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"

- **Advanced Health Assessment of Women: Skills and Procedures, 2014, Springer publishing**
- **Co-author, The Gyn Exam, 2012, Springer**
- **Visiting Scholar, Boston College**
- **Owned a private practice for 12 years in Massachusetts (1984-1996)**
- **Worked in Alaska for 7 years (1992-1999)**

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Mimi Secor, DNP, FNP-BC, FAANP Disclosure

Speaker: GenPath, Shionogi, Hologic

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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

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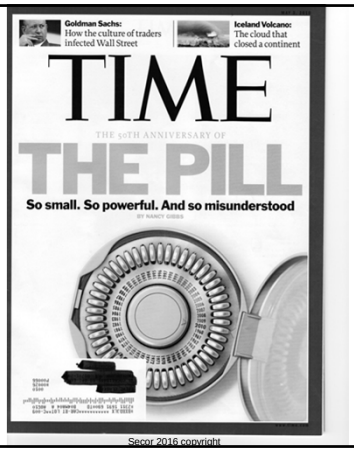
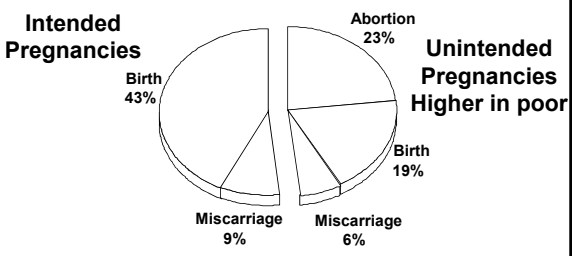


6.3 Million U.S. pregnancies: Intended vs.. Unintended



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!

If you've been swept off your feet
You've got 3 days to get them back on the ground

Emergency contraception
Use within 3 days of opening

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)**

Glasier A, Cameron ST, Blithe D, Scherrer B, Mathe H, Levy D, Gainer E, Ulmann A. Can we identify women at risk of pregnancy despite using emergency contraception? Data from randomized trials of ulipristal acetate and levonorgestrel. *Contraception*. 2011;84:363-7.

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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

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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)

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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, Skyla)**
  - 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)

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Typical Effectiveness of Contraception

Adapted from: WHO. Family Planning: A Global Handbook

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2010: US Medical Eligibility Criteria for Contraceptive Use (MEC) Update 2016

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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

http://www.cdc.gov

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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

Http://www.who.int/reproductivehealth/publications/family_planning/MEC-5/en/

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Handheld App:

“CDC Contraception 2016”
MEC
SPR

Medical Eligibility Criteria for Contraceptive Use

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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

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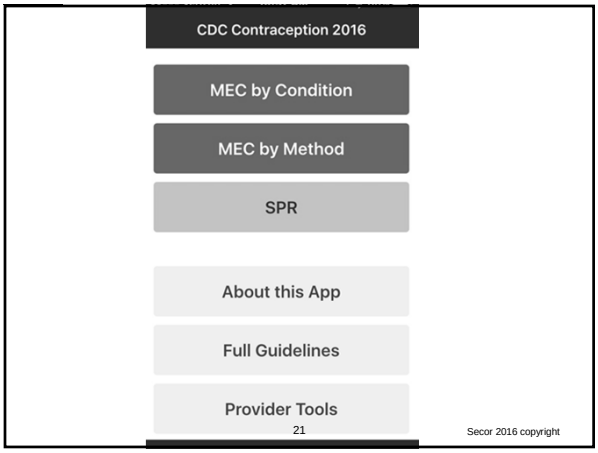

