Contraception in Medically Complicated Women
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Disclosure Statement
October 3, 2014
I have nothing to disclose.

Proportion of Women Using Contraceptive Method

Contraceptive Prevalence & Maternal Deaths

Effect of Unmet Need for Contraception

Unintended, despite method used
49%

Intended

Unintended, no method used

6.4 Million U.S. Pregnancies Annually

Objectives

Inspire you to prioritize patient-centered contraceptive counseling and provision in your practice

Make you comfortable using CDC Medical Eligibility Criteria (MEC) and the Selected Practice Recommendations

Review challenging contraceptive cases

1: STI and IUD   2: Counseling   3: VTE
4: Obesity, DM   5: Implant VB

Are you familiar with the US Medical Eligibility Criteria for Contraception?

a. Yes
b. No
Are you familiar with the US Selected Practice Recommendations for Contraception?

a. Yes
b. No

Can my patient use this method?

US Medical Eligibility Criteria (MEC)

<table>
<thead>
<tr>
<th></th>
<th>Can use the method</th>
<th>No restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Can use the method</td>
<td>Advantages generally outweigh theoretical or proven risks.</td>
</tr>
<tr>
<td>2</td>
<td>Should not use method unless no other method is appropriate</td>
<td>Theoretical or proven risks generally outweigh advantages</td>
</tr>
<tr>
<td>3</td>
<td>Should not use method</td>
<td>Unacceptable health risk</td>
</tr>
</tbody>
</table>
For each method... how to use?

- When to start – “anytime if reasonably sure that she is not pregnant”
- How long to use backup
- Special considerations – explain recommendations by MEC
- Missed or late doses

“Reasonably Sure Not Pregnant”

BOX 1. How To Be Reasonably Certain that a Woman Is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- It is 67 days after the start of normal menses
- She has had sexual intercourse since the start of last normal menses
- She has been correctly and consistently using a reliable method of contraception
- It is 67 days after spontaneous or induced abortion
- She is within 4 weeks postpartum
- She is fully or nearly fully breastfeeding (exclusively breastfeeding or the use of no more than one [65%] of foods and breastfed up to 6 months postpartum

With exception of IUD – can start and do pregnancy test in 2-4 weeks


Case #1

23 yo G0 is interested in using intrauterine contraception. When she was in college, she had Chlamydia. She has had 3 male partners in the past year.

Every 3-10 Years: Intrauterine Devices (IUD, IUC, IUD, IUS)

- **Copper T 380A IUD**
  - 0.8% failure (1 yr)

- **Levonorgestrel Intrauterine System (LNG-IUS)**
  - Levonorgestrel 20 mcg/day
  - 0.2% failure (1 yr)
  - **New LNG IUS** – 14 mcg/day
    - 3 years
Lower Dose LNG IUD

- Lower dose of progestin (14 mcg v. 20 mcg)
- Smaller size - 28 mm x 30 mm (v. 32mm x 32mm)
  - 3.8 mm diameter (1 mm less)
- Equivalent efficacy, expulsion risk
- Possibly more bleeding/spotting days
- 6-12% amenorrhea (v. 20-50% higher dose)
- May appeal to some women given its smaller size and shorter duration of use

Nelson, Obstet Gyneco, 2013

IUD Review

- Current IUDs do NOT cause PID!!!
  - Transient increased risk at time of insertion
    - 9.7/1000 w/in 20 days
    - 1.4/1000 after 20 days
  - STI at time of insertion increases risk
- Beyond time of insertion
  - Overall decreased risk with LNG IUS
  - No increased risk with Copper IUD
- Okay to treat for PID with IUD in place


Routine GC/CT screening NOT necessary!

- Retrospective cohort, n=57,728 IUDs
- Evidence-based STI screening, treat if + test

Overall PID risk = 0.54%

Women appropriately selected for non-screening

Screened Women: Risk of PID
  - Same day = Pre-insertion
    OR=.997 (.64, 1.54)

Accurate screening time day of insertion


IUD: CDC Guidelines

- CDC Guidelines
- C=continue
- I=Initiate
- Past PID
- Current PID or cervicitis
- High risk STI: caution

Selected Practice Recommendations

- Give anytime reasonable not pregnant – for IUD this is most important
- Cu IUD – no backup
- LNG IUD - If within 7 days of period – no backup
- If > 7 days – backup x 7 days
- Address bleeding tx
- No need for string check
- Evidence-based STI and PID

Case #1

23 yo G0 is interested in using intrauterine contraception. When she was in college, she had Chlamydia. She has had 3 male partners in the past year.

