Is This Method Safe for My Patient? Using the US Medical Eligibility Criteria for Contraceptive Use

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No disclosures for this lecture

Contraceptive Risk Analysis

- Define the risk of pregnancy
- Define the risk of the method
  - The intrinsic safety risks of the method
  - That the method will make the disease worse
  - That the method won’t work, including reduced efficacy
  - That the method will not be used effectively
  - That EC or abortion won’t be used as backup

WHO Medical Eligibility Criteria

- Combined hormonal contraceptives (CHC)
  - COC: Combined oral contraceptives
  - CIC: Combined injectable contraceptives
  - P/R: Patch and Vaginal Ring
- Progestin only contraceptives
  - POP: Progestin only pills
  - DMPA: Depo-MPA
  - IMPLT: Implanon contraceptive implant
- Intrauterine contraceptives
  - Cu-IUD: Copper T-380 IUD
  - LNG-IUD: Levonorgestrel IUS

• WHO Medical Eligibility Criteria for Contraceptive Use – 3rd edition - 2009
  - www.who.int/reproductive-health/publications/mec/
  - www.reproductiveaccess.org/contraception/WHO_chart.htm

• Purpose: who can use contraceptive methods
## WHO Medical Eligibility Criteria

<table>
<thead>
<tr>
<th>Category</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 of the method</td>
<td>Clinical judgment that this patient can safely use</td>
</tr>
<tr>
<td>4</td>
<td>The condition represents an unacceptable health risk if the method is used</td>
<td>Do not use the method</td>
</tr>
</tbody>
</table>

### Unique contributions
- Evidence based
- Comprehensive, up-to-date
- Only “accepted” guideline of its kind

### Considerations for use in US
- WHO Criteria were written to include “lowest common denominator” health systems
- Conservative for use in the US
- Consider as “tools not rules”
US MEC: Scope

- WHO MEC contains > 1800 recommendations
- No need to adapt majority of recommendations
  - Science is the same
  - Recommendations are widely used around the world, including in the US
- Majority of WHO recommendations used in US MEC
  - Exceptions: existing WHO recommendations that needed to be adapted for US context
- CDC reviews periodic changes to WHO guidelines
  - triggers reconsideration of UC MEC

Differences between US MEC and WHO MEC

Existing WHO guidance
- Breastfeeding and CHC
- Breastfeeding and progestin-only methods
- Postpartum IUCs
- Ovarian cancer and IUCs
- Fibroids and IUCs
- DVT/PE and hormonal contraception
- Valvular heart disease and IUDs

New medical conditions
- Rheumatoid arthritis
- Endometrial hyperplasia
- Inflammatory bowel disease
- Bariatric surgery
- Solid organ transplantation
- Peripartum cardiomyopathy

WHO Selected Practice Recommendations (SPR) for Contraceptive Use 2008

- 28 contraceptive practice guidelines; Q&A format
  - http://www.who.int/reproductive-health/publications/spr/index.htm
- CDC had planned to adapt SPR to US, but now will develop comprehensive recommendations
  - MEC: *who* can use contraception (e.g., safety)
  - SPR: *how* to use contraceptives (e.g., efficacy)
- To be published in MMWR as companion volume to CDC STD Treatment Guidelines
WHO Selected Practice Recommendations 2004

- Blood pressure measurement before initiation of OCs, POPs, DMPA, and implants
- Not recommended as “contributing substantially to safe and effective use of a hormonal contraceptive”
  - Breast or genital tract examination
  - Cervical cancer screening
  - STI risk assessment, physical exam, screening tests
  - Hemoglobin determination
  - Other routine lab tests

Case Study: Headaches

- Ms. K is a married 22 year old G3 P0 TAB3 woman who requests OCs
- Her first two pregnancies were at 17 and 19 years old and occurred while using condoms
- States that she had experienced occasional "sick headaches" over the past 9 months, and mentioned that two episodes had been so severe that she had to go home from work
**Headaches and Contraception**

