Contraceptive Update 2016:

The New CDC MEC Guidelines and More

R. Mimi Secor, DNP, FNP-BC, NCMP, FAANP
Onset, Massachusetts

R. Mimi Secor, DNP, FNP-BC, NCMP, FAANP

- Nurse Practitioner for 39 years
- Newton Wellesley ObGyn, Newton, MA
- DNP, 2015 Rocky Mtn University, Provo, UT
- 2013 Lifetime Achievement Award, MCNP (Mass)
- NEW! 3rd edition, “2016 AJN Book of the Year”
- Visiting Scholar, Boston College
- Owned a private practice for 12 years in Massachusetts (1984-1996)
- Worked in Alaska for 7 years (1992-1999)

Mimi Secor, DNP, FNP-BC, FAANP
Disclosure

Speaker: GenPath, Shionogi, Hologic
Objectives (100% Pharm)
Contraception Update

- Describe trends and contraceptive challenges facing clinicians and patients.
  15 minutes

- Explain the new CDC medical eligibility criteria for prescribing various contraceptive methods and medical conditions.
  30 minutes

- Discuss new contraceptive research regarding efficacy, risks, benefits as this pertains to prescribing.
  15 minutes
6.3 Million U.S. pregnancies: Intended vs. Unintended

- **Intended Pregnancies**:
  - Birth 43%
  - Miscarriage 9%
- **Unintended Pregnancies**:
  - Birth 19%
  - Miscarriage 6%

- **Higher in poor**

Henshaw, Family Planning Perspectives, 1998; 30:1

Family Planning Challenges

- High unplanned pregnancy rate continues
- Few easy, effective methods
- Low pt compliance & lack of knowledge
- Societal conflict about family planning
- Clinical challenge: little time, tight budgets
- Risk taking behaviors!
Emergency Contraception

Lack of Public Awareness Still...

- Progestin only - 0.75 mg (Plan B)
  - 2 pills po STAT: or 1 pill 12 hrs apart
    Taken within 72 hours of unprotected sex
  - 95% effective if taken within 24 hours
    - 89% effective if taken within 72 hours
  - SAFE, few side effects
- Over-The-Counter in most states > 17 yrs
- Less effective if BMI >26 !!!!! (165 lbs)


Emergency Contraception: Progestin Only- Obesity, Wt > #176

- Obesity impedes efficacy of EC
- European labelling contains this warning
- Lower serum levels than normal wt
- Doubling dose raised levels to normal wt levels
- Important to educate patients
- And offer other EC options:
  - IUC and Oral Ulipristal

Edelman AB et al. Contraception 2016 Jul;94:52
Emergency Contraception: Ulipristal

- **Ulipristal (ella)** 30 mg orally, 1 dose
- Up to 5 days after unprotected intercourse (UPI)
- Delays ovulation, NOT an abortifacient
- Preferred for Overweight/OBESE !!!
- Prescription required:
  - www.ella-kwikmed.com/
- Avoid if already pregnant
- Side effects = placebo
- Headache 18%, Nausea 12%, Abd pain 15%
- If BMI > 35, less effective (Glasier et al, 2011)

Contraceptive Options

- **Combination Hormonal Contraceptives (CHC)**
  - Orals
  - Transdermal Ethinyl Estradiol (EE) Patch, (Ortho Evra)
  - Vaginal EE Ring, (NuvaRing)
- **Progestin Only Contraceptives (POC)**
  - Etonogestrel Implant, (Nexplanon) 3 year rod (upper arm)
  - Depot Medroxyprogesterone, DMPA “Depo Provera”
  - IM 150 mg, SC 104 mg
  - LNG-IUD, Levonorgestrel (Mirena, Skylla)
  - Progestin only “Mini-pill”: Norgestrel (Ovrette), Norethindrone (Micronor, Nor-QD, Errin, Camilla)
- **Other:**
  - Sterilization, male/female (Essure)
  - CU-IUD (Paragard); Other: Condoms, Caps, Natural (NFP)

Typical Effectiveness of Contraception

Adapted from: WHO. Family Planning: A Global Handbook
2010: US Medical Eligibility Criteria for Contraceptive Use (MEC) Update 2016

No restriction for the use of the contraceptive method for a woman with that medical condition

Advantages of using the method generally outweigh the theoretical or proven risks

Theoretical or proven risks of the method usually outweigh the advantages – or that there are no other methods that are available or acceptable to the women with that medical condition

