

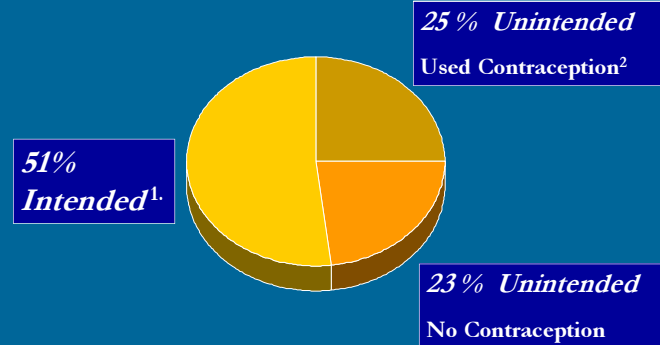
# Contraception Update

Family Medicine  
Board Review Course  
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## 6.3 Million Pregnancies in the U.S.



1. Finer et al, 2006
2. Jones RK, et al *Perspectives on Sexual and Reproductive Health*, 2002

## WHO Medical Eligibility Criteria

More evidence based than package insert

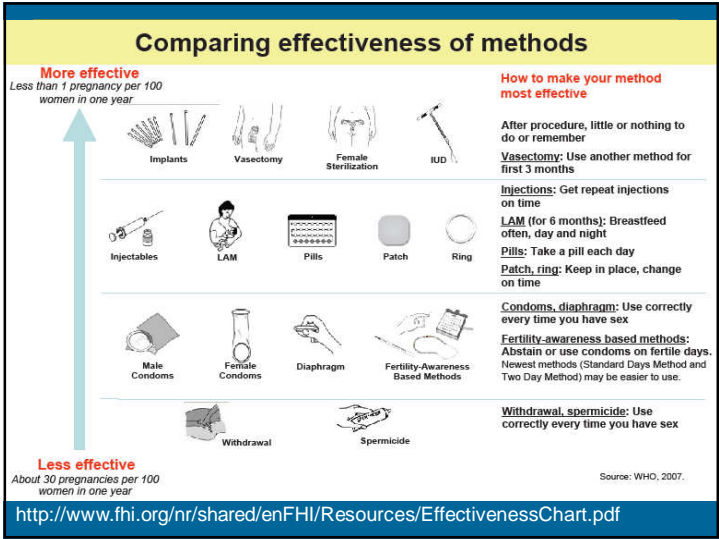
Classification	Description
1	Use method in any circumstances
2	Generally use the method- advantages outweigh theoretical or proven risks
3	Use of method not usually recommended unless other more appropriate methods are not available
4	Method not to be used- Condition represents an unacceptable health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

Medical Eligibility Criteria For Contraceptive Use. Third Edition. WHO, 2004  
<http://www.who.int/reproductive-health/publications/mec/>

### WHO Medical Eligibility for Initiating Contraceptive Methods

Condition	Quantitative methods (IUDs, implants, injectables)	Combined hormonal	Progestin only pill	Progestin injection	Progestin implant	Progestin ring	Contraceptive patch
<b>Smoking</b>							
10 or more cigarettes per day	3	3	2	2	2	2	2
1-9 cigarettes per day	2	2	2	2	2	2	2
10 or more cigarettes per day, age > 35	4	4	3	3	3	3	3
1-9 cigarettes per day, age > 35	3	3	2	2	2	2	2
10 or more cigarettes per day, age > 35, high risk factor	4	4	3	3	3	3	3
1-9 cigarettes per day, age > 35, high risk factor	3	3	2	2	2	2	2
<b>Obesity</b>							
BMI > 30	3	3	2	2	2	2	2
BMI > 30, high risk factor	4	4	3	3	3	3	3
<b>Diabetes</b>							
Controlled	2	2	2	2	2	2	2
Uncontrolled	3	3	2	2	2	2	2
<b>Cardiovascular</b>							
Controlled	2	2	2	2	2	2	2
Uncontrolled	3	3	2	2	2	2	2
<b>Hypertension</b>							
Controlled	2	2	2	2	2	2	2
Uncontrolled	3	3	2	2	2	2	2
<b>Stroke</b>							
Controlled	2	2	2	2	2	2	2
Uncontrolled	3	3	2	2	2	2	2
<b>Myocardial infarction</b>							
Controlled	2	2	2	2	2	2	2
Uncontrolled	3	3	2	2	2	2	2
<b>Deep vein thromboses</b>							
Controlled	2	2	2	2	2	2	2
Uncontrolled	3	3	2	2	2	2	2
<b>Stroke</b>							
Controlled	2	2	2	2	2	2	2
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<b>Deep vein thromboses</b>							
Controlled	2	2	2	2	2	2	2
Uncontrolled	3	3	2	2	2	2	2

[http://www.reproductiveaccess.org/contraception/downloads/WHO\\_Chart.pdf](http://www.reproductiveaccess.org/contraception/downloads/WHO_Chart.pdf)



