

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

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Objectives

- 1** Describe the various options for contraception management for women including their benefits and common side effects
 - 2** Contrast between selection of combined methods and progestin only hormonal methods
 - 3** 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 | Percentage of Women Experiencing an Unintended Pregnancy |
|------------------------------------|--|
| Levonorgestrel intrauterine system | 0.1% |
| 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% |

Lower
Failure
Rate

Less User
Dependent

Higher
Failure
Rate

More User
Dependent

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

Current Contraceptive Options

**Most
Effective**

Very
Effective

Moderately
Effective

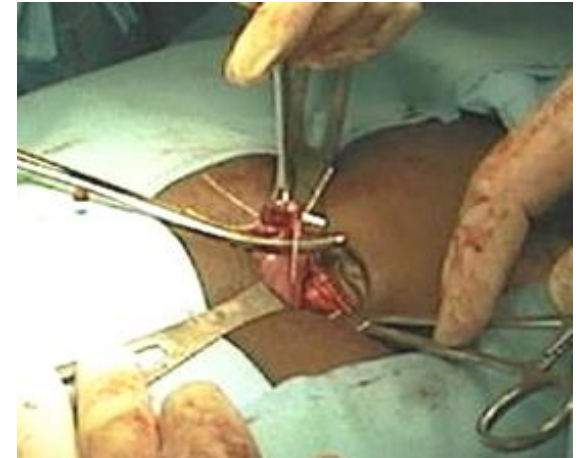
Effective



**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%



**Most
effective**

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

**Most
effective**

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
-

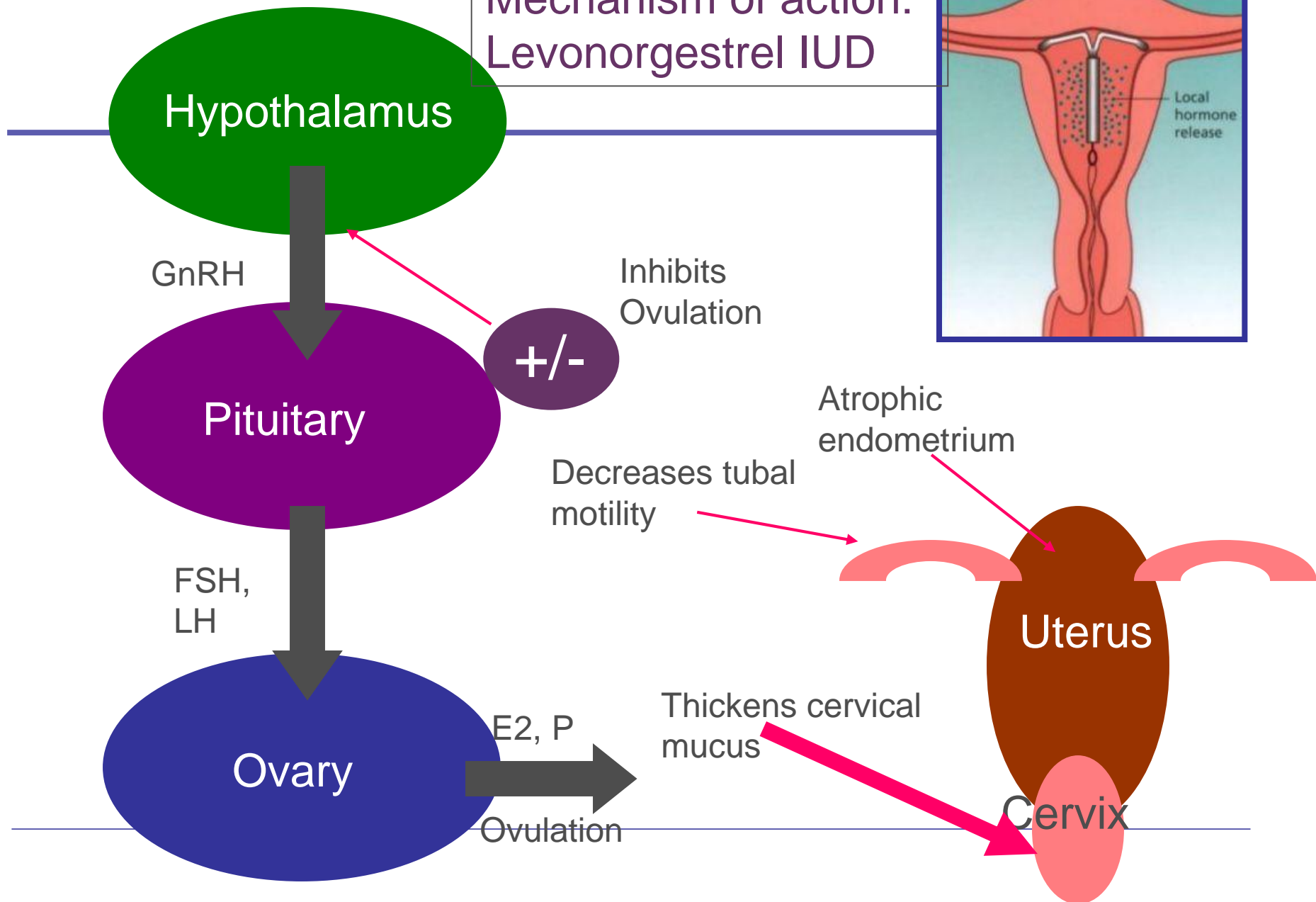
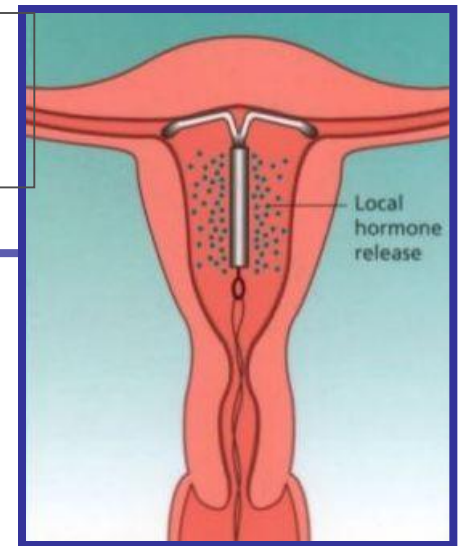
**Most
effective**

Levonorgestrel Intrauterine System (LNG IUS)



