Primary Care Update On Birth Control

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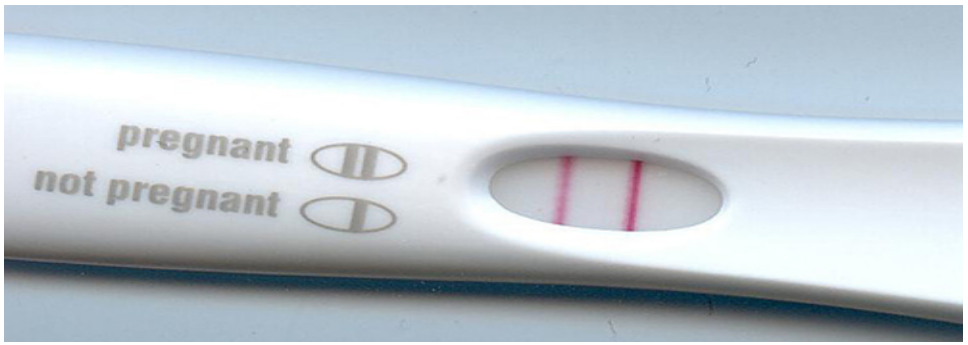
Primary Care Conference

Objectives

- Utilize Clinical Cases to Review Initiation of Contraception
- Provide Overview of US Medical Eligibility Criterion
- Management of Side Effects
- Review Long-Acting Reversible Birth Control (LARC)



Financial disclosures: NONE

United States Unintended Pregnancies

45%

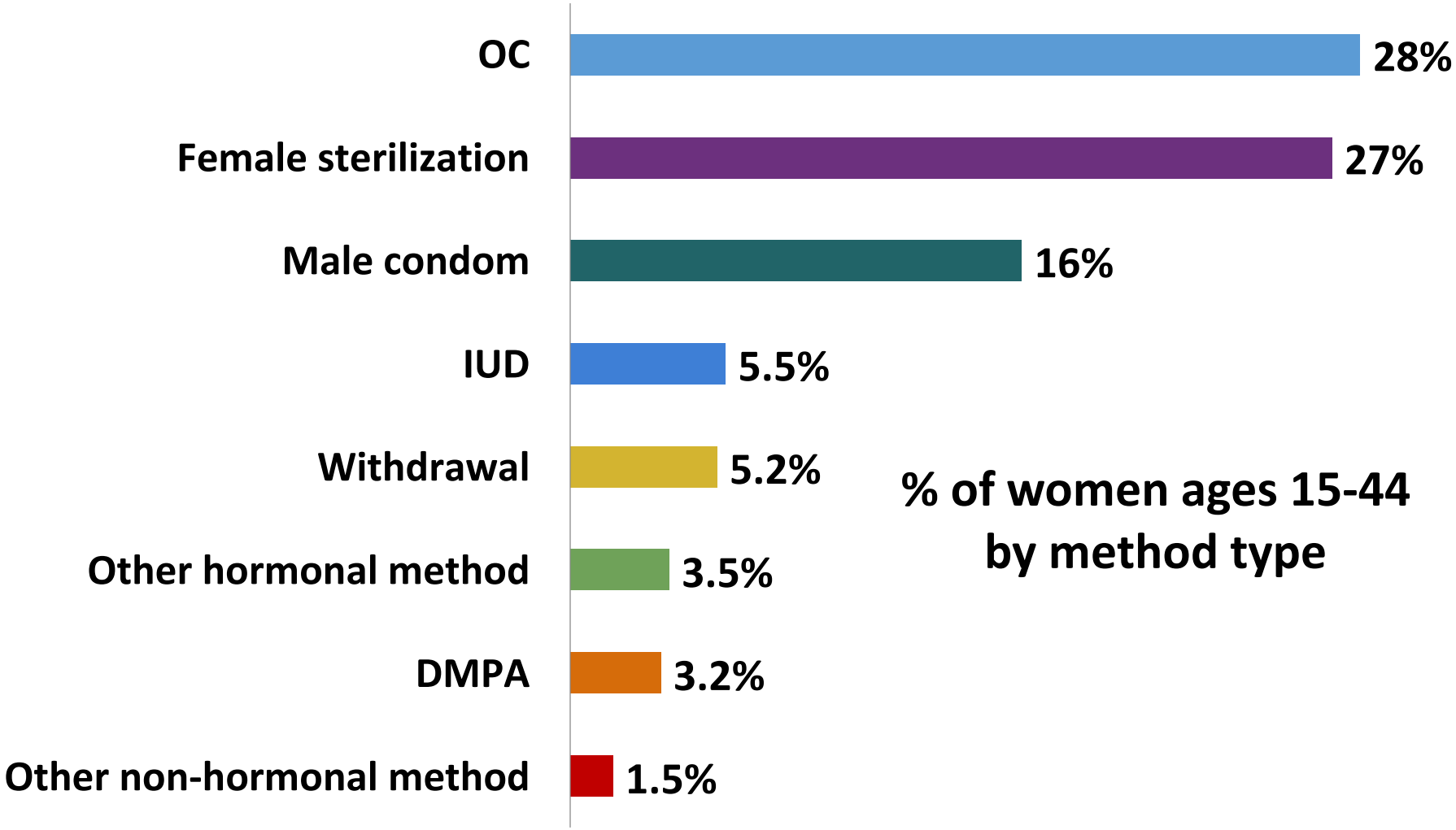
2.8 Million Unintended Pregnancies/year[1]

