Safe Prescribing for Female Vets with Mental Illness

Eleanor Bimla Schwarz, MD, MS
Center for Research on Health Care
Departments of Medicine, Epidemiology,
Obstetrics, Gynecology and Reproductive Sciences
Magee-Womens Research Institute
University of Pittsburgh

Objectives

- Recognize ways mental illness may affect women's reproductive health
- Recognize commonly prescribed meds which can induce birth defects if used during pregnancy
- Describe VA prescribing patterns of potentially teratogenic psychotropic medications

Mental Illness and Repro Health

- Mania
- Postpartum Depression
- History of abuse, MST
- Use of teratogenic medications

Munk-Olsen T, et al N Engl J Med. 2011
Munk-Olsen T, et al Arch Gen Psychiatry. 2012 Feb

FDA Classification System

- Class A: Fetal harm appears remote
- Class B: Animal studies revealed no evidence of fetal harm
- Class C: No adequate studies in women.
- Class D: Evidence of human fetal risk
  - Use in pregnant women may be acceptable for serious disease when no safer drugs exist
- Class X: Contraindicated in women who are or may become pregnant

Are women of reproductive age using class D and X Medications?

YES!!

Nationally, how often are potentially teratogenic meds prescribed?

Annually:

$$\frac{\text{11.7 million teratogenic Rx}}{\text{283 million prescriptions}} = \text{1 of every 25 Rx}$$

for women age 14-44 years who were not pregnant

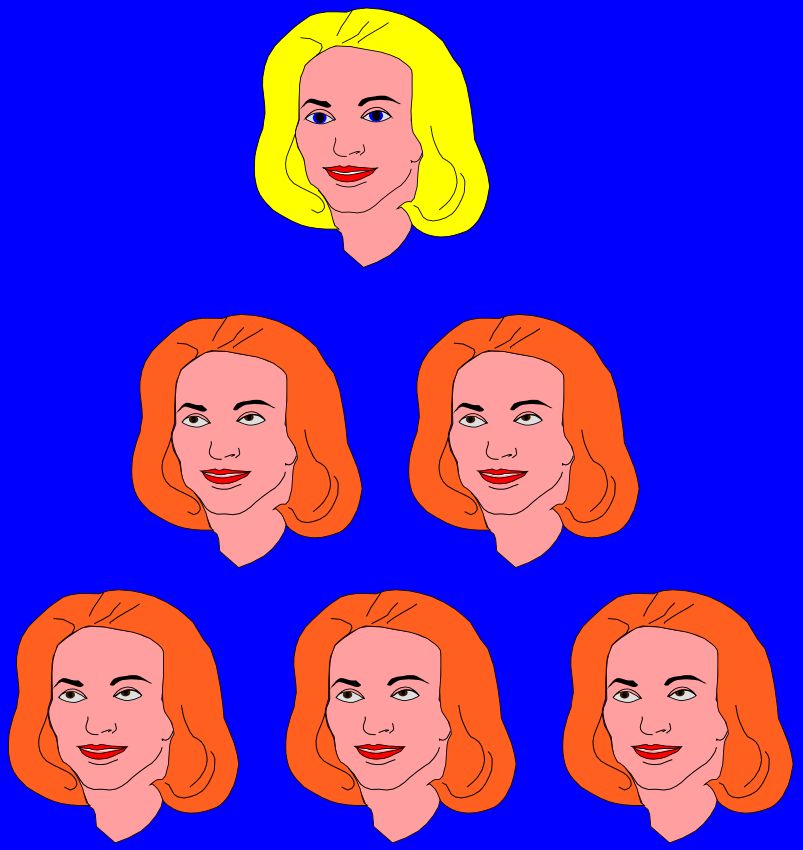
$$\frac{\text{11.7 million teratogenic Rx}}{\text{147 million outpatient visits}} = \text{1 of every 13 visits}$$

for women age 14-44 years who were not pregnant

Schwarz EB,et al. Am J Med 2005

In a large HMO in 2001…

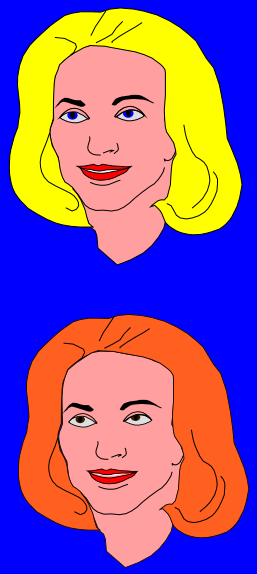
1/6 women filled
a class D or X Rx



Schwarz EB,et al. Ann Intern Med. 2007

Our Female Vets…

49% of female Vets
who received an Rx from a VA pharmacy received a potentially teratogenic Rx



