Chronic Disease, Obesity and Contraception Management

CFHC
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Objectives
At the end of this session, participants will be able to:

1) Utilize the 2010 CDC US Medical Eligibility Criteria for Contraception Use to advise patients on contraceptive options

2) Describe the Risks and Benefits of different contraception options against the risk of pregnancy in obese women and those with chronic medical disease.

Faculty Disclosure

No pharmaceutical support or commercial disclosures relevant to this talk.

Migraines, HTN, DVT, Coagulopathies and Obesity (and hopefully DM, liver disease, bariatric surgery)

- What do these conditions have in common?
  - Involvement of blood vessels
  - Estrogen increases coagulability of blood

- Why worry?
  - Will hormones increase risk of strokes, MI, other clot events?
  - How does this affect the contraceptive choice?

Epidemiology of Migraine in Women

Women are affected 3x more than men

- 20 million women in USA
- 40% of women in their lifetime
  - Before puberty: equally prevalent in both sexes
  - After puberty: 3x more women than men
  - Peaks in midlife
  - ↓ after menopause

Sarah
New Patient Visit
- 24-year-old non-smoker
- Sexually active
- On intake: checks off "headaches"
- Needs contraception
- BP 122/78, BMI 23
- Sarah’s aunt and grandmother have terrible "headaches"

Does Sarah have migraine?...

Use “PIN” for Diagnosis of Migraine
- Photophobia: Does light bother you?
- Impairment: Do your headaches limit you?
- Nausea: Do you feel nauseated?


ICHD Diagnostic Criteria for Migraine Without Aura
- At least 5 attacks with:
  - Headache lasts 4–72 hours w/o treatment or without successful treatment
- At least 2 of the following four symptoms:
  - Unilateral pain (60%)
  - Throbbing (70%)
  - Aggravation by movement
  - Moderate to severe pain

Adapted from IHS, Cephalalgia. 2004.

ICHD Diagnostic Criteria for Migraine Without Aura (cont’d)
- And at least 1 of the following 2 symptoms:
  - Nausea and/or vomiting
  - Photophobia and/or phonophobia
- Not attributed to organic disease

Adapted from IHS, Cephalalgia. 2004.

ICHD Diagnostic Criteria for Migraine with Aura
- At least 2 attacks with
- At least 1 fully reversible symptom w/o motor
  - Visual (flickering lights, zigzags, spots or lines, and/or loss of vision) + and/or
  - Sensory ("pins and needles" and/or numbness) + and/or
  - Dysphasic speech

Adapted from IHS, Cephalalgia. 2004.

ICHD Diagnostic Criteria for Migraine with Aura (cont’d)
- Symptoms of aura develop gradually over >5 min or different symptoms occur in succession over >5 min
- Each symptom last >5 and <60 min
- Migraine begins with aura or within <60 min
- Symptoms are fully reversible
- No organic disease
- Aura may occur in absence of headache (less typical)

Adapted from IHS, Cephalalgia. 2004.
Distribution of Migraine Types in Women

- 40% non-menstrual migraine
- 60% menstrual migraine
  - MRM comprises the majority of MM (46% of 60%)

Female Migraineurs

Sarah

Accurate diagnosis of migraine is essential for the safe prescribing of estrogen-containing contraception.

Sarah has headache without aura. She has no other risk factors for stroke. Sarah’s headaches are worse with menses, but do happen at other times.

Sarah

- Is Sarah eligible for estrogen-containing contraceptives? Might she opt for a patch or ring?

A) Yes: Low-dose estrogen contraception can be used in women under age 35 who have migraine without aura and no other risk factors for stroke.

B) No: OCPs should never be used in women who have migraine.

CDC MEC: Migraines, <35 yrs, no aura

<table>
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<tr>
<th>Method</th>
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<th>Continuation</th>
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<tbody>
<tr>
<td>Combined OC/patch/Ring</td>
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<tr>
<td>Progesterin-only pills</td>
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<td>2</td>
</tr>
<tr>
<td>DMPA</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Implants</td>
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<tr>
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<td>2</td>
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<tr>
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</tbody>
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Initiation vs. Continuation: New-onset migraines warrant re-assessment of hormonal contraception.

