US Medical Eligibility Criteria for Contraception

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No disclosures for this lecture

WHO Medical Eligibility Criteria

- 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”
WHO Medical Eligibility Criteria for Contraceptive Use – 3rd edition - 2004
- [WHO](http://www.who.int/reproductive-health/publications/mec/)
- [www.reproductiveaccess.org/contraception/WHO_chart.htm](http://www.reproductiveaccess.org/contraception/WHO_chart.htm)

WHO Selective Recommendations for Contraceptive Use 2008
- [http://www.who.int/reproductive-health/publications/spr/index.htm](http://www.who.int/reproductive-health/publications/spr/index.htm)

- **WHO Medical Eligibility Criteria**

  **Combined hormonal contraceptives (CHC)**
  - COC: Combined oral contraceptives
  - P/R: Patch and Vaginal Ring

  **Progestin only contraceptives**
  - POP: Progestin only pills
  - DMPA: Depo-MPA (DepoProvera)
  - LNG/ETG: Implanon contraceptive implant

  **Intrauterine contraceptives**
  - Cu-IUD: ParaGard IUD
  - LNG-IUD: Mirena IUS
### 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 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>Unacceptable health risk if the method is used</td>
<td>Do not use the method</td>
</tr>
</tbody>
</table>

### #1: Timing of the Postpartum Visit

**Background**

- Historically, the postpartum visit was recommended at 6 weeks to allow for uterine involution and the “return of normal pelvic anatomy”
- Developed before modern contraceptive options were available
- National guidelines have not revisited this topic to update based upon new evidence and technology
Post-partum Contraception: General Considerations

- Goals in choice of postpartum (pp) contraception
  - Efficacy: limit family size, adequate birth spacing
  - Support successful breastfeeding
  - In GDMs, avoid conversion to frank diabetes
- Most women begin intercourse within 1-2 months
  - 60-70% are sexually active by 6 weeks pp
  - Only 4% abstinent by the end of the 12th pp week

Post-partum Ovulation Patterns

- Resumption of ovulation in non-lactating women
  - Ovulate in 6-7 wks (median= 45 days)
  - None before 25 days from the delivery
- Resumption of ovulation in lactating women
  - Intensity, frequency, duration of suckling
  - Time elapsed since delivery
  - Maternal nutritional state
  - Rate of weaning: rapid > gradual weaning
  - Introduction of supplementary feeding (ovulation usually begins 6 weeks later)
### 2004 WHO Medical Eligibility Criteria

#### Not breastfeeding

<table>
<thead>
<tr>
<th></th>
<th>OC</th>
<th>P/R</th>
<th>POP</th>
<th>DMPA</th>
<th>Impl- lant</th>
<th>Cu- IUC</th>
<th>LN- IUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 48 hrs</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2-21 days</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>3</td>
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<tr>
<td>3-4 weeks</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>&gt; 4 weeks</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

### 2004 WHO Medical Eligibility Criteria

#### Breastfeeding women

<table>
<thead>
<tr>
<th></th>
<th>OC</th>
<th>P/R</th>
<th>POP</th>
<th>DMPA</th>
<th>Impl- lant</th>
<th>Cu- IUC</th>
<th>LN- IUC</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 6 weeks</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6 weeks- 6 months</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 6 months</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
Post-partum OC's: Effect on Lactation

- **Quality** (composition) of breast milk
  - No change, including iron and copper levels

- **Quantity** of breast milk
  - If started *before* establishment of lactation, high dose estrogen decreases quantity
  - If started *after* lactation is established, low dose OCs minimal effect on quantity

- POPs have no effect on quantity or content milk

- Women who use COCs have a lower incidence of breast feeding after the 6th pp month
  - Mean use: 3.7 mos with OCs vs. 4.6 mos controls

Post-partum OC's: Newborn Risk

- General rule: 1% of ingested drug secreted in milk

- Ethinyl estradiol dose reaching newborn is comparable to daily ovarian estradiol production

- Effect of OCs on breast-feeding infants
  - No short term differences vs. controls
  - A long term (5 year) study shows no effect on neurological development

- Newborn growth rates not affected by OC use
  - Any loss of milk volume compensated by increased suckling or food supplements
Post-partum OC's: Maternal Risk

- Changes in maternal clotting factors persist for 4 weeks after term delivery
  - Increased VTE risk up to 4 week post-partum
- Concern that coagulation effects from each of pregnancy and OC's may further increase risk of VTE
  - However, VTE rates have not been studied in postpartum low-dose OC users vs. controls
- Greater VTE risks not expected with POPs, since no change in clotting factors