- **Tension headache** is most common type
  - Muscle tightening and pain in neck, scalp
  - Improved with sleep, analgesics, relaxation
  - No interaction with hormones
- **Common (or simple) migraine headaches**
  - Unilateral or bilateral temporal pain
  - Nausea, vomiting, visual spots/flashing
  - Sonophobia (worse pain with sound)
  - Photophobia (worse pain with light)
  - No aura or focal neurologic symptoms

**Migraine Headache**

- **Classic migraine headaches**
  - Aura, before onset of migraine headache
  - Transient hemianopsia (unilateral loss of vision)
  - Unilateral paresthesias (sensory defects)
  - Hemiparesis (weakness or paralysis)
  - Aphasia (speech defects)

**Migraine Headaches**

**Pre-migraine aura**

- Associated with increased risk of stroke
- Symptom pattern
  - Occurs 6-60 minutes before headache
  - Flickering zig-zag line moves toward periphery
  - Scotomata (loss of vision)

**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>Without aura</td>
<td>I</td>
<td>C</td>
<td>I</td>
<td>C</td>
<td>I</td>
<td>C</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 ≥35</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>With aura</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>3</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

I: Initiate  C: Continue
**Headaches and Contraception: Management**

- Differentiate migraine from non-migraine headaches; obtain neurologist consultation if necessary
- If catamenial (menstrual) headaches, suggest OCs or NuvaRing in extended regimen
- CHC in women with common migraines
  - Use low estrogen effect product
  - Recommend frequent follow-up visits
  - If HA worsening frequency or severity, or new neurological symptoms, CHC must be discontinued
- Progestin-only methods, IUC are safe and effective

**Case Study: Type 2 Diabetes**

- 33 year old G3P3 woman with gestational diabetes diagnosed in 2nd pregnancy
- No insulin between 2nd and 3rd pregnancies, required insulin during third pregnancy, which ended 2 years ago
- Now on metformin for type 2 diabetes; considering switch to insulin due to poor control
- Would like to use a hormonal method of contraception, if possible

**Diabetes and Contraception**

- Progestins may increase insulin resistance, but not usually 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 2010: Diabetes**

<table>
<thead>
<tr>
<th></th>
<th>OC/P</th>
<th>POP</th>
<th>DMPA</th>
<th>Impl</th>
<th>LNG-IUD</th>
<th>Cu-IUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of 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></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>1</td>
</tr>
<tr>
<td>ii. Insulin-dependent</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</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 and Contraception: Management**

- Adjust insulin or oral hypoglycemic as necessary
- Combined hormonal contraceptives
  - Evaluate CV risk profile
  - Use low E (thrombosis) + low P (glucose control)
  - If possible, co-manage with primary care provider
- Progestin only methods
  - May cause insulin resistance and ▲blood glucose, but usually clinically insignificant
  - Do not increase risk of arterial thrombosis
- IUCs are safe and effective choice
- *Discuss preconception care with all diabetic women*

**Contraception and Gestational Diabetes Mellitus (GDM)**

- Older studies showed that OC may hasten insulin dependence; newer studies do not
- If GDM, ADA and ACOG recommend
  - 2 hour PGL (75 gm) 6 weeks postpartum
  - Given >50% chance of Type 2 DM in next 10 years, repeat diabetes screening annually, irrespective of contraceptive method
- GDMs who become frankly diabetic may continue combined hormonal contraceptives

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### ADA: Contraception After GDM

Damm P, Diabetes Care 2007; 30(S2):S236-241

<table>
<thead>
<tr>
<th>Method</th>
<th>OC</th>
<th>P/R</th>
<th>POP BF</th>
<th>POP Not BF</th>
<th>DMPA, Implants</th>
<th>IUC</th>
<th>Barriers</th>
<th>Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>“First choice”</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>“Not First choice”</td>
<td></td>
<td></td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td></td>
</tr>
</tbody>
</table>

