A Vignette-Based Approach to Addressing Hormonal Contraception

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Disclosures
> David A. Grimes, MD: Speaker for Bayer HealthCare Pharmaceuticals, Duramed Research, Inc., a subsidiary of Barr Pharmaceuticals, Ortho Women's Health and Urology, Wyeth Pharmaceuticals
> Consultant for Bayer HealthCare Pharmaceuticals, Duramed Research, Inc., a subsidiary of Barr Pharmaceuticals, Schering-Plough, Ortho Women's Health and Urology

Disclosures (continued)
> Receives research support from Ortho Women's Health and Urology and Wyeth Pharmaceuticals

Note: Staff and committee disclosures listed in packet

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Learning Objectives
• Recognize where unnecessary discontinuation of hormonal contraceptives may occur
• Apply principles of patient-centered care in provision of hormonal contraceptives
• Use effective counseling strategies for candidates of hormonal contraceptives
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“Medical care should be inspired by compassion and guided by science.”
Bertrand Russell


Cornerstones of Ideal Contraceptive Counseling

- Appreciate interplay between hormonal contraceptives and clinical conditions
- Address risks caused by unplanned changes in contraceptive methods
- Understand and communicate benefits and risks
- Provide a patient-centered approach

Appreciate Interplay

- Challenges between hormonal contraceptives and certain clinical conditions
- Conditions associated with use of hormonal contraception
- Hormonal contraception in patients who have medical conditions

Address Risks Caused by Unplanned Changes in Methods

<table>
<thead>
<tr>
<th>Unintended Pregnancies Each Year</th>
<th>Unintended Pregnancies Using Contraception</th>
</tr>
</thead>
<tbody>
<tr>
<td>50%</td>
<td>50%</td>
</tr>
</tbody>
</table>

Finer LG. Perspect Sex Reprod Health. 2006; Moreau C. Contraception. 2007.
Finer LS. In Brief. 2008.

Women Often Discontinue Hormonal Contraception

Discontinue use by 6 months: 28%
Discontinue use by 1 year: 33% - 50%


Understanding Benefits and Risks

Which 30-year-old female non-smoker has the highest risk of VTE?

- Woman using copper IUD
- Woman using low-dose COCs
- Woman who is pregnant
- Woman in postpartum period

2008 Reproductive Health
Education • Research • Advocacy
### Absolute Risk of VTE

<table>
<thead>
<tr>
<th>Condition</th>
<th>Incidence per 100,000 woman-years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-dose pills</td>
<td>10–15</td>
</tr>
<tr>
<td>Desogestrel-containing pills &amp; probably patch</td>
<td>20–30</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>95.8–172</td>
</tr>
<tr>
<td>Postpartum period</td>
<td>551.2</td>
</tr>
<tr>
<td>Each symbol = 100 woman-years</td>
<td></td>
</tr>
</tbody>
</table>


### Patient-Centered Approach

- Avoid recitation of facts
- Appreciate link to sexuality
- Ask: sexual history, partner status, and reproductive health plan
- Recognize influence of experience with hormonal contraception

### Reproductive Health Plan

**?** How important is it to you to avoid pregnancy now?

**?** What would you do if you became pregnant now?

**?** What is your desired family size?

**?** What is your intended timing for pregnancy?

**?** Are there health issues that you need to address before you become pregnant?

### Essential Components of Contraceptive Counseling

![Contraceptive Counseling Diagram]

- **Patient concerns**
- **Collect information**
- **Preferences**
- **Support final decision**
- **Discuss considerations**

### Vignette 1: Sofia

- 20-year-old college sophomore
- Presents for emergency contraception
- One partner during the past year
- Unprotected intercourse on day 15
- Self-discontinued COCs due to spotting

Which of the following is correct about expected bleeding patterns after taking EC?

