Objectives

- At the end of this talk you will be able to:
  - Find evidence about contraception for women with possible contraindications.
  - Encourage women to use longer-term contraceptive methods.
  - Help women choose and use contraception more effectively.

Outline

- Unintended pregnancy
- Contraceptive evidence
- Contraceptive methods updates
  - Natural Family Planning
  - Extended cycle combined hormonal methods
  - Patch and thrombosis
  - DMPA and BMD
  - IUC update
Jane is a 27 year-old woman taking combined oral contraceptive pills who presents to your clinic for an annual examination. She reports having missed two periods. Her urine pregnancy test is positive.

6.3 Million U.S. Pregnancies

- **52%** Intended
- **25%** Unintended Despite method use
- **23%** Unintended No method used


Unintended Pregnancies
(Approximately 3.0 Million Annually)

- **47%** Abortions
- **40%** Births
- **13%** Miscarriages

Abortion Rates in Western Industrialized Countries


How effective is the combined oral contraceptive for prevention of pregnancy?

Contraceptive Efficacy

- Efficacy
  - Perfect use v. actual or typical use
  - **Combined oral contraceptive pill**
    - 99.7% perfect use, 92% actual use
    - 10 million women using the pill: 1% ↓ efficacy = 100,000 unintended pregnancies in 1 year
Diary
Electronic Device

Cycle 1
Cycle 2
Cycle 3

Realities of Pill Use

Percent of Women (%)

Active Pills Missed

Potter L et al, Fam Plann Perspect. 1996.

Contraceptive Method Choice in the United States, 2002

Sterilization (male and female)
Pill
Condom
Injectable Withdrawal
IUD
Natural Family Planning
Patch
Other*

*Other includes diaphragm, ring, gel/foam, rods, and EC
Alan Guttmacher Institute, Facts In Brief, 2005.

Why did Jane get pregnant?
Why did Jane get pregnant?

Jane tells you that her insurance permitted her to obtain only one pack of pills each month, and she was late in getting her pack last month because of working until after the pharmacy was closed.

Barriers to Effective Contraception

- Systems Barriers
  - Political
  - Public funding
  - Insurance
  - Hospital Policies

Why did Jane get pregnant?

Jane tells you that she ran out of birth control pills last month, and that she tried to call the office to get an appointment, but the receptionist told her she was overdue for a pap smear. Today was the first day she could get an appointment.
Barriers to Effective Contraception

- Provider Barriers
  - Requiring examination before initiating methods
    - BP check for hormonal methods
  - Otherwise NO physical examination required
- Education about contraindications
  - Contraceptive evidence
  - Example: Can a woman with migraines use the combined pill?

Contraceptive Evidence: WHO Guidelines

Resource for evaluating risk from contraception in specific medical situations (Weighed against the risk from pregnancy)

Contraceptive Evidence: WHO Guidelines

- Medical Eligibility Criteria for Contraceptive Use
  - www.who.int full text on-line

- www.reproductiveaccess.org
  - Go to “providers” then under “clinical resources” you will see WHO guidelines.
  - Available in Word or PDF
  - Link to the comprehensive WHO list
Contraceptive Evidence: WHO Guidelines

1. No restriction
   - Use the method
2. Advantages of method outweigh the risks
   - Generally use the method
3. Risks outweigh the advantages
   - Use only if no other method available
4. Unacceptable health risk if method used
   - Do not use the method

Medical Eligibility Criteria for Contraceptive Use (www.who.int/reproductive-health)

Stroke

- The absolute risk of stroke in young women is low at <1 per 10,000 women-years.
- Risk factors:
  - Smoking
  - Age > 35
  - Obesity, FH of stroke <45
  - HTN, CVD, diabetes, hyperlipidemia
  - Migraine with and without aura
  - Combined hormonal contraception


Migraine, OCPs, and Stroke

- Migraine and stroke:
  - Migraine without aura: RR 1.6 – RR 3.0
  - Migraine with aura: RR 2.9 – RR 6.2
- COC and stroke:
  - RR 2.1 – RR 3.5

Migraine, OCPs, and Stroke

Synergistic effect of Migraine and COC

OR 8.7 (95% CI 5.0-15.0) ¹
OR 13.9 (95% CI 5.5-35.1) ²


Absolute Risks of Stroke

- 6 per 100,000 ♀ / year – healthy
- 12 per 100,000 ♀ / year – migraine
- 18 per 100,000 ♀ / year – migraine with aura
- 12 per 100,000 ♀ / year – healthy and COC
- 19 per 100,000 ♀ / year – migraine and COC
- 30 per 100,000 ♀ / year – migraine with aura and COC
- 34 per 100,000 ♀ / year – stroke in pregnancy