### Effectiveness Rates

	Typical Use	Perfect Use
Implanon	0.05	0.05
IUD		
Mirena (LNg releasing)	0.2	0.2
ParaGard (copperT)	0.8	0.6
Male Sterilization	0.15	0.10
Female Sterilization	0.5	0.5
Depo-Provera q3months	3.0 (7.0?)	0.3
Combined Hormonal methods (Pill, Patch and Vaginal Ring)	8.0	0.3

### Effectiveness Rates

	Typical Use	Perfect Use
Cap -- nullip	16	9
Sponge -- nullip	16	9
Diaphragm	16	6
Female Condom	21	5
Withdrawal	27	4
Male Condom	15	2

Hatcher, RA et al; *Contraceptive Technology 18th Edition*; 2007

- ### Medical Benefits of Hormonal Contraception
- Combined hormonal contraception (CHC) reduces:
    - Blood loss, PMS, dysmenorrhea, Ovarian cysts, acne, perimenopausal sx's, DUB, PCOS, Endometriosis
  - OC users reduce risk of ovarian Ca by 40%<sup>1</sup>, and by 80% after 10 yrs<sup>2</sup>
  - OC reduces risk of endometrial CA by up to 40%<sup>3</sup>
  - No increase risk of Breast CA in OC users<sup>4</sup>
1. Vessey et al *Br J Cancer* 1995. 2. Rosenberg et al *Am J Epidemiol* 1994  
3. JAMA 1987;257(6) 4. Marchbanks et al *NEJM* 2002;346:2025-2032

## Risk Comparisons (slide credit: Association of Reproductive Health Professionals)

### 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

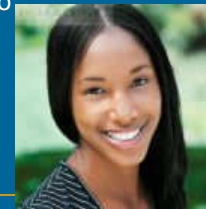
Trussell J, Jordan B. Contraception in press. Chang J, et al. MMWR 2003.  
Harvard Center for Risk Analysis 2006. Bennett P. In: Risk Communication and Public Health 1999.

## 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<sup>1,2</sup>

Von Hertzen et al. *Lancet* 2002;360:1803-10  
Arowoiolu AO, et al. *Contraception*. 2002;66:269-73

## Emergency Contraception

- EC use doubles when provided in advance<sup>1</sup>
  - Does not lead to decreased use of usual contraception, increase in STI or unprotected intercourse<sup>2</sup>
- Standing orders can improve access to EC:
- No Evidence Based Contraindications  
**Plan B WILL NOT DISRUPT AN IMPLANTED PREGNANCY**

1. Bissel et al *Soc Sci Med*.2003;57:2367-2378

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!**

Stewart F, et al. *JAMA*. 2001;285:2232-9.

## “Quick Start”

- “Quick Start” – start pill<sup>1,2</sup> ( patch<sup>3</sup>, shot, ring<sup>4</sup>, ) 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

1. Westhoff et al. *Contraception* 2002; 2. Westhoff et al. *Fertil Steril* 2003; 3. Murthy AS, et al. *Contraception*. 2005;72:333-6. 4. Westhoff CW, et al. *Obstet Gynecol*. 2005;106: 6. Balkus J, et al. *Contraception*. 2005;71:395-8.

## 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<sup>1</sup>
- Decreased efficacy, not contraindicated in women over 198 pounds<sup>2</sup>
- Breast discomfort and spotting > > in patch than OC for cycles 1 & 2<sup>3</sup>
- Average levels of circulating estrogen 60% higher though peak levels are lower compared to OCs



1. Sonnenberg et al. *Am J Obstet Gynecol*. 2005; 2. Ziemann M, *Fertil & Steril*, 2002  
3. Audet, et al. *JAMA*. 2001;285:2347-2354.

## 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**

Jick SS et al. *Contraception* 2006;73:223-228 and *Contraception* 2007;76:4-7  
Cole JA et al. *Obstet Gynecol* 2007;109:339-346

## 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 content<sup>1</sup>
- 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 << OCs<sup>2</sup>

Dieben, *Ob Gyn*, 2002 2. Bjarnadóttir RI, *Am J Obstet Gynecol*, 2002

## Vaginal Contraceptive Ring:

Off label, Extended cycle regimens

- The Ring is effective for up to 35 days<sup>1</sup>
- Continuous cycling, increases breakthrough bleeding<sup>2</sup>
- "Calendar month" use 1-27th of month, then off for rest of month

1. Mulders & Dieben, *Fertil Steril* 2001;75:865-70. 2. Miller, et al. 2005

## Extended Cycle Regimens: Why & How

- Traditional prescription flawed
- Symptoms w/ OC worse during withdrawal bleed<sup>1</sup>
  - Cyclic vs. extended cycle: less headaches, tiredness, bloating, menstrual pain<sup>2</sup>
- 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!<sup>3</sup>
- Can use any monophasic OC or Ring (off-label), not patch for brief manipulation, "Bicycling", "Tricycling", or Continuous

1. Sulak et al *Obstet Gynecol*. 2000;95:261-266 2. Edelman et al *Cochrane Review* 2006 3. Baerwald, *Contraception*, 2004

## 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<sup>1</sup>
    - 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

Anderson FD, et al. *Contraception*. 2003;68:89-96.