CDC MEC: Migraines, >35 yrs, no aura

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Initiation vs. Continuation: New-onset migraines warrant re-assessment of hormonal contraception.

CDC MEC: Migraines, any age, with aura

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"Continuation" recommendations apply if the condition (migraines) started after the contraceptive method did.
Migraine, OCPs, and Stroke

- 6 per 100,000 ♀ / year – healthy
- 12 per 100,000 ♀ / year – migraine
- 18 per 100,000 ♀ / year – migraine with aura
- 12 per 100,000 ♀ / year – healthy and COC
- 19 per 100,000 ♀ / year – migraine and COC
- 30 per 100,000 ♀ / year – migraine with aura and COC
- 34 per 100,000 ♀ / year – stroke in pregnancy

Attributable risk: 7-19 per 100,000 women per year ~ 4000 / year

So, What about estrogen containing contraception in women with Migraine?

- IHS: low-dose estrogen in women with simple visual aura
- ACOG: progestin only, intrauterine or barrier contraception
- CDC: absolute contraindication in all women with aura

Prescribing Contraception in Women with Migraines

- Use a Progesterone Only method with aura
- Lowest estrogen levels with ring
- Consider 20 or 25 mcg pills
- Consider eliminating the placebo week
- Follow-up in 1-3 months after initial Rx
- Stress need to discontinue method if Migraines worsen

Clara

- 42 yo G4P2 Tab 2, here to discuss birth control
- Has not had sex since divorce 5 years ago, but now in a relationship
- Used OCPs in the past and wonders if she can use them again
- PMH: gestational HTN and DM, random glucose in office normal, BP 128/79. Denies headaches or h/o DVT
- Fam Hx: Breast cancer in 40 yo sister and mom with h/o DVT

CDC MEC: Hypertension

<table>
<thead>
<tr>
<th>Method</th>
<th>Adequately controlled</th>
<th>140-159/90-99</th>
<th>&gt;160 SBP; &gt;100 DBP</th>
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<tbody>
<tr>
<td>Combined Methods</td>
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<td>3</td>
<td>4</td>
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<tr>
<td>Progestin-only pill</td>
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<td>1</td>
<td>2</td>
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<tr>
<td>DMPA</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Implant</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>LNG-IUD</td>
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</table>

Cardiovascular Risk Factors

<table>
<thead>
<tr>
<th>Current/ h/o ischemic heart disease</th>
<th>CHC</th>
<th>Implant</th>
<th>DMPA</th>
<th>Cu-IUD</th>
<th>LNG-IUS</th>
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<tbody>
<tr>
<td>Current</td>
<td>4</td>
<td>2/3</td>
<td>3</td>
<td>1</td>
<td>2/3</td>
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<tr>
<td>Stroke</td>
<td>4</td>
<td>2/3</td>
<td>3</td>
<td>1</td>
<td>2</td>
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<tr>
<td>Age &lt;35</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Age &gt;35 and smokers &lt;15 cigs/day</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Age &gt;35 and smokers &gt;15 cigs/day</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Combined Hormonal Contraception

- Cardiovascular Disease
  - 3/4 Multiple risk factors (smoking, DM, HTN, obesity, age)
  - 3: HTN currently controlled, SBP 140-159, DBP 90-99
  - 4: Systolic > 160, diastolic >100
  - 4: Vascular Disease
  - 4: Major surgery with prolonged immobilization
  - 4: Stroke, Ischaemic Heart Disease (History of or Current)
  - 4: Complicated Valvular disease
  - 2: h/o Gestational Hypertension
Hypertension: What if the meds are working?

