Contraception in Medically Complicated Women

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Disclosure
• I am a litigation consultant to a law firm contracted with Bayer Healthcare relating to the Mirena IUD

Do You Use the US MEC in Your Practice?
A. Every day (or more often)
B. Occasionally (a few times a week)
C. Rarely (a few times a month)
D. Never...they don’t apply to my practice
E. I’ve never heard of them!

Focus on safety in women using contraceptives

U.S. Medical Eligibility Criteria for Contraceptive Use, 2016

Centers for Disease Control and Prevention
Morbidity and Mortality Weekly Report
Recommendations and Reports / Vol. 65 / No. 3
July 29, 2016
CDC U.S. MEC 2016

- Addition of recommendations for
  - Cystic fibrosis
  - Multiple sclerosis
- Hormonal contraceptives & psychotropics, St. John’s wort
- ECPs: addition of ulipristal acetate

Updated
- Post-partum breastfeeding and CHC
- Dyslipidemias, migraines, superficial venous dz, GTD
- Women with HIV receiving antiretroviral therapy

US Medical Eligibility Criteria

<table>
<thead>
<tr>
<th>Categ</th>
<th>Definition</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No restriction in contraceptive use</td>
<td>Use the method</td>
</tr>
<tr>
<td>2</td>
<td>Advantages generally outweigh theoretical or proven risks</td>
<td>More than usual follow-up needed</td>
</tr>
<tr>
<td>3</td>
<td>Theoretical or proven risks outweigh advantages</td>
<td>Clinical judgment that the patient can use safely</td>
</tr>
<tr>
<td>4</td>
<td>Unacceptable health risk if the method is used</td>
<td>Do not use the method</td>
</tr>
</tbody>
</table>

Focus on efficacy in women and men using contraceptives
- Organized by method
- MMWR 2013; 62(5):1-60
Filling The “Gaps”

- Pregnancy testing and counseling
- Achieving pregnancy
- Basic infertility
- Preconception health
- Preventive health screening of women and men
- Contraceptive counseling, incl reproductive life plan

Case Study 1

- 33 year old G3P3 established patient seen for family planning health screening visit
- Using metformin for type 2 diabetes
- Mutually monogamous relationship
- Recent fasting lipid profile normal
- LMP 3 weeks ago; using condoms for contraception
- Cervical cytology test 2 years ago was negative
- Screened negative for HIV in each of her 3 pregnancies
- Would like to start oral contraceptives...today if possible

Case Study 1: What Would You Do?

A. Prescribe oral contraceptives
B. Advise against OCs because she is a diabetic
C. Ask her what the most important factors are to her in the selection of a method
D. Review all contraceptive options, routinely
E. Recommend an IUD or implant because they are the most effective methods
Approaches to Contraceptive Counseling

- **Client Centered**
  - **What You Want Is What You Get (WYW IWYG)**
  - **Shared Decision Making**

- **Clinician Centered**
  - **Directive**
  - **Informed Choice**

What You Want Is What You Get

- **Example**: “if you want the Pill, let’s make sure it’s safe for you”
- Little or no information sharing beyond medical history
- Client is active; clinician is passive, unless there is a method contraindication
- **Risks to the client**
  - Client may not know (much) about other options
  - Client choice may be biased by misinformation
  - Clinician has no input, unless contraindications

Directive Counseling

- **Example**: “here’s my opinion of the best method for you”
- Fits the illness model of a clinician-client relationship
- Clinician is active; client is passive
- Advice may be biased by the client’s age, sexual or pregnancy history, socio-economic status, or race/ethnicity
- **Risk to the client**
  - The client may feel pressured by the clinician
  - The method may not be best for her lifestyle, relationship, or acceptance of side effects
  - Relatively higher risk of discontinuation

Informed Choice

- **Example**: “here are all of the methods available to you, including the pros and cons”
- Foreclosed: info about a limited number of methods
- Clinician is active but makes no recommendation; the client is passive until the time to make a decision
- Maximizes client autonomy
- **Risk to the client**
  - Clinician has no input, unless contraindications
  - Client may not integrate the information given with her values and personal preferences
**Tiered Effectiveness**