Case #2

A 32 yo G3P1T2 presents asking for birth control. She has used the pill before, liked it, and wants it again. She was using the pill the two times she became pregnant and had abortions.

Contraceptive Counseling

- Preference-sensitive decision
- Patient-centered care
- Respect diverse priorities, concerns, experiences
  - Control
  - Safety concerns
  - Concern about or desire for side effects
  - Personal and friends’/family members’ experiences
  - Convenience
  - Efficacy
Contraceptive Counseling

- Develop awareness of your biases
- Engage in shared decision-making
- Questions to pose patients
  - Which method did you come today wanting to use?
  - Are you interested in one of the most effective? Convenient? What does convenient mean to you?
  - When – if ever – do you want a (another) child?
  - What method(s) have you used in the past?
  - What are you doing to protect yourself from STIs?
  - What side effects are you willing to accept or desire?

Contraceptive Method Use, U.S.*

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

9% failure rate in 1 year

? How many pills, on average, do women forget to take each month (not including placebo)?

Oral Contraceptives 2010: Missed Pills

Typical use ≠ Perfect use
Contraception Methods

Natural Family Planning

<table>
<thead>
<tr>
<th>Contraceptive Method</th>
<th>Failure Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Perfect Use</td>
</tr>
<tr>
<td>No Method</td>
<td>85%</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>4%</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>&lt;1%</td>
</tr>
<tr>
<td>Two-Day Method*</td>
<td>4%</td>
</tr>
</tbody>
</table>

* Including Cycle Beads

Trussell J. Contraceptive Efficacy. In Contraceptive Technology.

Barrier Methods

<table>
<thead>
<tr>
<th>Contraceptive Method</th>
<th>Failure Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Perfect Use</td>
</tr>
<tr>
<td>Condoms</td>
<td>2%</td>
</tr>
<tr>
<td>Cervical Cap (parous/nullip)</td>
<td>26%/9%</td>
</tr>
<tr>
<td>Sponge (parous/nulliparous)</td>
<td>20%/9%</td>
</tr>
<tr>
<td>Female Condoms</td>
<td>5%</td>
</tr>
<tr>
<td>Diaphragm</td>
<td>6%</td>
</tr>
</tbody>
</table>

Trussell J. Contraceptive Efficacy. In Contraceptive Technology.

Hormonal Methods

<table>
<thead>
<tr>
<th>Contraceptive Method</th>
<th>Failure Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Perfect Use</td>
</tr>
<tr>
<td>Progestin Pills</td>
<td>0.3%</td>
</tr>
<tr>
<td>Combined Pill/Patch/Ring</td>
<td>0.3%</td>
</tr>
<tr>
<td>Combined 1-month injection</td>
<td>0.3%</td>
</tr>
<tr>
<td>3-Month Injection</td>
<td>0.2%</td>
</tr>
<tr>
<td>Implants</td>
<td>0.05%</td>
</tr>
<tr>
<td>LNG IUD</td>
<td>0.2%</td>
</tr>
<tr>
<td>Copper IUD/LNG IUS</td>
<td>0.8%</td>
</tr>
</tbody>
</table>

Trussell J. Contraceptive Efficacy. In Contraceptive Technology.
### Daily: Combined Oral Contraceptives

- Estrogen + progestin
- Traditional prescription flawed
  - Daily x 3 weeks / 1 week off
- Extended cycle may ↑efficacy
- Movement toward OTC

### Extended Cycle: Shortened hormone-free week

- 23, 24 or 26 days hormones + 2-5 d placebo
  - Decreased ovarian activity at end of placebo
  - Shorter withdrawal bleeds
  - Similar breakthrough bleeding

24-day hormone pill - lower pregnancy rate
6.7% v. 4.7% over 3 years — HR 0.7 (CI 0.6-0.8)
- 3 FDA-approved products in US

### Extended Cycle: Fewer Hormone-free Weeks

- 12 weeks hormone/1 week off
  - 84 days LNG 150 µg/EE 30 µg; 7 days placebo
  - Decreased breakthrough bleeding over time

- Continuous for one year
  - Increased spotting in first six months
  - Median 1.5 days spotting in last trimester
- FDA-approved: ethinyl estradiol and levonorgestrel
  - 90 mcg levonorgestrel + 20 mcg EE

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**Patient Education Materials**

Many women do not understand efficacy and/or have other priorities.