- Timing and duration probably unchanged
- First menses longer than usual
- Bleeding duration probably shorter
- Pregnancy testing if no menses within 7 days after she normally would have expected her period to begin

*Raymond EG. Contraception. 2006.*
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Key Counseling Points

- Ask about concerns about EC
- Discuss effectiveness of desired methods
- Suggest ways to improve adherence for ongoing methods

Vignette 1: Sofia

- Menses start 4 days after EC
- She begins contraceptive patch
- Provider counsels about expected bleeding patterns

Hormonal Contraception and Unwanted Bleeding

- Frequent when changing or initiating method
- Common reason for discontinuation of COCs
- Often caused by missed or delayed pills
- Requires education in advance to avoid discontinuation

Bleeding Patterns and Hormonal Contraception

<table>
<thead>
<tr>
<th>Method</th>
<th>Initial</th>
<th>Longer Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>COCs</td>
<td>Spotting or BTB</td>
<td>Regular menses</td>
</tr>
<tr>
<td>Ring</td>
<td>Spotting or BTB</td>
<td>Irregular</td>
</tr>
<tr>
<td>Patch</td>
<td>Bleeding (BTB)</td>
<td>6% with absence of bleeding at 3 months</td>
</tr>
<tr>
<td>Progestin-only pills</td>
<td>Spotting or BTB</td>
<td>5% with absence of bleeding at 6 months</td>
</tr>
<tr>
<td>DMPA</td>
<td>Spotting or BTB</td>
<td>12% with absence of bleeding at 12 months</td>
</tr>
<tr>
<td>Implanon</td>
<td>Spotting or BTB</td>
<td>Lessens over time &lt;20% with absence of bleeding at 24 months</td>
</tr>
</tbody>
</table>

Managing Breakthrough Bleeding

- Check for missed or mistimed pills
- Rule out pregnancy and infection
- Review medications
- Evaluate for gastrointestinal disturbances
- Change formulations, delivery route
- Continue COC formulation with addition of NSAIDs or estrogen support

Vignette 2: Maria

- 30-year-old Latina, non-smoker, mother of two
- Blood pressure normal
- Weighs 189 pounds, has BMI of 30.9
- 5'5" tall
- Desires another child in future
- Has sedentary job
- Uses condoms, wants greater effectiveness

Vignette 2: Maria

Is Maria ineligible for COCs because of her weight?
- Not applicable: Does not meet the criteria for obesity
- Yes: Research shows high risk of failure in obese women
- No: Studies show small increase in risk

BMI Based on Height and Weight

<table>
<thead>
<tr>
<th>Type</th>
<th>BMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal Weight</td>
<td>18.5-24.9</td>
</tr>
<tr>
<td>Overweight</td>
<td>25-29.9</td>
</tr>
<tr>
<td>Obese</td>
<td>≥30</td>
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</tbody>
</table>

BMI Calculator


Obesity and Decreased Effectiveness of COCs

Attributable risk from obesity = 2-4 pregnancies per 100 woman-years

<table>
<thead>
<tr>
<th>BMI</th>
<th>Hazard Ratio</th>
<th>Typical Failure Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20</td>
<td>0.1</td>
<td>No Method: 85%</td>
</tr>
<tr>
<td>20-24.9</td>
<td></td>
<td>Spermicides: 29%</td>
</tr>
<tr>
<td>25-29.9</td>
<td></td>
<td>Diaphragm: 16%</td>
</tr>
<tr>
<td>≥30</td>
<td></td>
<td>Condom (male): 15%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Combined pill in obese women*: 13%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Combined pill and progestin-only pill: 8%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Contraceptive patch or vaginal ring: 8%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Copper IUD or LNG-IUS: &lt;1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hormonal implant: &lt;1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sterilization: &lt;1%</td>
</tr>
</tbody>
</table>

*Includes data on combined oral contraceptives only; does not include progestin-only pills

Trussell J. In: Contraceptive Technology. 2007.
Obesity and COC Failure

- Risk is higher with lower estrogen doses
- Risk of contraceptive failure is about 50% higher among obese women
- Combined hormonal methods are still good options

Obesity and Combined Hormonal Contraceptives

- COCs
  - Effectiveness may be lower if woman is obese
- DMPA
  - Effectiveness same if woman is obese
- Implanon Ring
  - Data on effectiveness and obesity not published

Obesity and Risk of VTE

Vignette 2: Maria

The following are contraceptive options for Maria:
- COCs
- Other combined hormonal contraceptives
- Copper IUD
- LNG-IUS