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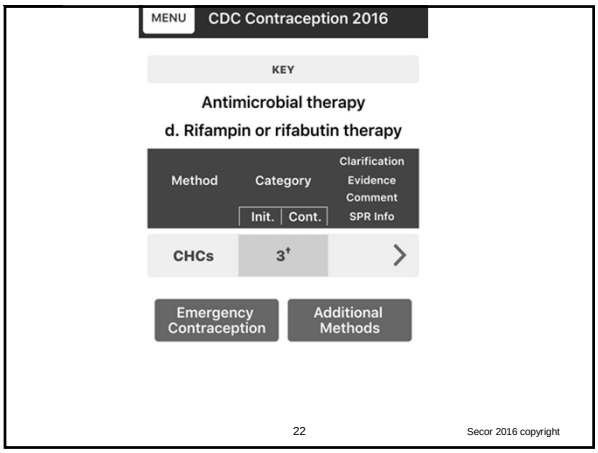
MENU
CDC Contraception 2016
KEY
Antimicrobial therapy
d. Rifampin or rifabutin therapy
Method
Category
Init.
Cont.
Clarification
Evidence
Comment
SPR Info
CHCs
3†
Emergency Contraception
Additional Methods
22
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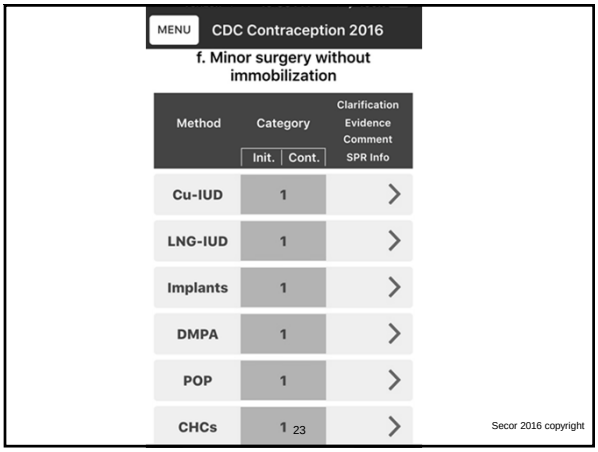
MENU
CDC Contraception 2016
f. Minor surgery without immobilization
Method
Category
Init.
Cont.
Clarification
Evidence
Comment
SPR Info
Cu-IUD
1
LNG-IUD
1
Implants
1
DMPA
1
POP
1
CHCs
1
23
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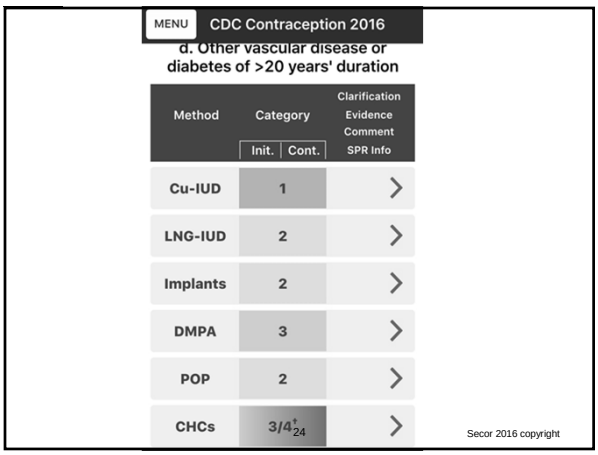
MENU
CDC Contraception 2016
d. Other vascular disease or diabetes of >20 years' duration
Method
Category
Init.
Cont.
Clarification
Evidence
Comment
SPR Info
Cu-IUD
1
LNG-IUD
2
Implants
2
DMPA
3
POP
2
CHCs
3/4†
24
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b. Migraine

ii. With aura

Method	Category		Clarification Evidence Comment SPR Info
	Init.	Cont.	
Cu-IUD	1		>
LNG-IUD	1		>
Implants	1		>
DMPA	1		>
POP	1		>
CHCs	4†	25	>

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Ischemic heart disease, current or history§

Method	Category		Clarification Evidence Comment SPR Info
	Init.	Cont.	
Cu-IUD	1		>
LNG-IUD	2	3	>
Implants	2	3	>
DMPA	3		>
POP	2	3	>
CHCs	4	26	>

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disease (e.g. older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglycerides)

Method	Category		Clarification Evidence Comment SPR Info
	Init.	Cont.	
Cu-IUD	1		>
LNG-IUD	2		>
Implants	2†		>
DMPA	3†		>
POP	2†		>
CHCs	3/4	27	>

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Obesity

a. BMI ≥30 kg/m^2

Method	Category		Clarification Evidence Comment SPR Info
	Init.	Cont.	
Cu-IUD	1		>
LNG-IUD	1		>
Implants	1		>
DMPA	1		>
POP	1		>
CHCs	2		>

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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

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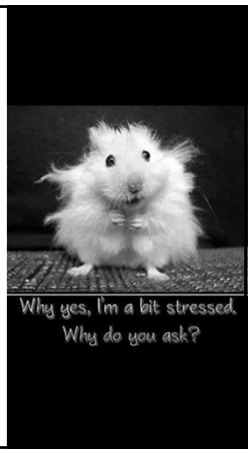
Relax!



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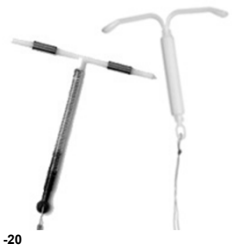
Intrauterine Systems: IUC Effectiveness = Sterilization

- 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

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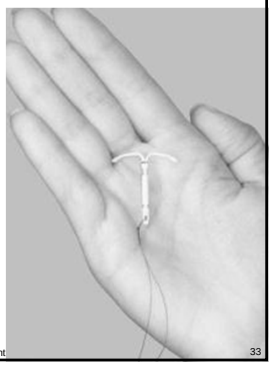
IUC: New, Smaller (Skyla) LNG containing, Similar to (Mirena)

- **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**



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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

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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

Duenas JL. *Contraception*. 1996.; Stanwood NL. *Obstet Gynecol*. 2002. Forrest JD. *Obstet Gynecol Surv*. 1996; Lippes J. *Am J Obstet Gynecol*. 1999. Otero-Flores JB. *Contraception*. 2003.; WHO. 2009.; Penney G. *J Fam Plann Reprod Health Care*. 2004.