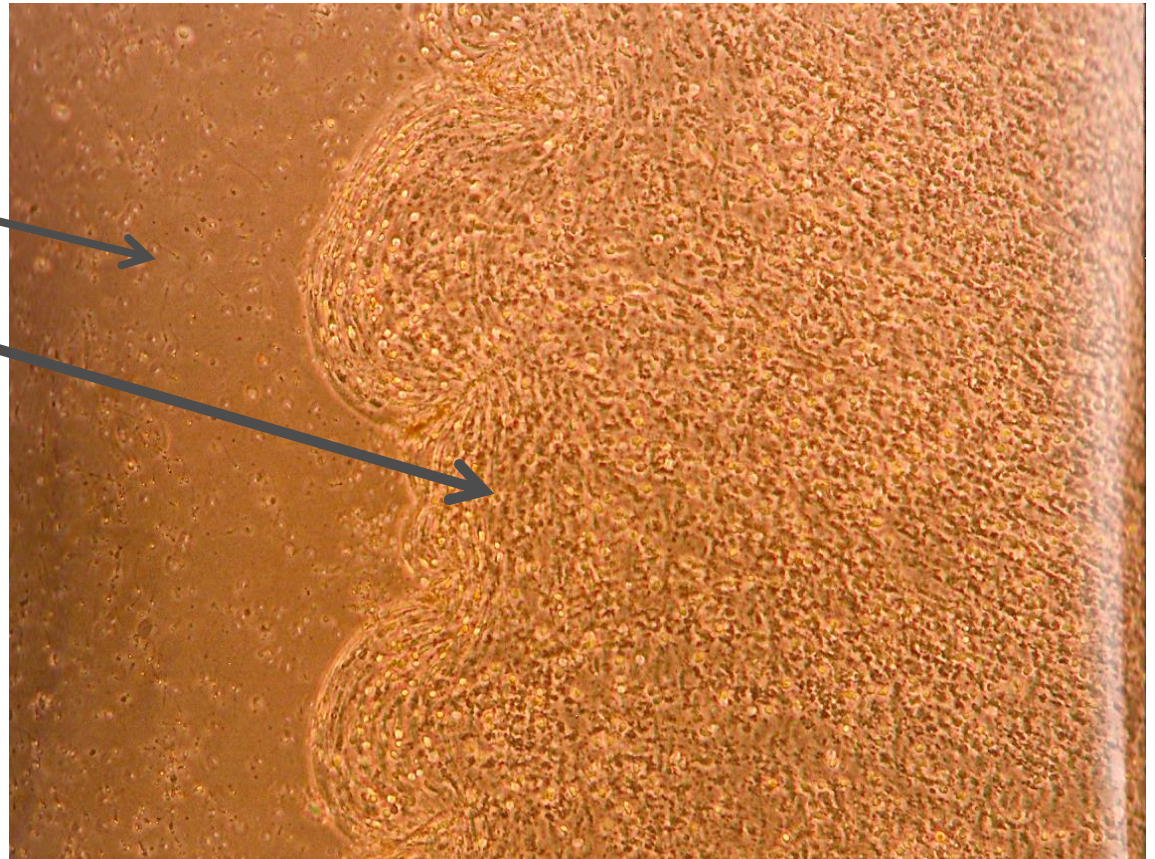
- Brand name: Mirena
- Generic name: Liletta
= 20 mcg levonorgestrel/day
- Approved for 5 years' use
- Failure Rates:
 - 1-yr perfect use= 0.1%
 - 1-yr typical use= 0.1%
 - Cumulative (5-yr)= 0.7%