## 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

## 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

## DMPA-IM 150 & Black Box Warning

- Loss of BMD happens in first 2 years  
 Pregnancy and nursing cause similar or > bone loss than DMPA<sup>1</sup>
- In teens, bone loss reversed within 12 months of discontinuation, and ultimately BMD was higher in the former than never users of DMPA<sup>2</sup>
- No increased incidence of osteoporosis or fractures w/ DMPA in >30yrs of worldwide use<sup>3</sup>
- No role for BMD evaluation or treatment with bisphosphonates<sup>4</sup>
- Experts feel FDA's recent "black box" labeling for DMPA is unnecessary and should not effect initiation or continuation<sup>4,5</sup>

1. Sowers *Obstet Gynecol*; 2000;96:189-93 2. Scholes *Arch Pediatr Adol Med* 2005;159:139-44  
 3. Westhoff C *Contraception*. 2003;68:75-87 4. ACOG Bulletin 2005 5. Kaunitz *Contraception* Jan 2008

## 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% 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)**

1. Hubacher *Contraception* 2004;69:437-446

2. Mosher WD et al. *Advance Data from Vital and Health Statistics* 2006

## 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

## Do IUDs cause STIs and PID?

- Transient PID risk of 1/1000 likely due to contamination at insertion<sup>1,2</sup>
- Okay to screen for STI and insert IUD at same visit<sup>3</sup>
  - 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<sup>3</sup>
  - Do not remove unless treatment failure
  - Dose and duration does not change
  - Don't remove for Actinomyces
- Prophylactic antibiotics not necessary<sup>4</sup>

1. Grimes, D *Lancet* 2001; 7358:6-7, 2. Grimes, D *Lancet* 2000; 356:1013-9

3. WHO 2005 4. Grimes *Cochrane Database* 2001, revised 2003

## IUDs DO NOT Increase Risk of Infertility

- Grimes, D. *Lancet* 2000; 356: 1013-19
  - Systematic review found no significant effect of IUD use on infection and infertility
  - Risk of developing PID with asymptomatic cervicitis similar with and without an IUD
- Hubacher D, et al. *NEJM* 2001; 345:561-7
  - Tubal infertility is linked to presence of antibodies to Chlamydia but NOT to a history of IUD use
    - Case control study of 1895 women
    - 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<sup>1-4</sup>
- Higher continuation rates with IUDs compared to OCs in teens<sup>1</sup>
- 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<sup>2-5</sup>

1. Suhonen S. *Contraception* 2004;69:507-512. 2. Nelson AL. *Obstet Gynecol Clin North Am.* 2000;27:723-740. 3. Dardano KL, Burkman RT. *Am J Obstet Gynecol.* 1999;181:1-5. 4. Li C. *Contraception* 2004;69:247-250. 5. Treiman K, et al. *Population Reports.* 1995.

## 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

1. Grimes Cochrane Database 2004 2. Andersson *Contraception* 1994;49  
3. Hubacher NEJM 2001;344:784-90

## Intrauterine Contraception facts

- Copper IUD can be used within 5-8 days of unprotected intercourse for **emergency contraception**
- May insert at any point in the menstrual cycle<sup>1</sup>
- May insert both devices immediately post-1<sup>st</sup> trimester abortion and 4 weeks post-partum
- Safe in woman with HIV and AIDs stable on ARVs- WHO class 2;
  - no increased risk of infection or viral shedding<sup>3,4,5</sup>

1. Medical eligibility criteria for contraceptive use WHO, 2004. 2. Hubacher NEJM 2001 3. Sinei et al, *Lancet* 1998 4. Morrison et al, *BJOG* 2001 5. Richardson et al, *AIDS* 1999

## 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<sup>1,2,3</sup>
- Endometrial protection from tamoxifen-induced changes and treatment for endometrial hyperplasia

1. Hurskainen et al *Lancet* 2001 2. Grigorieva et al *Fertil Steril* 2003;79(5):1194-98.  
3. Crosignani et al *Obstet Gynecol.* 1997;90(2):257-63.



## 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



Zheng SR, et al. Contraception. 1999;60:1-8.  
Croxatto HB, et al. Hum Reprod. 1999;14:976-81.

## 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; Meckstroth & Darney P, *Obstet Gynecol Clin North Am*, 2000.

## Sterilization Comparisons

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

## Helpful Resources

- Hatcher et al, Contraceptive Technology 2004
- Managing Contraception – book online @ ([www.managingcontraception.org](http://www.managingcontraception.org))
- WHO Medical Eligibility Criteria for Contraceptive Use 2004 ([www.who.int/reproductive-health/publications/mec/mec.pdf](http://www.who.int/reproductive-health/publications/mec/mec.pdf))
- Association of Reproductive Health Professionals (ARHP) ([www.arhp.org](http://www.arhp.org))
- Alan Guttmacher Institute ([www.guttmacher.org](http://www.guttmacher.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)