Disclosure

• I am a litigation consultant to a law firm contracted with Bayer Healthcare relating to the Mirena IUD
Focus on safety in women using contraceptives
• 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>
U.S. Selected Practice Recommendations for Contraceptive Use, 2013
Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition

• Focus on **efficacy** in women and men using contraceptives
• Organized by method
• MMWR 2016; 65(4):1-60

http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf
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
The “Suite” of CDC Family Planning Recommendations
2016 CDC MEC and SPR phone app
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?

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

Client Centered
- 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

Most Effective
- Implant: 0.05%*
- Reversible Intrauterine Device (IUD): 0.2% Copper T - 0.8%
- Male Sterilization (Vasectomy): 0.15%
- Female Sterilization (Abdominal, Laparoscopic, Hysteroscopic): 0.5%

Less than 1 pregnancy per 100 women in a year

Injectable: 6%
Pill: 9%
Patch: 9%
Ring: 9%
Diaphragm: 12%

6-12 pregnancies per 100 women in a year

Male Condom: 18%
Female Condom: 21%
Withdrawal: 22%
Sponge: 24% parous women, 12% nulliparous women

18 or more pregnancies per 100 women in a year

Fertility-Awareness Based Methods

Spermicide: 24%

Least Effective
- Spermicide: 28%

*The percentages indicate the number out of every 100 women who experienced an unintended pregnancy within the first year of typical use of each contraceptive method.
Shared Decision Making

• **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 Intention Counseling

<table>
<thead>
<tr>
<th>Reason</th>
<th>Question</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intent</strong></td>
<td>• Would you like to have (more) kids some day?</td>
<td>If not, discuss F,M sterilization</td>
</tr>
<tr>
<td><strong>Timing</strong></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><strong>Resolve</strong></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 can increase insulin resistance
  – Usually insignificant ▲ blood glucose
• Estrogen ▲ thrombosis risk if diabetic arterial 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></th>
<th>OC/P/R</th>
<th>POP</th>
<th>DMPA</th>
<th>Impl</th>
<th>LNG-IUD</th>
<th>Cu-IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hx gestational diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>1</td>
<td>1</td>
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</tr>
<tr>
<td>Nonvascular disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. Noninsulin-dependent</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>ii. Insulin-dependent</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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>
Diabetes
b. Nonvascular disease
   i. Non-insulin dependent

<table>
<thead>
<tr>
<th>Method</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cu-IUD</td>
<td>1</td>
</tr>
<tr>
<td>LNG-IUD</td>
<td>2</td>
</tr>
<tr>
<td>Implants</td>
<td>2</td>
</tr>
<tr>
<td>DMPA</td>
<td>2</td>
</tr>
<tr>
<td>POP</td>
<td>2</td>
</tr>
<tr>
<td>CHCs</td>
<td>2</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><em>Anytime</em></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>Maintain A1c levels as close to 7.0% as possible before conception</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All women of childbearing potential</strong></td>
</tr>
<tr>
<td>Provide preconception counseling starting at puberty</td>
</tr>
</tbody>
</table>

| Evaluate and treat women contemplating pregnancy              |
| • Retinopathy                                                |
| • Nephropathy                                                 |
| • Neuropathy                                                  |
| • CVD                                                         |

| Evaluate and consider risk/benefit profile of medications used for DM |
| Contraindicated/not recommended                                  |
| • Statins                                                     |
| • ACEIs (AT-converting enzyme inhibitor)                       |
| • ARBs (AT receptor blocker)                                   |
| • Non-insulin therapy, except metformin                        |

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
  – ▲ blood glucose usually is clinically insignificant
  – Do not increase risk of arterial thrombosis

• IUCs are safe and effective choice
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
  – *Discuss preconception glucose control with all diabetics*
Patient #2

• 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
US MEC 2016: Headaches

<table>
<thead>
<tr>
<th></th>
<th>OC/P/R</th>
<th>POP</th>
<th>DMPA</th>
<th>Impl</th>
<th>LNG-IUD</th>
<th>Cu-IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-migrainous</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Migraine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without aura</td>
<td>2*</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>With aura</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