Mechanism of action: Levonorgestrel IUD



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

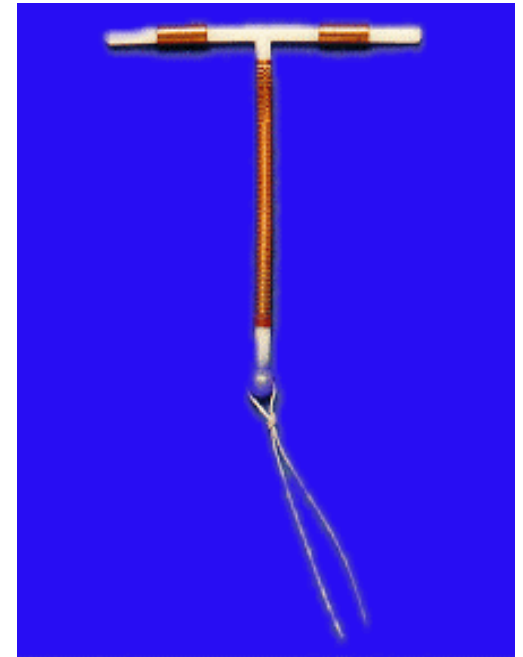
Noncontraceptive indications

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

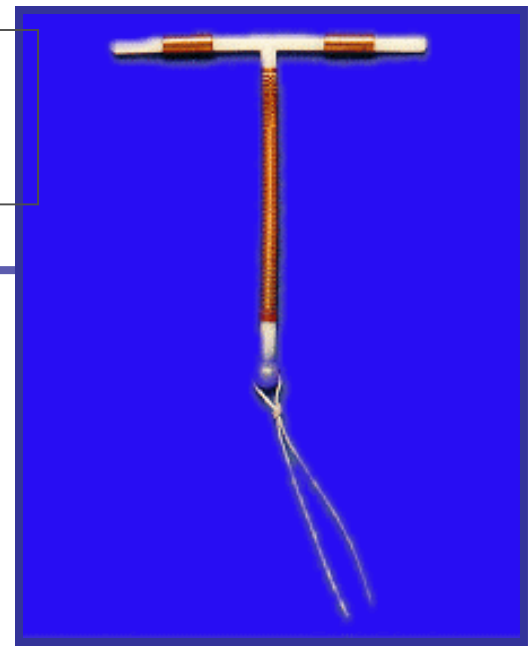
**Most
effective**

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



Mechanism of action:
Copper IUD



Hypothalamus

GnRH

Pituitary

FSH,
LH

Ovary

E2, P

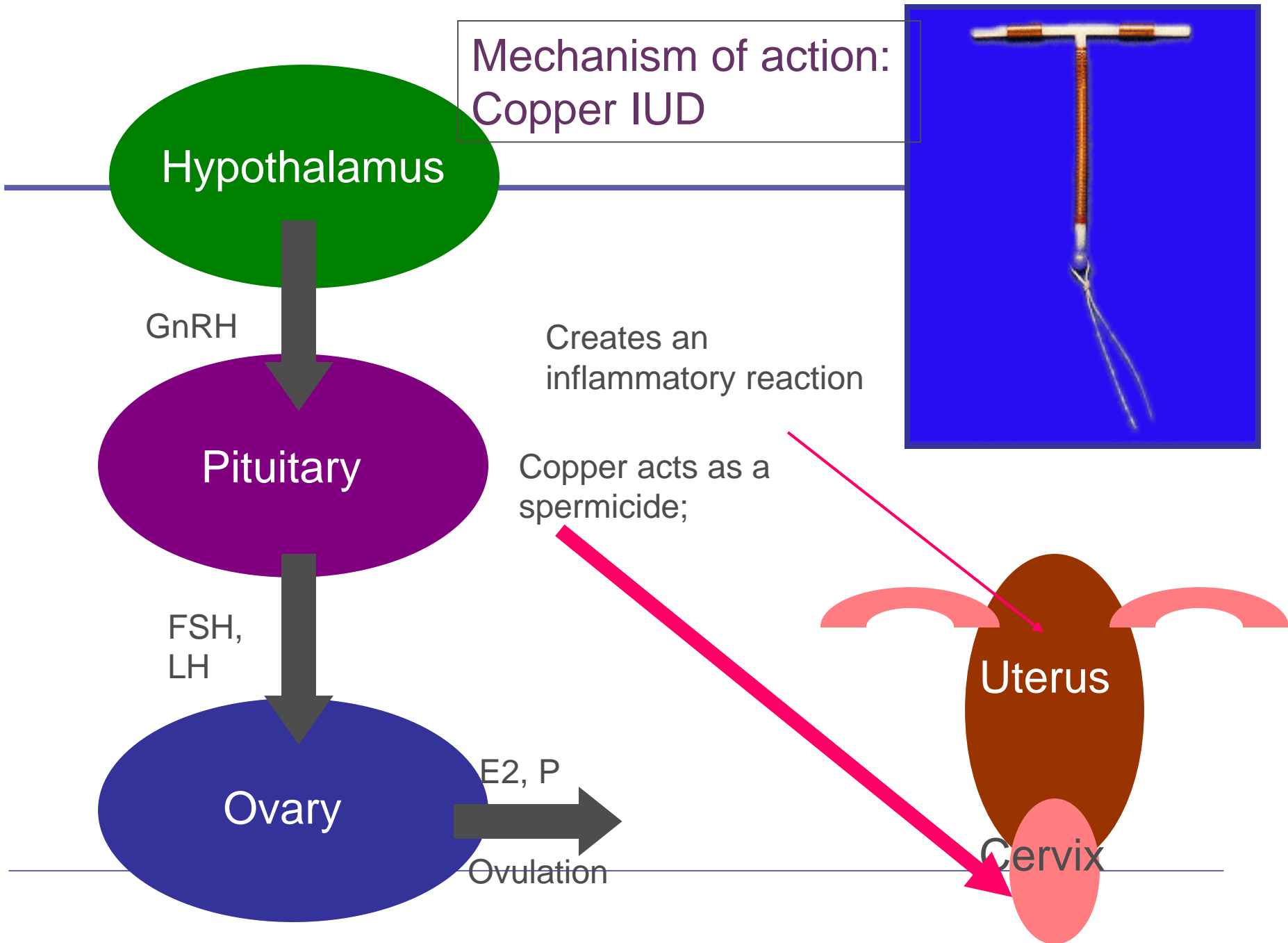
Ovulation

Creates an
inflammatory reaction

Copper acts as a