Teen pregnancy
7x higher then in some developed countries[2]

[1]Finer LB, et al Declines in unintended pregnancy in the United Status 2008-2011.N Engl J Med. 2016;374(9)843-852

[2]Secure GM et al. Provision of no –cost, long acting contraception and teen pregnancy N Engl J Med. 2014;371(14):1316-1323

U.S. Contraceptive Use[1]



[1]Mosher et al Use of contraception in the United Sated: 1982-2008. Vital Health Stat 23 2010 ; (29):1-44

50% of all pregnancies in the US are unintended

50% not using contraception

50% USING contraception

Global Goals

- Prevent unintended pregnancy
- Choose appropriate contraceptive methods
- Use methods correctly and consistently

Continuation Rates of Birth Control Methods, Aged 15-45, In the US[1]

	12 months	24 months
LARC	87%	77%
Non-LARC	57%	41%

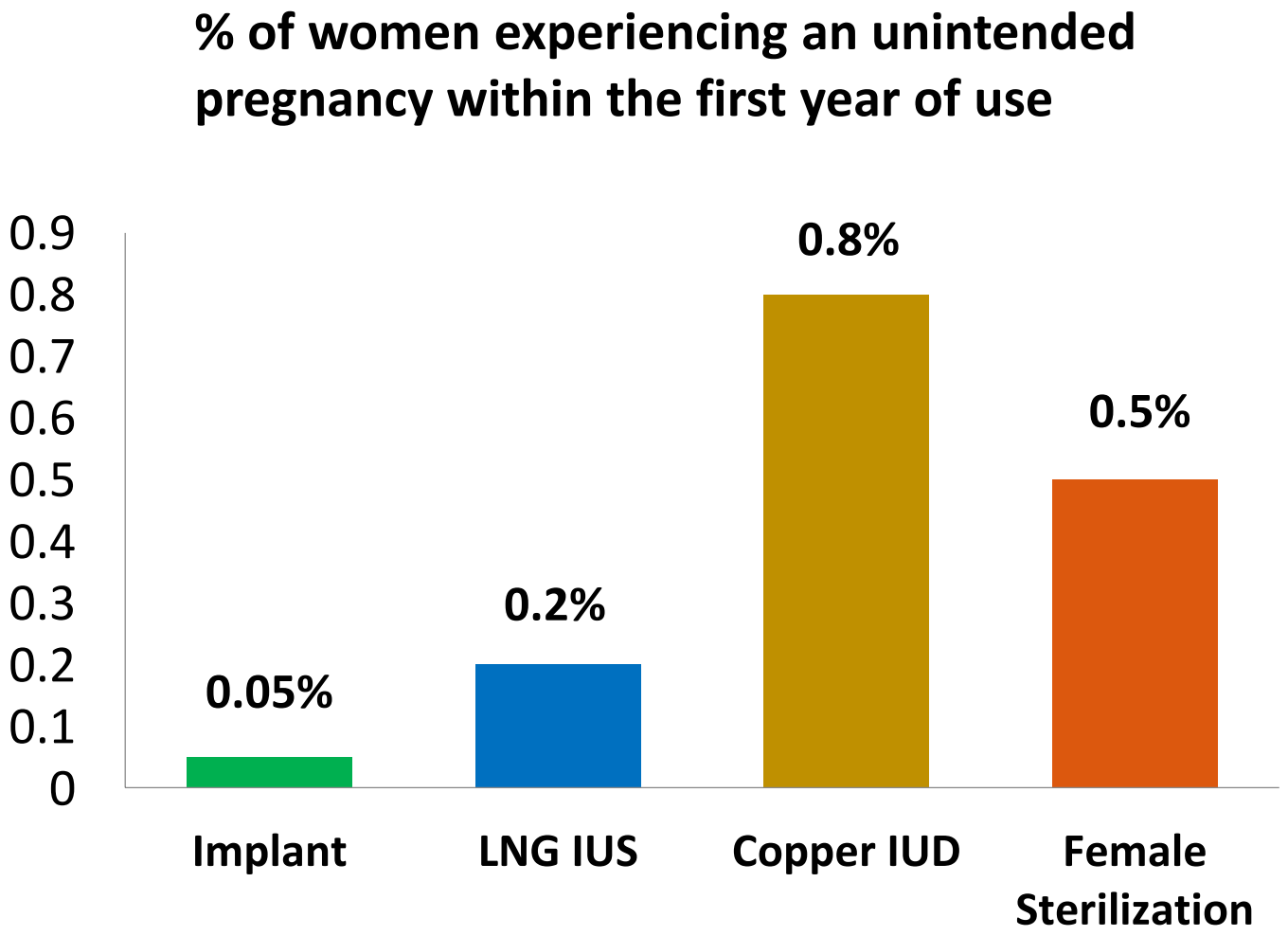
Non-LARC method	24 months
Pill	43%
Patch	40%
Ring	41%
DMPA (shot)	38%