Unacceptable health risk if the contraceptive method is used by a woman with that medical condition

2016 CDC US Medical Eligibility Criteria: Categories

1. No restriction for the use of the contraceptive method for a woman with that medical condition
2. Advantages of using the method generally outweigh the theoretical or proven risks
3. Theoretical or proven risks of the method usually outweigh the advantages – or that there are no other methods that are available or acceptable to the women with that medical condition
4. Unacceptable health risk if the contraceptive method is used by a woman with that medical condition

Contraception 2016

- Volume 94, Number 3, September 2016
- www.Contraceptionjournal.org
- MEC Update- Editorial
- Research gaps
- 6 Systematic Reviews!
  Breast feeding: P OK, CHC 6 wk PP NO
  SVD and CHC - NO
  Dyslipidemia - Unclear
Handheld App:

“CDC Contraception 2016”
MEC
SPR

Medical Eligibility Criteria for Contraceptive Use

CDC MEC SPR 2016: NEW App
Contraception Guidelines

US MEC = Medical Eligibility Criteria
- By condition
- By method

US SPR = Selected Practice Recommendations
- Initiation
- Exams and tests
- Routine f/u
- Missed doses
- Bleeding abnormalities
### FDA Contraception 2016

#### Key

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### FDA Contraception 2016

#### Antimicrobial therapy
d. Rifampin or rifabutin therapy

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### FDA Contraception 2016

#### f. Minor surgery without immobilization

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### FDA Contraception 2016

#### g. Other vascular disease or diabetes of >20 years’ duration

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### CDC Contraception 2016

#### b. Migraine

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### CDC Contraception 2016

#### Ischemic Heart Disease, current or history

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### CDC Contraception 2016

#### Diabetes, hypertension, low HDL, high LDL, or high triglycerides

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CDC MEC Update: 2016
HIV and Contraceptives
Revised Recommendations for the Use of Hormonal Contraception Among Women at High Risk for HIV Infection or HIV+
ALL OK BELOW:
- Combination Hormonal Contraceptives (CHC): Cat 1
- Progestin Only Pills (POPs): Cat 1
- Progestin Only Injectables (DMPA): Cat 1*
  *BUT-Unclear risk re: acquisition of HIV?
- IUC: No increase in shedding (both types) Cat 2, 2

CDC MEC 2016
Intrauterine Systems: IUC Effectiveness = Sterilization

- Copper T380 IUS (Paragard)
  - Approved for 10 years
  - Off-label for 12 years
  - Easier to insert if nulliparous

- Levonorgestrel IUC (Mirena)
  - Skyla- smaller device
  - Approved for 5, 3 years
  - Reduced menstrual bleeding
  - May reduce fibroids

Xu. Contraception Sep 2010: 82; 301-309, n -20

IUC: New, Smaller (Skyla) LNG containing, Similar to (Mirena)

- Levonorgestrel-releasing
- Total of 13.5 mg of LNG
- Approved: January 2013
- For 3 years
- Good for Nulliparous

- www.skyla-us.com
- Tel 1-888-842-2937
- Bayer HealthCare
  Manufactured in Finland

Relax!

Why yes, I’m a bit stressed. Why do you ask?
NEW IUC Approved: Liletta 2015

- Levonorgestrel-releasing IUC
- By Actavis/Medicines 360
- Will be offered at reduced cost to public health clinics
- Enrolled in the 340B drug pricing program

Dispelling Common Myths About IUCs

In fact, IUCs:
- Can be used by nulliparous women
- Can be used by women who have had an ectopic pregnancy
- Do NOT need to be removed for PID treatment
- Do NOT have to be removed if actinomyces-like organisms (ALO) are noted on a Pap test


Screening: Poor Candidates for Intrauterine Contraception

- Known or suspected pregnancy
- Puerperal sepsis
- Immediate post septic abortion
- Unexplained vaginal bleeding
- Cervical or endometrial cancer

WHO. 2009.
Screening: Poor Candidates for Intrauterine Contraception
- Uterine fibroids that interfere with placement
- Uterine distortion (congenital or acquired)
- Current PID
- Current purulent cervicitis
- Current chlamydia or gonorrhea
- Known pelvic tuberculosis

IUC: MEC Conditions

Age
- Menarche to <20: 2
- > 20: 1
- Nulliparous women: 2
- Postpartum: 2
  - <10 minutes PP, CU 1
  - Puerperal sepsis: 4