spermicide;

Uterus

Cervix



**Most
effective**

Copper IUD Considerations

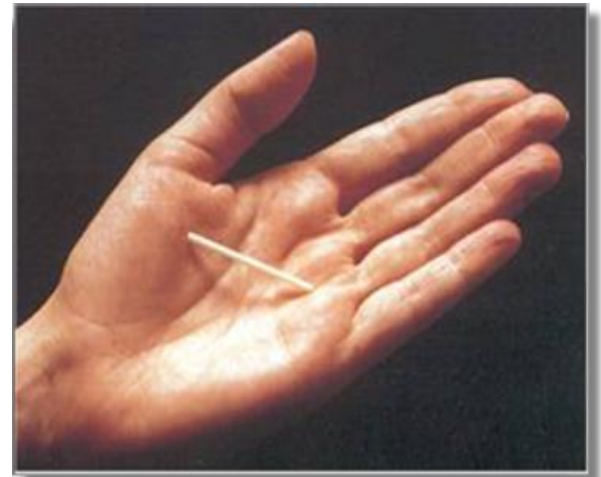
- Menstrual Changes
 - Average blood loss may increase by 50%
 - Dysmenorrhea (20%)
 - Removal rates of 11.9% in first year
 - Treat with scheduled NSAIDs starting 2 days prior to onset of menses



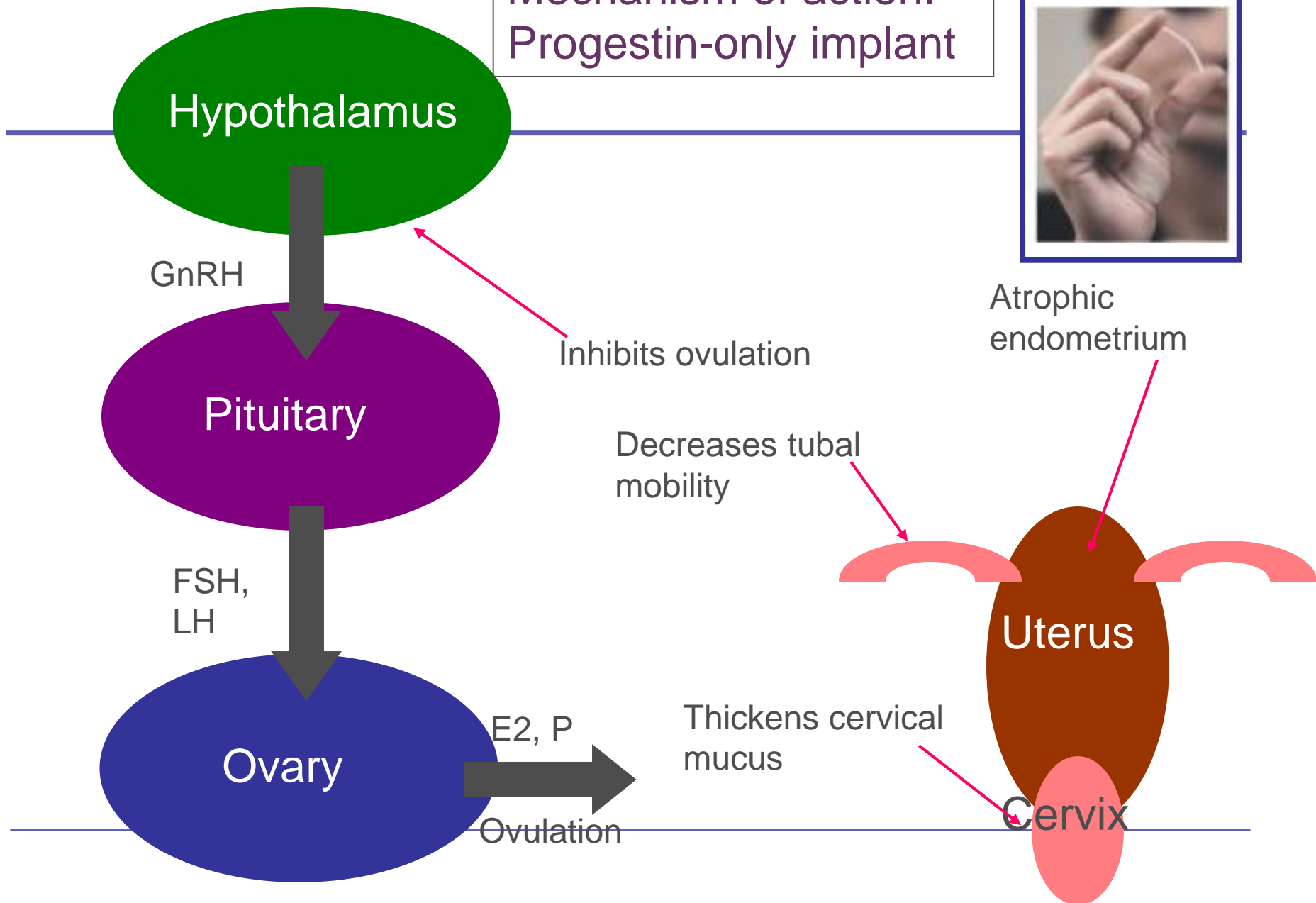
**Most
effective**

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



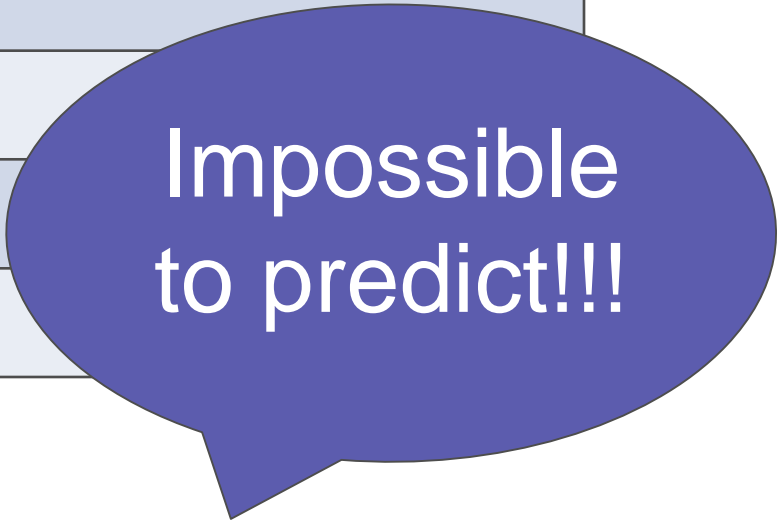
Mechanism of action:
Progestin-only implant