Attributable risk: 7-12 per 100,000 women per year

WHO: Headaches and CHC

<table>
<thead>
<tr>
<th>Initiate</th>
<th>Continue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-migrainous (mild or severe)</td>
<td>1</td>
</tr>
<tr>
<td>Migraine</td>
<td></td>
</tr>
<tr>
<td>(i) without focal neurologic symptoms</td>
<td></td>
</tr>
<tr>
<td>Age &lt; 35</td>
<td>2</td>
</tr>
<tr>
<td>Age &gt; 35</td>
<td>3</td>
</tr>
<tr>
<td>(ii) with focal neurologic symptoms</td>
<td></td>
</tr>
<tr>
<td>(at any age)</td>
<td>4</td>
</tr>
</tbody>
</table>

Prodrome = photo/phonophobia, N/V – These are not focal
Focal symptoms = vision changes, numbness, parasthesias

http://www.who.int/reproductive-health/publications/RHR_00_2_medical_eligibility_criteria_3rd/
Why did Jane get pregnant?

Jane tells you that she missed pills sometimes.

Barriers to Effective Contraception

- Individual Barriers
  - Help women choose best method for themselves
  - Encourage longer-term/more effective methods
- Quick Start:
  - Safe in Combined Hormonal Methods
  - Safe in DMPA
  - May be associated with increased continuation

Contraceptive Methods

- Natural Family Planning
- Barrier Methods
- Hormonal Methods
Contraceptive Methods

- Episodic: barrier methods, NFP
- Daily: pill, NFP
- Weekly: patch
- Monthly: vaginal ring
- Every 3 Months: injection
- Every 3 years: implant
- Every 5 years: IUC
- Every 10 years: IUC
- Permanent: sterilization

Natural Family Planning

<table>
<thead>
<tr>
<th>Contraceptive Method</th>
<th>Failure Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Typical Use</td>
</tr>
<tr>
<td>No Method</td>
<td></td>
</tr>
<tr>
<td>Periodic Abstinence</td>
<td></td>
</tr>
<tr>
<td>Standard Days Method**</td>
<td>5%</td>
</tr>
<tr>
<td>Ovulation Method</td>
<td>3%</td>
</tr>
<tr>
<td>Symptothermal</td>
<td>2%</td>
</tr>
<tr>
<td>Two-Day Method*</td>
<td>3%</td>
</tr>
</tbody>
</table>

* Including Cycle Beads

Barrier Methods

<table>
<thead>
<tr>
<th>Contraceptive Method</th>
<th>Failure Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Typical Use</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>4%</td>
</tr>
<tr>
<td>Condoms</td>
<td>2%</td>
</tr>
<tr>
<td>Cervical Cap (parous)</td>
<td>26%</td>
</tr>
<tr>
<td>Cervical Cap (nulliparous)</td>
<td>9%</td>
</tr>
<tr>
<td>Sponge (parous)</td>
<td>20%</td>
</tr>
<tr>
<td>Sponge (nulliparous)</td>
<td>9%</td>
</tr>
<tr>
<td>Female Condoms</td>
<td>5%</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>6%</td>
</tr>
<tr>
<td>Contraceptive Method</td>
<td>Failure Rate</td>
</tr>
<tr>
<td>--------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td></td>
<td>Perfect Use</td>
</tr>
<tr>
<td>Combined Hormonal Pills</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Progestin Only Pills</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Transdermal Patch</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Vaginal Ring</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>1-month Injection</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>3-Month</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Implants</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Copper IUD/LNG IUS</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

Contraceptive Methods Update

- Natural family planning
- Extended cycle combined hormonal methods
  - Pills and ring
  - Patch and thrombosis
  - Injectable and bone mineral density
  - Intrauterine contraception new label

Daily: Natural Family Planning

- Help women identify fertile days
- Fertility window 6-8 days
- Failure rate 12-22%
- TwoDay method
  - Simple, accurate method – quicker to learn
  - Two questions
    - Did I note secretions today?
    - Did I note secretions yesterday?
    - If yes to either, consider fertile
Natural Family Planning: Two-Day Method®

- Study of 450 women – 3, 928 cycles
- Failure rates:
  - 14% typical use
  - 3% perfect use (no intercourse)
  - 6% semi-perfect (barriers or withdrawal)
  - Half of pregnancies in first 3 months
  - Mean fertile window 12 days
  - High acceptability


Daily: Combined Oral Contraceptives

- Traditional prescription flawed
- Extended cycle may increase efficacy
  - Up to 47% of women have follicle ready to ovulate by day 7 of placebo week!
  - So if the start of the new pack is delayed, they are at high risk!