Postabortion
- First trimester: 1
- Second trimester: 2

IUC: Cardiovascular Disease

Hypertension: 1
except
- S >160/D>100 & vascular disease:
  LNG = 2

DVT/PE
- Cu: 1
- LNG: 2
- Acute DVT/PE: 2
- Known thrombosis 2
IUC Issues: Infection

- PID and IUC use: confined to early weeks
  - Low risk even then

- Large meta-analysis 22,908 insertions
  - Grimes et al. Cochrane Review 2004;3
  - Infection in first 20 days 9.7/1,000 woman years
    - From vaginal contamination despite aseptic technique
    - Infection rate after 20 days 1.4/1,000 woman yrs of use

PID with IUC:

- May leave IUC in place
- Treat infection
- Close follow-up, 1-3 days
- If not improved, consider removing IUC
- Counseling & Condoms
- If history of PID, increased risk for STIs

CDC, WHO, ACOG 2009-2010

Combined Hormonal Contraceptives:

CHC

Pills: medium
Patch- high
Ring- low
Serum EE Levels of Ring, OC & Patch
Ethinyl Estradiol (EE)

- Vaginal Ring: **Lowest EE serum levels**
- Orals (COC): Mid-range serum levels
- Transdermal Patch: **Highest EE serum levels**


NEW 2013: Risk of Thromboembolism/CV Events in CHC Users- DSP OC YES, Patch & Ring NO

- N 835,826, ages 10-50, population based cohort
- Conclusions:
  - In NEW users, DSP* was associated w higher risk of VTE/ATE relative to low dose CHC comparator
  - NO increased risk with Patch OR Vaginal Ring
- VTE in younger group (77% increase) 10-34 years
- ATE in older group (2 fold increase) 35-55 years

*Drospirenone

Sidney et al. Contraception 2013 Jan; 87 (1) :95-100

Hormonal Contraceptives and Coexisting Medical Conditions
**CHC- Category 4**  
Contraindications

- Smokers $\geq 35$
- Breast cancer
- Postpartum $< 21$ days
- Acute hepatitis/flare
- Severe cirrhosis
- Liver tumors
- Migraine with aura !!!
- Diabetes $> 20$ years
- Major surgery
- CVD
  - Ischemic, stroke,
  - Multiple risk factors
  - HTN $\geq 160/\geq 100$
- DVT/VTE
  - On therapy
  - Acute
  - History of

**CHC- Category 3**  
Relative Contraindications

- Drug interactions
  - Rifampicin
  - Certain anti-seizure meds
  - Lamictil incr. seizures
  - ARV meds (t)
  - Ritonavir-boosted PI
  - BP 140-159/90-9
- CVD: multiple risk factors
- Diabetes $< 20$ years: NO vascular complications
- Migraine without aura
- Hepatitis acute
- Bariatric surgery (bypass)
- Postpartum 21-42 days

**CHC: Age**

Menarche to $< 40$ years = C 1  
- 40 years old 2

Smoking
- $< 35$ smoker: 2
- $\geq 35$ smoker $< 15$/day: 3
- $> 35$ and smoke $> 15$/day: 4 !!!
Post-partum: CDC MEC 2013 Update

- < 21 days postpartum: No CHCs- Cat 4!
- 21-42 days Postpartum PLUS risk for VTE, Cat 3
- 21-42 days, NO risk factors, Cat 2
- > 42 days, No restrictions, Cat 1

- > 1 month postpartum, breast feeding, Cat 2
- < 1 month postpartum, breast feeding, Cat 3
- Post abortion, Cat 1

CHC, Smokers, Obesity and VTE Risk:

- Smokers risk of CVD Death & using COCs
  - 3.3 per 100,000 women if < 35 yr
  - 29.4 per 100,000 women if > 35 yr !!!!

- If BMI > 30 and CHC user
  - Risk < death faced by smokers younger than 35 yrs old (2.4 >BMI vs 3.3 smokers per 100,000)

- NO data on BMI > 40


CHC: Obesity

BMI > 30
- Category 2

- Possible increased risk of VTE, MI, stroke

- NOT more likely to gain
Obesity & Comb Hormonal Contraceptives (CHC): Failure Risk LOW !!!