- ACOG: Women <35yr well-controlled HTN can use combined methods if:
  - Otherwise healthy
  - No evidence of end-organ vascular damage
  - NO SMOKING
- Absolute risks of MI, stroke are low
- Balance with risks of pregnancy & benefits
- Current studies with low EE pills show minimal RR of stroke or increase BP

Venous Thrombosis and CHC

- ▲ DVT rates with increasing dose of estrogen
- OC and OrthoEvra have similar DVT risk (Jick, 2006)
  - NGM OCs: 4.2/10,000 women/year
  - Patch: 5.3/10,000 women/year
  - Age-adj RR: 1.1 (95% CI: 0.7-1.8)
- DVT risk declines with increasing duration of use
- Progestin type, dose have no (or minimal) impact

Shapiro S; Dinger J; Jol of Family Planning & Reproductive Health Care, 2010 Jan

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>General Population</th>
<th>Obesity (BMI ≥35kg/m²)</th>
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<tr>
<td>BMI ≥30</td>
<td>4-5</td>
<td>12-20</td>
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<td>BMI ≥35</td>
<td>10-30</td>
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<td>Age 45-49</td>
<td>25</td>
<td>40</td>
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<tr>
<td>Factor V Leiden mutation</td>
<td>40-40</td>
<td>40-75</td>
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<td>Factor V Leiden Homozygous</td>
<td>200-400</td>
<td>200-400</td>
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<tr>
<td>Pregnancy</td>
<td>100-200</td>
<td>200-400</td>
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</tbody>
</table>

Comparative Risks of VTE

- General population
- Low-dose OC
- High-dose OC
- Pregnancy

CDC MEC: History of DVT/PE Not on Anticoagulant Therapy

- Higher risk for recurrent DVT/PE
  - History of estrogen-associated DVT/PE
  - Pregnancy-associated DVT/PE
  - Idiopathic DVT/PE
  - Thrombophilia; antiphospholipid syndrome
  - Active cancer (metastatic, on therapy, or < 6 months after clinical remission)
  - History of recurrent DVT/PE

CDC MEC: Deep Venous Thrombosis

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>OC/P</th>
<th>POP</th>
<th>DMP</th>
<th>Imp</th>
<th>LNG-IUD</th>
<th>Cu-IUD</th>
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</thead>
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<td>Higher risk for recurrent DVT/PE (no risk factors)</td>
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<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
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<tr>
<td>Lower risk for recurrent DVT/PE (no risk factors)</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>1</td>
</tr>
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</table>
Prior Venous Thrombosis and CHC

Conventional wisdom

- If a woman has h/o idiopathic or post-partum DVT or VTE, may be predisposed to recurrence if given exogenous estrogen
  - Hence, avoid E-containing contraceptives

- If DVT related to another condition (e.g., immobilization, trauma), without a history of recurrence, E-containing contraceptives may be considered Category 3

CDC MEC: Deep Venous Thrombosis

<table>
<thead>
<tr>
<th>Category</th>
<th>OC/P</th>
<th>POP</th>
<th>DMP</th>
<th>Impl</th>
<th>LNG</th>
<th>Cu-IUD</th>
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</thead>
<tbody>
<tr>
<td>Acute DVT/PE</td>
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<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
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<tr>
<td>DVT/PE, anticoagulants ≥3 mo</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

ii) Lower risk for recurrent DVT/PE

Venous Thrombosis and CHC

- Superficial varicose veins and thrombophlebitis do not increase the risk of DVT or VTE, regardless method- safe

- Discontinue OC’s 30 days before major surgery
  - Only with prolonged immobility Cat 4.
  - Without prolonged immobility Cat 2

- Not necessary to interrupt OC’s before short operative procedures with early physical activity

Thrombophilias

- Thrombophilias: genetic mutations that increase likelihood of blood clots
  - IE: Factor V Leiden
  - Many women with one copy of mutation (heterozygous) asymptomatic
  - Highest risk of clot with homozygous

Known Thrombogenic Mutations

<table>
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Thrombophilias

Factor V Leiden mutation (FVL)
- Individuals with the FVLM have activated Protein C resistance and hypercoagulability
- Present in 70-90% of inherited thrombophilias
  - 20-40% of patients having a first DVT
  - 50% of those with > 1 episode of DVT
- 1-5% US pop; 5% Europeans; 15% of Scandinavians
- OC users with FVLM have 15 fold increased risk of DVT