**Informed Choice + Directive Counseling**

- Example: “what are you looking for in a method?”
- **Relational communication:** explore the client’s “back-story”
- **Task oriented communication**
  - Provide information about potential methods
  - Account for the client’s medical history
  - Identify client method preferences
  - Ensure that preferences are not biased by misinformation
  - Reach a mutually acceptable decision
- **Risks**
  - Takes clinician time and skill

**Reproductive Life Plan Counseling**

<table>
<thead>
<tr>
<th>Reason</th>
<th>Question</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intent</td>
<td>Would you like to have (more) kids some day?</td>
<td>If not, discuss F,M sterilization</td>
</tr>
</tbody>
</table>

**Timing**

- When do you think that might be?
- Would you like to become pregnant in the next 12 months?

SARC: OC, patch, ring, injections, barriers
LARC: IUD, Implant
NFP: fertility awareness, withdrawal
Reproductive Life Plan Counseling

<table>
<thead>
<tr>
<th>Reason</th>
<th>Question</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>Intent</td>
<td>• Would you like to have (more) kids some day?</td>
<td>If not, discuss F,M sterilization</td>
</tr>
<tr>
<td>Timing</td>
<td>• When do you think that might be? • Would you like to become pregnant in the next 12 months?</td>
<td>Discuss LARC vs. SARC vs. NFP</td>
</tr>
<tr>
<td>Resolve</td>
<td>• How important is it to you to prevent pregnancy until then?</td>
<td>Educate and counsel re: tiered effectiveness</td>
</tr>
</tbody>
</table>

The Process of Shared Decision Making

• “What is important to you about your method?”
  – Prior experience with contraceptive method(s)
  – Woman controlled method vs. shared with partner
  – Probes
    • Frequency of using method
    • Different ways of taking methods
    • Return to fertility
    • (Specific) side effects
    • Non-contraceptive “life-style” attributes of method

Contraceptive Counseling in a Nutshell

• Not...
  – What method do you want?
• Instead...
  – What do you want in a method?

Diabetes and Contraception

• Progestins may increase insulin resistance, but not to the point of clinically significant ▲ blood glucose
• Estrogen increases risk of thrombosis in vessels damaged by diabetic vascular disease
• CHC may be used in diabetics in the absence of clinically-manifest vascular disease, including
  – Retinopathy, nephropathy
  – Peripheral vascular disease, heart disease
**US MEC 2016: Diabetes**

<table>
<thead>
<tr>
<th>Condition</th>
<th>OC/P/R</th>
<th>POP</th>
<th>DMPA</th>
<th>Implant</th>
<th>LNG-IUD</th>
<th>Cu-IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hx gestational diabetes</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Nonvascular disease</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>i. Noninsulin-dependent</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>ii. Insulin-dependent</td>
<td>3/4</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Nephropathy/retinopathy/neuropathy</td>
<td>3/4</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Other vascular disease or diabetes of &gt;20 yrs’ duration</td>
<td>3/4</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

**SPR Appendix B: When To Start Using Specific Contraceptive Methods**

<table>
<thead>
<tr>
<th>Method</th>
<th>When to start</th>
<th>Back-Up</th>
<th>Exam</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cu-IUC</td>
<td>Anytime</td>
<td>none</td>
<td>pelvic exam</td>
</tr>
<tr>
<td>LNG-IUS</td>
<td>Anytime</td>
<td>If &gt;7d*</td>
<td>Pelvic exam</td>
</tr>
<tr>
<td>Implant</td>
<td>Anytime</td>
<td>If &gt;5d*</td>
<td>none</td>
</tr>
<tr>
<td>Injection</td>
<td>Anytime</td>
<td>If &gt;7d*</td>
<td>none</td>
</tr>
<tr>
<td>CHC</td>
<td>Anytime</td>
<td>If &gt;5d*</td>
<td>BP</td>
</tr>
<tr>
<td>POP</td>
<td>Anytime</td>
<td>If &gt;5d*</td>
<td>none</td>
</tr>
</tbody>
</table>

