6.3 Million Pregnancies in the U.S.

- 51% Intended
- 25% Unintended Used Contraception
- 23% Unintended No Contraception

1. Finer et al, 2006

WHO Medical Eligibility Criteria
More evidence based than package insert

<table>
<thead>
<tr>
<th>Classification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Use method in any circumstances</td>
</tr>
<tr>
<td>2</td>
<td>Generally use the method - advantages outweigh theoretical or proven risks</td>
</tr>
<tr>
<td>3</td>
<td>Use of method not usually recommended unless other more appropriate methods are not available</td>
</tr>
<tr>
<td>4</td>
<td>Method not to be used - Condition represents an unacceptable health risk</td>
</tr>
</tbody>
</table>

Comparing effectiveness of methods

Effectiveness Rates

<table>
<thead>
<tr>
<th>Method</th>
<th>Typical Use</th>
<th>Perfect Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implanon</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>IUD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mirena (LNG releasing)</td>
<td>0.2</td>
<td>0.2</td>
</tr>
<tr>
<td>ParaGard (copper T)</td>
<td>0.8</td>
<td>0.6</td>
</tr>
<tr>
<td>Male Sterilization</td>
<td>0.15</td>
<td>0.10</td>
</tr>
<tr>
<td>Female Sterilization</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Depo-Provera q3months</td>
<td>3.0 (7.0?)</td>
<td>0.3</td>
</tr>
<tr>
<td>Combined Hormonal methods</td>
<td>8.0</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Effectiveness Rates

<table>
<thead>
<tr>
<th>Method</th>
<th>Typical Use</th>
<th>Perfect Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cap – nullip</td>
<td>16</td>
<td>9</td>
</tr>
<tr>
<td>Sponge – nullip</td>
<td>16</td>
<td>9</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>Female Condom</td>
<td>21</td>
<td>5</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>27</td>
<td>4</td>
</tr>
<tr>
<td>Male Condom</td>
<td>15</td>
<td>2</td>
</tr>
</tbody>
</table>

Medical Benefits of Hormonal Contraception

- Combined hormonal contraception (CHC) reduces:
  - Blood loss, PMS, dysmenorrhea, Ovarian cysts, acne, perimenopausal sx, DUB, PCOS, Endometriosis
  - OC users reduce risk of ovarian Ca by 40%\(^1\), and by 80% after 10 yrs\(^2\)
- OC reduces risk of endometrial CA by up to 40%\(^3\)
- No increase risk of Breast CA in OC users\(^4\)

### Risk Comparisons

**Annual Risk of Death (per 100,000)**

- Skydiving: 100
- Driving: 20
- Pregnancy: 11.5
- Riding a bicycle: 0.8
- Airplane crash: 0.4
- Using OC*: 0.06

*Nonsmoker, under age 35

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### Alissa

- 17yo here for URI
- Sexually active for one year
- She has never had a pelvic exam
- LMP 3 weeks ago, no pelvic pain or discharge
- She had unprotected sex 4 days ago
- Urine pregnancy test is negative today

**What does Alissa need today??**

**When can she start her birth control?**

### Emergency Contraception

**Levonorgestrel 75mg tab: Plan B**

**Evidence Based Sig:** take both tabs at once, up to 5 days after unprotected sex

- Increased efficacy and no increase in side effects


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### Emergency Contraception

- EC use doubles when provided in advance
  - Does not lead to decreased use of usual contraception, increase in STI or unprotected intercourse

- Standing orders can improve access to EC:

- **No Evidence Based Contraindications**

  **Plan B WILL NOT DISRUPT AN IMPLANTED PREGNANCY**

2. Raine et al. *JAMA* 2005;293:54-62
What is Required Before Prescribing Hormonal Contraception?

- Medical History: Required
- BP: Helpful
- Breast exam, Pelvic exam, Pap, Hemoglobin, other lab tests, STI testing:

NOT REQUIRED!

“Quick Start”

- “Quick Start” – start pill\(^1,2\) (patch\(^3\), shot, ring\(^4\)) on day of visit- any time of the month.
- Confirm urine HCG negative
- EC if needed, then CHC w/in 24 hrs of EC
- Back-up with condoms for 7 days (9 day w/ DMPA)
- Urine HCG if no withdrawal bleed at end of cycle, or 2 weeks after DMPA injection
- Exposure of embryo to OC not teratogenic

Contraceptive Patch (Evra)

- Apply weekly x 3, then 1 wk off
  - Ethinyl Estradiol: 20 mcg/ day
  - Norelgestromin (Norgestimate)
- Place on arm, trunk, buttock
- Same contraindications as OCs. Typical use efficacy may be better than OCs\(^1\)
- Decreased efficacy, not contraindicated in women over 198 pounds\(^2\)
- Breast discomfort and spotting > > in patch than OC for cycles 1 & 2\(^3\)
- Average levels of circulating estrogen 60% higher though peak levels are lower compared to OCs

Ortho Evra and risk of Venous Thromboembolism (VTE)