Post-partum OC's: Clinical Guidelines

- Non-nursing women
  - COC starting 3-4 weeks postpartum
- Nursing women
  - Conservative approach
    » First 3 months: avoid COCs; POPs acceptable
    » ≥3 mo or weaned from breast: switch to COCs
  - Liberal approach
    » COCs once lactation well established (≥3-4 wks)
- If COCs used, use 20 mcg estrogen dose
  - LoEstrin 1/20, Micrette, Alesse
**Post-partum Long-acting Progestins**

- **DMPA**
  - Mildly lactogenic; no change in milk composition
- **Implants (Implanon, Norplant studies)**
  - If inserted ≥ 4-6 wks post-partum, no effects on milk volume, content, or newborn growth rates
- **Administration before hospital discharge**
  - **Advantage**
    - Protection if doesn’t return for post-partum visit
  - **Disadvantages**
    - Unnecessary for first 4 weeks
    - May be difficult to differentiate anatomic bleeding from method “side effect” bleeding

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**2004 WHO MEC: Postpartum IUC Insertion**

<table>
<thead>
<tr>
<th></th>
<th>Cu-IUD</th>
<th>LNG-IUD</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 48 hours</td>
<td>2</td>
<td>3</td>
<td>Evidence: There was some increase in expulsion rates compared to delayed insertion.</td>
</tr>
<tr>
<td>48 hours to 4 weeks</td>
<td>3</td>
<td>3</td>
<td>Evidence: There was some increase in expulsion rates compared to delayed insertion.</td>
</tr>
<tr>
<td>&gt; 4 weeks</td>
<td>1</td>
<td>1</td>
<td>Evidence: There was some increase in expulsion rates compared to delayed insertion.</td>
</tr>
<tr>
<td>Endometritis</td>
<td>4</td>
<td>4</td>
<td>Evidence: There was some increase in expulsion rates compared to delayed insertion.</td>
</tr>
</tbody>
</table>

- Guidelines are identical in lactating and non-lactating women
- Insert IUC within 15 minutes of placental delivery
- Use sponge forceps on cervical lip; 2\textsuperscript{nd} sponge forceps to insert
- Cut string flush with external cervical os
Lactational Amenorrhea Method (LAM)

- **Effectiveness**
  - Pregnancy rate: 1-2% by 6 months postpartum
  - 7% by 12 months; 13% by 24 months

- **Bellagio Conference Consensus (1989)**
  - Nurses "on demand" (≥ 5 feeds/day; > 65 min total)
  - Breast milk is only nutrition to newborn; no supplementary bottle feedings or other foods
  - No bleeding episode beyond 56 days from delivery
  - Nursing of newborn for less than 6 months

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**Lactational Amenorrhea Method**

- Beyond 6 months
- 10 weeks - 6 months
- Delivery - 10 weeks
The postpartum visit: it’s time for a change in order to optimally initiate contraception
Leon Speroff\textsuperscript{a}, Daniel R. Mishell Jr. \textsuperscript{b,*}

*Contraception 2008;78:90–98*

- “The 6 week postpartum visit is an anachronism”
- At the 3 week visit, evaluate whether no, partial or full (and exclusive) breast feeding
- Apply “The Rule of 3’s”
  - If no or partial breast-feeding, contraception should be initiated during the third postpartum week
  - If full breast-feeding, contraception should be started during the third postpartum month
- At the 3 month visit, initiate a method if breastfeeding or follow-up women who started a method at 3 weeks

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**Implications**

- **Delivery-3 weeks**
  - No method necessary, since *earliest* ovulation in non-lactating women is 25 days
- **3 weeks-3 months**
  - Fully lactating women: LAM alone is effective
  - Non-lactating women: all methods are appropriate
  - “Partially” breast-feeding: low dose or no estrogen\textsuperscript{*}
- **Beyond 3 months**
  - Fully lactating women: LAM no later than 6 months
  - Non-lactating women: all methods are appropriate
  - “Partially” breast-feeding: low dose or no estrogen\textsuperscript{*}

\textsuperscript{* Women who use combined OCs stop breast-feeding earlier
Post-Partum Contraceptive Coverage

- Commercial health insurance
  - Full contraceptive coverage
- Medi-Cal
  - “Full-scope” Medi-Cal: full contraceptive coverage
  - “Pregnancy-only”: eligibility for ends the last day of the month in which the 60th post-partum day occurs
    » Includes all Medi-Cal covered contraceptive methods
- Family PACT
  - Women with other health coverage (including Medi-Cal/pregnancy-only) are not eligible
  - Activate Family PACT only after Medi-Cal eligibility is no longer active