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*Baerwald, Contraception, 2004.*

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*Spona Contraception, 1998; Bachman Contraception, 2004; Endrikat Contraception, 2001; Dinger ObGyn, 2011.*

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*Anderson Contraception, 2003.*
Combined Hormonal Contraception

- Give anytime reasonable not pregnant
- If within 5 days of period – no backup
- If > 5 days – backup x 7 days
- Check blood pressure
- Give up to 1-year supply
- If 2+ days missed – backup x 7 days
- If in last week – omit HFI

Case #2

A 32 yo G3P1T2 presents asking for birth control. She has only used the pill before and liked it. She became pregnant on the pill each time she became pregnant.

Case #3

19 yo G0, newly sexually active, wants to start the contraceptive vaginal ring. But she is concerned about what she has read in the news about the ring causing blood clots.

Danger in the Ring

Why Is Potentially Lethal Contraceptive NuvaRing Still on the Market?

by Tawnya Peacock
DVT Risk with the Contraceptive Vaginal Ring (CVR)

- Retro cohort: 9,429,128 woman years
- Confirmed VTE events per 10,000 woman years
  - Non-users of hormonal contraception 2.1
  - Combined Oral Contraceptives 6.2 (RR 3.2)
  - Transdermal patches 9.7 (RR 7.9)
  - Vaginal ring 7.8 (RR 6.5)

Ring +1.6 additional cases / 10,000 women-years. Adjusted Rate Ratio 1.9 (1.3-2.7) v. COC

DVT Risk with the Contraceptive Vaginal Ring (CVR)

- Pros cohort - 66,489 woman years of observation
- Confirmed VTE events per 10,000 woman years
  - LNG COC 7.8
  - All COC 9.2
  - Vaginal ring 8.3

Ring - no increased risk compared with any pill. HR 0.8 (0.5-1.5)

DVT Risk with the Contraceptive Vaginal Ring (CVR)

- Sidney, et al., Contraception, 2013
- Retrospective cohort - 573,680 women
- Confirmed VTE events per 10,000 woman years
  - All COC – new users 8.2 (7.9-6.6)
  - Vaginal ring 11.3 (4.26-32)

Ring - in adjusted analyses no increased risk compared with the pill. HR 1.1 (0.6-2.2)
Case #3

19 yo G0, newly sexually active, wants to start the contraceptive vaginal ring.

- Conflicting level 2 evidence – may cause slight increase risk relative to COC
- Attributable risk very, very small
- Level I evidence that women use it correctly compared with pill
- May cause fewer unintended pregnancies and therefore fewer VTE overall

VTE & Oral Progestin Type

- Desogestrel and drospirenone COCs may increase risk of VTE
- BUT... Absolute risk remains low
  - Non-pregnant, no COCs: 2-4 per 10,000 ♀ yrs
  - Levonorgestrel COCs: 5.0 per 10,000 ♀ yrs
  - Desogestrel COCs: 6.5 per 10,000 ♀ yrs
  - Drospirenone COCs: 7.8 per 10,000 ♀ yrs

Choosing a COC

- Careful with very low-dose estrogen – ↑ bleeding
- Monophasic fine
- Levonorgestrel may cause fewer VTE
- No clear benefit of drospirenone
  - PMDD: fewer sx 6 months – equivalent at 2 yr
  - Acne: Equivalent to other pills

30 or 35 mcg EE + levonorgestrel
Shortened or erased placebo week if possible
Monophasic

CDC MEC

- All progestin-only methods are safe even if:
  1) Current VTE
  2) No anti-coagulation
  3) Provoked or unprovoked VTE
Case #4

38 yo G2P1T1 woman is seeking contraception. She had pre-eclampsia during her last pregnancy but otherwise reports she is healthy. Physical exam: Wt= 226 lbs, Ht= 5’5” (BMI=37.6) BP=138/89

