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## A Vignette-Based Approach to Addressing Hormonal Contraception

David A. Grimes, MD  
September 18, 2008



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## Acknowledgment

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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
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## 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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## Expert Medical Advisory Committee

Vanessa Cullins, MD, MPH, MBA (co-chair)  
Linda Dominguez, RN-C, NP  
Kamini Geer, MD  
David Grimes, MD (co-chair)  
Scott Spear, MD  
Sandy Worthington, MSN, WHNP-BC, CNM

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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

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Grimes DA. JAMA. 1993.

### Cornerstones of Ideal Contraceptive Counseling

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- 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

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### Appreciate Interplay

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

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### Address Risks Caused by Unplanned Changes in Methods

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

### Women Often Discontinue Hormonal Contraception

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Potter LS. In: *Patient Compliance in Medical Practice and Clinical Trials*. 1991.

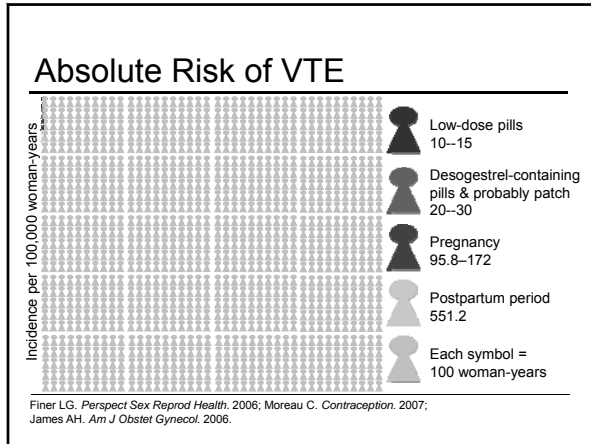
### Understanding Benefits and Risks

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

- A** Woman using copper IUD
- B** Woman using low-dose COCs
- C** Woman who is pregnant
- D** Woman in postpartum period

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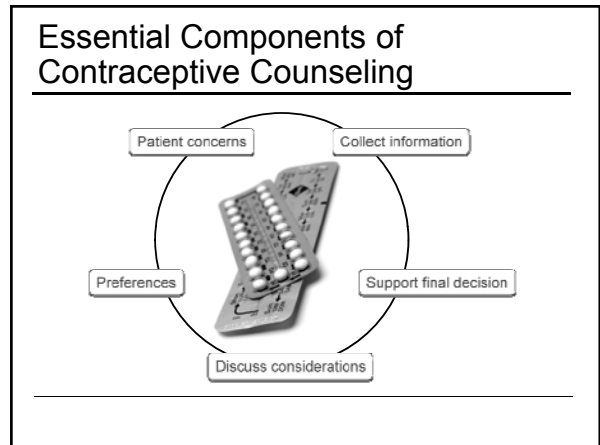


### Patient-Centered Approach

- 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?



### 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

### Vignette 1: Sofia

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

more...

Raymond EG. *Contraception*. 2006.

### Key Counseling Points

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

*more...*

### 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

Nelson A. In: *Contraceptive Technology*, 2007; Raymond EG. In: *Contraceptive Technology*, 2007.

### Bleeding Patterns and Hormonal Contraception

Method	Initial	Longer Term
COCs Ring Patch	Spotting or breakthrough bleeding (BTB)	Regular menses (except with continuous-use COCs)
Progestin-only pills	Spotting or BTB	Irregular 8% with absence of bleeding at 6 months
DMPA	Spotting or BTB	40-50% with absence of bleeding at 12 months
Implanon	Spotting or BTB	Lessens over time <20% with absence of bleeding at 24 months

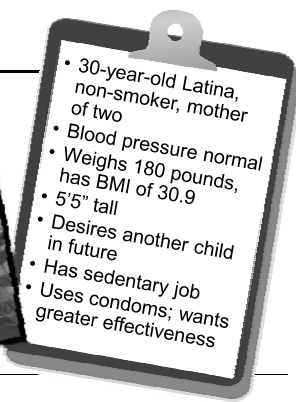
Hatcher RA. In: *Contraceptive Technology*, 2004a and 2004b; Nelson A. In: *Contraceptive Technology*, 2004; Nelson A. In: *Contraceptive Technology*, 2007; Raymond EG. In: *Contraceptive Technology*, 2007; Goldberg AB. In: *Contraceptive Technology*, 2007; Funk S. *Contraception*, 2005; Broome M. *Contraception*, 1990; Canto De Cetina TE. *Contraception*, 2001; Mishell DR Jr. *Am J Obstet Gynecol*, 1977.

### 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


Hatcher RA. In: *Contraceptive Technology*, 2004; Roy SN. *Drug Saf*, 2004; Lethaby A. *Cochrane Database Syst Rev*, 2002; Speroff L. In: *A Clinical Guide for Contraception*, 2005; Lopez LM. *Cochrane Database Syst Rev*, 2008.