- Efficacy of pill, patch, or vaginal ring NOT impaired by high BMI
- N 1523
- 128 Pregnancies
  
  Higher parity
  History of unintended pregnancies

http://dx.doi.org/10.1097/AOG.0b013e21828317cc

Combined Oral Contraceptives

- Contain estrogen & progestin
- Most newer formulations contain 20 – 35 mcg of ethinyl estradiol + 1 of 8 available progestins


Contraceptive Approaches

Comb Oral Contraceptives (COCs)

- Quick start: In-office or same day
- First day start: 1st day of menses
- Extended regimens
- Continuous
- Shorter “placebo” interval
- Low-dose placebo interval
COC: Initial Pill Selection

**Estrogen:** (cycle control primarily)
- Heavy periods: Higher estrogen 30-35 mcg
- “Normal” menses: Lower estrogen 20-25 mcg

**Progestin:** (contraceptive effects primarily)
- Levonorgestrel: Very safe, less BTB*
- Norethindrone: Safe, more BTB
- Drospirenone: Avoid if unknown family hx
  Or family hx of clots, or coagulopathies

MPR= Prescribers Reference, *BTB= breakthrough bleeding

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Which Ocs are Lowest Risk: re PE, Ischemic Stroke, MI? May 2016

- French Cohort Study of 5 Million Women!
- **Lowest risk:** 20 mcg EE** plus Levonorgestrel 17.3/100,000 for PE (crude event rate)
  LEVONORGESTREL is safest Progestin!
- **Highest risk:** 30 mcg EE** plus Desogestrel 52.1/100,000 for PE (crude event rate)
  AVOID!!!

**EE = Ethinyl estradiol**

Weill A et al. BMJ 2016 May 10;353:i2002
http://dx.doi.org/10.1136/bmj.i2002

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COC: EE/LNG, (Quartette) by Teva: NEW 2013

**Goal:** to Minimize BTB

- 91-day oral regimen
- **Triphasic:** with Ethinyl Estradiol/EE
- Estrogen, EE increases at 3 distinct points over the first 84 days
- Progestin, “Levonorgestrel” remains consistent
- 7 days of ethinyl estradiol 10mcg
Estradiol Valerate, Dienogest (Natazia)  
2012 FDA Approved for Menorrhagia
- 2 dark yellow = 3 mg Estradiol Valerate
- 5 red = 2 mg EV and 2 mg Dienogest
- 17 light yellow = 2 mg EV, 3 mg Dienogest
- 2 dark red = 1 mg EV
- 2 white = inert pills

OCs and Breakthrough Bleeding (BTB)  
Early vs Later Use BTB
- BTB declines over 1st year, TTT
- Rule out infection: Esp. chlamydia!!!
- Take same time each day: < 4 hours
- NSAIDS for 5 days !!!
- Change progestin: levonorgestrel, norgestimate
- Increase estrogen
- Generic to Brand
- Later use BTB: 4 to 7 placebo pills

Venous Thrombosis: Risk and COCs*  
2 - 3 X incr. risk: 8-10/10,000 women/years
RISKS !!!
- First 3 months of CHC* use, RED FLAGS!
- Age, especially smokers
- BMI higher: no data > 40
- ESTROGEN, higher dose
  - 20 mcg = 20% lower VT risk versus 30 mcg
  - 50 mcg = 50% higher VT risk vs. 30 mcg
  - 70% difference!
- PROGESTIN type, risk may differ
  *Combination hormonal contraceptives = CHC

FDA Warning 2011:
Drospirenone & Risk of Non-fatal VTE

- 2 fold increased risk, compared to Levonorgestrel
- 30.8/100,000 woman years for Drospirenone
- 12.8/100,000 woman years for Levonorgestrel


Research: Drospirenone & Risk of Non-fatal VTE
2 Fold Increased Risk, Compared to Levonorgestrel

- Pankert S, Sharples K, Hernandez RK, Jick SS. Risk of venous thromboembolism in users of oral contraceptives containing drospirenone or levonorgestrel: nested case-control study based on UK General Practice Research Database. BMJ 2011; 342:d139.
Combination Hormone Contraceptives, CHC 2016
NEW Medical Criteria: OK=2, NO=3

- Hepatitis acute viral = 3-4, 2
- Chronic.................................1,1
- Carrier..............................................1,1
- Liver adenoma.........................2
- Liver malignancy.........................4
- Broad Spectrum Antibiotics............1
- Anticonvulsants & Rifampin............3
  - Reduced efficacy of OC/CHC

