Contraception in the Community

Adapted by Jill Gallin, CPNP
Assistant Professor of Clinical Nursing

U.S. Pregnancies: Unintended vs. Intended


Unintended pregnancies:

- 49%

Intended pregnancies:

- 51%

Unintended births:

- 22.5%

Elective abortions:

- 26.5%

Adolescents Who Have Had Intercourse


The Need for Contraception

Unintended pregnancies (%) by Age


The Need for Contraception

Pregnancies Ending in Abortion by Age

*Does not include miscarriages.


Adolescent Pregnancy

An International Perspective—Developed Countries

Reproduced with permission from The Alan Guttmacher Institute. Sex and America’s Teenagers, 1994.
Adolescents Delay Seeking Medical Contraceptive Services

- Made no visit: 31%
- Before/same month: 12%
- 1-3 months after: 11%
- 4-6 months after: 12%
- 7-12 months after: 11%
- 1 y or more after: 29%

Adolescents’ Contraception at First Intercourse

- No method: 52%
- Condom: 23%
- OCs: 8%
- Withdrawal: 13%
- Other: 4%

Method Use, Last Intercourse Young Women, 14 to 22 years old

Properties of Contraceptives Desired by Women

- Highly effective
- Prolonged duration of action
- Rapidly reversible
- Privacy of use
- Protection against STD
- Easily accessible

Optimizing Patient Choices

- Effectiveness
- Theoretical
- Actual
- Importance of not being pregnant
- Likelihood and ability to comply
- Frequency of intercourse
- Age
- Cost and ability to pay
- Side effects
- Perceptions, misperceptions, risk/benefit
- Concomitant drug use
- Health status and habits

Alan Guttmacher Institute. Sex and America’s Teenagers, 1994

FDA Advisory Committee’s Recommendation on Delay of Pelvic Exam

“Physical examination may be deferred until after initiation of oral contraceptives if requested by the woman and judged appropriate by the clinician.”


Common Contraceptive Choices

- Oral contraceptives: combined, progestin-only
- Long-acting
  - Injectable
  - Implant
- IUD: copper T, progestin-only
- Barrier contraceptives
- Spermicides
- Natural family planning
- Emergency contraceptives
- Female/male sterilization

Current Trends in Contraception

- Developing new delivery systems
- Increasing access to a full range of options
- Emphasizing better compliance
- Widening use of emergency contraception

Oral Contraceptives

- Dosing: every day same time
- Rx refill
- Cost
- Not so private
- Side Effects
- Contraindications
- See handout
- Combined
- Progesterone only

Levonorgestrel and Norethindrone

Plasma Levels After Single Oral Dose

Drugs That Decrease the Effectiveness of OCs

- Anticonvulsants
  - Barbituates (including phenobarbital and primidone)
  - Phenytoin
  - Carbamazepine
  - Toprimate
  - Vigabatin
- Anti-infectives
  - Rifampin
  - Griseofulvin

Drugs That Do Not Decrease the Effectiveness of OCs

- Anti-infectives
  - Tetracycline
  - Doxycycline
  - Ampicillin
  - Metronidazole
  - Quinolone antibiotics
Noncontraceptive Benefits of OCs

- **Cycle-related:**
  - Irregular cycles
  - Dysmenorrhea
  - Menorrhagia
  - Anemia
  - Functional ovarian cysts

- **Cancer reduction:**
  - Ovarian
  - Endometrial
  - Colorectal

**Studie Show OCs Reduce Risk of Ovarian Cancer**

<table>
<thead>
<tr>
<th>Study Reference</th>
<th>Relative Risk (log scale)</th>
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**Summary of RR with ever-use of OC:**

- 0.64 (95% CI, 0.57–0.73)

**Ovarian Cancer and OCs Risk Reduction by Years of Use**

- **Relative Risk (log scale):**
  - 0.1 to 1.0
  - 1.0 to 10.0

**Studies Show OCs Reduce Risk of Ovarian Cancer**

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**Ovarian Cancer and OCs Risk Reduction by Years of Use**

- **Relative Risk (log scale):**
  - 0.1 to 1.0
  - 1.0 to 10.0

**OCs Reduce Risk of Ovarian Cancer in High-Risk Women**

- **BRCA1 and BRCA2 mutations increase ovarian cancer risk**
  - 45% increased risk in carriers of BRCA 1
  - 25% increased risk in carriers of BRCA 2

