Contraception Update

April 9, 2013
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UMass Memorial Medical Center
• I have no actual or potential conflict of interest in relation to this program/presentation
Objectives

• Improve your understanding of the types of contraception
  – Awareness of medical eligibility criteria
• Introduce new LARCs, OCPs
• Review use of LARCs in adolescents
• Discuss considerations and controversies in contraception
  – OCPs, IUDs, obesity
• Analyze patient scenarios to identify appropriate contraceptive options
Importance of Contraception

• ~50% of pregnancies unintended
• 42% end in pregnancy termination
  – 3.2 million in 2006
  – 54% used method of contraception (condoms, OCP)
• Birth spacing
• Reduce adolescent pregnancy rate, meet needs for family planning= WHO Millennium Development Goal 5 to reduce maternal mortality

Guttmacher Institute
www.who.int
Contraceptive Use

- >99% of women 15-44 who have had intercourse have used contraception
- Current users: 62% = 38.4 million
- 63% use non-permanent methods
- 8.5% long-acting reversible methods
  - <1% sub-dermal implants

www.guttmacher.org
ACOG Practice Bulletin 133, February 2013
18 types of Contraception

- Abstinence
- Withdrawl
- “Outercourse”
- Family Planning
- Barriers
  - Sponge, cervical cap, diaphragm, condom, female condom
- Spermicide
- Emergency Contraception
- Lactational Amenorrhea

- Hormonal- cycles retained
  - Pill
  - Patch
  - Ring
- Hormonal- cycles altered
  - Mini pill
  - Depo-Provera
- Long Acting Reversible Contraceptives
  - Copper IUD
  - Progesterone IUDs
  - Progesterone subdermal implant
- Female sterilization
- Male sterilization

http://www.plannedparenthood.org/health-topics/birth-control-4211.htm
<table>
<thead>
<tr>
<th>Method</th>
<th>No. of users (in 000s)</th>
<th>% of users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pill</td>
<td>10,700</td>
<td>28.0</td>
</tr>
<tr>
<td>Tubal sterilization</td>
<td>10,400</td>
<td>27.1</td>
</tr>
<tr>
<td>Male condom</td>
<td>6,200</td>
<td>16.1</td>
</tr>
<tr>
<td>Vasectomy</td>
<td>3,800</td>
<td>9.9</td>
</tr>
<tr>
<td>IUD</td>
<td>2,100</td>
<td>5.5</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>2,000</td>
<td>5.2</td>
</tr>
<tr>
<td>Three-month injectable (Depo-Provera)</td>
<td>1,200</td>
<td>3.2</td>
</tr>
<tr>
<td>Vaginal ring (NuvaRing)</td>
<td>900</td>
<td>2.4</td>
</tr>
<tr>
<td>Implant (Implanon or Norplant), one-month injectable (Lunelle) or patch (Evra)</td>
<td>400</td>
<td>1.1</td>
</tr>
<tr>
<td>Periodic abstinence (calendar)</td>
<td>300</td>
<td>0.9</td>
</tr>
<tr>
<td>Other*</td>
<td>200</td>
<td>0.4</td>
</tr>
<tr>
<td>Periodic abstinence (natural family planning)</td>
<td>100</td>
<td>0.2</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>†</td>
<td>†</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>38,214</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

*Includes emergency contraception, female condom (or vaginal pouch), foam, cervical cap, Today sponge, suppository or insert, and jelly or cream (without diaphragm). †Figure does not meet standards of reliability or precision.
## Overview of Efficacy

Table 2 | Currently available contraceptive choices and estimated failure rates for typical and perfect use during the first year of use. Effectiveness is expressed as the number of unintended pregnancies occurring in a year for every 100 women using the method. Adapted from Trussell¹