Obesity and Contraception

Obesity & Contraceptive Efficacy:
- OCPs: no clear difference\(^1\)\(^2\)
  Longer time to steady state\(^1\)
- Ring: no difference\(^1\)\(^2\)
- ETG implant:
  -lower serum level,
  but still inhibitory\(^4\)
- Patch: increased failure\(^5\) if >90kg
  - BUT BMI more relevant measure
  - No effect with BMI\(^1\)\(^2\)
- IUC: no difference
- DMPA: no difference\(^1\)
  -may need longer needles

Obesity and Contraceptive Risks
- VTE risk
  - COCs & obesity are independent RF for VTE
  - Obesity doubles risk of VTE
- No data show synergistic, increased risk
- Risk is lower than pregnancy (29/10,000 ♀-yrs)

\(^1\) Lopez LM 2010 Cochrane
\(^2\) McNicholas 2013 Obstet Gynecol
\(^3\) Edelman, Contraception, 2009; \(^4\) Wesshoff 2005
\(^5\) Ziemann 2002 Fertil Steril
## Contraception & Weight Gain

- **COC, Patch, Ring:** none or age-expected change\(^1,3,6\)
- **LNG-IUS:** age-expected wt gain\(^4\)
- **ETG implant:** minimal if any effect\(^5\)

### References
1. O’Connell 2001 Contraception
2. Gallo 2004 Obstet Gynecol
3. Berenson 2009 AJOG
5. Darney 2009 Fertil Steril
6. Beksinka 2010 Contraception
7. Pantoja 2010 Contraception
8. Bonny 2010 Contraception

### Notes
- Ave 5-6 kg over 3-5yrs\(^3,6\)
- Baseline BMI:
  - BMI<25
  - BMI 25-30
  - BMI>30

## Metabolic Syndrome

- Constellation of findings which increase risk of CHD, stroke, & type 2 DM

### Three or more:
- Hypertension
- Insulin resistance
- Central obesity
- High triglycerides
- Low HDL

### Criteria
- **Hypertension**
  - Systolic ≥130/85

- **Insulin resistance**
  - FBS ≥100

- **Central obesity**
  - Waist circumference ≥35”

- **High triglycerides**
  - ≥150 mg/dL

- **Low HDL**
  - ≤50mg/dL

## CDC MEC

### Lipids
- **CHC:** TGL, HDL, LDL
- **PCOS:** improved LDL/HDL ratio\(^2\)
- **ETG implant:** Chol, LDL, HDL\(^4,5\)

### BP
- **OCPL:** 5% of OCP users develop reversible Htn (7mm Hg)\(^2\)

### Insulin Resistance

#### Women without DM:
- **COC:** No impact\(^1\)
- **Ring:** improved IR in PCOS\(^3\)
- **ETG implant:** no effect\(^3\)

#### Women with DM:
- **COC:** No RCTs. Increase in FBG 103-112
- **ETG implant:** no effect vs. non-obese women

### Note
- **Obese women:** DMPA increased IR v. non-obese women

### References
1. Winkler 2009 Contraception
3. WHO 1989 Contraception
4. Merki-Feld 2008 Clin Endocrinol
5. Inal 2008 Eur J Contracept Rept Health Care
7. Grimes 2009 Cochrane Database
8. Battaglia 2009 Fertil Steril
10. Skouby 1984 Fertil Steril
11. Bonny 2010 Contraception
12. CDC 1984 CPRS
13. CDC 1984 CPRS
Bariatric Surgery & Contraception

- Advisable to wait 1-2 years after surgery before planning pregnancy.
- Fecundity & pregnancy rates often increase after surgery.
  - Especially in adolescents (13% vs. 6%).
- Recommend non-oral methods for surgeries that impair GI absorption.
  - Decreased absorption of OCPs.