Provider should:
- Review contraceptive options
- Counsel and support weight reduction
- Encourage an exercise plan
- Schedule visit for weight-reduction follow-up
- All of the above

Obesity and Risk of VTE

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Key Counseling Points
• Provide risk information
• Encourage practical steps for weight loss
• Review reproductive health plan
• Schedule follow-up visits for preventive health care

Vignette 3: Elizabeth
Do you:
• Check bone mineral density at hip and spine?
• Tell her to stop DMPA?
• Neither

Bone Densitometry Testing
• Studies of bone effects of DMPA are based on surrogate markers
• Testing is NOT generally indicated in women who use DMPA
• No standards exist for evaluating BMD in pre-menopausal women

Vignette 4: Susan
• 52-year-old married non-smoker
• Regular menstrual cycles for 2 years
• Night sweats have disrupted sleep for 9 months
• Fatigue causes problems at work
• Uses condoms

Key Counseling Points
• Provide information about bone loss
• Discuss benefits and risks of various options
• Ask about concerns regarding menopause
Vignette 4: Susan

Which has not been shown to reduce vasomotor symptoms?
- Regular exercise
- Hormonal therapy with estrogen-progestin
- Topical progesterone
- DMPA

Options:
- Lifestyle changes to reduce hot flashes
- Trial of COCs or other combined hormonal methods
- Other interventions based on history and physical findings

Key Counseling Points
- Focus on patient’s concerns
- Collect information on contraceptive preference
- Provide information on COCs and other combined hormonal methods

Vignette 5: Marianna
First step you take:
- Prescribe topical testosterone
- Switch COCs
- Ask about the nature of “libido problem”
- Send her for sex counseling

Sexual Dysfunction in Women
- Diminished desire
- Difficulties with arousal or lubrication
- Difficulty in achieving orgasm or inability to do so
- Associated pain
Vignette 5: Marianna
What is a possible cause of diminished sexual interest?
- Erectile dysfunction in partner
- COCs
- Sleep deprivation
- Endometriosis
- All of the above

Vignette 5: Marianna
Which should Marianna’s provider check?
- Total and free testosterone
- Dehydroepiandrosterone-sulfate (DHEA-S)
- Sex hormone-binding globulin (SHBG)
- None of the above

COCs and Sexual Dysfunction
- Inconsistent association
- Wide range of normal free testosterone
- No valid marker available
- Most women with low values do not have dysfunction
- Some COC users report improved sexual function

Androgen Therapy in Women
- Increases desire and arousal in women with surgical menopause
- With estrogen, improves sexual function in postmenopausal women
- May improve function in premenopausal women who have intact ovaries
- Long-term effects not known

Options to discuss with patient:
- Try stopping COCs
- Look for help with care-giving responsibilities
- Start stress-reduction techniques

Key Counseling Points
- Outline her concerns
- Collect information on lifestyle
- If indicated, suggest evaluation of partner
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Vignette 6: Jessica
- 25-year-old graduate student, healthy, non-smoker
- Known to have a gene (BRCA) mutation
- Mother developed breast cancer at 39
- Uses condoms
- Wants more effective contraception

Is Jessica a candidate or ineligible for COCs?
- Ineligible due to increased risk of breast cancer
  - A candidate because COCs confer no increased risk in BRCA-positive women
  - A candidate if negative for BRCA1

BRCA Mutations
Lifetime risk of breast cancer 60% to 85%
Likelihood of BRCA higher if:
  - Young age at diagnosis
  - Bilateral breast cancer
  - History of both breast and ovarian cancer
  - Multiple cases in family
  - Both breast and ovarian cancer in family
  - Ashkenazi Jewish heritage

Contraceptive Options
- All combined hormonal methods
- Progestin-only methods
- Barrier methods
- IUDs

Key Counseling Points
- Ask about family history
- Provide information on use of COCs in women with BRCA gene
- Ensure that she understands the importance of continued breast cancer screening

Take-Home Points
- Myths can restrict contraceptive choices
- Restrictions have consequences
- Information allows for informed decisions
- Reproductive plan encourages holistic approach