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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.

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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**

WHO. 2009.

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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

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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

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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
  - Farley et al. Lancet 1992;339:785-8 (1st large analysis)
  - 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

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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

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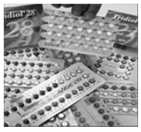
Combined Hormonal Contraceptives: CHC

Pills: medium



Patch- high

Ring- low

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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**

Van den Heuvel et al. Contraception Sept 05;72:168

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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

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Hormonal Contraceptives and Coexisting Medical Conditions

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CHC- Category 4 Contraindications

- Smokers ≥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 ≥160/≥100
- DVT/VTE
  - On therapy
  - Acute
  - History of

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CHC- Category 3 Relative Contraindications

- Drug interactions
- Rifampicin
- Certain anti-seizure meds ie 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

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CHC: Age

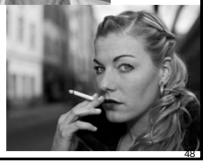
Menarche to <40 years = C 1

- 40 years old 2

Smoking

- <35 smoker: 2
- ≥35 smoker <15/day: **3**
- **>35 and smoke >15/day: 4 !!!**





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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

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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**

Trussell J, et al. Commentary, Obesity, CHC and VTE. Contraception. 2008;77:143-46.

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CHC: Obesity

BMI > 30

- **Category 2**
- **Possible increased risk of VTE, MI, stoke**
- **NOT more likely to gain**

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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

McNicholas C et al. Contraceptive failures in overweight and obese combined hormonal contraceptive users. Obstet Gynecol 2013 Mar; 121:585. http://dx.doi.org/10.1097/AOG.0b013e31828317cc

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Very Effective

Combined Oral Contraceptives

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

Trussel J. Contraceptive Technology. 2007. Rosenberg MJ. *Reprod Med*. 1995. Potter L. *Fam Plann Perspect*. 1996. Mosher WD. *AdvanceData*. 2004. Hardman JG. McGraw-Hill. 1996. Goldzieher JW. *Fertil Steril*. 1971. Moghissi KS. *Fertil Steril*. 1971.

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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

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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

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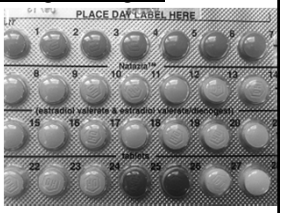
Estradiol Valerate, Dienogest (Natazia) 2012 FDA Approved for Menorrhagia

- 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**

Am J Ob Gyn, 2006;195:935

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

Lidegaard et al. BMJ 2009 Aug; 339: van Hylckama et al. MEGA case control study. BMJ 2009 Aug; 339:

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**

Jick, Hernandez. BMJ 2011;340:d2151 doi:10.1136/bmj.d2151

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

- Seeger JD, Loughlin J, Eng PM, Clifford CR, Cutone J, Walker AM. Risk of thromboembolism in women taking ethinylestradiol/drospirenone and other oral contraceptives. Obstet Gynecol **2007**; 110(3):587-93.
- Dinger JC, Heinemann LA, Kühl-Habich D. The safety of a drospirenone-containing oral contraceptive: final results from the European Active Surveillance Study on oral contraceptives based on 142,475 women-years of observation. Contraception **2007**; 75:344-54.
- Lidegaard Ø, Løkkegaard E, Svendsen AL, Agger C. Hormonal contraception and risk of venous thromboembolism: national follow-up study. BMJ **2009**; 339:b2890.
- Van Hylckama V, Helmerhorst FM, Vandenbroucke JP, Doggen CJM, Rosendaal FR. The venous thrombotic risk of oral contraceptives, effects of oestrogen dose and progestogen type: results of the MEGA case-control study. BMJ **2009**; 339:b2921.
- Parkin L, 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:d2139.
- Jick SS, Hernandez RK. Risk of non-fatal venous thromboembolism in women using oral contraceptives containing drospirenone compared with women using oral contraceptives containing levonorgestrel: case-control study using United States claims data. BMJ **2011**; 342:d2151.