Screening For Inherited Thrombophilias In Asymptomatic Woman?
- ACOG and CDC do not suggest routine screening before starting COCs
- ~10 million American women use COCs; ~ 5% of them likely to carry Factor V Leiden (FVL) mutation.
- Incidence of VTE with COC use (30 to 40 events per 100,000 person years)


Maybe screen for thrombophilia....
- Consider screening in women with a family history of VTE in several relatives, or one relative with VTE under the age of 50 years
- History, History, History....ask about family history of thrombotic events before prescribing CHC

Screening For Inherited Thrombophilias In Asymptomatic Woman?
- Estimated mortality rate from VTE
  - 3 in 1 million for COC users
  - 14 in 1 million in COC users with FVL mutation
- > 92,000 women need to be screened to prevent one death [Creinin]
- Cost to prevent one death > $300 million) [Creinin]

Anticoagulation?
- Increased risk of severe menorrhagia
- When contraceptive method used as therapy, rather than solely to prevent pregnancy, risk-benefit ratio may differ....”
- DMPA: Injection site hematomas – no increased risk
- Can consider combined hormonal contraception on a case-by-case basis.


Anticoagulation?

- Anticoagulants like coumadin – increase risk of birth defects!
- Think Highly effective contraception!
- LNG IUD has --FDA Indication-- to treat heavy bleeding in women who want IUD
  - Hemostatic effect may not last all 5 years – consider early replacement.

Coagulation disorders that increase bleeding

- E.g., Von Willebrands
  - Significant menorrhagia in young women
- No category in CDC or WHO MEC
- Principles:
  - Decreasing menstrual blood loss is a goal
  - No method is contraindicated
  - Methods that decrease menstrual blood loss and frequency of menstruation are beneficial

Coagulation disorders: Options

- Combined methods: likely to decrease menstrual blood loss and improved cycle control
  - If there are no other contraindications
  - Consider effectiveness
- Progestin methods: may have unpredictable bleeding patterns, but magnitude of menstrual blood loss is generally lower
  - Implant
    - Irregular bleeding is a side effect
    - Magnitude of blood loss?
    - Not a lot of data in this population
- IUD: LNG IUD excellent choice w/ 80% reduction in blood loss

Tracy

- 23 yo G0P0
- BMI 34
- BP 137/76
- Seeking contraception
- Worried that the pill might make her gain more weight
- Doesn’t want anything put in her vagina.
- What can we tell her?

Obesity and Contraception

Obesity Trends* Among U.S. Adults

(*BMI ≥30, or ~ 30 lbs. overweight for 5’ 4” person)
Obesity Trends* Among U.S. Adults

2005

(*BMI ≥ 30, or ~ 30 lbs. overweight for 5’ 4” person)

No Data          <10%           10% – 14%          15% – 19%          20% – 24%          25% – 29%          ≥30%

COC, Patch, Ring

BMI ≥ 30 = Category 2

Rationale:
► VTE more common, but absolute risk small
► Equal rates of MI, weight gain
► Decreased efficacy for patch >90kg (by weight not BMI)
Hormonal Contraceptive & Obesity

CHCs and Weight Gain

- 3 placebo-controlled, RCTs did not find evidence supporting causal association between COCs or patch and weight gain.
- Most comparisons of different CHCs showed no substantial difference in weight.


POP and Weight Gain

- Little evidence of weight gain using POPs.
- Mean gain <2 kg for most studies up to 12 months.
- Similar wt gain for comparison group using another contraceptive.
- No significant ↑ in the risk of stroke, myocardial infarction, or VTE among users of POPs compared with non-users.


LNG IUS and Weight Gain

No studies of LNG IUS that met inclusion criteria.