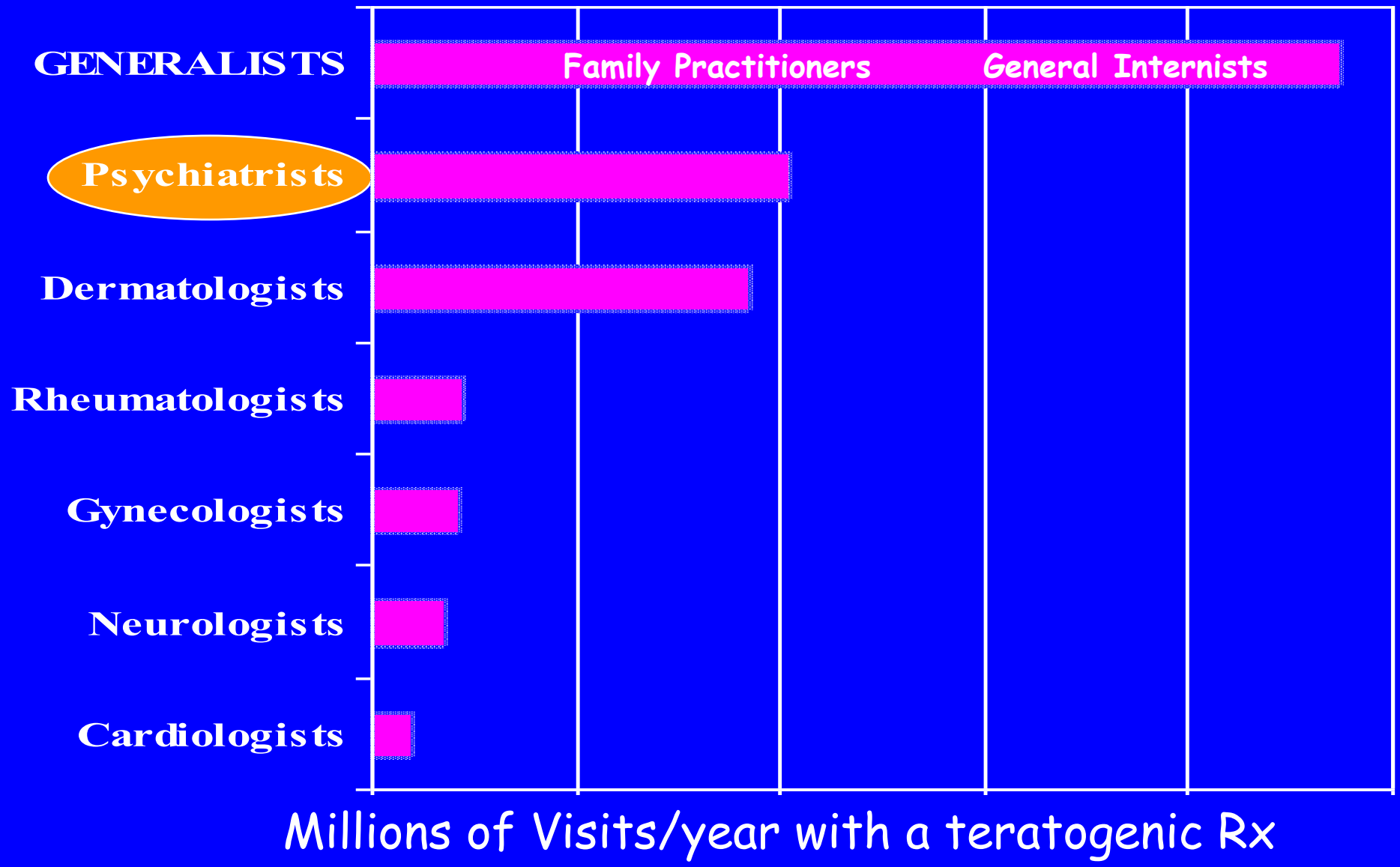
Schwarz EB, et al Med Care Sept 2010

Unfortunately

- Unintended pregnancy is common
  - 49% of US pregnancies
  - 5% of US women each year

The Alan Guttmacher Institute, 2010

Who's writing these prescriptions?



