Contraceptive Update: 
2016 CDC Family Planning Guidelines

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Disclosure

- I am a litigation consultant to Bayer Healthcare relating to the Mirena IUD

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>
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</tbody>
</table>
Case Study: Nancy

- 33 year old G2P2 seen for 6 week post partum visit
- Is fully breast feeding her infant, who was born at 34 weeks and who has problems with suckling
- She would like to start OCs, but is willing to consider other options

Clinician thought process

- “I don’t want her to use a method that will reduce the volume of breast milk”

Questions

- What should you tell her about CHCs and lactation?

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)
Post-partum COC'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 have minimal effect on quantity
- POPs have no effect on quantity or content milk
- Duration of breast feeding
  - 3.7 months in COC users vs. 4.6 months controls

COC: Combined oral contraceptives

Post-partum COC's: Newborn Risk

- 1% of ingested drug secreted in milk
- Ethinylestradiol dose reaching newborn is comparable to daily ovarian estradiol production
- Growth rates not affected by COC use
  - Any loss of milk volume compensated by increased suckling or food supplements
- Infant development
  - No short term metabolic differences vs. controls
  - 5 year study: no effect on neuro development

Post-partum OC's: Maternal Risk

- Changes in clotting factors last up to 6 weeks
  - Greater VTE risk to 6 weeks post-partum
- Concern that coagulation effects from pregnancy and COC's may increase risk of VTE
  - VTE not studied in low-dose OC users vs controls
- VTE risk of COC always > benefit if < 3 weeks pp
- Increased VTE risk not expected with progestin only methods, since no change in clotting factors

Post-Partum CHC: Non-Breastfeeding

US MEC 2016

<table>
<thead>
<tr>
<th>Category</th>
<th>US MEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) &lt; 21 days postpartum</td>
<td>4</td>
</tr>
<tr>
<td>b) ≥ 21 days to 42 days postpartum</td>
<td></td>
</tr>
<tr>
<td>i) with other risk factors for VTE</td>
<td>3</td>
</tr>
<tr>
<td>ii) without other risk factors for VTE</td>
<td>2</td>
</tr>
<tr>
<td>c) &gt; 42 days postpartum</td>
<td>1</td>
</tr>
</tbody>
</table>
Risk Factors for Post-partum DVT/PE

- Age ≥35 years
- Previous VTE
- Thrombophilia
- Immobility
- Transfusion at delivery
- BMI ≥30
- Postpartum hemorrhage, postcesarean delivery
- Preeclampsia
- Smoking

Post-Partum CHC: Breastfeeding
US MEC 2016

<table>
<thead>
<tr>
<th>Days from delivery</th>
<th>POP</th>
<th>DMPA</th>
<th>Implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 21 days</td>
<td>2*</td>
<td>2*</td>
<td>2*</td>
</tr>
<tr>
<td>21-29 days</td>
<td>2*</td>
<td>2*</td>
<td>2*</td>
</tr>
<tr>
<td>30-42 days; &gt; 42</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
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*2 In breast feeding women; 1 in non-breast feeding
POC: Progestin-only contraception
POP: Progestin-only pill

POC Use Among Breastfeeding Women: A Systematic Review

- Review of 47 studies
- “Evidence fails to demonstrate adverse breastfeeding outcomes or negative health outcomes in infants such as restricted growth, health problems, or impaired development”
- Largely consistent with previous evidence

Phillips SJ, Tepper NK, Contraception. Sep 24, 2015
Why Are POCs MEC-2 for < 30 Days PP in Women Who Are Breastfeeding?

- Theoretical concerns about effects of progestin exposure on the developing, neonatal brain are based on studies of progesterone effects in animals
- Whether similar effects occur after progestin exposure in human neonates is not known

Implant and DMPA Post-partum

Administration before hospital discharge

- **Advantages**
  - Protected if the post-partum visit is missed
  - Time-limited Medicaid eligibility
- **Disadvantages**
  - Unnecessary for first 4 weeks
  - Anatomic bleeding vs. drug side effect
  - Implant insertion kit may not be reimbursed as separate line item if global (per diem) hospital billing

Postpartum Contraceptive Implants

Not Breastfeeding

- Insert at any time, incl. immediately postpartum
- Need for back-up contraception
  - If ≥ 21 days pp and no return of menses, abstain from intercourse or use back-up for the next 7 days
  - If menstrual cycles have returned and it has been >5 days since menses started, abstain from intercourse or use back-up for the next 7 days

Breastfeeding

- Can be inserted at any time
- Need for back-up contraception
  - If <6 months pp, amenorrheic, and fully or nearly fully breastfeeding, no additional backup
  - If ≥ 21 days pp and no return of menses, abstain from intercourse or use back-up for the next 7 days
  - If cycles have returned and >5 days since menses, abstain or use back-up for next 7 days
Academy of Breastfeeding Medicine, Clinical Protocol #13