<table>
<thead>
<tr>
<th>Method</th>
<th>Percentage of women who had an unintended pregnancy in the first year of use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progestogen-only etonogestrel implant</td>
<td>Typical use*: 0.05, Perfect use†: 0.05</td>
</tr>
<tr>
<td>Vasectomy</td>
<td>0.15, 0.10</td>
</tr>
<tr>
<td>Levonorgestrel intrauterine system (IUS)</td>
<td>0.2, 0.2</td>
</tr>
<tr>
<td>Medroxyprogesterone acetate (Depo-Provera)</td>
<td>Injection: 6, 0.2</td>
</tr>
<tr>
<td>Oral contraception (combined contraceptive</td>
<td>pill or progestogen-only pill): 9, 0.3</td>
</tr>
<tr>
<td>Combined hormonal patch</td>
<td>9, 0.3</td>
</tr>
<tr>
<td>Combined hormonal ring</td>
<td>9, 0.3</td>
</tr>
<tr>
<td>Female sterilisation</td>
<td>0.5, 0.5</td>
</tr>
<tr>
<td>Copper intrauterine device</td>
<td>0.8, 0.6</td>
</tr>
<tr>
<td>Male condom</td>
<td>18, 2</td>
</tr>
<tr>
<td>Fertility awareness methods</td>
<td>24, 0.4-5</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>22, 4</td>
</tr>
<tr>
<td>Female condom</td>
<td>21, 5</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>12, 6</td>
</tr>
<tr>
<td>None</td>
<td>85, 85</td>
</tr>
</tbody>
</table>

*Typical use includes failures due to "user error" and is based on data from the USA National Surveys of Family Growth and may apply only to US women.
†Perfect use refers to efficacy achieved under research conditions and is based on various international published trial data.

Bateson et al Newer non-oral hormonal contraception. BMJ 2013; 346:f341
<table>
<thead>
<tr>
<th>Method</th>
<th>% of women experiencing an unintended pregnancy within the first year of use</th>
<th>% of women continuing use at one year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Typical use¹</td>
<td>Perfect use²</td>
</tr>
<tr>
<td>No method</td>
<td>85</td>
<td>85</td>
</tr>
<tr>
<td>Spermicides</td>
<td>29</td>
<td>18</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>27</td>
<td>4</td>
</tr>
<tr>
<td>Fertility awareness-based methods</td>
<td>25</td>
<td>5</td>
</tr>
<tr>
<td>Standard days methodb</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Two day methodb</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Ovulation methodb</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Sponge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parous women</td>
<td>32</td>
<td>20</td>
</tr>
<tr>
<td>Nulliparous women</td>
<td>16</td>
<td>9</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>Condom</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female (Reality)</td>
<td>21</td>
<td>5</td>
</tr>
<tr>
<td>Male</td>
<td>15</td>
<td>2</td>
</tr>
<tr>
<td>Combined pill and progestogen-only pill</td>
<td>8</td>
<td>0.3</td>
</tr>
<tr>
<td>Evra patch</td>
<td>8</td>
<td>0.3</td>
</tr>
<tr>
<td>NuvaRing</td>
<td>8</td>
<td>0.3</td>
</tr>
<tr>
<td>Depo-Provera</td>
<td>3</td>
<td>0.3</td>
</tr>
<tr>
<td>Combined injectable (Lunelle)c</td>
<td>3</td>
<td>0.05</td>
</tr>
<tr>
<td>IUD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ParaGard (copper T)</td>
<td>0.8</td>
<td>0.6</td>
</tr>
<tr>
<td>Mirena (LNG-IUS)</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>Implanon</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>Female sterilization</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Male sterilization</td>
<td>0.15</td>
<td>0.10</td>
</tr>
</tbody>
</table>

Emergency contraceptive pills: treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%.¹⁰

Lactational amenorrhea method: LAM is a highly effective, temporary method of contraception.¹¹

Abstinence

- Those intentionally refraining from sexual activity to avoid conception
- Population unmeasured
- The only 100% effective form of contraception
  - Typical use includes those who “slip” and have sex unexpectedly
- Increased abstinence decreases teen pregnancy
- No education program focusing exclusively on abstinence has delayed sexual activity
- 60% of students break vow of virginity by college
- 50% of 15-17 year olds believe oral sex does not compromise virginity

The problem with Withdrawl

• 24% “typical” failure
• Relies on male judgment of inevitable ejaculation
• Pre-ejaculate may contain semen
• Semen on the vulva/leg
• “Outercourse”
Family Planning
“Fertility-Awareness”

- Rise in temp of 0.5 degrees = luteal phase
- Change to wet, stretchy mucous for the ~3-4 days before/during/after ovulation
- Ovulation predictor kits
- Calendar Method
- Standard Method
  - 26-32d cycles-avoid intercourse days 8-19
Barriers
In the Moment