Schwarz EB,et al. Am J Med 2005

Are these chronic meds?

	Women who filled >=1 Rx N=38,205		Rx per woman per year	Days supply per woman per year
	N	%	Average #	Average
Psychiatric	**20155**	**52.8**	**4.2**	**133.5**
Antidepressant	**5162**	**13.5**	**2.8**	**116.0**
Benzodiazepine	**16430**	**43.0**	**3.9**	**112.5**
Antihypertensive	8115	21.2	2.7	195.5
Statin	8790	23.0	2.1	153.5
Neurologic	**4687**	**12.3**	**3.4**	**134.0**
Tetracycline	6235	16.3	1.0	28.0
Warfarin	547	1.4	4.9	164.5
Retinoid	75	0.2	2.2	65.5
Other	7562	19.8	1.3	34.5

Schwarz EB, et al Med Care

Among Female Vets

Receipt of family planning services (e.g. contraception, contraceptive counseling or pregnancy testing) was documented for

- 56% of those who filled class D or X meds
- 52% of women who filled class C meds
- 36% of women filling only class A or B meds

Schwarz EB, et al Med Care

What affects rates of safe prescribing to women of reproductive age?

Clinic characteristics

- VA Women's clinic OR=1.96*

Provider characteristics

- *Not* gender, age, race, or tenure
- Gyn > non-gyn
- NPs/PAs/CNMs > MDs

Schwarz EB, et al. Am J Med 2005
Schwarz EB, et al. Ann Intern Med 2007
Schwarz EB et al. Med Care 2010

Do YOU know?

If 100 fertile women are sexually active, how many would you expect to become pregnant within one year if they use no form of contraception?

- 5%
- 25%
- 50%
- 85%

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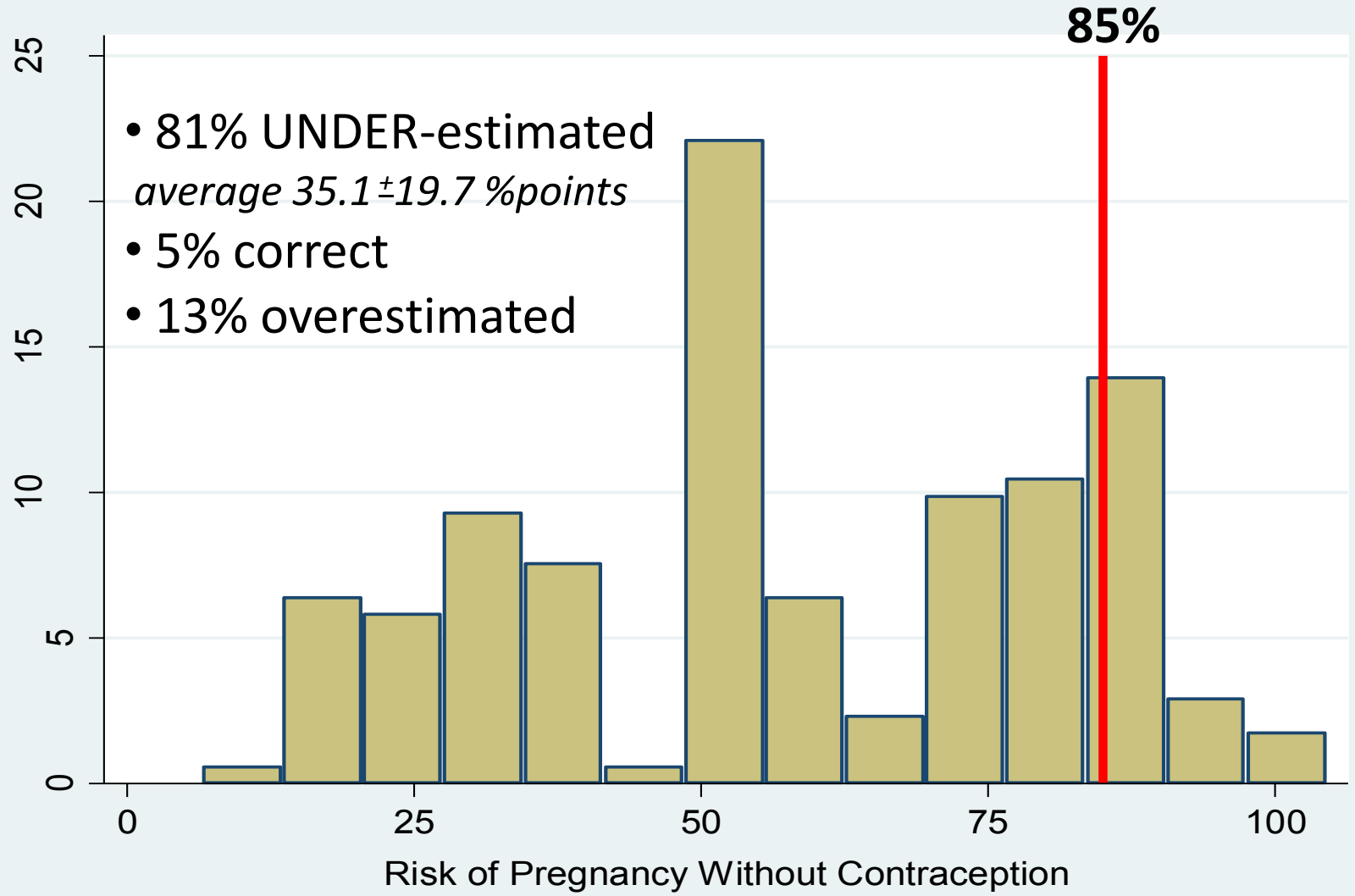
- 50%
- **85%**