Combination Hormonal Contraceptives/ CHC
NEW  2016 Medical Criteria

- Hypertension:
  - Controlled 3
  - BP 140-159/90-99 3
  - BP > 160/100 4

- HTN in Pregnancy 2

- Vascular disease 4

CHC MEC 2016

- History of DVT/PE 4
- Acute DVT/PE 4

- Family History of DVT/PE
  1st degree relative 2
- Thrombogenic mutation 4 !!!
  Factor V Leiden, prothrombin, protein S
  2-20 x Fold increased risk !!!
CHC: History of DVT, PE, 2016

NOT on anticoagulant

Higher risk of recurrence: 4
- Estrogen associated
- Pregnancy associated
- Idiopathic
- Thrombophilia
- Cancer
- History of recurrence

Lower risk for recurrence: 3

CVD: DVT & PE, 2016

- Family History: 1st degree 2
- Major surgery:
  - Prolonged immobilization: 4
  (Not defined!)
  - No prolonged immobilization: 2
- Minor surgery: no immobilization 1

NEW 2016: Headaches and CHC/ Combination Hormonal Contraceptives

- Non-migraine 1, 2
- Migraines
  - Without Aura
  - Any age 2
  - With Aura, ANY age 4

WHO, CDC, ARHP, Planned Parenthood
International Headache Society 2009-2010
**CHCs: Drug Interactions**

**Antiretroviral therapy**
- NRTIs: 1
- NNRTIs: 2
- Ritonavir-boosted protease inhibitors: 2

**Antimicrobial therapy**
- Broad-spectrum antibiotics: 1
- Antifungals: 1
- Antiparasitics: 1
- Rifampicin: 3

**Anticonvulsant therapy**
- COC: reduced efficacy
- So minimum 30μg EE dose
- Lamotrigine (Lamictal)...3
  - Possible incr. seizures !!

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**Low Libido!**
- Lower estrogen
- Change method

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**Breast Cancer Family History and OC NO Increased Risk**

Systematic review 1966 – 2008 (USPSTF) 42 years
- 10 studies, 1 pooled analysis of 54 studies
- 4 studies suggest some women may be at increased risk esp. if took OCs prior to 1975

**Conclusion:**
- OCs did NOT significantly influence risk
Ovarian Cancer and OCs Protection with 15 years of Use!
Massive reanalysis study; 45 studies, n= 23,257 women

- 50% lower risk if used for 15 years: even non-continuous!!!
- Longer duration associated with lower risk
- Protection up to 30 yrs after stopping OC !!!!
- Protects low AND high risk women
- 100,000 deaths prevented worldwide!
- Could prevent 30,000 cases annually in US


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2012: Update- Package Insert
Transdermal Patch: Package Information (PI)

- “You will be exposed to about 60% more estrogen than an OCP with 35 mcg of estrogen.” = 56 mcg

- NEW per FDA (May 2012)
  “the benefits outweigh the risks”, but consumers must be educated about the risks

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2010: NO Incr. Risk of Nonfatal VTE in Users of Contraceptive Transdermal Patch:

- n 297,262

- Compared to users of OCs containing NGM/EE 35 mcg
  Observational case-control study
- 56 cases of VTE, 212 matched controls: New users only!
  PharMetrics US-based, longitudinal database on 55 million lives back to 1995
  Medical claims & diagnoses from managed care
- OR 1.1 (95% CI 0.6-2.1)
- NO increased risk compared to NGM/EE containing OCs

Dore et al. Contraception 2010 May; 81(5):408-413
VTE OR 2.0 extension study, n=38, c=148 (297,262 women)
When new data pooled w previous data no increased risk
Jick, Kaye, Li and Jick. Contraception 2007;76: 4-7. (BU SOM Boston)
Same authors. Contraception 2006;73:223-228. 17 month study
2012: Incr. Risk of Nonfatal VTE in Users of Contraceptive Patch and Ring: n 1.5 million

- Danish national registries used

Risk of thrombosis:

- Non-users 2/10,000
- 6.2/10,000 exposure years w COC (2-3 x incr. risk)
- 9.7/10,000 exposure years w Patch (7.5 x incr. risk)
- 7.8/10,000 exposure years w Ring (6.5 x incr. risk)

- Implant or LNG IUS users: NO increased risk

BMJ 2012;344 doi: 10.1136/bmj.e2990 (Published 10 May 2012)
BMJ 2012; 344:u2990.