### Vignette 2: Maria



- 30-year-old Latina, non-smoker, mother of two
- Blood pressure normal
- Weighs 180 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 ←

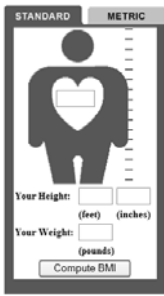
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### BMI Based on Height and Weight

Normal Weight BMI	Overweight BMI	Obese BMI
18.5-24.9	25-29.9	≥30

National Institutes of Health. Calculate Your Body Mass Index. Available at: [www.nhlbisupport.com/bmi/](http://www.nhlbisupport.com/bmi/).

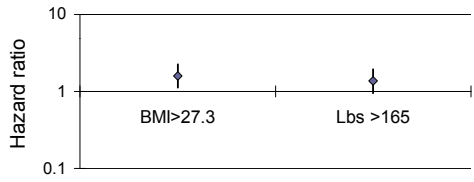
### BMI Calculator



National Institutes of Health. Calculate Your Body Mass Index. Available at: [www.nhlbisupport.com/bmi/](http://www.nhlbisupport.com/bmi/).

### Obesity and Decreased Effectiveness of COCs

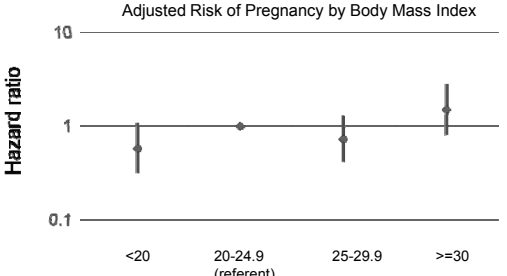
Attributable risk from obesity = 2-4 pregnancies per 100 woman-years



Holt VL. *Obstet Gynecol.* 2005.

### And...

#### Adjusted Risk of Pregnancy by Body Mass Index



Brunner LR. *Ann Epidemiol.* 2005.

### Typical Failure Rates

No Method	85%
Spermicides	29%
Diaphragm	16%
Condom (male)	15%
Combined pill in obese women*	13%
Combined pill and progestin-only pill	8%
Contraceptive patch or vaginal ring	8%
Copper IUD or LNG-IUS	<1%
Hormonal implant	<1%
Sterilization	<1%

\*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

Trussell J. In: *Contraceptive Technology*, 2004; Holt VL. *Obstet Gynecol*. 2005.


### Obesity and Combined Hormonal Contraceptives

<b>COCs Patch</b>	<b>DMPA</b>	<b>Implanon Ring</b>
Effectiveness may be lower if woman is obese	Effectiveness same if woman is obese	Data on effectiveness and obesity not published

Jain J. *Contraception*. 2004; Croxatto HB. *Hum Reprod*. 1999; Funk S. *Contraception*. 2005; Ziemann M. *Fertil Steril*. 2002; Oddsson K. *Contraception*. 2005; Ahrendt HJ. *Contraception*. 2006.


### Other Contraceptive Options for Obese Women

- Copper IUDs
- LNG-IUS
- Barrier methods
- Sterilization



Trussell J. *Contraception for Obese Women* [slide presentation]. 2007.

### Vignette 2: Maria




The following are contraceptive options for Maria:

- COCs
- Other combined hormonal contraceptives
- Copper IUD
- LNG-IUS

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### Vignette 2: Maria

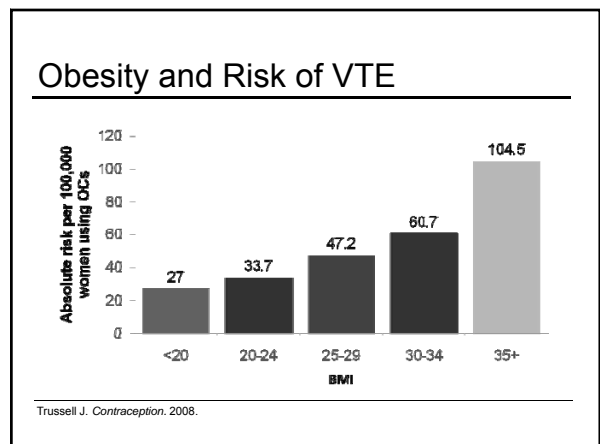


Provider should:


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

*more...*

National Institutes of Health. *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults*. 1998. Available at: [www.nhlbi.nih.gov/guidelines/obesity/ob\\_gdtns.pdf](http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdtns.pdf)



### Key Counseling Points

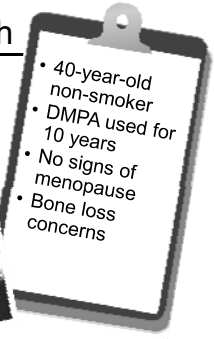



- Provide risk information
- Encourage practical steps for weight loss
- Review reproductive health plan
- Schedule follow-up visits for preventive health care

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### Vignette 3: Elizabeth




- 40-year-old non-smoker
- DMPA used for 10 years
- No signs of menopause
- Bone loss concerns

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more...