Female
More expensive ($3)
Latex free
Reusable
Oil-based lubricants

Male
Comfort level
Proper use
Barriers
In Advance

- Use with spermicide
- Leave in x 6 hours
Spermicide

- Insert
- Tablet
- Suppository
  - Must melt in to foam
- Film
  - Must dissolve (15’)
- Jelly/foam
- Good for ~an hour
- Vegan form
- May increase STDs (nonoxynol-9)
Emergency Contraception

- Yuzpe method
- Progesterone only
- Ulipristal
- Copper IUD

CDC NCHS Data Brief: Use of EC among women age 15-44; Feb 2013
Emergency Contraception

- The Yuzpe combination method:
  - 0.1 mg of ethinyl estradiol and 0.5 mg levonorgestrel
    - Preven Emergency Contraceptive Kit
    - No longer available
    - Can use OCPs
    - Reduce risk of pregnancy by 75% (within 72h)

Gold and Jamshidi, Contemporary Obgyn. March 2013: 34-39
<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Formulation</th>
<th>No. of Pills/Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-Ogestrel</td>
<td>0.03 mg ethinyl estradiol 0.30 mg norgestrel</td>
<td>4</td>
</tr>
<tr>
<td>Lo/Ovral</td>
<td>0.03 mg ethinyl estradiol 0.30 mg norgestrel</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>(light orange pills)</td>
<td></td>
</tr>
<tr>
<td>Nordette</td>
<td>0.03 mg ethinyl estradiol 0.15 mg levonorgestrel</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>(light orange pills)</td>
<td></td>
</tr>
<tr>
<td>Levlen</td>
<td>0.03 mg ethinyl estradiol 0.15 mg levonorgestrel</td>
<td>4</td>
</tr>
</tbody>
</table>
Plan B

• The progestin-only method
  – Two tablets 0.75 mg of levonorgestrel
  – 12 hours apart
  – starting **within 72 hours** of unprotected sexual intercourse
Plan B One-Step

- 1.5mg Levonorgestrel
- Same indications, side effects as Plan B
- Equal (possibly better) efficacy than Plan B
How effective is EC?

• When taken within 72 hours:
  – Progestin-only regimens reduce the risk of pregnancy by 89%
• Within 24 hours, progestin-only ECPs reduce the risk of pregnancy by 95%

How does EC work?

• Delaying or inhibiting ovulation*
• Altering tubal transport of sperm and/or ova
• EC is not effective after implantation, therefore not an abortifacent

ACOG Committee Opinion 542, November 2012 Emergency Contraception
Does EC have side effects?

- Nausea and vomiting
- Breast tenderness, fatigue, irregular bleeding, abdominal pain, headaches, and dizziness
- **Less common** using progestin-only ECPs
- Generally subside within 48 hours

- Affect the timing of the menstrual cycle in 10-15%
  - If the next menstrual cycle is more than one week late...pregnancy test!
NEW!

- August 2010: “Ella”
- Ulipristal-selective progesterone receptor modulator
- Prevents LH surge/ovulation
- Prevents implantation

- Effective up to 5 days (120 hr) post intercourse
- Requires Rx
- ?safe in pregnancy
Ella data

• Ulipristal when used within 24hrs and 3-5 days was more effective than levonorgestrel
• Equivalent when used 24-72 hrs
• Pooled data from 2183 US + European women
• Predictors of effectiveness
  – Not being obese
  – Not having subsequent episodes of unprotected coitus

Glasier et al. Lancet 2010;375:555-562
Moreau et al. Contraception 2012
Grimes. OB GYN 2012; 1477-78
Available OTC since 2007

• Ready access **not** associated with less hormonal contraceptive use or more unprotected sex

• Rx required for age <17
  – Government issued photo ID age > 17
  – Dept of Health and Human Services overruled FDA in 2011
  – 4/5/13: Judge Korman “politically motivated, scientifically unjustified, contrary to agency precedent”
Access to EC

• Pharmacy barriers estimated to occur 30% of the time
• 2010 study of 943 commercial pharmacies in 5 cities across the US
  • 47% in low-income neighborhoods
  • Average cost $45
  • 80% had EC available
  • 19% of callers told they could not obtain the medication
• 6 states allow pharmacists to refuse to dispense

Copper IUD as EC

- Most effective, preventing 99% of pregnancies when inserted within 5 days
- 10 years of protection
- Usual risks of perforation, expulsion apply
- Underutilized
- Rethink IUD insertion timing “requirements” regarding chance of pregnancy