Pregnant within 1 year if NO contraception?



Know her plans

- When, if ever, would you like to have a baby?
- How are you trying to avoid pregnancy?

Cumulative failure rates

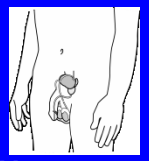
"During a lifetime of use of reversible methods, the typical woman will experience 1.8 contraceptive failures"

Trussell J & Vaughan B, Fam Plann Perspect 1999

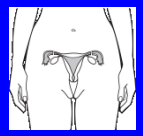
Typical effectiveness of contraceptive methods

More effective

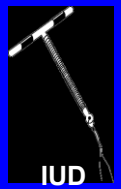
Implant



Vasectomy

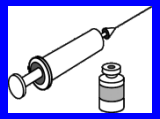


Female Sterilization



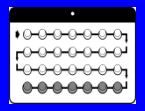
IUD

Less than 1 pregnancy per 100 women in one year



Injectables

Ring

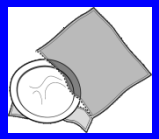


Pills

Patch

Lactation Amenorrhea

About 3-8 pregnancies per 100 women in one year



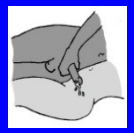
Male Condoms

Female Condoms

Diaphragm

Sponge

Fertility-Awareness Based Methods



Withdrawal

Emergency Contraception

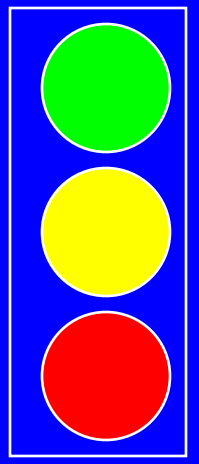
Spermicide

About 30 pregnancies per 100 women in one year

Less effective

adapted with permission from the WHO 2006

Cumulative failure rates



	1 year	3 year	5 year
IUD or Implant	<1%	<1%	<1%
Pills	8%	22%	34%
Condom	15%	39%	56%
	17%	42%	60%

Thonneau PF Almont TE.

Am J Obstet Gynecol. 2008

Does efficacy of documented contraceptive method affect rates of positive pregnancy tests after filling a potentially teratogenic Rx?

Yes!

Women 15-44 yrs with a positive pregnancy test within 3 months of filling a potentially teratogenic Rx	%
Overall	1.0
Women with any contraceptive documentation	0.8
Women with a most effective contraceptive method	0.2

Schwarz EB, et al Ann Intern Med 2007

Complicated patient?

Guidance is available!