- 2 studies out, both retrospective case-control studies from insurance claims data
  - Jick et al, 2006 Nested case-control design based on information from PharMetrics; 59K patch, 147K OC users
    - did not show increased risk of VTE: OR .9 (CI 0.5–1.6) and OR 1.1 (CI 0.6–2.1) with 2006 data, when compared to OCs containing 35mcg ethinylestradiol (EE) and norgestimate
  - Cole et al, 2007. United Health Care claims data and chart reviews; 99K patch 257K OC users
    - did show odds ratio 2.4 (CI 1.1-5.5) for VTE among patch users compared to OCs with 35 mcg EE and norgestimate
- Bias: new patch users vs. new and prior OC user

Vaginal Contraceptive Ring: Nuva Ring

- Maintains lowest daily serum estrogen levels of all options
  - 15 µg/dy Ethinyl estradiol
  - Etonogestrel (desogestrel)
- 1 ring per cycle
- Flexible soft inert ring
- Obesity doesn’t affect efficacy
- Improves microflora content¹
- No GI interference with absorption
- Avoids liver first-pass metabolism

¹. Archer et al. Fertil Steril 2002

Vaginal Contraceptive Ring

- High adherence and continuation
- Easily placed and removed
  - Tampon “applicator”
  - No wrong location
- Most don’t notice during sex
- Expulsion rare
- May remove up to 3 hours
- Irregular bleeding << OCs²


Vaginal Contraceptive Ring: Off label, Extended cycle regimens

- The Ring is effective for up to 35 days¹
- Continuous cycling, increases breakthrough bleeding²
- “Calendar month” use 1-27th of month, then off for rest of month


Extended Cycle Regimens: Why & How

- Traditional prescription flawed
- Symptoms w/ OC worse during withdrawal bleed¹
  - Cyclic vs. extended cycle: less headaches, tiredness, bloating, menstrual pain²
- Treatment for:
  - anemia, dysmenorrhea, heavy bleeding, PMS, depression, menstrual migraines, endometriosis, PCOS
- Extended cycle may increase efficacy
  - Up to 47% of women have follicle ready to ovulate by day 7 of placebo week!³
- Can use any monophasic OC or Ring (off-label), not patch for brief manipulation, “Bicycling”, “Tricycling”, or Continuous

### Extended Cycle Dedicated Products

- **Seasonale™**
  - FDA approved 2003
  - 150mcg levonorgestrel + 30 mcg EE
  - 12 weeks (84 active pills), 1 week off (7 placebo pills)
  - Increased spotting
  - Body weight not a contributing factor
  - Quasense is generic version
- **Seasonique™**
  - 150mcg levonorgestrel + 30 mcg EE in the first 84 pills
  - 7 days of low dose estrogen, 10mcg EE
- **Lybrel™**
  - 90 mcg levonorgestrel + 20 mcg EE in each pill
  - Daily continuous use with no placebos for a year


### Progestin-Only Injection: Depo Medroxyprogesterone Acetate (DMPA-IM 150mg q12wk)

- Irregular bleeding is expected and Amenorrhea is normal: 50% at 1 year, 80% at 5 years
- May decrease seizure frequency and sickle crisis
- Helped decrease teen birth & abortion rate past
- Privacy, adherence, efficacy, decreased PID risk
- Sub Q formulation- Depo-low 104mg q 12 wks

### Shortened hormone free interval (HFI)

Possible increased efficacy by suppressing follicular growth more effectively – 4 days of placebo rather than 7

- Particularly important with 20mcg EE pills
- Decreased symptoms related to menses
- Decreased unscheduled bleeding

- **Loestrin 24 Fe:** 24 days of 20 mcg EE + 1 mg norethindrone
- **Yaz:** 24 days of 20 mcg EE + 3 mg drospirenone
  - Spironolactone analog- check K only if pt using ACE, ARB, heparin, long term NSAIDS
- **Mircette:** 20 mcg EE + 0.15 mg desogestrel x 21 days, 10 mcg EE x 5 days, 2 days of placebo

### DMPA-IM 150 & Black Box Warning

- Loss of BMD happens in first 2 years
  - Pregnancy and nursing cause similar or > bone loss than DMPA
- In teens, bone loss reversed within 12 months of discontinuation, and ultimately BMD was higher in the former than never users of DMPA
- No increased incidence of osteoporosis or fractures w/ DMPA in >30yrs of worldwide use
- No role for BMD evaluation or treatment with bisphosphonates
- Experts feel FDA’s recent “black box” labeling for DMPA is unnecessary and should not effect initiation or continuation

Intrauterine Contraception (IUDs)

**Worldwide most common reversible form of contraception**

Options available in the US today

- **Copper T 380A (ParaGard)**
  - Effective 12 years and No hormones
  - Increased blood loss and cramping with regular periods

- **Levonorgestrel releasing system (Mirena)**
  - Effective 5 (maybe 7) years
  - Very low dose progestin
  - Irregular spotting & bleeding. No menses 20% at 1yr, 80% at 5yr
  - Many non-contraceptive benefits

- Negative US perception b/c Dalkon Shield. Caused plummet of US use (10% of women used IUD mid-70's)

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Evidence based shift of eligible candidates

- **CuT380A-ParaGard Label Change 2005**
  - Mirena package insert outdated; can use Evidence Based indications off-label

- **Expanded patient profile**
  - Nulliparous women
  - History of ectopic pregnancy
  - Past history of PID or STI
  - More than one partner

- **Contraindications**
  - Acute cervicitis or PID; High personal risk for cervicitis or PID

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Do IUDs cause STIs and PID?