Lactational Amenorrhea

- Full-time breastfeeding x 6 months
  - Q 4-6 hours
- NO menses
- NO formula
- Rate of pregnancy= ~1%
  - NOT zero

Hormonal Contraception
WHO medical eligibility criteria (MEC)

- Mobile app
- Wheel


<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>WITH CLINICAL JUDGEMENT</th>
<th>WITH LIMITED CLINICAL JUDGEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Use method in any circumstances</td>
<td><strong>Yes</strong> (Use the method)</td>
</tr>
<tr>
<td>2</td>
<td>Generally use the method</td>
<td><strong>No</strong> (Do not use the method)</td>
</tr>
<tr>
<td>3</td>
<td>Use of method not usually recommended unless other more appropriate methods are not available or not acceptable</td>
<td><strong>No</strong> (Do not use the method)</td>
</tr>
<tr>
<td>4</td>
<td>Method not to be used</td>
<td><strong>No</strong> (Do not use the method)</td>
</tr>
<tr>
<td>CONDITION</td>
<td>COC/P/R</td>
<td>CIC</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>---------</td>
<td>-----</td>
</tr>
<tr>
<td>SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>People with SLE are at increased risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>of ischaemic heart disease, stroke</td>
<td></td>
<td></td>
</tr>
<tr>
<td>and venous thromboembolism. Categories</td>
<td></td>
<td></td>
</tr>
<tr>
<td>assigned to such conditions in this</td>
<td></td>
<td></td>
</tr>
<tr>
<td>guidance should be the same for</td>
<td></td>
<td></td>
</tr>
<tr>
<td>women with SLE who present with</td>
<td></td>
<td></td>
</tr>
<tr>
<td>these conditions. For all categories</td>
<td></td>
<td></td>
</tr>
<tr>
<td>of SLE, classifications are based</td>
<td></td>
<td></td>
</tr>
<tr>
<td>on the assumption that no other risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>factors for cardiovascular disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>are present; these classifications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>must be modified in the presence of</td>
<td></td>
<td></td>
</tr>
<tr>
<td>such risk factors.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Positive (or unknown) antiphosphol</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>phospholipid antibodies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Severe thrombocytopenia</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>c) Immunosuppressive treatment</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>d) None of the above</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>GESTATIONAL TROPHOBLASTIC DISEASE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Decreasing or undetectable β-hCG</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>(human chorionic gonadotropin) levels</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b) Persistently elevated β-hCG levels</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>or malignant disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VIRAL HEPATITIS</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>a) Acute or flare</td>
<td>3/4⁺</td>
<td>2</td>
</tr>
<tr>
<td>b) Carrier</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>c) Chronic</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
US Medical Eligibility Criteria for Contraceptive Use
CDC, 2010

• Color chart in English and Spanish

• iPhone app

• http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usmec.htm

  1. No restriction (method can be used)
  2. Advantages generally outweigh theoretical or proven risks
  3. Theoretical or proven risks usually outweigh the advantages
  4. Unacceptable health risk
<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>
<tr>
<td>Ischemic heart disease‡</td>
<td>Current and history of</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Liver tumors</td>
<td>a) Benign</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>i) Focal nodular hyperplasia</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>ii) Hepatocellular adenoma‡</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>b) Malignant‡</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Multiple risk factors for arterial cardiovascular disease</td>
<td>(such as older age, smoking, diabetes and hypertension)</td>
<td>3/4*</td>
<td>2*</td>
<td>3*</td>
<td>2*</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Obesity</td>
<td>a) ≥30 kg/m² body mass index (BMI)</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>b) Menarche to &lt; 18 years and ≥ 30 kg/m² BMI</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Ovarian cancer‡</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parity</td>
<td>a) Nulliparous</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>b) Parous</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Past ectopic pregnancy</td>
<td></td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Pelvic inflammatory disease</td>
<td>a) Past, (assuming no current risk factors of STIs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(i) with subsequent pregnancy</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>(ii) without subsequent pregnancy</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>b) Current</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>2*</td>
</tr>
<tr>
<td>Peripartum cardiomyopathy‡</td>
<td>a) Normal or mildly impaired cardiac function</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(i) &lt; 6 months</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>(ii) ≥ 6 months</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>b) Moderately or severely impaired cardiac function</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Postabortion</td>
<td>a) First trimester</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
<td>1*</td>
</tr>
</tbody>
</table>
Common class 3 or 4 conditions