1. ACOG Practice Bulletin 105, 2009
2. Merhi 2007 Fertil Steril
4. Merhi 2007 Gynecol Obstet Invest

Emergency Contraception

- Oral LNG 120 mg x 1, up to 5 days
- Ulipristal Acetate
  - Selective progesterone receptor modulator
  - Mechanism:
    - Delay follicular rupture
  - Will not harm existing pregnancy
  - Dosing:
    - 30mg, FDA-approved up to 5 days

1. Brache 2010 Hum Reprod
Emergency Contraception: Ulipristal Acetate

Effectiveness:1,2
“Non-inferior” to LNG: 1.4% vs. 2.2%

Meta-analysis of 3445:
- 120 hrs: OR = .55 (.32-.93)
- 24 hrs: OR = .35 (.11-.93)

**More effective for obese women3
- Obese vs Normal/underweight:
  - LNG: OR 4.41 [2.05-9.44], p=.0002
  - No efficacy >80 kg
  - UA: OR 2.62 [0.89-7.00], NS

Side effects: Headache (20%), nausea (12%)

Alternatives to LNG EC & Ulipristal Acetate?

- Copper IUD - <0.1% failure
  - VERY effective as EC up to 5+ days
  - SPR can place beyond 5 days if not more than 5 days after ovulation
  - More effective than LNG EC

- Mifepristone (10, 25 or 50 mg)
  - More effective than LNG
  - Yuzpe regimen
  - More side effects and less effective

Case #4

38 yo G2P1T1 obese woman desires birth control.
- Assess for other risk factors
- If none all methods safer than pregnancy
- If smoker or other RF – may avoid CHC
- DMPA – concern for insulin resistance and weight gain
- For EC – recommend UPA

Case #5

28 yo G4P1 had a subdermal etonogestrel (ETG) implant placed 7 months ago. She has had bleeding every day for the last 6 weeks.
New ETG Subdermal Implant

- Replaced prior in November, 2011
- Identical but with radiopaque rod
- Easier-to-use inserter
- Must complete FDA-approved training

Women who Discontinue due to Bleeding Irregularities

<table>
<thead>
<tr>
<th></th>
<th>CHC</th>
<th>DMPA</th>
<th>LNG-IUD</th>
<th>Cu-IUD</th>
<th>Implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/3</td>
<td>3%</td>
<td>7-12%</td>
<td>2.5%</td>
<td>5%</td>
<td>10%</td>
</tr>
</tbody>
</table>

1/3 of women who discontinue implant do so for bleeding

1. Datey 1995 Contraception
2. Cropsey 2010 J Women’s Health
3. Colli 1999 Contraception
4. Suhonen 2004 Contraception
5. Rivera 1999 Contraception

ETG Implant & Bleeding

- 17 bleeding-spotting days/90d
- Infrequent: 34%
  - Amenorrhea 22%
  - Prolonged bleeding 18%
  - Frequent bleeding 6%

Implant & Bleeding: Counseling!!

- Pre-insertion expectations
  - Bleeding usually light
  - “irregularly irregular”
  - Unpredictable for entire 3 years

- May improve dysmenorrhea
  - 77% with dysmenorrhea had resolution of sx

1. Darney 2009 Fertil Steril
2. Mansour 2010 Contraception
### Implant: Bleeding Treatment

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Evidence?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. COC x 21d/7d (3 mo) or Estrogen alone (0.5 mg estradiol x 21 d) (3 mo)</td>
<td>Minimal</td>
</tr>
<tr>
<td>2. Cyclic progestin (MPA 10bid) x 21d/7d (3mo)</td>
<td>Anecdotal</td>
</tr>
<tr>
<td>3. POP daily up to 3 mo</td>
<td>Anecdotal</td>
</tr>
<tr>
<td>4. NSAIDs, COX-2 inhibitors x 5-10d Transaminic acid 500 bid x 5d</td>
<td>Minimal Anecdotal</td>
</tr>
</tbody>
</table>

CDC SPR: Rule out causes of bleeding. NSAIDS 5-7 days Estrogen or CHC 10-20 days

Adapted from Mansour et al 2010, and 2011 Contraception

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### Case #5

28 yo G4P1 had a subdermal etonogestrel (ETG) implant placed 7 months ago. She has had bleeding every day for the last 6 weeks.

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### Summary

- Unintended pregnancy remains a common problem in the US.
- Remember that in most circumstances unintended pregnancy poses greater risk than contraception.
- CDC and ACOG provide useful resources for caring for patients with complex medical conditions.

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### References

- Many easily accessible resources exist to help solve contraception quandaries. . . .

UCSF Family Planning Consult Service
(415) 443-6318
Thanks to Carolyn Sufrin, Mike Policar and Merrie Warden for sharing slides.