* After the first day of menstrual bleeding

**SPR Appendix C: Exams And Tests Needed Before Method Initiation**

<table>
<thead>
<tr>
<th>Examination</th>
<th>Needed for</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
<td>OC, patch, ring</td>
</tr>
<tr>
<td>Clinical breast examination</td>
<td>None</td>
</tr>
<tr>
<td>Weight (BMI)</td>
<td>Hormonal methods</td>
</tr>
<tr>
<td>Bimanual examination, cervical inspection</td>
<td>IUC, cap, diaphragm</td>
</tr>
<tr>
<td>Glucose, Lipids</td>
<td>None</td>
</tr>
<tr>
<td>Liver enzymes</td>
<td>None</td>
</tr>
<tr>
<td>Thrombogenic mutations</td>
<td>None</td>
</tr>
<tr>
<td>Cervical cytology (Papanicolaou smear)</td>
<td>None</td>
</tr>
<tr>
<td>STD screening with laboratory tests</td>
<td>None</td>
</tr>
<tr>
<td>HIV screening with laboratory tests</td>
<td>None</td>
</tr>
</tbody>
</table>

**ADA 2014 Guidelines: Preconception Care**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintain A1c levels as close to 7.0% as possible before conception</td>
<td>Provide preconception counseling starting at puberty</td>
</tr>
<tr>
<td>Evaluate and treat women contemplating pregnancy</td>
<td>• Retinopathy</td>
</tr>
<tr>
<td></td>
<td>• Nephropathy</td>
</tr>
<tr>
<td></td>
<td>• Neuropathy</td>
</tr>
<tr>
<td></td>
<td>• CVD</td>
</tr>
<tr>
<td>Evaluate and consider risk/benefit profile of medications used for DM</td>
<td>Contraindicated/not recommended</td>
</tr>
<tr>
<td></td>
<td>• Statins</td>
</tr>
<tr>
<td></td>
<td>• ACEIs (AT-converting enzyme inhibitor)</td>
</tr>
<tr>
<td></td>
<td>• ARBs (AT receptor blocker)</td>
</tr>
<tr>
<td></td>
<td>• Non-insulin therapy, except metformin</td>
</tr>
</tbody>
</table>

ADA, Diabetes Care 2014; 37 (supp 1): S14-S80
Diabetes and Contraception: Management

- Combined hormonal contraceptives
  - Evaluate CV risk profile
  - Use low E (thrombosis risk) + low P (glucose control)
  - Adjust insulin or oral hypoglycemic as necessary
- Progestin only methods
  - May cause insulin resistance and \textbf{\textit{\textcolor{red}{\textbf{\uparrow}}}} blood glucose, but usually clinically insignificant
  - Do not increase risk of arterial thrombosis
- IUCs are safe and effective choice
- \textit{Discuss preconception care with all diabetic women}

Patient Management

- QFP: counseling based upon shared decision making
- MEC: can use OCs with same day start
- SPR: assess BP, BMI only
- STD: no STI screening tests indicated
- HIV: screening not necessary
- Cancer screening: optional clinical breast exam
- Preconception care
  - \textit{Discuss preconception glucose control with all diabetics}

Case Study #2

- 19 year old G\textsubscript{0} woman is seen for a periodic health screening visit (aka, a “Well Woman” visit)
- Same male partner for the past year
- Feeling well; no complaint of vaginal discharge, abnormal bleeding, dyspareunia
- Weight: 210 pounds; BMI: 32 kg/m\textsuperscript{2}
- Using contraceptive patch; asks about insertion of LNG-IUS
- \textbf{Questions}...
  - Which methods are acceptable relative to BMI and age?
  - What needs to be done at her “check-up” visit?

