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
  - Injectable
  - 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 1\textsuperscript{ST} YEAR TYPICAL USE

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

Current Contraceptive Options

Most Effective → Very Effective → Moderately Effective → 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%

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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
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

- GnRH
- FSH, LH
- E2, P

- Inhibits Ovulation
- Increases tubal motility
- Thickens cervical mucus
- Atrophic endometrium

Hypothalamus → Pituitary → Ovary → Uterus → Cervix
Does the levonorgestrel containing IUD prevent fertilization?

Sperm blocked by cervical mucus

RA Lewis, 2009
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
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

Copper IUD creates an inflammatory reaction. Copper acts as a spermicide.
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

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

Hypothalamus

Pituitary

Ovary

Mechanism of action:
Progestin-only implant

- Inhibits ovulation
- Decreases tubal mobility

- Thickens cervical mucus

- Atrophic endometrium

GnRH

FSH, LH

E2, P

Ovulation

Cervix

Uterus
Implant Counseling Consideration: Bleeding patterns

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

<table>
<thead>
<tr>
<th>Bleeding pattern</th>
<th>Percent of cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amenorrhea</td>
<td>21%</td>
</tr>
<tr>
<td>Infrequent bleeding</td>
<td>33%</td>
</tr>
<tr>
<td>Frequent bleeding</td>
<td>6%</td>
</tr>
<tr>
<td>Prolonged bleeding</td>
<td>17%</td>
</tr>
</tbody>
</table>

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

Guiahi M. Short-Term Treatment of Bothersome Bleeding... Obstet Gynecol 2015.
Bleeding pattern on OCP

Combined oral contraceptive pill

Day

Heavy
Normal
Light
Spotting
None

Guiahi M. Short-Term Treatment of Bothersome Bleeding...Obstet Gynecol 2015.
Current Contraceptive Options

Most Effective

Very Effective

Moderately Effective

Effective
• 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

- Inhibits Ovulation
- Atrophic Endometrium
- Thickens cervical mucus
DMPA Considerations

• Menstrual Changes
  • Irregular bleeding is common initially
  • Amenorrhea is normal:
    • 50% at 1 year, 80% at 5 years

• Upon discontinuation:
  • Menstruals 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

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%

Very effective

Trussel J. Contraceptive Technology. 2007
Mechanism of action: Combined hormonal Contraception (pill, patch, ring)

- Hypothalamus
  - GnRH
  - Pituitary
    - FSH, LH
    - Inhibits Ovulation
  - Ovary
    - E2, P
    - Ovulation
  - Uterus
    - Decreased Tubal Motility
    - Thickens Mucus
  - Cervix
- Combined hormonal Contraception
  - Inhibits Ovulation
  - Decreased Tubal Motility
  - Thickens Mucus
OCP Side effects

• KNOWN:
  ▪ Nausea (PM dosing)
  ▪ Breast tenderness (time)

• UNKNOWN:
  ▪ Libido
  ▪ Weight gain
Transdermal Patch

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

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
**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

Hypothalamus

GnRH

Pituitary

Inhibits Ovulation

FSH, LH

E2, P

Ovary

Ovulation

Uterus

Endometrium

Thickens cervical mucus

Mechanism of action: Progestin-only Pills
Estrogen vs. Progestin
Thromboembolism

Thrombosis

Circulatory Stasis

Endothelial Injury

Hypercoagulable State
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.
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

Which Contraceptive Methods are Safe for my Patient?
US Medical Eligibility Criteria for Contraceptive Use

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

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No restriction for the use of the contraceptive method for a woman with that medical condition</td>
</tr>
<tr>
<td>2</td>
<td>Advantages of using the method generally outweigh the theoretical or proven risks</td>
</tr>
<tr>
<td>3</td>
<td>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</td>
</tr>
<tr>
<td>4</td>
<td>Unacceptable health risk if the contraceptive method is used by a woman with that medical condition</td>
</tr>
</tbody>
</table>

The table below provides a summary of the U.S. Medical Eligibility Criteria for Contraceptive Use, 2010. Each cell indicates whether contraception is acceptable (A), reversible sterilization (S), or no contraception (N) based on various medical conditions and drug effects. The criteria are divided into categories such as age, anatomic abnormalities, and breast disease, among others. The table also includes notes on most contraceptive methods for sexually transmitted infections (STIs) and the male latex condom reduces the risk of STIs and HIV. For complete guidance, visit [www.cdc.gov/reproductivehealth/contraception](http://www.cdc.gov/reproductivehealth/contraception).
## Warnings for CHC

<table>
<thead>
<tr>
<th>CDC MEC Medical Condition</th>
<th>CHC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heavy smoker &gt; 35</td>
<td>4</td>
</tr>
<tr>
<td>&lt;4-6 weeks postpartum</td>
<td>3</td>
</tr>
<tr>
<td>Uncontrolled HTN</td>
<td>4</td>
</tr>
<tr>
<td>H/o DVT or PE</td>
<td>3-4</td>
</tr>
<tr>
<td>Migraine with aura</td>
<td>4</td>
</tr>
<tr>
<td>Diabetes with vascular disease</td>
<td>3-4</td>
</tr>
<tr>
<td>Severe Cirrhosis</td>
<td>4</td>
</tr>
<tr>
<td>Hx Bariatric Sx- malabsorptive</td>
<td>3</td>
</tr>
<tr>
<td>Mod/ Severe Peripartum Cardiomyopathy</td>
<td>4</td>
</tr>
<tr>
<td>Inflammatory bowel disease</td>
<td>2-3</td>
</tr>
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# Safety with progestin-only methods

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<th>Progestin-only</th>
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<td>Inflammatory bowel disease</td>
<td>2-3</td>
<td>1-2</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Condition</th>
<th>I</th>
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</thead>
<tbody>
<tr>
<td>Combined pill, patch, ring</td>
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<tr>
<td>Progestin-only pill</td>
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<td>Injection</td>
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<td>Implant</td>
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<tr>
<td>LNG-IUD</td>
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<tr>
<td>Copper-IUD</td>
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<td>Breastfeeding</td>
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</tr>
<tr>
<td>a) &lt; 1 month postpartum</td>
<td>3*</td>
<td></td>
<td>2*</td>
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<td>2*</td>
<td></td>
<td>2*</td>
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<td>1*</td>
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</tr>
<tr>
<td>b) 1 month or more postpartum</td>
<td>2*</td>
<td></td>
<td>1*</td>
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<td>1*</td>
<td></td>
<td>1*</td>
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<td>1*</td>
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</tr>
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Case Presentation 1

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- Ready to be discharged from hospital & desires contraception
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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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Sub-condition</th>
<th>Combined pill, patch, ring</th>
<th>Progestin-only pill</th>
<th>Injection</th>
<th>Implant</th>
<th>LNG-IUD</th>
<th>Copper-IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflammatory bowel disease</td>
<td>(Ulcerative colitis, Crohn’s disease)</td>
<td>2/3*</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
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

### History of Bariatric Surgery

<table>
<thead>
<tr>
<th>Condition</th>
<th>Sub-condition</th>
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<th>Implant</th>
<th>LNG-IUD</th>
<th>Copper-IUD</th>
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<td>History of bariatric surgery†</td>
<td>a) Restrictive procedures</td>
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<td>b) Malabsorptive procedures</td>
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<td>P/R: 1</td>
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</table>
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."