Contraceptive Vaginal Ring:

- Very low steady dose
  - 120 μg/day etonogestrel
  - 15 μg/day ethinyl estradiol
- Flexible (54 mm)
- Easy to insert
- One ring per cycle:
  - 3 weeks in, 1 week ring-free
  - Or change monthly
- Less BTB than with OC
  - With “Quick Start”


Progestin-Only Contraceptives:

- Pills (POP), Injections, Implants
Progestin Only:

**Age**
- POP ..................1
- DMPA <18 , >45 2

**Breastfeeding**
- < 1 month ............2
- ≥ 1 month 1

**Postpartum** ..............1
**Postabortion** ..............1

**Past ectopic**
- POP ..................2

Progestin Only: Misc Conditions

**Smoking:** .....................1

**Obesity:** .....................1
<18 ..........................2

**Bariatric:**
Malabsorptive procedures

**POPs (Mini Pills) only** 3
**Sz meds, Rifampin, ARV** 3

Progestin Only: Hypertension

**Adequately controlled**
- POP, Implant ......1
- DMPA...............2

**S ≥ 160/D ≥ 100**
- POP/I..................2
- DMPA .............3

**Elevated BP**
S 140-159/D 90-99
- POP, Implant ......1
- DMPA...............2

**HTN in pregnancy** ......1
**Progestin Only: SAFE**
NO Evidence of Incr. DVT/ PE Risk

**DVT/ PE**
- History or acute………………2
- On or off anticoagulant 2
- Major surgery, immobilized…2
- Thrombotic mutations………2
- Family History………………1
- Superficial thrombosis………1

**Progestin Only: Headache w Aura!**

<table>
<thead>
<tr>
<th>Rheumatic</th>
<th>Neurologic</th>
</tr>
</thead>
<tbody>
<tr>
<td>SLE</td>
<td>Headaches, non-migraine: 1</td>
</tr>
<tr>
<td>• Positive or unknown APL</td>
<td>Migraines</td>
</tr>
<tr>
<td>antibodies</td>
<td>No aura</td>
</tr>
<tr>
<td>• Severe thrombocytopenia:</td>
<td>Start OC</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>• Immunosuppressed …………2</td>
<td>Aura:</td>
</tr>
<tr>
<td>RA</td>
<td>Start</td>
</tr>
<tr>
<td>• POP, I</td>
<td>1</td>
</tr>
<tr>
<td>• DMPA</td>
<td>Aura: Continue</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Liver tumors/Severe cirrhosis</td>
<td>Epilepsy:</td>
</tr>
<tr>
<td>3</td>
<td>Depressive disorders: 1</td>
</tr>
<tr>
<td>Breast cancer current</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

**Contraceptive Implant:**
“Nexplanon” with NEW Inserter
- Single rod, “Radiopaque”: Mid- upper arm, above “groove”
- Progestin only
- Etonogestrel
- 3 year contraceptive
- High efficacy > 99%
- No weight restriction
- Inhibits ovulation
- Unpredictable bleeding
- Special training required

Adapted from www.contraceptiononline.org

Mansour et al. Contraception 2010 sep;82:243-49
Advantages

**DMPA: Medroxyprogesterone Acetate**

- Effective, easy, convenient
- Shorter menses, no menses
- No backup needed 1st month
- No BMI weight restriction
- May be used in smokers esp. >35 yrs
- OK if ESTROGEN contraindicated

- Injection schedule: 4 week grace period *(don't tell pt)*


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**DMPA, HIV or at High Risk for HIV and MEC: NEW: CDC Update June 2012**

- Safe: Category 1,2 (encourage condoms too)
  - Combined oral contraceptives
  - Progestin-only pills
  - Depot DMPA
  - Implants
- Women at high risk for HIV !!!!
  - Caution re: use of Progestin-only injectables
  - Inconclusive evidence re: HIV acquisition risk

MMWR, June 22, 2012 / 61(24):449-452

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**2015 New Study: DMPA and HIV Risk**

- This new meta-analysis adds to evidence suggesting that *depot medroxyprogesterone acetate* (DMPA, marketed as Depo-Provera) *is associated with increased risk for HIV acquisition.*

- 12 observational studies that evaluated the association between hormonal contraception and HIV acquisition in women in sub-Saharan Africa.