- POPs are “first line” in T1 diabetics, non-lactating GDMs
- DMPA, implants are first line if compliance with a daily method is a problem or methods with estrogen are contraindicated
- Avoid OC, patch, and ring if CV disease or risk factors

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**Case Study: Type 2 Diabetes**

- Check lipid profile
- If given progestin-containing method, monitor blood glucose levels closely
- **Preferred methods**
  - IUCs
  - Progestin only method
- **Acceptable methods**
  - OC (low E, low P), Patch, Ring
- **Unacceptable risk**
  - None
Case Study: Liver Disease

- 24 year old G₂ P₀ TAB₂ woman would like to use “the Pill” or OrthoEVRA patch
- Previous history of IV drug use, but now clean
- Has 4 or 5 sexual partners per year
- Tested positive for hepatitis B virus (HBsAg+) 2 years ago; liver enzymes are mildly elevated
- Tested negative for hepatitis C and HIV
- Occasional drinker; no longer smokes

Liver Disease and Contraception: Management

- Few studies of CHC and liver disease
- Combined hormonal contraceptives, P/R
  - Determine the specific diagnosis
  - Order/review liver function tests
  - If no/ minimal ▲: OK to start; repeat LFTs in 2-3 months
- Progestin only methods have no effect on liver disease
- IUCs are safe and effective choice

US MEC 2010: Liver Disease

<table>
<thead>
<tr>
<th>Cirrhosis</th>
<th>OC/P/R</th>
<th>POP</th>
<th>DMPA</th>
<th>Imp-plant</th>
<th>LNG-IUS</th>
<th>Cu-IUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild, compensated</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Severe, decomp-ensated</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Viral hepatitis</td>
<td>Acute or flare</td>
<td>I:3/4</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Carrier/Chronic</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Case Study: Seizure Disorder

- 24 year old G₁ P₀ TAB₁ has a history of seizures since 15 years old
- Maintained on phenytoin and carbamazepine
- Last seizure was 3 years ago; last visit to neurologist was 2 years ago
- Previously told that “OCs would not work” for her and that she should not use them
- Now in college and is highly motivated to prevent unintended pregnancy
Seizure Disorders

- Goals in contraceptive management of women with seizure disorders
  - Seizure control with anti-epileptic drugs (AEDs)
  - Highly effective contraception; exposure to some AEDs is associated with anomalies
  - Minimize interaction of AEDs and contraceptive
- Most women will have no change in the frequency or severity of seizure activity due to hormonal contraceptives

AEDs: Non Inducers of Hepatic Enzymes

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Brand name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethosuximide</td>
<td>Zarontin</td>
</tr>
<tr>
<td>Levetiracetam</td>
<td>Keppra</td>
</tr>
<tr>
<td>Tiagabine</td>
<td>Gabitril</td>
</tr>
<tr>
<td>Valproic acid</td>
<td>Depakene, Depakote</td>
</tr>
<tr>
<td>Vigabatrin</td>
<td>Sabril</td>
</tr>
<tr>
<td>Zonisamide</td>
<td>Zonegran</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>Klonopin</td>
</tr>
<tr>
<td>Pregabalin</td>
<td>Lyrica</td>
</tr>
</tbody>
</table>

Enzyme Inducing Anti-Epileptic Drugs (AEDs)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Brand name</th>
<th>E reduction</th>
<th>P reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamazepine</td>
<td>Tegretol ®</td>
<td>42%</td>
<td>58%</td>
</tr>
<tr>
<td>Felbamate</td>
<td>Felbatol ®</td>
<td>13%</td>
<td>42%</td>
</tr>
<tr>
<td>Lamotrigine</td>
<td>Lamictal ®</td>
<td>None</td>
<td>19%</td>
</tr>
<tr>
<td>Oxcarbazine</td>
<td>Trileptal®</td>
<td>48%</td>
<td>32%</td>
</tr>
<tr>
<td>Phenytoin</td>
<td>Dilantin ®</td>
<td>49%</td>
<td>42%</td>
</tr>
<tr>
<td>Topiramate</td>
<td>Topamax ®</td>
<td>15-33%</td>
<td>None</td>
</tr>
</tbody>
</table>