Implant Counseling Consideration: Bleeding patterns

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

| Bleeding pattern | Percent of cycles |
|---------------------|-------------------|
| Amenorrhea | 21% |
| Infrequent bleeding | 33% |
| Frequent bleeding | 6% |
| Prolonged bleeding | 17% |



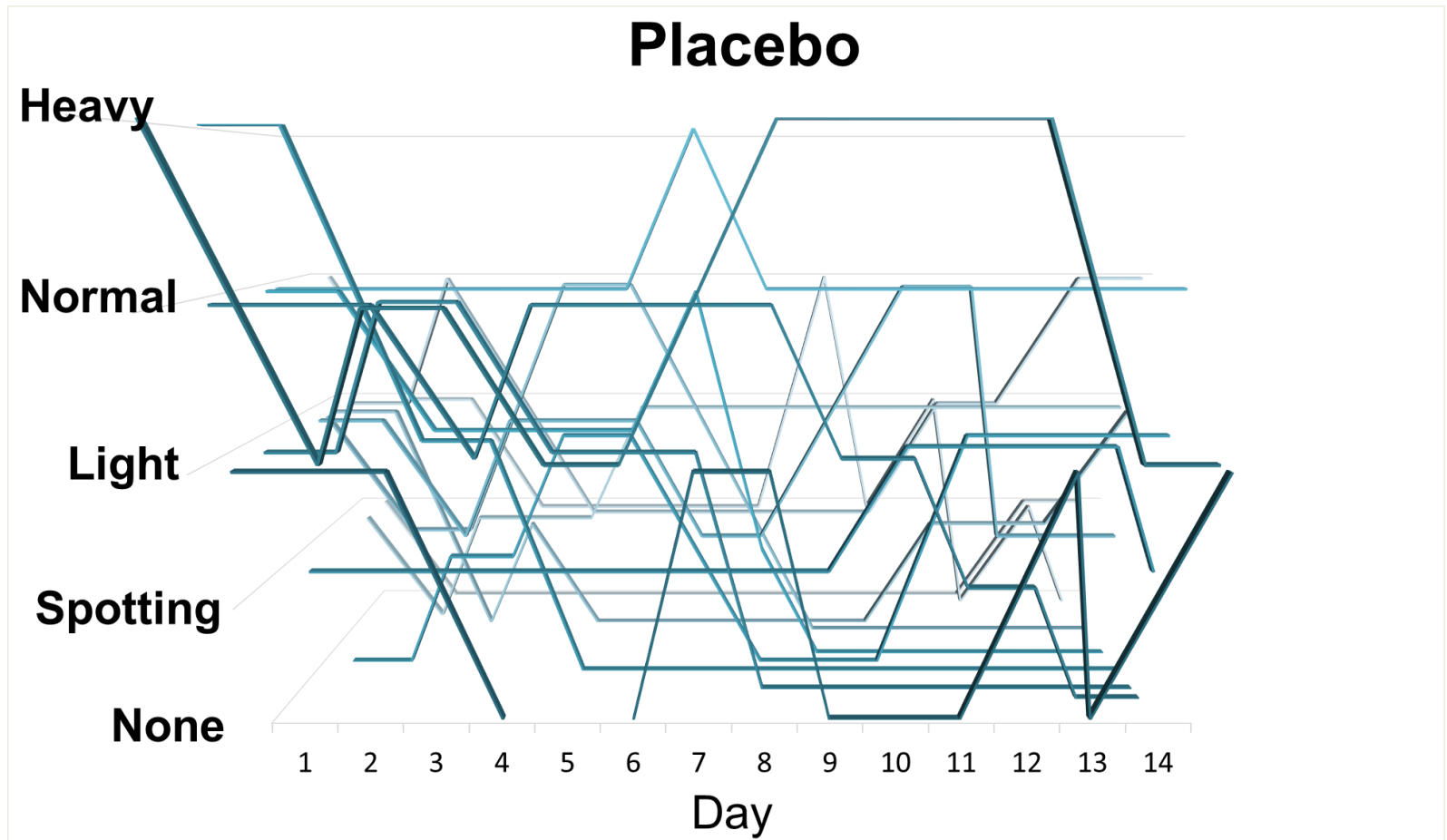
Impossible
to predict!!!

Implant continuation

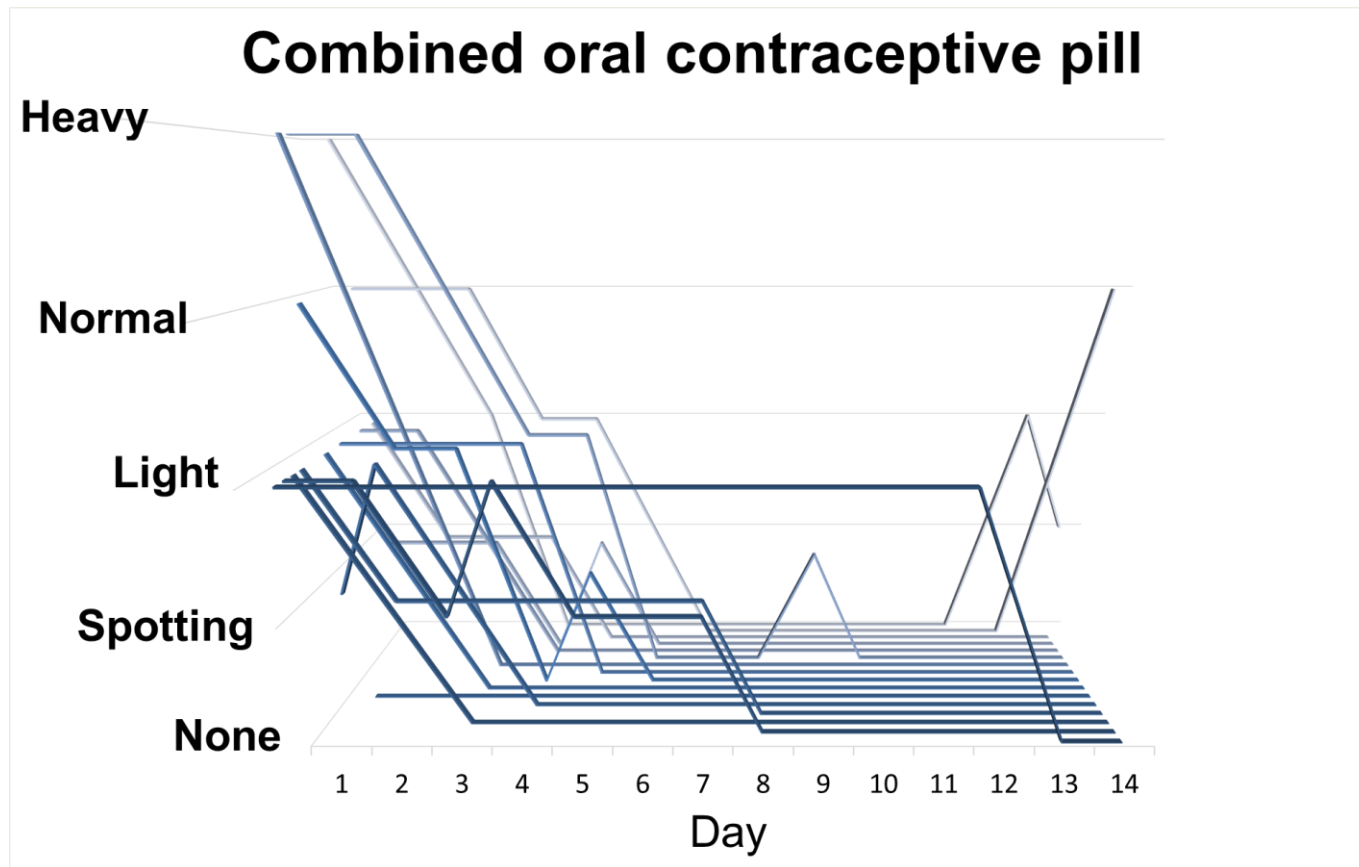


- Continuation at 1 year= 88%
- Continuation at 2 years= 82% (53-90%)
- Most common reason for removal= “bothersome bleeding”
 - 11.3% in clinical trials
 - Typically prolonged, frequent episodes
 - “Tipping point” for removal