- **OCs reduce ovarian cancer risk in carriers of BRCA1 or BRCA2**
  - 20% reduction with short-term OC use (≤3 y)
  - 60% reduction with long-term OC use (≥6 y)
Studies Show OCs Reduce Risk of Endometrial Cancer

- Horwitz et al., 1979
- Weiss et al., 1980
- Kaufman et al., 1980
- Kelsey et al., 1982
- Hulka et al., 1982
- Pettersson et al., 1986
- CASH, 1987
- Hulka et al., 1982
- Kelsey et al., 1982
- Ramcharan et al., 1981
- Trapido, 1983
- LaVecchia et al., 1986
- Pettersson et al., 1986
- Koumantaki et al., 1989
- WHO, 1991
- Brinton et al., 1983
- Jick et al., 1993
- Ramcharan et al., 1981

Relative Risk

0.00 0.50 1.00 1.50 2.00 2.50 3.00 3.50

Case Control

Cohort

Studies Show OCs Reduce Risk of Endometrial Cancer

Ovarian and Endometrial Cancers and Low-Dose OCs

- Ovarian cancer
- If protective effect is due to prevention of "incessant ovulation," low-dose OCs are likely protective
- Endometrial cancer
- Data on protective effect indicate no significant difference between 35 µg and >50 µg EE OCs

Bone Mass and OC Use Studies Examining Association

- 9/13 studies show positive effects
  - Up to 12% increase in BMD vs. control subjects
  - Greatest protection with OC use of ≥10 y
  - Primarily an estrogen effect; progestins may be important
- 4 studies show neutral effect
- No studies show decreased BMD with OC use

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Higher Bone Density More Likely in OC Users

- OC users
- Non-OC users

Higher Bone Density Association With Longer OC Use


Do 20 µg EE OCs Increase Bone Mineral Density?

- 20 µg EE OCs: significant increases in vertebral bone density (oligomenorrheic, perimenopausal women)
- 0.625 mg conjugated equine estrogens (HRT) = ~ 5 µg EE
- 5 µg EE doses: demonstrate bone-sparing properties
- 20 µg EE OCs: protective benefits are maintained in perimenopausal women

Acne

- Androgen-stimulated disorder
- All OCs:
  - Are antiandrogenic
  - Reduce free testosterone
  - Improve acne for most women

Acne Improvement with OCS

Reductions in Inflammatory Lesion Counts at Cycle 6* EE 35 µg/NGM (Ortho Tri-Cyclen) vs. Placebo

Reductions in Total Lesion Counts at Cycle 6* EE 35 µg/NGM (Ortho Tri-Cyclen) vs. Placebo

*Negative change indicates improvement.
Reductions in Inflammatory Lesion Counts at Cycle 6
EE 20 µg/LNG 100 µg (Alesse) vs. Placebo

Mean % Change

Study 1  Study 2

EE 20 µg/LNG 100 µg  Placebo

P<.05  P<.05

Reductions in Total Lesion Counts at Cycle 6
EE 20 µg/LNG 100 µg (Alesse) vs. Placebo

Mean % Change

Study 1  Study 2

EE 20 µg/LNG 100 µg  Placebo

P<.05  P<.05

How OCs Improve Acne
- ↓ Ovarian and adrenal androgen secretion
- ↑ SHBG to bind androgens
- ↓ 5α-reductase activity

Primary Dysmenorrhea
Incidence

<table>
<thead>
<tr>
<th>Grade</th>
<th>Wilson (n=88) Mean age 15</th>
<th>Sundell (n=460) Mean age 19</th>
<th>Age 24</th>
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</thead>
<tbody>
<tr>
<td>0 (none)</td>
<td>9%</td>
<td>28%</td>
<td>33%</td>
</tr>
<tr>
<td>1 (mild)</td>
<td>27%</td>
<td>35%</td>
<td>35%</td>
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<tr>
<td>2 (moderate)</td>
<td>41%</td>
<td>23%</td>
<td>22%</td>
</tr>
<tr>
<td>3 (severe)</td>
<td>23%</td>
<td>15%</td>
<td>10%</td>
</tr>
<tr>
<td>Absenteeism*</td>
<td>26%</td>
<td>51%</td>
<td>34%</td>
</tr>
</tbody>
</table>

* Missed classes or work.