#2 Post Abortion IUC Insertion
2004 WHO MEC, Cochrane Review

**Background**

- No difference in complications for immediate versus delayed insertion of an IUD after abortion
- Expulsion more likely when an IUD was inserted following a 2nd trimester vs. 1st trimester abortion
- No differences in safety or expulsions for post-abortion insertion of an LNG-IUD vs. Cu-IUD
Impact of Immediate Postabortal Insertion of IUC on Repeat Abortion
Goodman S, Contraception 2008;78:143-148

- Conducted at N. CA Planned Parenthood sites 2002-2005
- Retrospective cohort study design
  - Cases: 673 women with post-AB IUC insertion
  - Controls: 1,346 women using other contraceptives
  - Followed for 14 months after abortion procedure
- Results
  - IUC group: 36.4 abortions per 1000 woman-years
  - Controls: 91.3 abortions per 1000 woman-years
  - Hazard ratio (unadjusted) = 0.38 (0.27-0.53)
  - HR (adjusted for, race, marital status) = 0.37 (0.26-0.52)

Implications

- Of 1.3 million abortions annually in US, about half are repeat procedures
- 40% of women scheduled for delayed IUC insertion did not return for the procedure
- Up to 83% of women ovulate with the first cycle after the procedure
- Immediate post-abortal IUC insertion is a safe, effective, practical, and underutilized intervention that can reduce repeat unintended pregnancy and repeat abortion by two-thirds
#3 Contraception and Gestational Diabetes Mellitus (GDM)

**Background**

- Older studies showed POPs (only if breast feeding) and DMPA may hasten diagnosis of type 2 DM
- GDMs who become frankly diabetic may continue combined or progestin-only contraceptives
- If GDM, both ADA and ACOG recommend
  - 75 gm 2-hour PGL test 6 weeks postpartum
  - Given >50% chance of Type 2 DM in next 10 years, repeat diabetes screening annually, irrespective of contraceptive method

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**WHO MEC 2004: Diabetes**

- History of gestational diabetes: all are WHO-1
- DM *without* vascular disease (± insulin)
  - WHO-1: Cu-IUD
  - WHO-2: All others
- DM *with* vascular disease or DM > 20 years
  - WHO-3: OC, P/R, DMPA
  - WHO-2: POP, Implanon, LNG-IUD
  - WHO-1: Cu-IUD
### 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 cardiovascular disease or risk factors

### Implications

- WHO states that contraceptive options in women with gestational diabetes are identical to other women
- Concern regarding the use of POPs, DMPA, implants are based on weak retrospective studies and apply only to breast-feeding women
- Much more critical issues for GDMs are…
  - Effective use of contraception for birth spacing
  - Being screened for Type 2 diabetes with a glucose load test annually
  - If progression to T2DM, control of blood sugar before the beginning of subsequent pregnancies
#4 Missed Hormonal Contraceptives

**Background**

- Instructions for missed contraceptive doses are complex; may not be understood by women
- Highest risk of ovulation when hormone free interval is longer than 7 days, either by delaying start or by missing hormone doses during the 1st week
- Ovulation rarely occurs after 7 consecutive days of combined oral contraceptive use

**Missed Hormonal Contraceptives: New Recommendations**

Soc Ob GYN of Canada, JOGC 2008; 219:1050-62

- Reviewed contradictory instructions published by WHO, *Contraceptive Technology*, and ACOG
- Evaluated evidence regarding
  - Ovarian follicular development on sequential days that hormones are used (or not)
  - Pharmacokinetics of oral vs non-oral contraceptives
  - Studies of contraceptive efficacy
- Developed simple clear instructions to minimize pregnancy risk without using EC
Missed Hormonal Contraceptives: New Recommendations
Soc Ob GYN of Canada, JOGC 2008; 219:1050-62

- The hormone free interval (HFI) shouldn’t exceed 7 days, as the risk of ovulation is greatest
- In the 1st week
  - Back-up should be used after ≥1 missed dose until 7 days of use occur. Consider EC
- In the 2nd and 3rd week
  - If < 3 days are missed, eliminate the next HFI
  - If ≥3 days are missed, back-up contraception and consideration of EC should be added

Missed Combined OCs

1 or more active COCs missed

During week 1
- Miss ≥ 1 pill
  - Take 1 asap, then 1 daily till end of pack
  - Back-up (B/U) method for 7 days
  - Consider EC

During week 2 or 3
- < 3 pills missed
  - Take 1 asap, then 1 daily till end of pack
  - Discard placebo
  - Start new cycle of COC w/o HFI

- ≥3 pills missed
  - Take 1 asap, then 1 daily till end of pack
  - Discard placebo
  - Start new cycle of COC w/o HFI
  - B/U + consider EC
**Missed Contraceptive Patch**