Daily: Extended Use Pills

- Shortened hormone-free week
  - 23 days or 24 days hormones
  - Failure rate up to 1.3%
  - Decreases ovarian activity at end of placebo
  - Shorter withdrawal bleeds
  - Similar breakthrough bleeding
  - Few products approved by FDA
    - Yaz® and Loestrin ® 24 FE

Daily: Extended Use Pills

- Decreased frequency of hormone-free wks
- Regimens
  - 6 wks on/1 wk off; 12 wks on/1 wk off - "Tricycling"
  - Flexible
- Tricycle Failure 0.6% - Lower than conventional?
- FDA-approved
  - 84 days LNG 150 µg/EE 30 µg; 7 days placebo
    (Seasonale®)
  - Seasonique™ adds 10 mcg EE during placebo


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Tricycle Breakthrough bleeding/spotting

<table>
<thead>
<tr>
<th>Cycle (days)</th>
<th>Median Number of BTB/Spotting Days/Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (1-84)</td>
<td>12</td>
</tr>
<tr>
<td>2 (93-175)</td>
<td>6</td>
</tr>
<tr>
<td>3 (183-266)</td>
<td>6</td>
</tr>
<tr>
<td>4 (274-357)</td>
<td>4</td>
</tr>
</tbody>
</table>


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Daily: Extended Use Pills

- Continuous Use – studied up to one year
  - 2 RCTs and 2 cohort trials – no efficacy data
  - Increased spotting in first six months, comparable in second six months
    - Median 1.5 days spotting in last trimester
  - Up to 72% amenorrhea at one year
  - High acceptability

Extended cycle: Is Something Building Up Inside?

- Endometrial biopsy data – no hyperplasia
  - Tricycle regimen, short hormone-free, cont.
  - 1 year continuous: 11% weakly proliferative
- Ultrasound data - thin endometrial stripe in study of continuous x 6 months
  - Traditional use decreases risk of endometrial cancer


Pill Instructions

- Initiation:
  - If Sunday or Quick Start – backup for 7 days
  - System for remembering
- Continuation:
  - If miss one: do nothing
  - If miss two: take forgotten pills every 12 hours
  - Continue and backup contraception x 7 days
  - If beginning of pack and unprotected sex: ECP
  - If extended cycle: no need for ECP
  - If miss more than two:
    - If unprotected sex: take ECP, restart OC next day
    - Backup for 7 days

Weekly: Transdermal Contraceptive System “Patch”

- Ortho Evra®
  - 20mcg EE & 150mcg norelgestromin
- One patch each week for 3 weeks, then week off
- Constant serum levels
- Failure rate 0.9%
- Women are more compliant than with pill. (88% v. 78%)

TCS/ "Patch"
- Easily placed and removed
- High acceptability and compliance
- Few side effects - comparable to pills except
  - 20% skin irritation – 2% stopped method
  - More breast discomfort in first 2 cycles (19%) than pills (6%)
  - More spotting (20%) than pills in first 2 cycles
  - 3% detached

Body Weight
- 5 of 15 treatment failures in women with baseline body weight >90 kg (198 lb)
  - This subgroup <3% of total study population
  - Higher failure rate in heavier women


TCS and thrombosis
- Increased risk thrombosis?
  - Numerator and denominator are unclear
  - New user bias
  - Serum levels slightly higher than 35 mcg pill
    - Slight increase in AUC in 2nd and 3rd wk
  - Case-control study – VTE patch v. 35 mcg pill
    - OR 1.1 (95% CI 0.7-1.8)
  - Risk of thrombosis may or may not be higher than other combined methods

Patch Instructions

- Initiation:
  - Prescribe replacement patches (up to 3)
  - If day other than first day menses – backup 7 days
- If the PATCH FREE interval is >9 days (late restart), apply a new patch and use backup contraception for 7 days
- No band-aids, tattoos, or decals on top of patch as this might alter absorption of hormones
- Smooth edges down when you first put it on
- Avoid the same site 2 consecutive weeks

Patch Instructions

- Location of patch should not be altered mid-week
- Women should check the patch daily to make sure all the edges remain closely adherent to skin
- Single replacement patches are available through pharmacists.
- Unlike pills, the time of day the patch is changed doesn’t matter
- Disposal: fold over self. Place in solid waste. Do not flush down toilet.