Primary Dysmenorrhea

- Reduction of dysmenorrhea was the most statistically and clinically significant predictor of consistent OC use
- Adolescents with severe dysmenorrhea who experienced positive effects (decreased cramping or flow) were 8 times more likely to be consistent pill users (missed ≤3 pills per month) than others

Primary Dysmenorrhea

- 50% of women and 80% of adolescents report pain with menses
- OCs reduce menstrual fluid volume and prostaglandin levels
- OCs provide marked improvement of symptoms
- NSAIDs complement OC use
How OCPs Improve Primary Dysmenorrhea

- By ovulation inhibition, progesterone-stimulated endometrial prostaglandin production is reduced.
- By reducing menstrual flow, which contains prostaglandins.

OC Compliance

A Real Concern with Adolescents

- Daily pill taking habit difficult.
- Cost considerations.
- Obtaining refills.
- Misinformation about the pill.

Reported Pill Use vs. Actual Pill Use

Pill-Taking Behaviors by Age

Reasons for OC Discontinuation

All Ages
What Happens When Women Discontinue OCs

- 42% discontinue without consulting their healthcare provider
- 19% discontinue without selecting another contraceptive method
- 69% choose a less-effective contraceptive method

Patients at Risk for BTB

- First-time users
- Inconsistent users
- Users at risk for chlamydial cervicitis and endometritis
- Smokers

Breakthrough Bleeding in OC New Starts

35 µg EE OC vs. Two 20 µg EE OCs

No significant differences

Breakthrough Bleeding in OC Switchers

35 µg EE OC vs. Two 20 µg EE OCs

No significant differences

OC Formulations and BTB

- Rates reported for different OCs are highly variable depending on study design and other factors
- Few randomized, prospective studies directly compare BTB between OCs
- Data do not support perception that 20 µg EE OCs generally have more BTB than 30–35 µg EE OCs

BTB May Signal Chlamydia

- Chlamydial infections are common in women of childbearing age — detected in 9.2% of female military recruits
- BTB in women previously well regulated on OCs is an added marker for chlamydial infection
- 29% of OC users with BTB tested positive for *Chlamydia trachomatis* vs. 11% without BTB but at high risk
Smoking Affects Rates of BTB

Relative Risk of Estrogen-Related Side Effects
35 µg EE OC vs. Two 20 µg EE OCs

Adolescents’ Anticipated vs. Reported Side Effects
EE 20 µg/LNG 100 µg Formulation

Relative Risk of
Event
Alesse
Placebo
P-Value
Adverse event
Breast tenderness
Nausea
20% report fear of weight gain is a reason they would not take or stop taking OCs
27% of those who had never taken OCs say, among other reasons, this was because of fear of weight gain
17% of current or previous OC users cite fear of gaining weight as a reason for discontinuation

Women’s Perceptions About Weight Gain and OCs

Weight Gain Is Not A Trivial Concern for OC Users

- Adolescents
  - Major fear leading to discontinuation
  - 85% of suburban teens cited weight gain as an important concern
- Adult women
  - Common reason for self-initiated discontinuation

- 20% report fear of weight gain is a reason they would not take or stop taking OCs
- 27% of those who had never taken OCs say, among other reasons, this was because of fear of weight gain
- 17% of current or previous OC users cite fear of gaining weight as a reason for discontinuation


Controlled Studies Fail to Show Weight Gain Linked to OC Use

Goldzieher et al., 1971
Placebo-controlled, double-blind crossover (N=380)
Weight gain (>5 lb) occurred in approximately 25% of women; no significant difference between placebo and OC groups (>50 µg EE)

Reubinoff et al., 1995
Prospective, randomized (N=49)
No statistical difference in weight gain (>0.5 kg) between OC users and nonusers (50 µg EE)

Hordinsky et al., 2000
Placebo-controlled, double-blind crossover (N=721)
No statistical difference in mean weight change after 6 mo between OC users and nonusers (EE 20 µg/LNG 100 µg, Alesse)

The Press Underreports Studies of OC Benefits

Media emphasizes negative rather than positive news about OCs
  - All studies showed positive health effects
  - 8 out of 9 studies ignored by major newspapers

Management of Side Effects

Preventive/Anticipatory Guidance
- Acknowledge that side effects can be bothersome and uncomfortable
- Discuss breakthrough bleeding, nausea, weight gain at initial visit
- Set realistic expectations and counsel
  - Most side effects improve over time
  - Acne improvement is not immediate