DMPA and Weight Gain

- About ¼ of DMPA users had early weight gain.
- Early weight gainers had greater intensity—much steeper slope of wt gain than regular wt gainers.
- Risk factors for early wt gain were:
  - BMI < 30
  - Parity ≥1
  - Self-reported increased appetite after 6 months
- Most DMPA users who gain excessive weight gain ≥5% within 6 months.
- We can use these data to predict who is at risk of excessive gain and counsel them appropriately.


DMPA and Weight Gain

- Teens on DMPA gain more weight than teens on COCs.
- Teens who gained > 5% of baseline weight at 3 (6) months were at high risk at gaining even more weight at 12 months.
- Overweight teens may be more likely to have significant weight gain on DMPA.

Contraceptive Ring And Efficacy

NuvaRing is not associated with an increased failure rate for women in the highest weight decile (>166 lbs) versus the rest of the study population.


Etonogestrel Implant and Obesity

No difference in efficacy seen in obese women, but not included in original trials

Chart review of >300 women found obese women significantly less likely to have implant removed for bleeding


Safety and Etonogestrel Implant

- Not studied in obese women
- No negative effect on the endothelial parameter NO or on the cardiovascular risk parameters
  - CRP
  - Cholesterol/HDL ratio
- ↓SHBG was seen & might be an advantage for the risk of DVT.


COCs and Efficacy

Four studies found statistically significant ↑ risk of contraceptive failure with ↑BMI


Continuous COCs and Efficacy

March 2012

- Crude pregnancy rates were similar across weight and BMI deciles
- No discernable differences observed between deciles using either BMI or weight classification criterion

Westhoff CL, Hait H, Reape KZ. Body weight does not impact pregnancy rates during use of a low-dose extended regimen 91-day oral contraceptive Contraception 2012; 85(3):235-239.

COC: and ovarian suppression

No meaningful differences between the normal-weight and obese participants, or between the participants randomly assigned to the 20mcg ethinyl estradiol /100mcg levonorgestrel or 30mcg ethinyl estradiol /150 mcg levonorgestrel OCP

**Efficacy Levonorgestrel and Ulipristal Emergency Contraception**

- The variable with the most highly significant impact on the risk of pregnancy was BMI
- The risk of pregnancy was 1.5 X > if BMI >25 and >3 X ↑ if BMI >30 compared to BMI < 25


**LNG VS. UPA EC**

- Efficacy in Overweight Women

- The effect of BMI was more pronounced in women treated with LNG than with UPA.
- Overweight women taking LNG had >2X risk of pregnancy compared with normal-wt or underweight women.
- Risk was not different for UPA


**LNG VS. UPA EC**

- Reduced Efficacy in Obese Women

- For obese women LNG >4X greater pregnancy risk vs. normal-weight or underweight women.
- For obese women UPA >2X greater risk of pregnancy vs. normal-weight or underweight women.
- Rapid risk of ↓↓ efficacy with LNG with increasing BMI.


**Bariatric Surgery**

- **Restrictive**
  - Decreases stomach “storage capacity” & delays emptying
  - No effect on intestinal absorption
  - Examples: Vertical banded gastroplasty, laparoscopic adjustable gastric band, laparoscopic sleeve gastrectomy
- **Malabsorptive**
  - Involves removal of much of stomach & bypasses foregut
  - Interferes with/ decreases intestinal absorption of calories and nutrients
  - Example: biliopancreatic diversion (not common)
- **Restrictive-malabsorptive**
  - A combination of the above 2 mechanisms
  - Roux-en-Y gastric bypass
  - One of the most common operations in the US
Contraception after Bariatric Surgery: Why?

- With decreasing weight and accompanying metabolic changes, menstrual cycles may normalize and fertility improve.
- Guidelines are to delay pregnancy for 1 to 2 years after surgery.
  - Postoperative complications, metabolic changes.
- Many surgical patients are women of reproductive age.