Bleeding pattern on placebo



Bleeding pattern on OCP



Current Contraceptive Options

Most
Effective

Very
Effective

Moderately
Effective

Effective

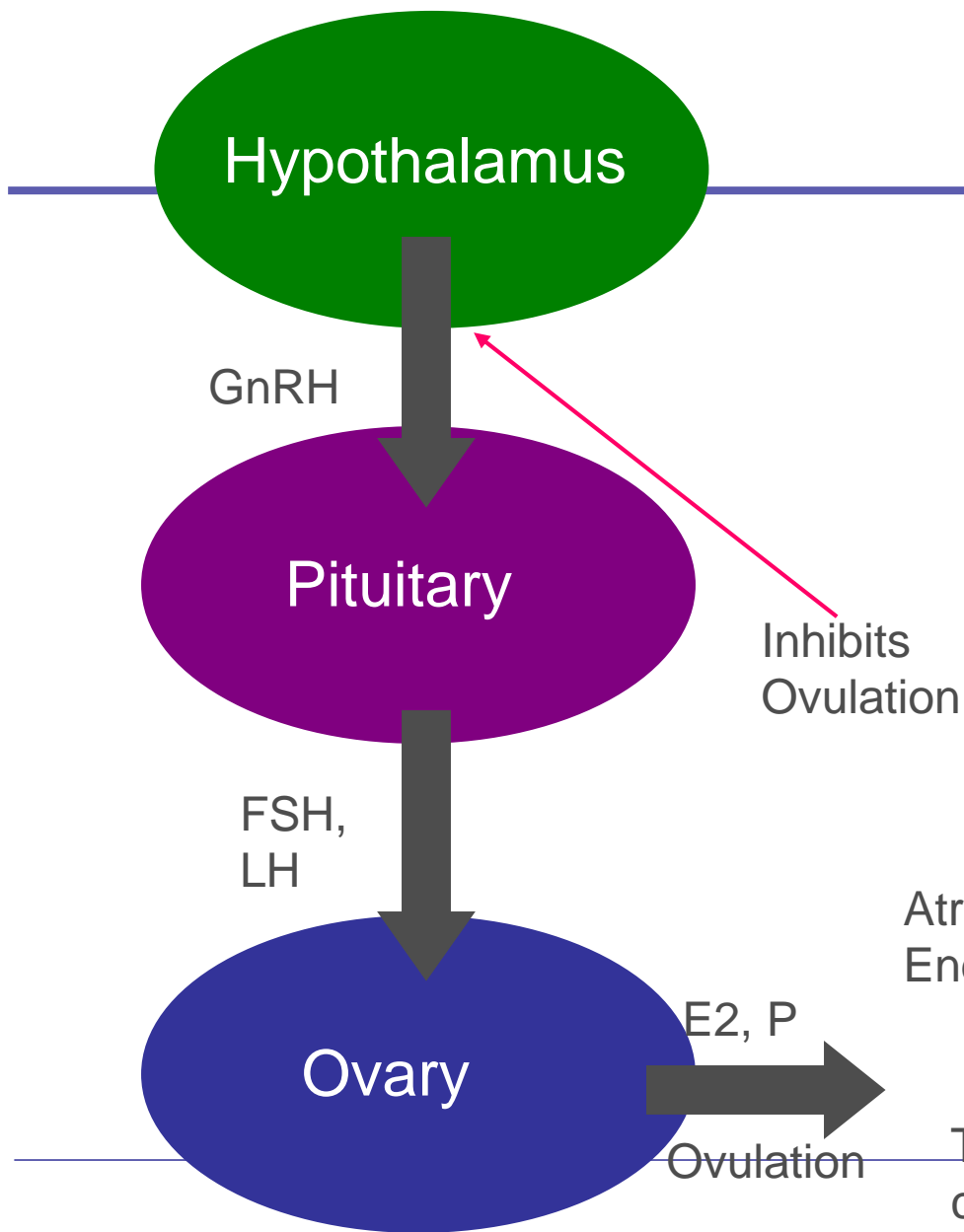


**Very
effective**

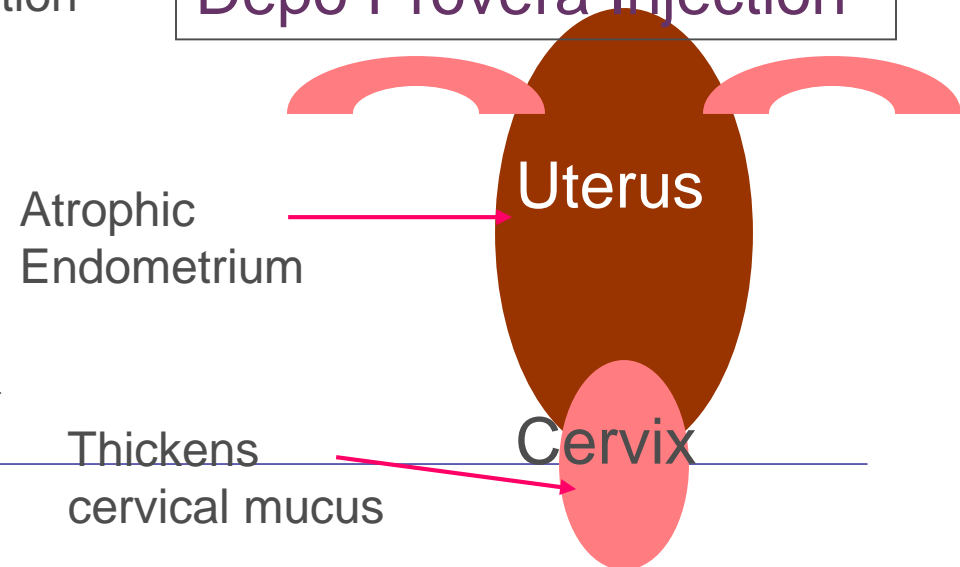
Injectable



- 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

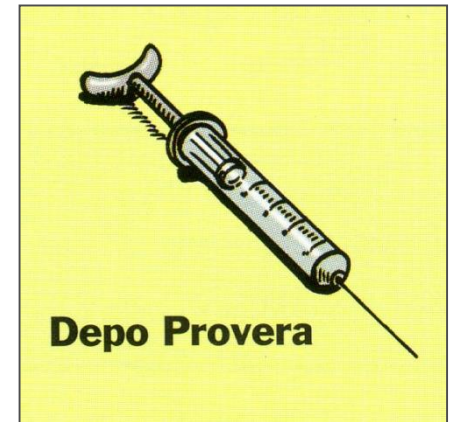


Mechanism of action:
Depo Provera Injection



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**

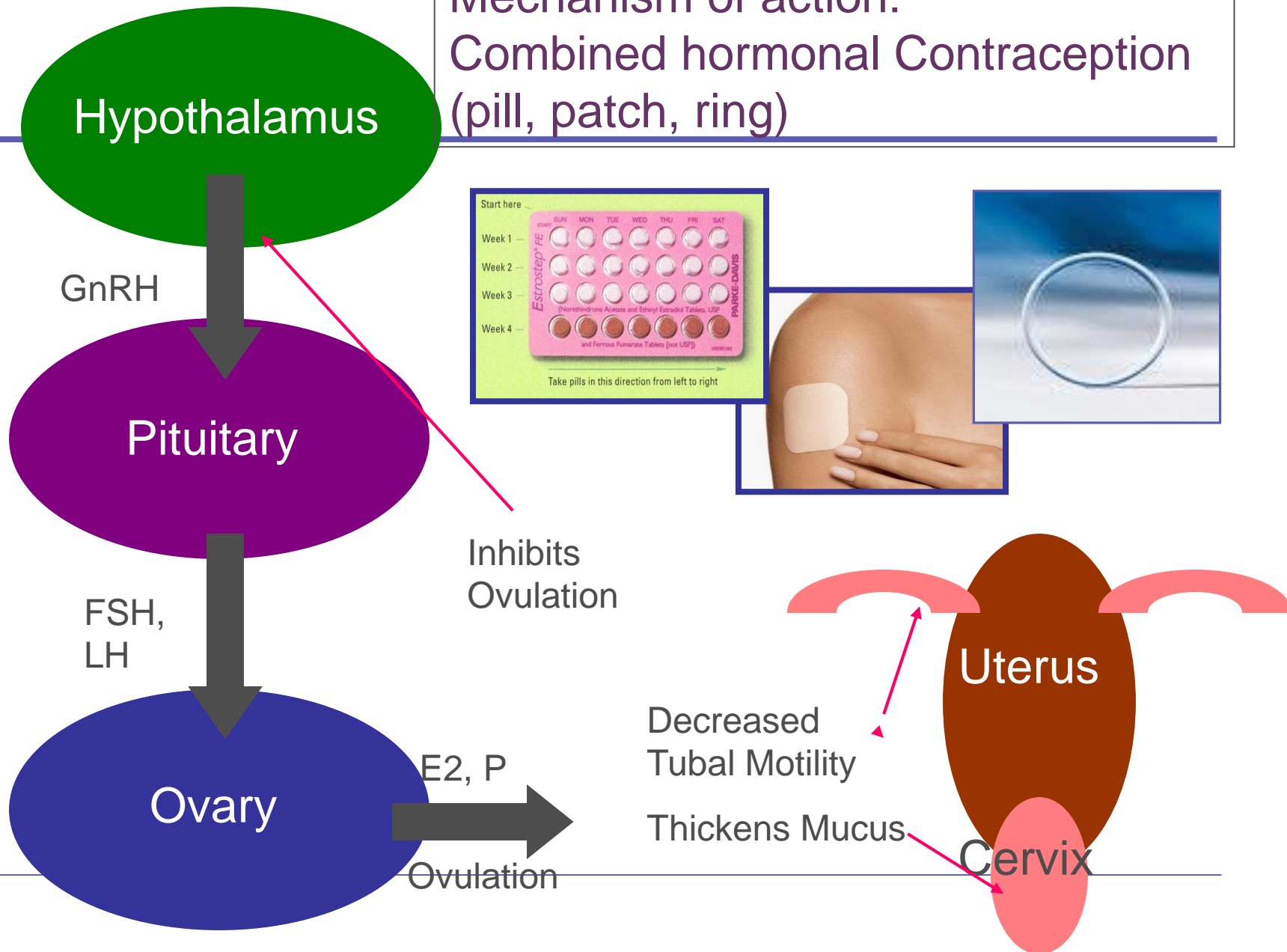
Combined Hormonal Contraceptives

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%



Trussel J. Contraceptive Technology. 2007 Rosenberg MJ. Reprod Med. 1995; Potter L. Fam Plann Perspect. 1996; Mosher WD. AdvanceData. 2004. Hardman JG. McGraw-Hill. 1996.; Goldzieher JW. Fertil Steril. 1971.; Moghissi KS. Fertil Steril. 1971.

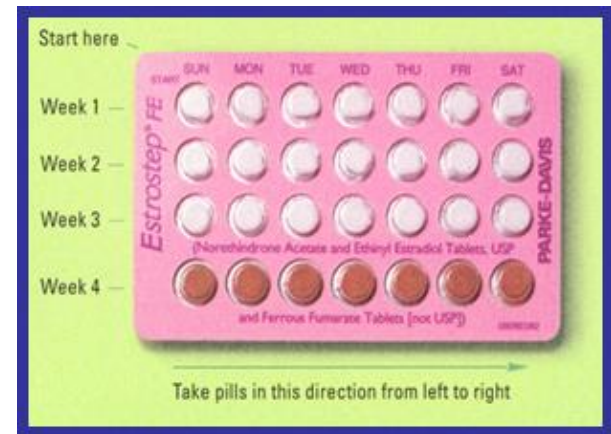
Mechanism of action: Combined hormonal Contraception (pill, patch, ring)