- Smoking age >35
  - ±15 cigarettes/day
- HTN
  - >160/100
- Risk factors for CV disease
  - Age, smoking, HTN, DM
- VTE personal history
- Migraines with aura
Combination Oral Contraceptive “OCPs”, “COCs”, “the pill”

• 20mcg, 30/35mcg ethinyl estradiol (EE)
• Monophasic, triphasic
• 21 or 28 day packaging

• First gen progesterone= norethindrone
• Second gen= levonorgestrel
• Third gen (less androgen, more clots) = desogestrel, norgestimate
• Fourth= drospirenone
OCPs

**Estrogen**
- Inhibits FSH/follicle
- Maintains uterine lining
- Headaches, nausea, clots
- Libido

**Progesterone**
- Inhibits LH surge
- Cervical mucous
- Opposes estrogen at uterine lining
- Chemically similar to androgens
- Breast tenderness, acne, mood change, cholesterol profile, diuresis
- Withdrawal → bleeding
New(er) OCPs

• Range of progesterones with different metabolic effects
  – New progesterone: nomegestrol “NOMAC”

• New estrogen: Estradiol valerate
  – Natazia 26/2
  – 4 phases of estrogen dosing

• Add estrogen back at end of placebo week
  – Mircette: 21 (20mcg EE)/2/5 (10mcg EE)

• Add iron, folate

• Chewable
New(er) OCPs

• Seven day placebo week unnecessary
  – Breakthrough FSH rise
• Shorter placebo: 24/4 (LoEstrin, Yaz, Generess)
• Continuous formulas:
  • Lybrel=20mcg
• Seasonale= 84 days 30mcg, one week placebo
• Seasonique=84 days 30mcg, one week 10mcg
  – LoSeasonique
Ortho-Evra
“The Patch”

• Ethinyl Estradiol
• Norelgestromin
• Caution if weight >195lb
• Serum levels EE over 24 hours 60% higher than in 30mcg OCP

Kaunitz et al. OBG Management; March 2013. www.obgmanagement.com
The Patch and VTE

- Epidemiology studies estimate VTE risk up to 2x higher
- FDA black box warning 2004
New Patches

• “AG200-15”
  – Ethinyl estradiol/levonorgestrel
  – 60% lower EE concentrations vs 35mcg OCP

• Levonorgestrol-only patch

• Contraceptive Clinical Trial Network

Kaunitz et al. OBG Management. March 2013 [www.obgmanagement.com](http://www.obgmanagement.com)
Jensen, J. AJOG; October 2011: S21-25
Nuva Ring
“The Ring”

- 15mcg EE and 120mcg etonogestrel/day
- Latex-free
- Should not be out >3 hours
- Hormonal levels reasonable through week 4
  - Easy to manipulate cycles
  - 24/4
- Vaginal discharge
- Insertion/Removal
Progestin-only Pill
“Mini-pill”

- 35mcg norethindrone
- No placebo week
- Short half-life
- Higher failure rate (if not breastfeeding)
- Usually used if high risk for estrogen use
Depo-Provera
“Depo” “DMPA”

• Depot Medroxyprogesterone acetate
• 150mg IM/104mg SQ every 3 months
  – 14 weeks
• Atrophic endometrium without vasomotor sx
• Variable data on weight gain (0-6kg)
• Bleeding pattern improves over time
• Decrease in BMD after 1-2 yrs ~5%
  – Clinical significance?
  – Recovers at 1-2 years
Progesterone and VTE

- Package inserts label VTE as contraindication to use
- ACOG and CDC: acceptable uncomplicated history of VTE
- USMEC Category 3 if current VTE, cardiovascular risk
Long-Acting Reversible Contraceptives
“LARCs”

• Copper IUD
• Progesterone IUD
• Progesterone Sub Dermal Implant

http://www.wired.com/magazine/2011/07/ff_iud/all/?pid=6100&viewall=true
Copper IUD
“Copper T” “ParaGard”

• 1988
• 10* years
• Inflammation/copper interferes with fertilization and implantation
• Pregnancy rate 2.2% cumulative/12 years
  – 0.8%/year
• Use post abortion, as EC
• No: Uterine distortion, active infection, unexplained AUB, Wilson’s
Copper IUD

- Caution: menorrhagia, dysmenorrhea
- 9% early removal
  - 2% for increased menses
- History of expulsion, perforation, poor positioning
  - Proceed, with caution
Progesterone IUD “Mirena”