* Classification is for women without any other risk factors for stroke (e.g., age, hypertension, and smoking)
# US MEC 2010: Headaches

<table>
<thead>
<tr>
<th></th>
<th>OC/P/R</th>
<th>POP</th>
<th>DMPA</th>
<th>Impl</th>
<th>LNG-IUD</th>
<th>Cu-IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-migrainous</strong></td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Migraine</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Without aura</strong></td>
<td>I</td>
<td>C</td>
<td>I</td>
<td>I</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>Age &lt;35</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Age &gt;35</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td><strong>With aura</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>– Any age</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

I: Initiate  C: Continue
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
Patient #3

- 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 who she receives her preventive services and has her well woman visits
- She weighs 200 lbs and is 5 feet, 4 inches tall
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
Levonorgestrel 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
Patient asks for EC

Counsel for Cu-IUC

What is her BMI?

- <25: Oral EC options acceptable
- 26-29: Counsel that LNG is less effective
- 30-34: LNG EC failure rate 4x higher; ineffective
- >35: Counsel that UPA likely is ineffective, but can use if refuses Cu-IUC

Rapkin RB, Creinin M, OBG Management 2011; 23(8): 16-24
What is her BMI?

- **<75kg (165 #)**
  - Oral EC options acceptable

- **76-80 kg**
  - Counsel that LNG is less effective

- **80-88 kg**
  - LNG EC failure rate 4x higher; ineffective

- **> 88kg**
  - Counsel that UPA likely is ineffective, but can use if refuses Cu-IUC

LNg limit 176 lbs (80kg)

UPA limit 194 lbs (88kg)
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
The Emergency Contraception Website

Your website for the “Morning After”

For Healthcare Providers

- How do I get listed on your website?
- Q&A about Over-the-Counter access to emergency contraception
- EC dosing quick reference table
- Educational and promotional materials
- Emergency contraception online training

http://ec.princeton.edu/for-providers.html
Disruptive Innovation Defined

• An innovation that creates a new market and value network and eventually disrupts an existing market, displacing established market leaders and alliances

• “Significant societal impact" as an aspect of disruptive innovation

• Tend to be produced by outsiders
What Disruptive Innovation Means

DI can reshape entire industries...

<table>
<thead>
<tr>
<th>Old Economy</th>
<th>New Economy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classified ads</td>
<td>Craigslist</td>
</tr>
<tr>
<td>Long distance calls</td>
<td>Skype</td>
</tr>
<tr>
<td>Record stores</td>
<td>iTunes</td>
</tr>
<tr>
<td>Research libraries</td>
<td>Google</td>
</tr>
<tr>
<td>Local stores</td>
<td>Amazon, eBay</td>
</tr>
<tr>
<td>Taxis, rental cars</td>
<td>Uber, Lyft</td>
</tr>
</tbody>
</table>
There's finally an Uber for birth control
Telemedicine: On-line HC Prescription

- Nurx (app.nurx.co/)
- Mavenclinic.com
- PRJKT Ruby (projectruby.com)
- Lemonaidhealth.com
- Planned Parenthood Direct
Telemedicine Prescription of HC: Benefits

• **Convenience**...no clinic visit, no exam
  – No travel and parking expense
  – Lessen opportunity cost

• **Access** to most hormonal contraceptives
  – Except DMPA, implant, LNg-IUD

• **Targeted to millennials**
  – Love technology
  – Prefer on-line shopping
  – Believe seeing a clinician is “too much of a pain”
Telemedicine Prescription of HC: Benefits

- Confidential
- Inexpensive (no cost if insurance used)
- Don’t need a relationship with a PCP
- No legislative approval; clinicians write Rx
- Reduction in unintended pregnancies?
Telemedicine Prescription of HC: Risks

• Some women will miss the opportunity for detailed counseling and shared decision making
  – Loss of educational opportunity for LARC

• More women will forego well woman visits