- Exclusively breastfeeding women are very unlikely to become pregnant in the first 6 weeks after birth
  - HC has minimal benefit, and early initiation may derail exclusive breastfeeding intentions
- Unless the risk of unplanned pregnancy or loss to follow-up is high, early initiation HC in breastfeeding women is not recommended

Risk Factors for Lactation Problems

- Previous BF problems or breastfed infant with slow weight gain
- Perinatal complications (hemorrhage, infection, LBW or preterm (<37wks)
- Hormone related infertility
- Med illnesses: hypothyroidism, diabetes, cystic fibrosis
- Maternal age: advanced or adolescent
- Psychosocial problems, especially depression
- Obesity (BMI >30 kg/m²)
- Lack of breast enlargement during pregnancy
- Previous breast surgery that severed ducts or nerves
- Previous breast abscess
- Extremely or persistently sore nipples
- Mother and infant separation or mother needing to pump

Breastfeeding and Hormonal Contraceptives: Striking a Balance

- Pro
  - Opportunity to initiate contraception when the risk of unplanned pregnancy or loss to follow-up is high
- Con
  - Exclusively BF women are extremely unlikely to become pregnant in the first 6 weeks post-partum
  - The period of exclusive breast feeding (12 weeks) is critically important and varies among women
- Hence: shared decision making is paramount and must be tempered by the interval since delivery
MEC 2016: Updated Comment

- "Discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives while considering each woman’s desire to breastfeed, risk of breastfeeding difficulties and risk of unintended pregnancy”
- "Women at risk for breastfeeding difficulties, include women with previous breastfeeding difficulties, certain medical conditions, certain perinatal complications, and those who deliver preterm”

Postpartum IUD Insertion
US MEC 2016

<table>
<thead>
<tr>
<th>Postpartum, including C/S</th>
<th>LNG-IUS</th>
<th>Cu-IUD</th>
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<tbody>
<tr>
<td>&lt;10 min after delivery of placenta*</td>
<td>1-nonBF</td>
<td>1</td>
</tr>
<tr>
<td>10 min after delivery of placenta to &lt;4 wks*</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>&gt;4 wks post partum</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Puerperal sepsis</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

- Higher rates of expulsion should be considered
- BF: women who are breast-feeding their newborn

Hot Topics in Family Planning

- New methods in the next few years
  - Extended use vaginal ring
  - Low dose contraceptive patch
  - Novel IUD designs
- Increasing use of telemedicine will increase access to hormonal contraceptives
- National contraceptive quality metrics

Distribution Systems for Hormonal Contraceptives (HC)

- Historically...
  - Clinician prescribed, pharmacy filled
  - Clinician prescribed, clinic furnished
- Newer alternatives
  - Nurse (RN) furnished, via standing orders
  - Pharmacist prescribed and furnished
  - Clinical services at retail sites
  - Telemedicine: On-line clinician prescribed
App-Based Telemedicine

Nurx: https://app.nurx.co

Birth Control
Delivered to you without a visit to the doctor. With or without insurance. Starting at $15/month.

www.projectruby.com

www.mavenclinic.com

www.lemonaidhealth.com

Alternative Delivery System Benefits

• Convenience...no clinic visit, no exam
• Don’t need a relationship with a PCP
• Confidential
• Inexpensive (no cost, if insurance used)
• No legislative approval; clinicians write Rx
• Targeted to millennials
  – Love technology
  – Prefer on-line shopping
  – Believe seeing a doctor is too much of a “pain”

Alternative Delivery System Benefits

• Clients have access to most contraceptives (except DMPA, implant, IUD)
• Remove the barrier of time lost at a clinic (and lessen opportunity cost)
• No travel and parking expense
• Reduction in unintended pregnancies?
Alternative Delivery System Risks

- Some women will miss the opportunity for detailed counseling and shared decision making
  - Loss of educational opportunity for LARCs
- More women will forego well woman visits
- Visits at some family planning clinics may continue to decline

Contraceptive Care Measure #1

**Use of Most & Moderately Effective Methods**

- Percentage of women aged 15-44 years at risk of unintended pregnancy that is provided a most or moderately effective contraceptive method
- An *intermediate outcome* measure

Contraceptive Care Measure #2

**Access to LARC**

- Percentage of women aged 15-44 years at risk of unintended pregnancy that is provided an IUD or contraceptive implant
- A measure of *access*
Contraceptive Care Measure #3

Contraceptive Care- Postpartum

- % of women 15-44 who had a live birth and were provided (in 3 days and 60 days of delivery) with a
  - Most or moderately effective method
  - LARC method