- 2001
- 5 years*, Levonorgestrel
- Cavity undistorted, 6-10cm
- Menstrual bleeding reduced by 75%
- Amenorrhea 20% in first year
- Most reports of adverse effects related to bleeding pattern

Burke AJOG; October 2001:S14-17
Mirena

- Failure 0-0.2/100 women years
  - 0.2%/year
- Ectopic 0.01%/year
- Expulsion rate 2-10%
  - Greater if nulliparous (22%)
  - Sound at least 6cm
Mirena

• Perforation rate 1/1000
  – Multinational study of 700 perforations/10 yrs
  – 8% detected at time of insertion
• Office exam 4-12 weeks after insertion
• No string: US, KUB

Adolescents and IUDs

- 82% of adolescent pregnancies are unplanned
  - Usually choose condom, OCP, patch, DMPA

- 1 year discontinuation rates:
  - Higher than older women/more unintended pregnancies
  - LARCs: Continuation rates higher (~80%) and unintended pregnancy lower

- Study that removed cost barrier and included full counseling on options: 2/3 of females aged 14-20 used LARCs

ACOG Committee Opinion 539, October 2012
Safety

- Most infection in first 20d and related to insertion
- Risk of PID returns to baseline thereafter
- 0-2% in absence of cervical infection
  - 0-5% with undetected infection
- History of gonorrhea/chlamydia does not prevent insertion
  - Wait 3 weeks
Safety

- High rate of gonorrhea and chlamydia in adolescents
- CDC recommends yearly screening age <25
- Screen before/at time of insertion
  - Positive Chlamydia after insertion does not increase risk PID if promptly treated
- No role for antibiotic prophylaxis
Will Insertion Be Difficult?

- 50% report discomfort
- Plan ahead: anticipatory guidance, NSAIDs, anxiolytics, paracervical blocks
- Misoprostol does not help
• Bayer’s new 3 year Levonorgestrel-releasing IUD- February 2013
• 28x30mm (vs 32 x 32mm)
• Pregnancy rate 0.9%
• 21% discontinued study treatment
  – Vulvovaginitis (20%), bleeding (7%)
• New insertion device
Sub Dermal Implant

“Nexplanon”

- 68mg etonorgestrel, 4cm rod
- 3 years
- Elaborate insertion and removal training
- Rapid onset/return of fertility
- Excellent efficacy
  - 0.05% failure*
- #1 reason early discontinuation: unpredictable bleeding pattern (15%)
- Bruising common, infection rare, migration/difficult removal

Nexplanon vs Implanon

- FDA approved: November 2011
- Radio-opaque
- New delivery device
Barriers to LARCs

• Lack of familiarity/misperceptions, cost, access, confidentiality

• ACOG: efficacy, reversibility, few medical contraindications, LARCs should be offered “first line”

ACOG Committee Opinion 539, October 2012
Sterilization “BTL” “Tubal” “Tubes Tied”

• Laparoscopic approach
  – GETA
  – Bipolar, Filshie Clip, Falope Ring
  – Salpingectomy

• Post abortion

• Postpartum mini-laparatomy
  – Body habitus!
  – L+D logistics
  – After 8-9% of all deliveries

• “Interval”
Hysteroscopic Tubal Occlusion “Essure”

• Adiana off market
• Hysteroscopic approach= less anesthesia, potential office procedure
• Requires tubal visibility/patency
  – 96% successful placement
• 3 month HSG patency rate: 3.5%
  – 6month: 0%
### Sterilization Efficacy

#### Table 1. Pregnancy Rates by Sterilization Method

<table>
<thead>
<tr>
<th>Method</th>
<th>5-year (per 1,000 procedures)</th>
<th>10-year (per 1,000 procedures)</th>
<th>Ectopic (per 1,000 procedures)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postpartum partial salpingectomy</td>
<td>6.3</td>
<td>7.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Bipolar coagulation*</td>
<td>16.5</td>
<td>24.8</td>
<td>17.1</td>
</tr>
<tr>
<td>Silicone band methods</td>
<td>10.0</td>
<td>17.7</td>
<td>7.3</td>
</tr>
<tr>
<td>Spring clip</td>
<td>31.7</td>
<td>36.5</td>
<td>8.5</td>
</tr>
<tr>
<td>Hysteroscopy (Essure)†</td>
<td>1.64</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Vasectomy</td>
<td>11.3</td>
<td>No association</td>
<td></td>
</tr>
</tbody>
</table>
Sterilization Complications

