2-3
Severe Cirrhosis		3
Hx Bariatric Sx- malabsorptive		1 3
Mod/ Severe Peripartum Cardiomyopathy		2
Inflammatory bowel disease	2-3	1-2

Common pitfalls (for the internist)

- Consider the additive effects of multiple concerns
 - Multiple risk factors (older age, smoking, diabetes, HTN) → CDC MEC 3/4 for CHC and 3 for DMPA
- No contraception= unplanned pregnancy= greater risks than contraception
- Assume most patients are having sex
 - Not only give contraception, check pregnancy test even if on contraception

Cases



- Which hormonal methods are safe for her to use?
 - A. Combined hormonal methods only
 - B. Progestin-only methods only
 - c. Any hormonal method

Breastfeeding



Condition	Sub-condition.	Combined pill, patch, ring	Progestin-ordy pill	byection	Emploant	TNG-10D	Copper-IUD	
		I C	I C	I C	I C	I C	I C	
Breastfeeding	a) < 1 month postpartum	3±	2*	2*	2*			
	b) 1 month or more postpartum	2*	l*	l*	l [‡]			



- Which hormonal methods are safe for her to use?
 - A. Combined hormonal methods only
 - B. Progestin-only methods only
 - c. Any hormonal method



- Is this method safe for her?
 - A. Yes
 - B. No

Safe even if nulliparous

Inflammatory Bowel Disease



Condition	Sub-condition.	Combined will			Progestin-only pill		byeeten		Implant	dill. SN. i			copperation
	J	I	С	I	С	I	С	I	С	I	С	I	С
Inflammatory bowel disease	(Ulcerative colitis, Crohn's disesse)	2/3	2/3*		2		2		l	l		l	



- Is this method safe for her?
 - A. Yes (Category 1)
 - B. No



- What do you need to know before deciding whether to recommend this method?
 - A. How much weight has she lost?
 - B. What type of surgery did she have?
 - c. What pill formulation did she use previously?

Bariatric surgery



- Most effective weight loss treatment for morbid obesity
- From 1998 to 2005, incidence increased 800%
- Women account for 83% of procedures among reproductive age (ages 18-45)

Types of Bariatric surgery



- Restrictive procedures:
 - Decrease storage capacity of stomach
 - Ex: vertical banded gastroplasty, laparoscopic adjustable gastric band, laparoscopic sleeve gastrectomy
- Malabsorptive procedures:
 - Decrease absorption of nutrients and calories by shortening functional length of small intestine
 - Ex: Roux-en-Y gastric bypass (most common in US), biliopancreatic diversion





 Consensus: Pregnancy should be avoided for 12-24 months after surgery

History of Bariatric Surgery



Condition	Sub-condition	Combined pill, patch, ring		Progestin-only pill		Injection		Implant		TNGIOD		Copper-IUD			
		Ι	С	I	С	I	С	I	С	I	С	I	С		
History of bariatric	a) Restrictive procedures	l			1		1		1]	l	1	l		
swgetyl	b) Malabsorptive procedures	_	COCs: 3 P/R: 1		3		3		1		1		l	1	



- What do you need to know before deciding whether to recommend this method?
 - A. How much weight has she lost?
 - B. What type of surgery did she have?
 - c. What pill formulation did she use previously?

Conclusions

- Physicians must be aware that women with medical co-morbidities face increased risks:
 - Combined hormonal contraception
 - Unintended pregnancy
- CDC MEC can guide safe prescription.
- Most long-acting reversible contraceptive methods are safe and effective options.



"Well, I'm on the pill. I also use a diaphragm with a contraceptive sponge and Alan wears a condom. Plus we abstain completely from sex."