- Transient PID risk of 1/1000 likely due to contamination at insertion
  1. Hubacher Contraception 2004; 99:437-446
  2. Mosher WD et al., Advance Data from Vital and Health Statistics 2006

- Okay to screen for STI and insert IUD at same visit
  3. Some protocols moving to “may, not must” screening for STIs (Family Pact and Planned Parenthood)

- Okay to treat STI and PID with IUD in place
  3. Do not remove unless treatment failure
  4. Dose and duration does not change
  5. Don’t remove for Actinomycosis

- **Prophylactic antibiotics not necessary**

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IUDs DO NOT Increase Risk of Infertility

  1. Systematic review found no significant effect of IUD use on infection and infertility
  2. Risk of developing PID with asymptomatic cervicitis similar with and without an IUD

- Hubacher D. et al., NEJM 2001; 345:561-7
  3. Tubal infertility is linked to presence of antibodies to Chlamydia but NOT to a history of IUD use
  4. Case control study of 1895 women
  5. Compared 1311 infertile nulliparous women with 584 primigravid controls

- **Rapid return to fertility after removal of both devices**

---
IUDs in Young and Nulliparous Women

- Safe and effective in nulliparous women and women <20yrs old with low risk of PID- WHO class 2\(^1\)-4
- Higher continuation rates with IUDs compared to OCs in teens\(^1\)
- Progestin IUD is great choice for nulliparous women with menorrhagia and/or dysmenorrhea
- IUD expulsion, bleeding, and pain are slightly more likely among nulliparous women\(^2\,-\,5\)

Intrauterine Contraception facts

**Mechanism of Action:**

- IUDs DO NOT cause Abortion:
  - LNG IUDs thicken cervical mucus, suppress endometrium, & have some anovulatory effect
  - Copper IUDs act as a spermicide
- IUDs DO NOT increase risk of ectopic pregnancy
  - recommended in women w/ H/O ectopic- WHO Class 1
- Both IUDs offer protection against endometrial CA

Levonorgestrel IUS:

**Non Contraceptive Benefits and Indications**

- Treatment for Dysmenorrhea and PMS
- Treatment for Menorrhagia: 90% decrease in blood loss
- Decreased bleeding and surgical intervention for DUB, fibroids, endometriosis and adenomyosis\(^1\,-\,3\)
- Endometrial protection from tamoxifen-induced changes and treatment for endometrial hyperplasia

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Progesterone Implant: Implanon™

- 4cm flexible rod (etonogestrel)
- Effective for 3 years
- **High Efficacy**: No pregnancies in 73,000 cycles – 2,300 women
- Inhibits ovulation within one day
- Rapid return to fertility
- Irregular bleeding primary side effect
- FDA Approved July 2006


Implanon

- Minor procedure to insert and remove
- High acceptability (90% in one year)
- Mechanism of Action
  - Primarily inhibits ovulation
  - Secondarily increases viscosity of cervical mucus
- Compared with COCPs:
  - more acne (19%), less nausea (3%) and breast tenderness (9%)
- Can only be inserted and removed by trained clinicians who attend a company sponsored program [www.implanon-usa.com](http://www.implanon-usa.com) or call 1-877-467-5266

Package insert Organon, Inc. 2006
Darney P, Eur J Contracept Reprod Health Care, 2000;

Sterilization Comparisons

<table>
<thead>
<tr>
<th></th>
<th>Hysteroscopic Sterilization (Essure)</th>
<th>Tubal Ligation</th>
<th>Vasectomy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incisions</td>
<td>None</td>
<td>1-2</td>
<td>1-2</td>
</tr>
<tr>
<td>Typical anesthesia</td>
<td>Local or IV Sedation</td>
<td>General</td>
<td>Local</td>
</tr>
<tr>
<td>Peritoneal entry</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Resume activities</td>
<td>1-2 days</td>
<td>4.4 days</td>
<td>2 days</td>
</tr>
<tr>
<td>Effectiveness rate</td>
<td>99.74% @5 years</td>
<td>98.82% @ 4 years</td>
<td>98.87% @ 5 years</td>
</tr>
</tbody>
</table>

Helpful Resources

- Hatcher et al, Contraceptive Technology 2004
- Managing Contraception – book online @ [www.managingcontraception.org](http://www.managingcontraception.org)
- Association of Reproductive Health Professionals (ARHP) [www.arhp.org](http://www.arhp.org)
- Alan Guttmacher Institute (www.agi-usa.org)
- [www.contraceptiononline.org](http://www.contraceptiononline.org)
- [www.plannedparenthood.org](http://www.plannedparenthood.org)
- [www.rhedi.org](http://www.rhedi.org)
- [www.reproductiveaccess.org](http://www.reproductiveaccess.org)