Body Weight and Contraception

- Four issues about body weight relate to each method
  - Will the method cause excess weight gain?
  - Is the failure rate higher in obese women?
  - Are there medical risks attributable to the method in obese women (compared average weight)?
  - What is the WHO-MEC category and why?
- Pregnancy and childbirth among obese women are far more dangerous than are either contraception or sterilization
### Body Weight and Contraception

<table>
<thead>
<tr>
<th>Weight gain</th>
<th>OC</th>
<th>Patch</th>
<th>DMPA</th>
<th>Implant</th>
<th>IUC</th>
<th>Tubal</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>No</td>
<td>Yes*</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

↑ failure rate in obese:
- No △
- Yes #
- No △
- No △
- No △
- No △

Medical risk in obese women:
- ↑DVT risk
- No studies
- None
- None
- Difficult insertion
- Surgical complications

US-MEC:
- 2 2 1/2 ** 1 1 Not rated

* Mainly in obese adolescents and those who experience a ≥5% body weight increase within 6 months of DMPA initiation
# If weight > 90 kg, increase of 2-4 failures/100 couples/year
** < 18 yrs of age and ≥30 kg/m² BMI

### SPR: Initiation of LNG-IUDs

**Timing**
- The LNG-IUD can be inserted at any time if it is reasonably certain that the woman is not pregnant

**Need for Back-Up Contraception**
- If inserted <7 days since LMP, no additional protection
- If inserted >7 days since LMP, abstain from intercourse or use additional protection for the next 7 days

### US MEC: Age and Parity

<table>
<thead>
<tr>
<th>OC/ P/R</th>
<th>POP</th>
<th>DMPA</th>
<th>Implant</th>
<th>LNG-IUS</th>
<th>Cu-IUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;40 yo</td>
<td>1</td>
<td>1</td>
<td>&lt;18 yo</td>
<td>1</td>
<td>&lt;18 yo</td>
</tr>
<tr>
<td>≥40 yo:</td>
<td>2</td>
<td>&gt;40 yo: 1</td>
<td>18-45 yo</td>
<td>1</td>
<td>≥20 yo</td>
</tr>
</tbody>
</table>

Nullip:
- 1 1 1 1 1 1

Parous:
- 1 1 1 1 1 1

### Examinations and Tests Needed Before Initiation of a Cu-IUD or an LNG-IUD

- Bimanual exam and cervical inspection are necessary
- Screen for CT and GC according to national guidelines
  - If not yet screened, perform at the time of insertion
- If purulent cervicitis or GC or CT, do not place IUD (MEC-4)
- If a very high individual likelihood of STD exposure generally should not have IUD insertion (MEC-3)
SPR: IUD Recommendations

• Prophylactic antibiotics not recommended
• Pre-treatment with misoprostol not recommended
• Routine follow-up after IUD insertion
  – No routine follow-up visit is required
  – Advise a woman to return at any time
  • To discuss side effects or other problems
  • If she wants to change the method
  • When it is time to remove or replace the IUC

Obese Adolescent and Contraception: Management

• DMPA is not an ideal choice for her because of the potential for additional weight gain
  – If DMPA chosen, baseline weight and recheck in 6 months
• All methods work as well in obese women as with average weight women, except the contraceptive patch
• The efficacy of emergency contraceptive pills is poor in obese women
• IUCs and implants are an excellent choice for adolescents, obese women, and obese adolescents

Patient #3

• Ms. K is a married 22 year old G₂ P₀ TAB₂ established client who is seen for pregnancy determination visit
• Her first two pregnancies were at 17 and 19 years old and occurred while using condoms
• She stated that she has occasional “sick headaches”, but no aura before headaches begin
• She does not want to be pregnant
• Interested in starting OCs
• Visit 38 minutes; 25 minutes counseling

Migraine Headache: Complications

• Migraine with aura associated with stroke risk
  – An increased relative risk
  – A low absolute risk