Lamotrigine (Lamictal)

- Each drug increases the metabolism of the other
- In a Lamotrigine user started on OCs
  - Lamotrigine levels drop by 49% (41-64%)
  - Seizure activity increases
  - Side effects of lamotrigine ▲ when OC stopped
- If using OCs, use higher start dose of Lamotrigine
- If using Lamotrigine and initiating OCs
  - Double Lamotrigine dose before starting OCs
  - Before stopping OCs, cut Lamotrigine dose by half

Thorneycroft I, Epilepsy and Behavior 2006;9:31
US-MEC 2010: Lamotrigine

- OC/P/R are considered US-MEC 3 because pharmacokinetic studies show levels of lamotrigine decrease during COC use
- This recommendation applies only where lamotrigine monotherapy is taken with COCs
- Anticonvulsant treatment regimens that combine lamotrigine and non-enzyme inducing AEDs (such as Na valproate) do not interact with COCs

2010 US MEC: Drug Interactions

<table>
<thead>
<tr>
<th>Drug</th>
<th>OC P/R</th>
<th>POP</th>
<th>DMPA</th>
<th>Implant</th>
<th>Cu-IUC</th>
<th>LN-IUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enzyme-Inducing Anticonvulsants</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Lamotrigine</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Rifampin (E-I)</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Antifungals, incl Griseofulvin</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Other antibiotics</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Women Using El-AEDs Management

- Ideal contraceptives
  - IUCs (Mirena, ParaGard)
  - DMPA: high efficacy; improves seizure control
    - Unknown if DP-104 reduces seizure activity
- Oral contraceptives...non-evidence based
  - Use at least 35 mcg EE + high progestin product
  - Shorten hormone free interval to 4 days or less
- Avoid “low progestin” contraceptives
  - OrthoEvra patch; progestin only pills

Thorneycroft I, Epilepsy and Behavior 2006;9:31

USMEC: Inflammatory Bowel Disease

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>COC/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>IBD (Ulcerative colitis, Crohn’s disease)</td>
<td>2/3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

For women with IBD with increased risk for VTE (active or extensive disease, surgery, immobilization, steroid use, vitamin deficiencies, fluid depletion), the risks for COC/P/R use generally outweigh the benefits
### History of Bariatric Surgery
**USMEC 2010**

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>OC/P/R</th>
<th>POP</th>
<th>DM PA</th>
<th>Implant</th>
<th>Cu IUC</th>
<th>LN-IUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restrictive procedures: decrease stomach storage capacity</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Malabsorptive procedures: shorten functional length of the SB</td>
<td>COCs: 3 P/R: 1</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Bariatric procedures with a malabsorptive component have the potential to decrease OC effectiveness, further decreased by long-term diarrhea and/or vomiting.

### Peripartum Cardiomyopathy
**USMEC 2010**

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>OC/P/R</th>
<th>POP</th>
<th>DM PA</th>
<th>Implant</th>
<th>Cu IUC</th>
<th>LN-IUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal or mildly impaired cardiac function</td>
<td>&lt;6 mo</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>&gt;6 mo</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Moderately or severely impaired cardiac function</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

### Solid Organ Transplantation
**USMEC 2010**

<table>
<thead>
<tr>
<th>CONDITION</th>
<th>OC/P/R</th>
<th>POP</th>
<th>DM PA</th>
<th>Implant</th>
<th>Cu IUC</th>
<th>LN-IUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complicated: graft failure, rejection, cardiac allograft, vasculopathy</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>I = 3</td>
<td>I = 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>C =2</td>
<td>C =2</td>
</tr>
<tr>
<td>Uncomplicated</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

Women with Budd-Chiari syndrome should not use OC/P/R because of the increased risk for thrombosis.