• Laparoscopy complication rates up to 1.6%
  – Mortality 1-2/100,000 (GETA)
• Essure
  – Tubal perforation 1-3%
  – Coil expulsion 0.4-2.2%
  – Vasovagal syncope (office)
  – 0.01% had nickel sensitivity reaction-contraindication removed 2011
Sterilization Counseling

- Permanence!
- Reversibility limited with Essure
  - Cost
- Medicaid “tubal papers”
  - Age 18-20, Age >21
- Regret rate higher age <30
  - 20% vs 5%
  - LARCs!
- Questionnaire
Are you thinking of permanent birth control?

Female sterilization is a surgical procedure whereby the Fallopian Tubes are interrupted. This method cannot be considered 100% effective but it is permanent and **cannot be reversed**.

Female sterilization can happen in two ways. Both procedures are performed in the Operating Room but you will go home the same day the procedure is done.

1. **Tubal Ligation.** This is a procedure where you are completely asleep and a camera called a **laparoscope** is inserted through an incision in the belly button. A band is then placed on the Fallopian Tubes and they are blocked.

2. **Essure system.** With this you may choose to be awake. A camera called a **hysteroscope** is placed through your cervix into the uterus and metal coils are placed in the Tubes. There are no incisions made. This method requires a special X-Ray be taken 3 months after the procedure to be certain the tubes are blocked. You must continue to use birth control until this X-Ray is done.

Your physician will review these procedures in detail before any surgery is arranged.

If you are considering a permanent sterilization, please answer the following questions to help us determine if this procedure is right for you.

1. Why do you desire sterilization as a method of birth control?

2. What other methods of birth control have you tried?

3. Are you unhappy with your current method of birth control? If yes, why?

4. Have you considered using an IUD (Intra-Uterine Device) for birth control?

5. Are you happy being a parent?
   If no, why?

6. Are you happy with your partner?
   If no, why?

7. If in the future you had a different partner, do you think you would want another baby?

8. If one or all of your children died, would you want another baby?

9. Do you and your partner agree that sterilization is a good option for you?

10. Have you discussed vasectomy (permanent sterilization procedure for men) with your partner? If no, would you like more information about this?

I am aware of and understand other methods of birth control. I understand Tubal Ligation to be a permanent method of birth control.

Patient Signature: ___________________________ Date: ____________

Physician Signature: ___________________________ Date: ____________
Male Sterilization

- 6.2% of women rely on this
- Office procedure
- Evaluation and discussion
- Procedure
- Post-procedure Semen Analysis
  - 98% azospermia at 6 months
- Efficacy: 0.15% failure rate
- Reversibility: 50-70%
Contraceptive Considerations

• Cancer
  – “The pill gives you cancer”

• Future fertility
  – “I thought it was a good idea to take a break”

• Obesity

• Medication Interactions

• Pregnancy
  – “What if I get pregnant on the pill?”
Cancer

• Any OCP use: lower incidence uterine (RR 0.43), ovarian (RR 0.6), colorectal cancer (RR 0.8)

• No change in breast cancer (RR 1 for current or previous users)

• Multiple RCT prove Mirena protects endometrium with ERT

• Cohort studies in Tamoxifen users

• 201 patients with endometrial hyperplasia + 59 with atypia
  – Regression in 93.5%/86%

Maguire, Westhoff. AJOG. 2011;205:S4-8
Fertility

- Hormone-independent follicular development and apoptosis continues regardless of contraception, pregnancy, age
- Hormonal contraception does not “save eggs”
- Rapid return to fertility post contraception
  - Depo-Provera (10 months)
  - 80% pregnant within one year Mirena removal
Obesity

• BMI \geq 30 is category 1 or 2 in USMEC for hormonal contraception
• Most FDA trials exclude obese women
• 2010 Cochrane analysis of hormonal contraceptives in women with BMI \geq 25
  – OCP OR 1.91 pregnancy risk
  – Patch failure ↑ with weight (not BMI)
  – No trials with current implant, ring
  – No pregnancies in injectable group

Lopez, et al. 2010
Common Medication Interactions

• Antiepileptics: carbamazepine, oxcarbazepine, phenobarbital, phenytoin, topiramate
• Antibiotics: rifabutin, rifampicin
  – Others: Case reports, low incidence
• Anti-retrovirals: protease inhibitors, NNRTIs efavirenz and nevirapine, elvitegravir*
• Herbs: St. John’s wort
• Diazepam has reduced clearance

Bateson et al Newer non-oral hormonal contraception. BMJ 2013; 346:f341
Murphy. Contraception. 2005
Tseng and Hills-Niemen. Expert Opinion Drug Metab Tox. 2013
“I got pregnant on...”