OCP Side effects

Very
effective

- **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
-

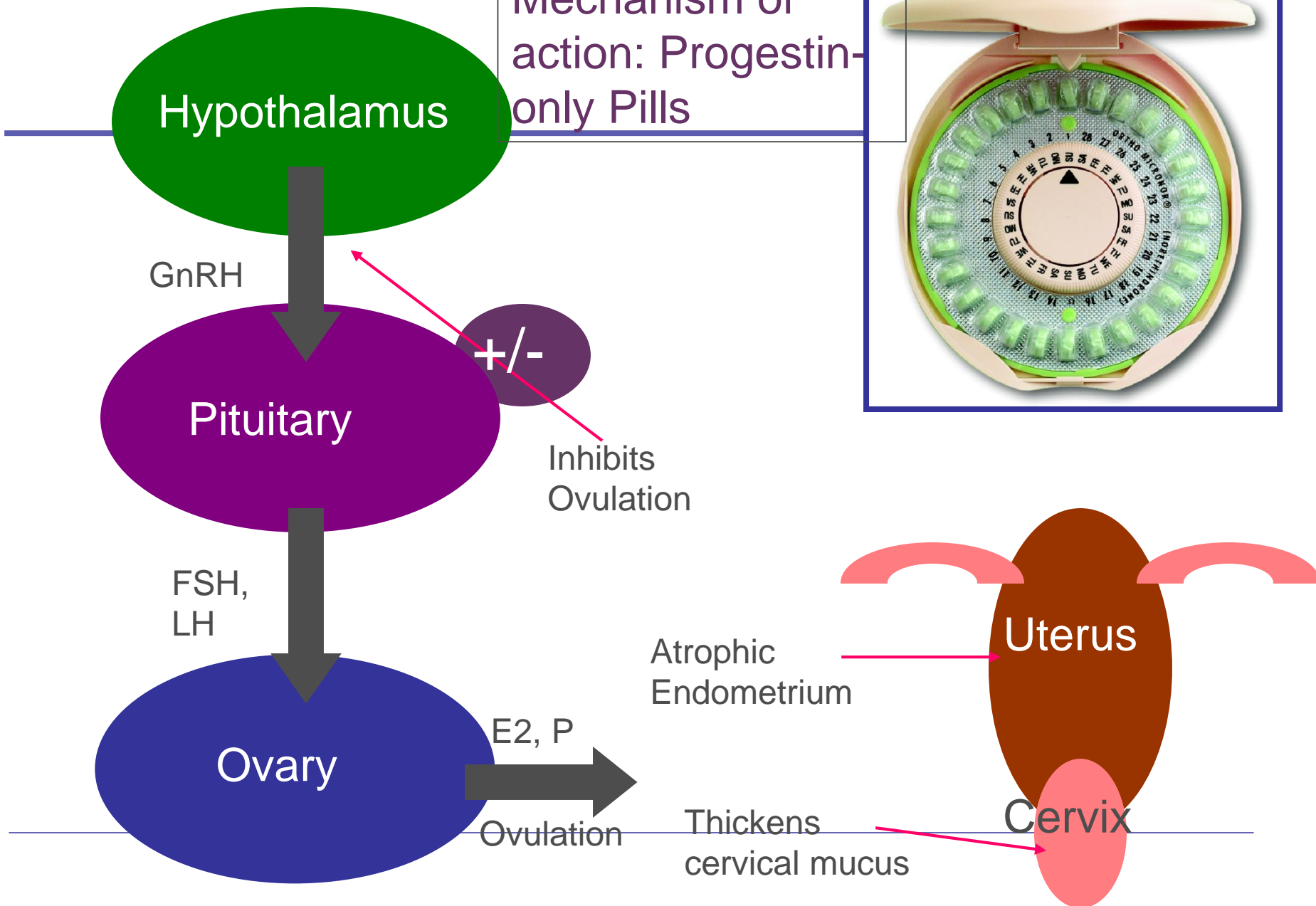
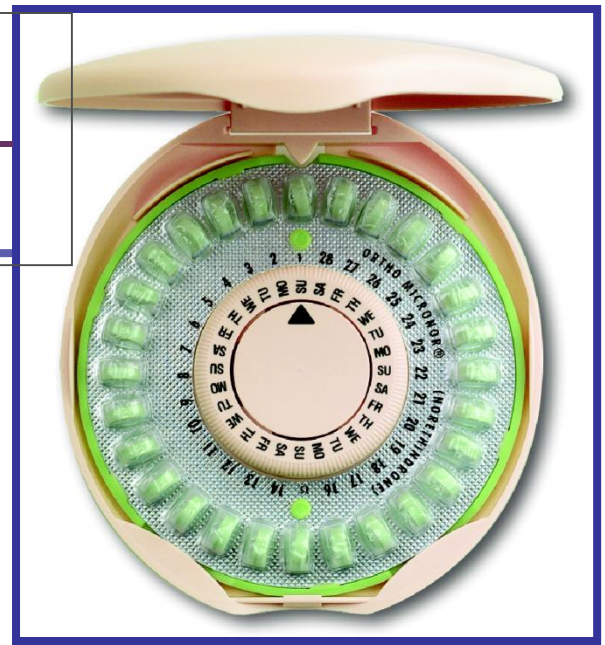
**Very
effective**

Progestin-Only Oral Contraceptives



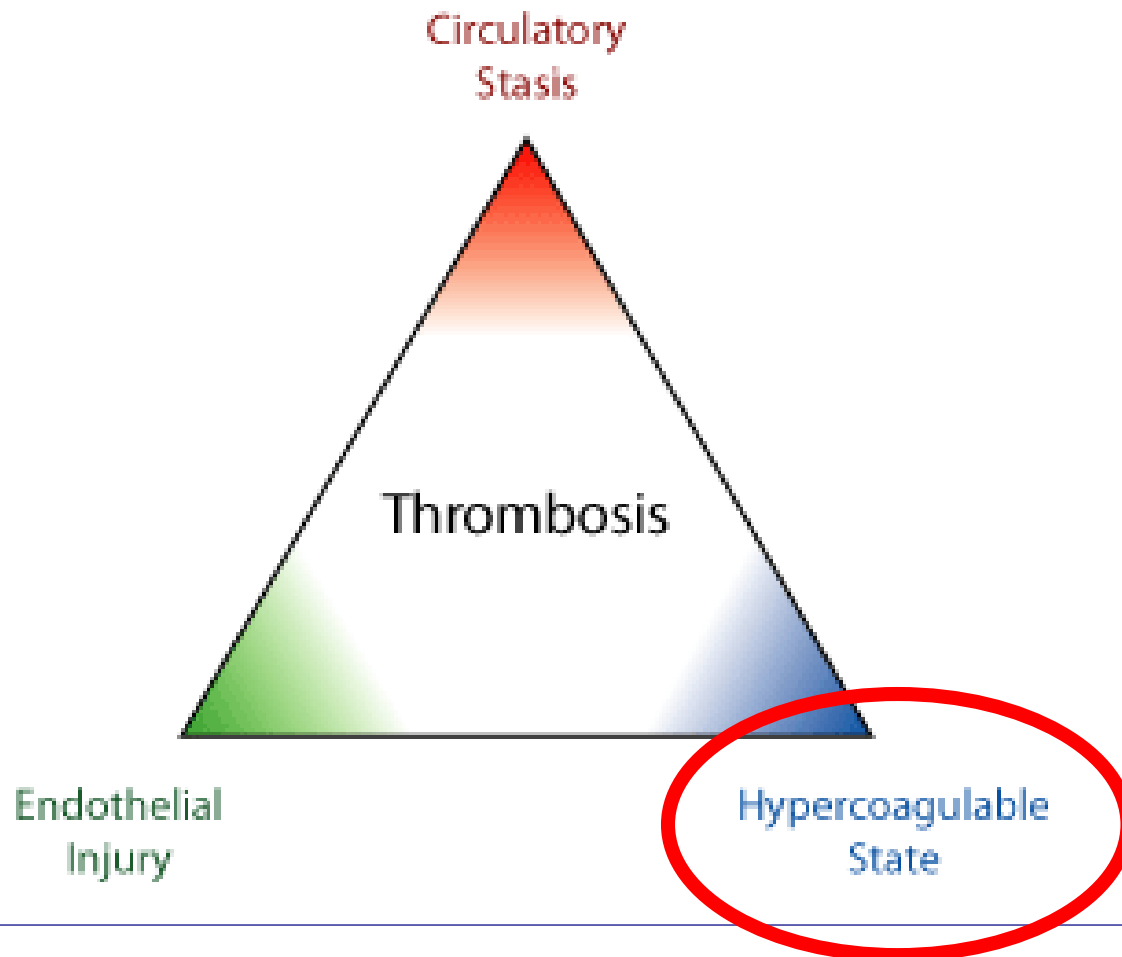
- Called the “mini-pill”
- Two formulations:
norethindrone & norgestrel
- Option for lactating women
- No placebo pills
- Less forgiving
 - 3 hr delay → requires back-up x 48 hrs, consider EC
 - Miss one pill → use EC and back-up x 1 week