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**DMPA – Category 3, 4**

Cat 3
- CVD
  - Hypertension
    - >160/>100
  - Stroke
  - Ischemic CVD
  - Multiple risk factors
  - Liver tumors, cirrhosis

Cat 4
- Breast cancer-current
- Unexplained vaginal bleeding

---

**Effects of Long Term DMPA on BMD**

- DMPA > 2 yrs had a significant adverse effect on BMD
  - 2.8% loss after 1 yr, 5.8% loss after 2 years

**BUT GOOD NEWS!**

- Large, cross sectional study of 3500 ethnically diverse pts
  - Used DMPA >10 years
  - Reversibility of loss complete in 2 to 3 years


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**NEW 2013: DMPA and Bone Health**

**No Increased Fracture Risk**

- Large retrospective cohort study
- N 312,395

- Fracture risk did NOT increase after initiation of DMPA
  - “Black Box warning should be removed by the FDA”

(http://dx.doi.org/10.1097/AOG.0b013e318283d1a1)
BMD, Identifying “at Risk Patients”

- Vaginal pH check routinely
  Normal pH of 4.0 is yellow = normal estrogen levels!
- Atrophic Vaginitis
  - High pH, pallor, scant discharge, WBCs, small cells
- Add back Estrogen- may be considered
  - Ethinyl Estradiol 20 mcg oral daily
  - Vaginal Ring: may reduce BTB and bone loss!

Dempsey et al, Contraception 82 (Sept 2010) 25–255

Progestin Only:
No Evidence of Incr. DVT/PE Risk

DVT/PE
- History or acute: 2
- On or off anticoagulant: 2
- Major surgery, immobilized: 2
- Thrombotic mutations: 2
- Family History: 1
- Superficial thrombosis: 1

Dempsey et al, Contraception 82 (Sept 2010) 25–255
Progestin Only: Cardiovascular Disease

**Ischemic heart disease/Stroke**
- Initiation:
  - POP: 2
  - DMPA: 3
- Continuation:
  - POP: 3

**Valvular heart disease:** 1

**Peripartum cardiomyopathy**
- Mild: 1
- Moderate/severe: 2

**Hyperlipidemia:** 3

Progestin Only (PO):

**Rheumatic**
- SLE
  - Positive or unknown APL antibodies: 3
  - Severe thrombocytopenia: 3
  - Immunosuppressed: 2
- RA
  - POP, I = 1
  - DMPA = 2

**Neurologic**
- Headaches, non-migraine: 1
- Migraines
  - No aura: 2
  - Start OC: 1
  - Aura:
    - Start: 2
    - Continue: 3!!!
- Epilepsy: 1
- Depressive disorders: 1

PO: Reproductive Tract Conditions

**Category 1:**
- Endometriosis
- Benign ovarian tumors
- Severe dysmenorrhea
- Gestational trophoblastic disease
- Benign breast disease
- FHx breast cancer
- Endometrial hyperplasia or cancer
- Ovarian cancer
- Uterine fibroids
- STIs, PID
- HIV/AIDS

**Category 2:**
- Irregular, heavy, or prolonged vaginal bleeding
- CIN/Cervical cancer (DMPA)
- Undiagnosed breast mass

**Category 3:**
- Past breast cancer (>5 years)
- Unexplained vaginal bleeding

**Category 4:**
- Current breast cancer
Resources

  www.mimisecor.com

- ARHP.org
  “Contraception” Journal with membership
  Many other resources
  Contraceptive choices, online tool kit for patients

References

- MMWR. US Medical Eligibility Criteria for Contraceptive Use, 2016 (July 29), 65(3);1-104.

- www.CDC.gov
  MEC Wheel, posters, MEC summary charts, PDF of full guidelines

Resources

- U.S. Selected Practice Recommendations (US SPR) for Contraceptive Use, 2013
  http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USSPR.htm

- Journal Watch Women’s Health
  www.jwatch.org

  www.Amazon.com
Objectives (100% Pharm)
Contraception Update

- Describe trends and contraceptive challenges facing clinicians and patients.
  15 minutes

- Explain the new CDC medical eligibility criteria for prescribing various contraceptive methods and medical conditions.
  30 minutes

- Discuss new contraceptive research regarding efficacy, risks, benefits as this pertains to prescribing.
  15 minutes

Questions
Thank you and good luck!

Mimi Secor, DNP, FNP-BC, NCMP, FAANP

www.mimisecor.com
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