### Vignette 3: Elizabeth



Do you:

- Check bone mineral density at hip and spine?
- Tell her to stop DMPA? ←
- Neither

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### 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

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Seeman E. Bone. 2007.

### Key Counseling Points





- Provide information about bone loss
- Discuss benefits and risks of various options
- Ask about concerns regarding menopause

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### Vignette 4: Susan




- 52-year-old married non-smoker
- Irregular menses for 2 years
- Night sweats have disrupted sleep for 9 months
- Fatigue causes problems at work
- Uses condoms

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### Vignette 4: Susan




Which has **not** been shown to reduce vasomotor symptoms?

- Regular exercise
- Hormonal therapy with estrogen-progestin
- Topical progesterone ←
- DMPA

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### Vignette 4: Susan




Options:

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

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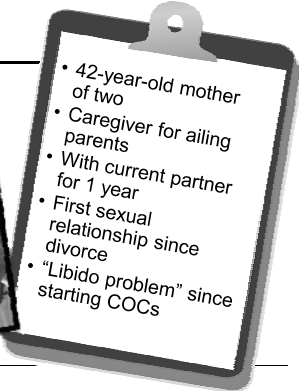

Nelson AL. In: *Contraceptive Technology*, 2007; Kuohung W. *Contraception*, 2000.

### 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



- 42-year-old mother of two
- Caregiver for ailing parents
- With current partner for 1 year
- First sexual relationship since divorce
- "Libido problem" since starting COCs

### Vignette 5: Marianna



First step you take:


- Prescribe topical testosterone
- Switch COCs
- Ask about the nature of "libido problem" ←
- Send her for sex counseling

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### 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 ←

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### 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 ←

more...

### 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


Davis SR. *JAMA*. 2005; Graham CA. *Psychoneuroendocrinology*. 2007.

### 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

Sherwin BB. *Psychoneuroendocrinology*. 1985; Watts BB. *Obstet Gynecol*. 1995; Lobo RA. *Fertil Steril*. 2003; Sarrel P. *J Reprod Med*. 1998; Goldstat R. *Menopause*. 2003.

### Vignette 5: Marianna




Options to discuss with patient:

- Try stopping COCs
- Look for help with care-giving responsibilities
- Start stress-reduction techniques


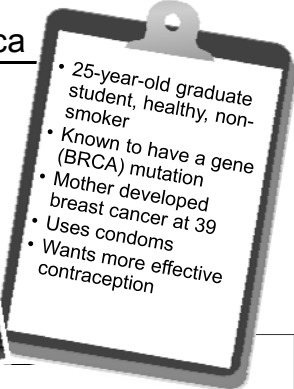
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### Key Counseling Points




- Outline her concerns
- Collect information on lifestyle
- If indicated, suggest evaluation of partner

### 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

### Vignette 6: Jessica



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

Brose MS. J Natl Cancer Inst. 2002; Thompson D. J Natl Cancer Inst. 2002; Frank TS. J Clin Oncol. 2002; Srivastava A. Oncology. 2001; Shattuck-Eidens D. JAMA. 1997; Couch FJ. N Engl J Med. 1997


### Contraceptive Options



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

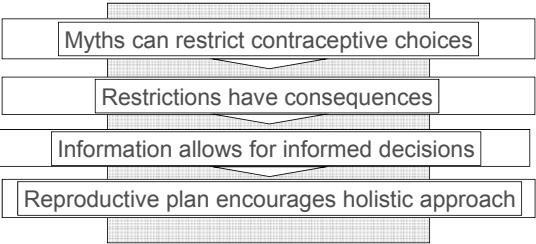
Milne RL. Epidemiol Biomarkers Prev. 2005.

### 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

### Expert Medical Advisory Committee



**Vanessa Cullins, MD, MPH, MBA (co-chair)**  
Vice President for Medical Affairs  
Planned Parenthood Federation of America  
New York, NY



**Linda Dominguez, RN-C, NP**  
Southwest Women's Health and Planned Parenthood of New Mexico  
Albuquerque, NM



**Kamini Geer, MD**  
Fellow, Family Planning; Montefiore Medical Center  
Department of Social and Family Medicine  
Bronx, NY

*more...*

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**David Grimes, MD (co-chair)**  
Vice President of Biomedical Affairs  
Family Health International  
Durham, NC



**Scott Spear, MD**  
Medical Director  
Planned Parenthood of the Texas Capital Region  
Austin, TX



**Sandy Worthington, MSN, WNHP-BC, CNM**  
Program Director  
Planned Parenthood Federation of America  
Philadelphia, PA