Monthly: Contraceptive Vaginal Ring

- Nuvaring®
  - 15 mcg EE & 120 mcg desogestrel
- One ring each month
- Ring in vagina for 3 weeks
- Ring removed for one week
- Constant, low hormone levels
- Failure rate 1.2%

Miller, Obstetrics and Gynecology, 2005
CVR/ “Ring”
- Easily placed and removed
- Most women and men don’t notice during sex
- High acceptability and compliance
- Few side effects – comparable to pills except
  - Less spotting 5% (significantly less in first month)
  - 1% stop method because of discharge
  - 2.5% stop method because of discomfort

Dieben, Ob Gyn, 2002

Monthly: Extended Cycle Ring
- Study of conventional, 8 wks, 12 wks, cont.
  - All regimens well-tolerated
  - Extended: Fewer bleeding days and more spotting days
- Potential for use on a monthly basis
  - Serum levels for 35 days

Ring Instructions
- Initiation:
  - First five days of menses - if not backup x 7 days
  - The ring can be left in for up to 35 days
  - May remove up to 3 hours (not recommended)
  - If ring is out for more than 3 hours use back-up for 7 days
  - Always have two rings on hand in case one is lost
  - Rings may be stored at room temperature for up to 4 months
  - Disposal: fold over self. Place in solid waste. Do not flush down toilet.
  - Ring floats in toilet
Every 3 months: Progestin Injection

- **Depo Provera®**
  - Medroxyprogesterone acetate 150 mg
  - Given every 3 months IM
- Failure rate 0.3%
- High acceptability
- New depo-subQ provera™
  - Low-dose (104 mg) version
  - Similar side effects, unknown bone effect

Progestin Injection

- Requires visit to provider
- One injection lasts at least 13 weeks
- Extremely private
- Side effects:
  - Delayed return to fertility (9-10 months)
  - Irregular bleeding, amenorrhea (50% at 1 yr)
  - Weight gain (5 lbs at 1 year, 16 lbs at 5 yrs)
  - Black Box Warning: Decreased bone mineral density (3% in 2 yrs) appears to resolve after discontinuation.
    - FDA recommends limiting to 2 years in young women.
    - WHO does not agree – good evidence resolution, and no fx outcome data

DMPA Instructions

- Initiation:
  - Prefer start days 1-5
  - Quick start okay – backup x 7 days
- Do not massage area for few hours
- Anticipate side effects – bleeding, weight
- Counsel about Calcium and exercise
- If >13 wks since last injection – abstinence, EC, condoms
Progestin Injection and BMD

- Black Box: limit to 2 yrs in young women.
  - WHO does not agree
- Decreased BMD resolves after discontinuation.
  - Study of 170 adolescents ¹
    - 1-2 % decrease in BMD per year
    - 12 months after discontinuation: normal
  - Study of 183 women, ages 18-39 ²
    - 1% decrease in BMD per year
    - 30 months after discontinuation: normal

Weigh risks against risk of pregnancy


Every 3 years: Single-Rod Implant

- Implanon™
  - Etonogestrel 60mcg/day
- FDA-approved
- One implant for 3 years

- Continuous low hormone levels
- Failure rate <0.1%

Single-Rod Progestin Implant

- **Efficacy:** No pregnancies in initial trials
- High acceptability
- Continuation 75%-90% at one year
- Few side effects
  - 22% no periods
  - 40% with irregular bleeding – mostly spotting
- Compared with pills more acne (19%), less nausea (3%) and breast tenderness (9%)

¹ Data on file. Organon, Inc. 1999
Every 5-10 Years: IUD Available in the United States

- Copper T 380A IUD - PARAGARD®
- LNG IUS - MIRENA®
  - Levonorgestrel 20 mcg

IUD Efficacy

- **Mirena®**
  - Effective for 5 (7) years
  - 0.1% failure in one year
  - 1.1% failure in seven years
- **Paragard®**
  - Effective for 10 (12) years
  - 0.8% failure in one year
  - 1.4% failure in seven years
- Comparable to TL failure rate of 1.9%/10 yrs


Worldwide Use of IUD

Estimated Use Among Married Women of Reproductive Age

IUD: Dispelling Common Myths

- In fact:
  - DO NOT cause pelvic infection after insertion
  - DO NOT impair future fertility
  - CAN be used for nulligravidas

IUD Acceptability & Side Effects

- High acceptability
  - 80-90% of women continue for one year
  - Approximately 25% continue for seven years
- Side effects
  - Discomfort at time of insertion
  - Abnormal vaginal bleeding
- Rare complications
  - Uterine perforation <.01%
  - Expulsion 5%
  - PID – 1/1000 at time of insertion