MEC RESTRICTIVE bariatric surgery:

<table>
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<th>Type</th>
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<tbody>
<tr>
<td>Combined pill, patch, ring</td>
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MEC MALABSORPTIVE bariatric surgery:

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<tbody>
<tr>
<td>Combined or progestin-only pill</td>
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</tr>
<tr>
<td>Combined patch or ring</td>
<td>1</td>
</tr>
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<td>DMPA</td>
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Diabetes and Contraceptives

- Minimal to no effect on:
  - HgbA1C
  - Insulin requirements
  - Lipid metabolism
- COCs
  - Small studies noted no increase in vascular complications.
CDC MEC Diabetes Mellitus

**Liver Disease**
- Viral-related liver disease - Hepatitis A, B, or C
- Worldwide, 400 million chronic carriers of Hep B
  - Long-term consequences: cirrhosis and hepatocellular carcinoma
- Benign liver tumors include hepatocellular adenomas and focal nodular hyperplasia
  - Primarily diagnosed in young, healthy women

<table>
<thead>
<tr>
<th>DM only during pregnancy</th>
<th>COC/P/R</th>
<th>POP</th>
<th>DMPA</th>
<th>IMPLANT</th>
<th>LNG-IUD</th>
<th>Cu-IUD</th>
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<table>
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<th>No vascular disease</th>
<th>COC/P/R</th>
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<th>IMPLANT</th>
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<th>Vascular disease or &gt; 20 yrs</th>
<th>COC/P/R</th>
<th>POP</th>
<th>DMPA</th>
<th>IMPLANT</th>
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<th>Cu-IUD</th>
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</tbody>
</table>

*Initiation/Continuation

Vascular disease includes retinopathy, neuropathy, nephropathy

Adapted from the U.S. Medical Eligibility Criteria for Contraceptive Use, 2010

Liver Disease and Contraceptives
- Estrogens and progestins metabolized in the liver
  - Estrogens also act directly via receptors
- COCs do not increase transaminase levels, disease progression, or risk of hepatocellular carcinoma with chronic viral hepatitis
  - Only one small trial investigated acute hepatitis
- Limited studies show no increase in lesion number or size with OCs in women with focal nodular hyperplasia
- COC may progress hepatocellular carcinoma

**CDC MEC Liver Disease**

- Acute hepatitis: 3-4
- Chronic hepatitis: 1
- Mild cirrhosis: 1
- Severe cirrhosis: 4
- Focal nodular hyperplasia: 2
- Adenoma or hepatoma: 4

*Initiation/Continuation

Adapted from the U.S. Medical Eligibility Criteria for Contraceptive Use, 2010

**Bottom line (Summary)**

The use of contraception is almost always safer than pregnancy, in women with chronic medical conditions

**Easy answer to everything: why not condoms?**

- Sure!
- As long as they are combined with a more reliable method.
- If you are worried, CDC MEC are easy to access:

  www.cdc.gov/mmwr/pdf/rr/rr5904.pdf

Or just Google it: “CDC MEC”
Green Light!
(CDC MEC Cat 1 and 2)

- IUDs are Category 1 or 2 for pretty much anyone
- Progestin methods do not carry the same concerns for thrombotic risk as estrogen methods.
  - Implants good option too
- Combined methods may still be appropriate for some women with chronic conditions.
  - Consider effectiveness & woman’s needs

Yellow Light!
(CDC MEC Category 3)

- CHC and:
  - Migraine > age 35
  - New-onset migraine < age 35
  - History of DVT/PE & low risk for recurrence
  - Hypertension: controlled, not severe
  - Smoking > 35 yo & < 15 cigarettes/day
  - Diabetes and end organ damage or > 20 yrs
- POC and:
  - Malabsorptive bariatric surgery
  - Uncompensated Cirrhosis

Red Light!
(CDC MEC Category 4)

- Combined pill/patch/ring and:
  - DBP > 160 or SBP > 100
  - Ischemic heart disease
  - Known thrombogenic mutations
  - New onset Migraine > 35 yo or Migraine w/ aura
  - Acute DVT/PE or h/o & high risk for recurrence
  - Malignant liver tumors
  - Smoking > 35 yo & > 15 cigarettes/day
- POPs and: current breast cancer