• Hormonal contraception:
  – No consistent findings of fetal abnormalities, growth restriction, genitalia abnormalities

• IUD:
  – Increase in first and second trimester miscarriage, PTD, infection
  – Remove if strings visible/placenta not involved

• Delay in pregnancy identification/diagnosis
Contraceptive Controversies

- Yaz and clots
- Mirena and class action suit
Yaz and Beyond

• Yaz/Beyaz, Yasmin/Safyral
• 3mg drospirenone, 20mcg/30mcg EE ± 450mcg folate
• FDA approved for: contraception, PMDD, moderate acne treatment, folate supplementation
Drospirenone and VTE

• Anti-adrenalcorticoid effect, spironolactone-like properties
• Raises K+, diuresis, aldosterone may decrease coagulability
• European cohort and case-control studies showed increased risk VTE
  – No control for smoking status, BMI
FDA and label change

• Large prospective multi-national study of new users and FDA sponsored study of all users:

• Increased VTE rate compared to 3 other progesterones
  – No adjustment for obesity, smoking
  – FDA panel 57 page “Combined Hormonal Contraceptives and the Risk of Cardiovascular Disease Endpoints”
FDA and label change

• Risk elevated in first 12 months of use
  – After that comparable to other second-generation OCPs
  – Women aged 10-34

• “COCs containing DRSP may be associated with a higher risk of VTE than COCs containing levonorgestrel or some other progestins. Before initiating Beyaz in a new COC user or a woman who is switching from a contraceptive that does not contain DRSP, consider the risks and benefits”
Yaz Lawsuit Settlements
Don’t File a Yaz Lawsuit Until You Read This

FDA found that Bayer Healthcare Pharmaceuticals had failed

Don’t File a Yaz Lawsuit Until You Read This

News Alert: Yaz Lawsuit settlements with Bayer are going well. For those of our clients that qualify, victims that we represent with blood clots, deep vein thrombosis...
ACOG Response
November 2012

- Reminder of “high risk” for VTE based on CDC category 3, 4
- Decisions regarding choice left to patient and provider
- No need to discontinue

Committee Opinion 540: Risk of Venous Thromboembolism Among Users of Drospirenone-Containing Oral Contraceptive Pills
Mirena in The Media

• Class Action Lawsuit Settlement Investigation
• “Migration” and perforation after initial insertion and follow-up
“The Wandering Mirena”


• Case reports IUD in place then missing 15 months later, or sooner with no laparoscopic evidence of perforation.
Summary

• “New” methods of birth control are really more of the same
  – Pills, implants, IUDs, block the tubes

• Wide variety of oral contraceptive options means you should be able to find one that is right for your patient
  – Trial and error plus logic
  – Consult medical eligibility criteria
  – Consider medication interactions
Summary

• Patients can be reassured re: contraceptives effects on fertility, cancer, their overall health
  – Important given media barrage

• IUDs can be used liberally
  – Nulliparas, adolescents, those with history of STD exposure/infection, fibroids, those considering sterilization

• Birth spacing and pregnancy planning has nothing but benefits
Case 1

• A 17 year old G0 has been on oral contraceptive pills for 2 years. She is doing well and leaves for college in June. What contraceptive options do you discuss with her?
  • None
  • Condoms
  • Depo Provera
  • Nexplanon
  • Mirena
Case 1 b

- What if last year she was screened and treated for Gonorrhea?
- She has a new Rx for Vyvanase?
- She has a new Rx for Tegretol?
Case 2

- A 45 year old G3P3 is recently divorced. Her health is good but her stress is high. Her menstrual cycles have become irregular. What contraceptives do you offer her?
  - None
  - Condoms
  - OCPs
  - Progesterone-only
  - IUDs
  - Sterilization
Case 2b

• What if she has HTN?
• Is obese?
• Smokes tobacco?
• Reports she has initiated unprotected sexual activity with a new male partner?
• Reports she has initiated unprotected sexual activity with a new female partner?