<table>
<thead>
<tr>
<th>Condition</th>
<th>Odds ratio</th>
<th>Stroke/10,000/yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>No migraine or OCs</td>
<td>1.0</td>
<td>6</td>
</tr>
<tr>
<td>Migraine without aura</td>
<td>1.8</td>
<td></td>
</tr>
<tr>
<td>Migraine with aura</td>
<td>2-4</td>
<td>18</td>
</tr>
<tr>
<td>Migraine + COCs</td>
<td>6-14</td>
<td>54</td>
</tr>
<tr>
<td>Migraine with smoking</td>
<td>7-10</td>
<td></td>
</tr>
<tr>
<td>Migraine +smoking + OC</td>
<td>34.4</td>
<td></td>
</tr>
</tbody>
</table>

Edlow AG, Bartz D. Rev in Obstet Gynecol, 2010; 3(2): 55-65
Headaches and Contraception: Management

- Differentiate migraine from non-migraine headaches
  - If unclear, seek neurologist consultation
- Menstrual headaches: extended regimen OCs or NuvaRing
- CHC in women with migraines without aura
  - Use low estrogen dose product
  - Recommend frequent follow-up visits initially
  - If HA worsening frequency or severity, or new neurological symptoms, discontinue CHC
- Progestin-only methods, IUC are safe and effective

Case Study: Patient #4

- A 25 year old new patient is seen with a request for EC
- She had UPI with a new partner 4 days ago, on day 10 of her usually 30 day cycle
- Not in a relationship and has intercourse infrequently
- She has a PCP from whom she receives her preventive services and has her well woman visits
- She weighs 200 lbs and is 5 feet, 4 inches tall
- Face-to-face time was 17 minutes
- What should be done for her?
**Levonorgestrel (LNG) ECPs**

- **Single dose 1.5 mg LNG tablet**
  - Labeled for use within 72 hours of UPI
  - Efficacy is good 0-72 hours; “moderate” 72-120 hours
- **Products**
  - Plan B One-Step®
  - Generic one-dose tablets
  - Two-tablet products now obsolete

**Ulipristal Acetate (UPA): Ella®**

- Selective progesterone receptor modulator
- Taken orally in single 30 mg dose
- Approved in Europe (2009) for up to 5 days
- **Mechanism of action**
  - Prevent ovulation, with follicles up to 18-20 mm
  - Inhibits implantation, but higher dose required
- **Failure rate vs. LNG (meta-analysis 0-120 hours after last sex)**
  - UPA 1.3% vs. LNG 2.2%
  - Odds Ratio = 0.55 (0.32-0.93)

**Acquiring EC**

- LNG ECPs available OTC
  - No age restrictions; no ID needed
  - Prices range from $40 (generic) - $50 (brand name)
- UPA requires a prescription
- ECPs are included in “preventive services without cost sharing” feature of the ACA
  - Health plans may cover some or all EC products
  - Require a prescription for both LNG and UPA

**Copper IUC (Cu-IUC) as Emergency Contraception**

- Efficacy: failure rate is 0.1%
- Can be inserted up to 5 days after ovulation
  - Implantation occurs 6-12 days following ovulation
  - If a woman had UPI* 3 days before ovulation, the IUD could prevent pregnancy if inserted up to 8 days afterward
  - Because of the difficulty in determining the day of ovulation, protocols allow insertion ≤ 5 days after UPI
- LNG-IUS has not been studied; not recommended for EC

UPI*: unprotected intercourse
**SPR 2016: Initiation of Regular Contraception After ECPs**

- **UPA**
  - Wait 5 days before starting hormonal contraception
  - Abstain from UPI or use barrier contraception for 7-14 days or until her next menses, whichever comes first
- **Levonorgestrel**
  - Any contraceptive method can be started immediately
  - Abstain from UPI or use barrier contraception for 7 days
- Advise the woman to have a pregnancy test if she does not have a withdrawal bleed within 3 weeks

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Rapkin RB, Creinin M, OBG Management 2011; 23(8): 16-24