How to Improve Successful Use of OCs
- Emphasize the many noncontraceptive benefits
- Cue pill-taking to daily activity
- Provide spare pack; advise to keep as emergency backup
- Provide written instructions
- Train office contact person to respond to calls

Improving Successful OC Use

Anticipatory Guidance
- Individualize counseling to patient’s concerns and history
- Breakthrough bleeding
- Amenorrhea
- Side effects decrease over time
- Demonstrate how to use the actual pill pack
- Missed pills
  - “Don’t stop taking the pills before calling me”

Adolescent Counseling
- Caution that OCs do not prevent STDs
- Discuss condom use: "How are you protecting yourself from AIDS?"
- Ask how she plans to discuss condom use with her partner
- Discuss emergency contraception
Depo Provera (3-month shot)

- Synthetic progesterone
- Private
- Requires clinic visit Q 3 months
- Effective in 24 hours
- Side Effects
- Contraindications
  - Unexplained vaginal bleeding
  - Pregnancy

Comparison of New Contraceptive Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Oral</th>
<th>Injectable</th>
<th>Implant</th>
<th>Ring</th>
<th>Patch</th>
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<tbody>
<tr>
<td>Effective</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Contraceptive Implant</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
| Levonorgestrel Intrauterine System: Mirena
  - Releases 20 µg of levonorgestrel per 24 hrs
  - Duration: 5 years
  - Packaged with sterile inserter
  - High efficacy
  - Pearl Index of 0.1

Implanon Efficacy, Safety and Tolerability

- No pregnancies in 1,200 women-years of exposure
- Good safety profile
- Irregular bleeding is most common adverse effect
- Requires clinician visit for initiation and discontinuation
- Single implant systems using newer progestins may solve some of the adverse effects and problems presented by earlier implants

Levonorgestrel Intrauterine System: Mirena

- Requires clinician visit for initiation and discontinuation
- Early spotting
- Significant reduction in menstrual blood loss and high rate of amenorrhea
- High rates of continuation
**Vaginal Ring: NuvaRing**
- NuvaRing releases 15 µg of ethinyl estradiol and 120 µg of etonogestrel daily
- Worn for 3 out of 4 weeks
- Self insertion and removal
- Pregnancy rate 0.65 per 100 woman-years

**NuvaRing Efficacy**

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<thead>
<tr>
<th>NuvaRing to-Treat</th>
<th>NuvaRing Protocol</th>
</tr>
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<tbody>
<tr>
<td>Women</td>
<td>1,145</td>
</tr>
<tr>
<td>Treatment cycles</td>
<td>12,109</td>
</tr>
<tr>
<td>Pregnancies</td>
<td>6</td>
</tr>
<tr>
<td>Pearl Index</td>
<td>0.65 (0.08–1.16)</td>
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**NuvaRing Cycle Control and Tolerability**
- Good cycle control
- Irregular bleeding was rare (2.6% - 6.4% of evaluable cycles)
- Withdrawal bleeding occurred (97.9% - 99.4% of evaluable cycles)
- Well tolerated and well accepted by users and their partners (only 5% of partners objected to use)

**NuvaRing Compared to OC: Irregular Bleeding**

*P<0.001 for COC vs NuvaRing

**Contraceptive Patch: Ortho Evra**
- Patch contains 6 mg norelgestromin and 0.75 mg ethinyl estradiol
- Delivers continuous systemic doses of hormones
- 150 µg norelgestromin (NGMN)
- 20 µg ethinyl estradiol (EE)
- Direct comparisons to oral contraceptive delivery doses cannot be made

**Ortho Evra Efficacy and Compliance**
- High Efficacy
  - Overall Pearl Index of 0.88
  - After 6 cycles, overall pregnancy possibility is half that of OC users
  - May be less efficacious in women ≥198 lb (90 kg)
  - NIH study in progress
  - Compliance is superior with Ortho Evra compared to OC
  - Ortho Evra compliance unaffected by age
  - Lower compliance with OC in younger compared with older subjects
Conclusions

- Clinicians should not assume they know what a woman’s contraceptive needs are
- After listening to a woman’s concerns, counseling should be non-directive and informative
- A menu of contraceptive options should be presented to all reproductive-aged women
- Consider using computer-based instruction or videos before the clinician consult to optimize education
- With good counseling, women will select a contraceptive method that best suits their needs