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MENU CDC Contraception 2016

a. History of DVT/PE, not receiving anticoagulant therapy

i. Higher risk for recurrent DVT/PE (one or more risk factors)
- History of estrogen-associated DVT/PE
- Pregnancy-associated DVT/PE
- Idiopathic DVT/PE
- Known thrombophilia, including antiphospholipid syndrome
- Active cancer (metastatic, on therapy, or within 6 months after clinical remission), excluding non-melanoma skin cancer
- History of recurrent DVT/PE

Method	Category		Clarification Evidence Comment SPR Info
	Init.	Cont.	
CHCs	4		

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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

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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

CDC.gov/mec 2010.

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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 !!!

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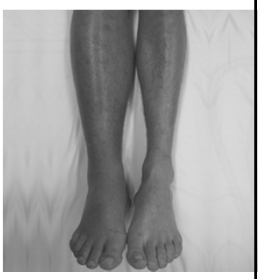
CHC: History of DVT, PE, 2016

NOT on anticoagulant

<u>Higher risk of recurrence:</u> 4

- Estrogen associated
- Pregnancy associated
- Idiopathic
- Thrombophilia
- Cancer
- History of recurrence



<u>Lower</u> risk for recurrence: 3

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CVD: DVT & PE, 2016

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

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NEW 2016: Headaches and CHC/ Combination Hormonal Contraceptives

- **Non-migraine 1, 2**
- **Migraines**

Without Aura

- **Any age 2**

<u>With Aura, ANY age</u> 4

WHO, CDC, ARHP, Planned Parenthood International Headache Society 2009-2010

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CHCs: Drug Interactions

Antiretroviral therapy

- NRTIs: 1
- NNRTIs: 2
- Ritonavir-boosted protease inhibitors: 2

Anticonvulsant therapy

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

Antimicrobial therapy

- **Broad-spectrum antibiotics 1**
- Antifungals 1
- Antiparasitics 1
- **Rifampicin 3**
  - **Reduces OC efficacy**

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Low Libido!

- Lower estrogen
- Change method

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**

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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 w/ 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

Collaborative Group. Epid studies on ovarian cancer; 45 studies; 23,257 women, 87,303 controls. *Lancet.* 2008. Jan 26;371:303

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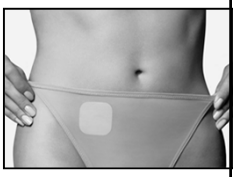
2012: Update- Package Insert Transdermal Patch: Package Information (PI)

- "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

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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

BMJ2012;344doi: 10.1136/bmj.e2990(Published 10 May 2012)
BMJ 2012; 344:e2990.

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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"

Westhoff et al. Ob Gyn 2005 Jul;106:89-96.

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Progestin-Only Contraceptives:

Pills (POP), Injections, Implants

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Progestin Only:

Age

- POP ……1
- **DMPA <18 , >45 2**

Breastfeeding

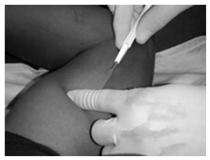
- **< 1 month** ……**2**
- ≥ 1 month 1

Postpartum ……1

Postabortion……1

Past ectopic

- **POP……..2**



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Progestin Only: Misc Conditions

Smoking: ……1

Obesity: …… 1

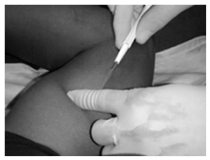
<18 ……... 2

Bariatric:

Malabsorptive procedures

POPs (Mini Pills) only 3

Sz meds, Rifampin, ARV 3



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Progestin Only: Hypertension

Adequately controlled

- POP, Implant ……1
- DMPA……...2

Elevated BP

S 140-159/D 90-99

- POP, Implant …….1
- DMPA……..2

S ≥ 160/D ≥ 100

- POP/ I…… 2
- **DMPA 3**

HTN in pregnancy……1

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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!

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

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)**

Paulen et al. Contraception 2009 Oct; 80: 391-408.

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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.

Ralph, McCoy, Shiu, & Padian. (2015). Hormonal contraceptive use and women's risk of HIV acquisition: a meta-analysis of observational studies. Lancet. http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(14)71052-7/abstract

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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**

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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

Arias et al. Dialogues in Contraception. Spring 2007; 11(1):1-11. Shaarawy et al. Contraception. 2006; 74: 297-302.

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

JWWH Jan 2008, p3 and National Vital Stat Rep 2007;56:1

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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"**

Lanza LL et al. Use of depot medroxyprogesterone acetate contraception and incidence of bone fracture. Obstet Gynecol 2013 Mar; 121:593. (http://dx.doi.org/10.1097/AOG.0b013e318283d1a1)

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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

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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

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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**

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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

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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

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Resources

- Carcio & Secor. 2014. Advanced Health Assessment of Women (3nd ed). Springer publishing, NY, www.springerpub.com
  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
- Hatcher et al. 2010. **Contraceptive Technology Update** (20nd edition), Ardent Press
  - 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

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Questions

Thank you and good luck!

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

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