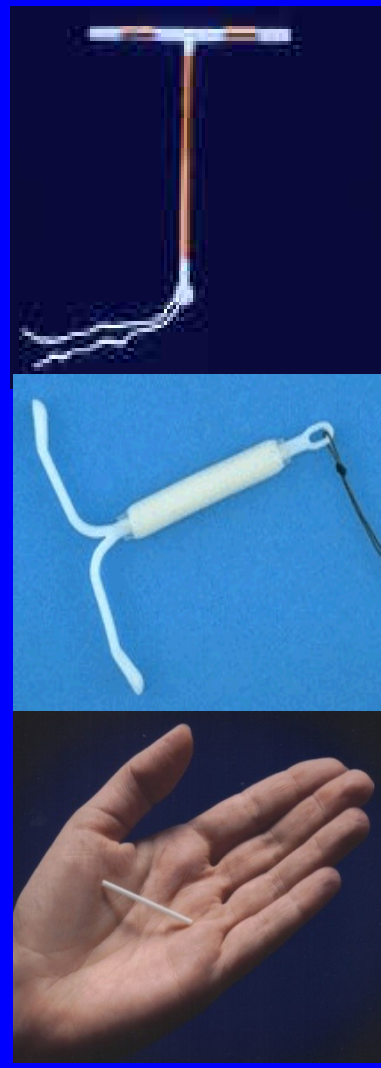
- the CDC “US Medical Eligibility Criteria”
  - http://www.cdc.gov/mmwr/pdf/rr/rr59e0528.pdf
- the WHO Medical Eligibility Criteria for Contraceptive Use, 4th edition
  - http://whqlibdoc.who.int/publications/2010/9789241563888_eng.pdf

Category	Interpretation
1	**No restriction for use** Use method for any circumstance
2	**Advantages outweigh theoretical/proven risks** Generally use the method
3	**Theoretical/proven risks outweigh advantage** Generally not recommended unless no other method available or acceptable
4	**Unacceptable health risk** Do not use

LOW-DOSE COMBINED ORAL CONTRACEPTIVES (COCs) < 35 µg of ethinylestradiol	**COCs do not protect against STI/HIV. If there is risk of STI/HIV (including during pregnancy or postpartum), the correct and consistent use of condoms is recommended, either alone or with another contraceptive method. Male latex condoms are proven to protect against STI/HIV.**	
CONDITION	**CATEGORY** I=Initiation C=Continuation	**CLARIFICATIONS / EVIDENCE**
CARDIOVASCULAR DISEASE		
Multiple risk factors for arterial cardiovascular disease (such as older age, smoking, diabetes and hypertension)	3/4	**Clarification:** When a woman has multiple major risk factors, any of which alone would substantially increase the risk of cardiovascular disease, use of COCs may increase her risk to an unacceptable level. However, a simple addition of categories for multiple risk factors is not intended; for example, a combination of two risk factors assigned a category 2 may not necessarily warrant a higher category.
Hypertension		
For all categories of hypertension, classifications are based on the assumption that no other risk factors for cardiovascular disease exist. When multiple risk factors do exist, risk of cardiovascular disease may increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.		
a) History of hypertension, where blood pressure CANNOT be evaluated (including hypertension in pregnancy)	3	**Clarification:** Evaluation of cause and level of hypertension is recommended, as soon as feasible. **Evidence:** Women who did not have a blood pressure check before COC use had an increased risk of acute myocardial infarction and stroke.(15-19)
b) Adequately controlled hypertension, where blood pressure CAN be evaluated	3	**Clarification:** Women adequately treated for hypertension are at reduced risk of acute myocardial infarction and stroke as compared with untreated women. Although there are no data, COC users with adequately controlled and monitored hypertension should be at reduced risk of acute myocardial infarction and stroke compared with untreated hypertensive COC users.

3 Simple Ways to Prevent Medication-induced Birth Defects

- **ParaGard®** "copper T" (1988)
  - Labeled use for 10 years
  - Effective in studies for 12-20 yrs
  - Heavier cramping/menstrual bleeds
- **Mirena®** levonorgestrel (2001)
  - Labeled for 5 years, Studied to 7 yrs
  - Irregular spotting/Amenorrhea
- **Nexplanon®** etonogestrel (2006)
  - Labeled use for 3 years
  - Irregular bleeding



Sivin I. Contraception. 2007;Ronnergdag Acta Obstet Gynecol Scand. 1999 ;Inki P Contraception. 2007; Power J 2007; PMID: 17636668;Darney P 2009; PMID: 18423453;Steiner MJ 2010; PMID: 20159174

Hepatic enzyme inducers

- Decrease effectiveness of hormonal contraceptives
  - Carbamazepine
  - Barbiturates
  - Phenoparbital
  - Primidone
  - Effavirenz
  - St. John's Wort
- ParaGard® "copper T" still works well

Sivin I. Contraception. 2007;Ronnergdag Acta Obstet Gynecol Scand. 1999 ;Inki P Contraception. 2007; Power J 2007; PMID: 17636668;Darney P 2009; PMID: 18423453;Steiner MJ 2010; PMID: 20159174

Thank You!

Questions?

schwarzeb@upmc.edu