**Delayed application or detached >24 hrs**

- **During week 1**
  - Detached >24h or unsure
    - New patch asap
    - Keep same patch change day
    - Make a cycle of 3 patches
    - B/U + consider EC

- **During week 2 or 3**
  - Detached <72h
    - New patch asap
    - Keep same patch change day
    - Finish the cycle and start a new 3 patch cycle w/o HFI
  - Detached ≥72h
    - New patch asap
    - Keep same change day
    - Finish the cycle and start a new 3 patch cycle w/o HFI
    - B/U + consider EC

**Missed Contraceptive Ring**

**Delayed insertion ≥24h or removal ≥3h hrs**

- **During week 1**
  - Removal >3h or unsure
    - Insert ring asap
    - Keep till scheduled removal day
    - B/U for 7 days
    - Consider EC

- **During week 2 or 3**
  - Removal <72h
    - Insert ring asap
    - Keep till scheduled removal day
  - Removal ≥72h
    - Insert ring asap
    - Keep till scheduled removal day
    - Start a new cycle with a new ring w/o HFI
    - B/U + consider EC
### Missed Progestin Only Pills

Pill-taking is delayed >3h OR missing >1 pill

Unprotected intercourse in the past 5 days

- **Yes**: EC recommended
  - Take 1 pill the next day and take 1 daily
  - B/U for 48 h
  - Consider EC
- **No**: Take 1 pill asap
  - Continue 1 pill daily at the same hour
  - B/U for 48 h

### Missed Contraceptive Injection

Last injection given <14 weeks

- Give next injection asap
  - If PT is neg and unprotected sex in past 5 days, give EC+injection asap
  - B/U method for 7d
  - B-hCG 3 wks later

Last injection ≥ 14 weeks

- Unprotected sex in past 14d
  - Yes
    - If PT is neg and unprotected sex >5 days ago, give next injection asap
    - B/U method for 7d
    - PT 3 wks later
  - No
    - If PT is negative, give next injection asap
    - B/U method for 7d
For women with narrow cervical canal
   – Prime cervix with misoprostol 400 mcg a few hours before insertion

For pain management
   – Oral NSAID 400 mg PO and/or
   – Instill lidocaine in uterine cavity with an endometrial sampler
   – The sampler can be used instead of sound to measure depth of uterus
Cervical priming with sublingual misoprostol prior to insertion of an intrauterine device in nulliparous women: a randomized controlled trial

Saav I et al., Human Reproduction 2007; 22, (10): 2647

- 80 nulliparas treated 1 hour prior to IUD insertion
  - Misoprostol 400 mcg SL and diclofenac 100 mg
  - Diclofenac 100 mg PO alone (control group)

Findings
- Insertion easier with misoprostol than control group
- Pain scores no different in the two groups
- Most side effects equal
  » Shivering, diarrhea more common in misoprostol group

Misoprostol for IUC Insertion

Table 2: Difficulty of IUD insertion, as estimated by the inserter

<table>
<thead>
<tr>
<th>Estimation of difficulty</th>
<th>Misoprostol group, n = 39 (%)</th>
<th>Control group, n = 40 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy</td>
<td>29 (74.4)</td>
<td>22 (55.0)</td>
</tr>
<tr>
<td>Intermediate or difficult</td>
<td>10 (25.6)</td>
<td>18 (45.0)</td>
</tr>
</tbody>
</table>

\[ P = 0.039; \text{Fisher’s Exact test, mid-P-value. Degrees of freedom } = 1. \]

- Conclusion
  - Misoprostol can facilitate IUD insertion and reduce the number of difficult and failed attempts of insertions in women with a narrow cervical canal
The annual pelvic exam

- Is **not** a routine part of annual assessment for women 13-20 yo, unless medically indicated
- Is a routine part of preventive care for all women 21 years of age and older, even if Pap screening is not needed
Implications

In sexually active asymptomatic adolescents (< 21 y.o.), evidence-based screening visits, with or without a contraceptive prescription, consist of:

- Blood pressure check, BMI, and PNP
- PNP = Pee, not Pap
- Pee: Chlamydia NAAT
- Pap: not until 3 years after sexual debut
- Pelvic exam: not until 21 years old

#6 Emergency Contraceptive Products

- Change in the age threshold for OTC dispensing
  - Available without prescription @ 17 years old
  - Prescription only for women under
- Plan B® One-Step (now Teva; previously Duramed)
  - Single dose tablet; 1.5 mg levonorgestrel
  - Labeled for 72 hours from last intercourse
  - Plan B (2 tablet product) no longer available
- Next Choice (generic/ Watson Pharma)
  - Same as the two tablet Plan B® product
  - Labeling: 1 tab Q12 hours; off label: 2 tablets at once