Mechanism of action: Progestin-only Pills



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

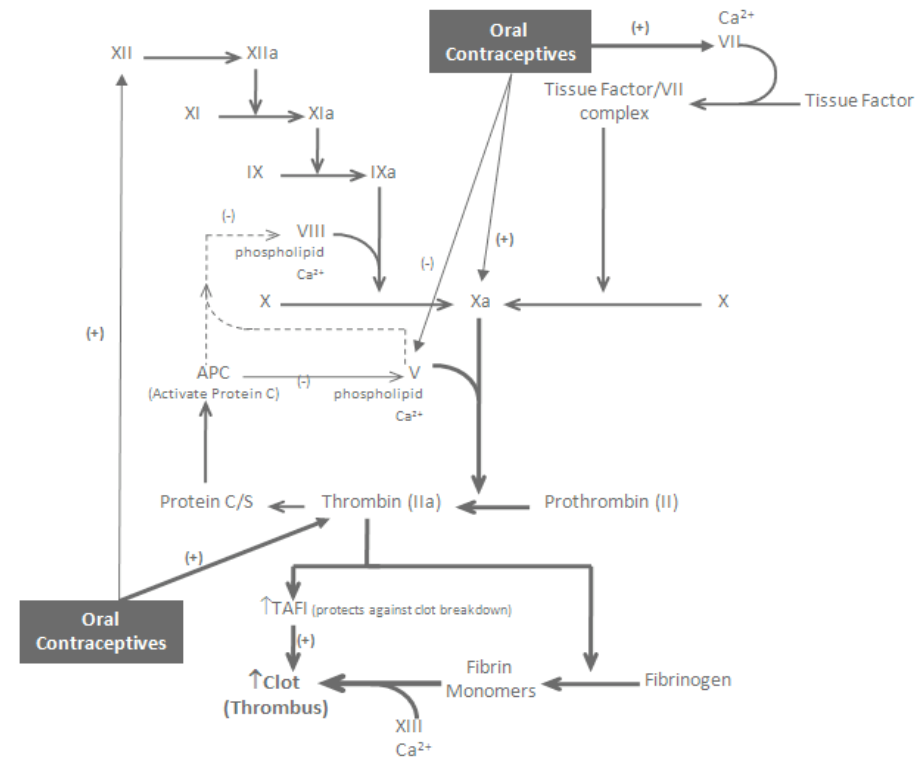
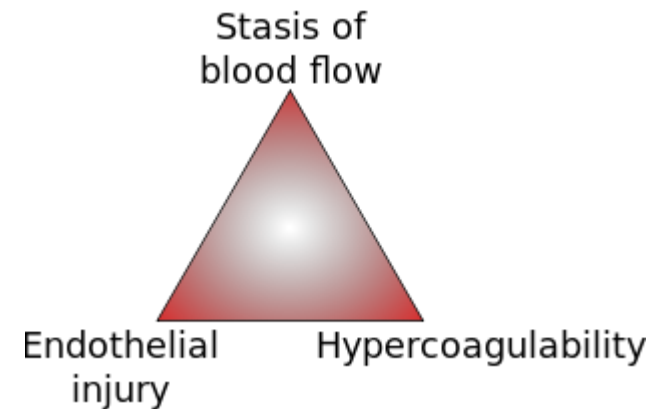


Figure 1. Coagulation cascade of a patient taking estrogen containing oral contraceptives.
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Selection of candidates for CHC

- 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

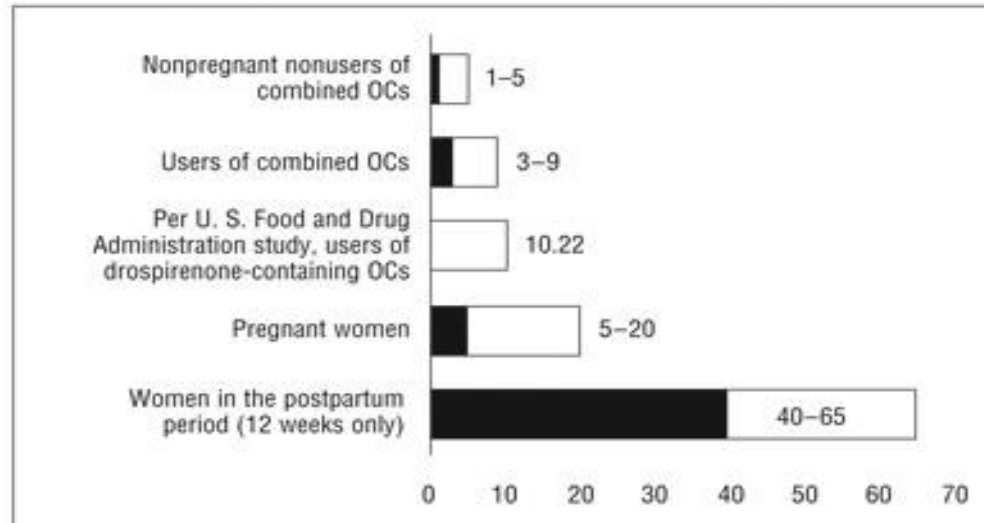


Fig. 1. Likelihood of developing a blood clot (number of women with a blood clot per 10,000 women-years). Abbreviation: OC indicates oral contraceptives. Adapted from Food and Drug Administration. FDA drug safety communication: updated information about the risk of blood clots in women taking birth control 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



Morbidity and Mortality Weekly Report

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 |

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 | 4 | 1 | |
| <4-6 weeks postpartum | 3 | 2 | |
| Uncontrolled HTN | 4 | 2-3 | |
| H/o DVT or PE | 3-4 | 2 | |
| Migraine with aura | 4 | 2-3 | |
| Diabetes with vascular disease | 3-4 | 2-3 | |
| Severe Cirrhosis | 4 | 3 | |
| Hx Bariatric Sx- malabsorptive | 3 | 1 | 3 |
| Mod/ Severe Peripartum Cardiomyopathy | 4 | 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

Case Presentation 1

- 30-year-old
- PPD #2
- Ready to be discharged from hospital & desires contraception
- Plans to breastfeed



- 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-only pill | | Injection | | Implant | | LNG-IUD | | 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* | | 1* | | 1* | | 1* | | | | | |

Case Presentation 1

- 30-year-old
- PPD #2
- Ready to be discharged from hospital & desires contraception
- Plans to breastfeed



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

Case Presentation 2

- 
- 25-year-old
 - Has Crohn's disease
 - Desires long-term reversible contraception
 - Thinking about levonorgestrel-releasing IUD



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

Safe even if nulliparous

Inflammatory Bowel Disease



| Condition | Sub-condition | Combined pill, patch, ring | | Progestin-only pill | | Injection | | Implant | | LNG-IUD | | Copper-IUD | |
|-------------------------------|--|-------------------------------|---|---------------------|---|-----------|---|---------|---|---------|---|------------|---|
| | | I | C | I | C | I | C | I | C | I | C | I | C |
| Inflammatory bowel disease | (Ulcerative colitis, Crohn's disease) | 2/3* | | 2 | | 2 | | 1 | | 1 | | 1 | |

Case Presentation 2

- 
- 25-year-old
 - Has Crohn's disease
 - Desires long-term reversible contraception
 - Thinking about levonorgestrel-releasing IUD



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

Case Presentation 3

- 30-year-old
- History of bariatric surgery 6 months ago
- Was using COCs before surgery & wants to restart



- 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
-

Bariatric Surgery



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

| Condition | Sub-condition | Combined pill, patch, ring | | Progestin-only pill | | Injection | | Implant | | LNG-IUD | | Copper-IUD | |
|-------------------------------|-----------------------------|-------------------------------|---|---------------------|---|-----------|---|---------|---|---------|---|------------|---|
| | | I | C | I | C | I | C | I | C | I | C | I | C |
| History of bariatric surgery† | a) Restrictive procedures | 1 | | 1 | | 1 | | 1 | | 1 | | 1 | |
| | b) Malabsorptive procedures | COCs: 3 | | 3 | | 1 | | 1 | | 1 | | 1 | |
| | | P/R: 1 | | | | | | | | | | | |

Case Presentation 3

- 30-year-old
- History of bariatric surgery 6 months ago
- Was using COCs before surgery & wants to restart



- 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."