IUD Vaginal Bleeding

<table>
<thead>
<tr>
<th>Study Group</th>
<th>Mean Blood Loss (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>35</td>
</tr>
<tr>
<td>Paragard</td>
<td>50-80</td>
</tr>
<tr>
<td>Mirena</td>
<td>5</td>
</tr>
</tbody>
</table>

- After 12 mos: average 90% decrease blood
- Increased spotting common in first 3-6 months

IUD and PID

History: Dalkon Shield—inherent design flaw ↑ risk

- **Current methods do NOT cause PID**
  - Transient increased risk at time of insertion with IUC
  - 1/1000 women in US trial with screening
  - Up to 8/1000 in worldwide trial with no screening
  - No increased risk after 20 days after insertion
  - Caused by bacteria in the cervix at time of insertion
  - Beyond time of insertion
  - Overall decreased risk of LNG IUS
  - No increased risk of Copper IUD
  - No relationship between IUD and tubal infertility


Who is a candidate for IUD?

- Women of any reproductive age seeking long-term, highly effective contraceptive
  - Comparable cost to other methods if used for > 2 yrs
  - Immediate return to fertility
  - Low risk for having sexually transmitted infection
    - High risk for current STI – screen before insertion.
    - Many experts suggest screening at time of insertion for low-risk women.
  - Women who haven’t been pregnant
    - May have higher chance of discomfort on placement and with periods, and expulsion

Paragard “Contraindications”

**New Label**

- Pregnancy or suspicion of pregnancy
- Distorted uterine cavity
- Acute PID or history of PID
- Post-partum endometritis or infected abortion in past 3 months
- Uterine or cervical cancer or unresolved abnormal Pap smear
- Genital bleeding of unknown source

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Paragard “Contraindications”
New Label cont.’

- Untreated acute cervicitis or vaginitis
- Wilson’s disease
- Allergy to copper
- Patient or partner with multiple partners
- Increased susceptibility to infection (AIDS, leukemia, etc)
- Genital actinomycosis
- Current IUD in place

- Mucopurulent cervicitis
- Wilson’s disease
- Allergy to copper
- Previously placed intrauterine contraceptive that has not been removed

IUD Instructions

- Teach patient to check strings
- Counsel patient about anticipated side effects
- Choosing which IUD/IUS
  - Length of desired contraception
  - Hormonal versus copper (few side effects)
  - Bleeding: heavier and regular or lighter and irregular

The Pill?

- Pills: daily (problematic)
  - Some women are good at taking pills
  - Extended use may decrease failures
- Other methods fewer opportunities to forget
Jane decides to use the vaginal ring, and she places it in your office (quick start!) You also send her home with a prescription for emergency contraception.

Emergency Contraception Pills

- Pills taken to prevent pregnancy after unprotected intercourse
- Birth control pills containing estrogen/progestin or progestin alone
- One dedicated progestin product: Plan B (progestin)
- 1st dose immediately, 2nd in 12 hours
  - OR both progestin-only pills at same time
- Take up to five days after act
- Main side effect of combined: vomiting (20%)
- Much rarer with progestin-only (6%)

Emergency Contraception Efficacy

(use after one act of unprotected intercourse)

If 100 women have unprotected sex in the 2nd or 3rd week of their cycle...

...8 will become pregnant without EC

...2 will become pregnant using combined EC (75% reduction)

...1 will become pregnant using progestin EC (89% reduction)

Using EC Pills

- Use at any time in cycle except during menses
- No pregnancy test or physical examination needed
- Begin contraception immediately
  - If no menses within 21 days, pregnancy test
- Offer prescription and/or pills in advance
  - Studies show women are more likely to use EC, and NOT more likely to stop usual contraceptive
- Over-the-counter availability approved by FDA, 18 and over

Conclusion

- Too many unintended pregnancies
- Many effective methods available
  - Minimize barriers to contraception
  - Encourage more effective methods
  - Remain up-to-date about evidence

Resources

- Medical Eligibility Criteria for Contraceptive Use
  - www.who.int, full text on line or $23!!
- Books
WHO Guidelines

- www.reproductiveaccess.org
- Go to “providers” then under “clinical resources” you will see WHO guidelines.
- Available in Word or PDF
- Link to the comprehensive WHO list

On-line Resources

- ARHP (www.arhp.org)
- Managing contraception (www.managingcontraception.org)
- www.contraceptiononline.org