[1] Secura, G et al. Provision of No-Cost, Long-Acting Contraception and Teenage pregnancy. N Engl Med 2014 Oct 2:371 (14):1216-1323.

Reduction in Pregnancy, Birth and Abortion Rate in the United States (mean # per 1000 teens-2008)

	Pregnancy	Birth	Abortion
LARC	3.4	19.4	9.7
Non-LARC	158.5	94	41.5

Reversible Contraception that Works as Well as Sterilization



Contraception Resources from the CDC: 2016 U.S. Selected Practice Recommendations for Contraceptive Use

Division of Reproductive Health

Centers for Disease Control and Prevention

US Medical Eligibility (MEC)/SPR Criterion

US MEC
US SPR

CDC

Medical eligibility criteria (MEC) is a document that was produced and designed by the CDC. Original publication- 2010

- It includes recommendations for specific contraception options based up preexisting medical condition or characteristics of the patient

SPR

- Focuses on how to initiate contraception
- Reviews tests recommended prior to initiation
- Outlines any follow up required

http://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf

US Medical Eligibility Criterion for Contraceptive Use 2016

Category	Definition	Recommendation
1	No restriction in the contraception use	Use method
2	Advantages generally outweigh theoretical or proven risk	More then usual follow-up needed
3	Theoretical or proven risk usually outweigh the advantages	Use clinical judgment to ensure patient can use safely
4	Unacceptable health risk if the method is used	Do not use this method

CASE #1- Birth Control Risk/Benefit

28 y/o G1 is 3 weeks postpartum and wants to ensure she doesn't get pregnant, what options are there for her

- ✓ no menses
- ✓ No PMH
- ✓ Monogamous
- ✓ Breastfeeding

Contraception Counseling

- ✓Efficacy
- ✓Medical History
- ✓Ease of use
- ✓Future fertility
- ✓Prior contraceptive history
- ✓Sexual history – monogamous, multiple partners

Birth Control Pills

The most popular method of reversible birth control in the U.S.

- Typical failure rates for adolescents: 9-18%
- In adults failure rates range: 3-6%
- Compliance in adolescence: 44-55%

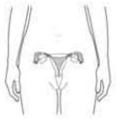
Comparing Effectiveness of Family Planning Methods

More effective

Less than 1 pregnancy per 100 women in 1 year

Implants

IUD

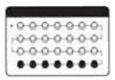


Female sterilization

Vasectomy

Injectables

LAM



Pills

Patch

Vaginal ring

Male condoms

Diaphragm

Female condoms

Fertility awareness methods

Less effective

About 30 pregnancies per 100 women in 1 year

Withdrawal

Spermicides

How to make your method more effective

Implants, IUD, female sterilization: After procedure, little or nothing to do or remember

Vasectomy: Use another method for first 3 months

Injectables: Get repeat injections on time

Lactational amenorrhea method, LAM (for 6 months): Breastfeed often, day and night

Pills: Take a pill each day

Patch, ring: Keep in place, change on time

Condoms, diaphragm: Use correctly every time you have sex

Fertility awareness methods: Abstain or use condoms on fertile days. Newest methods (Standard Days Method and TwoDay Method) may be easier to use.

Withdrawal, spermicides: Use correctly every time you have sex

USAID FROM THE AMERICAN PEOPLE

World Health Organization

Sources:

Steiner MJ, Trussell J, Mehta N, Condon S, Subramaniam S, Bourne D. Communicating contraceptive effectiveness: a randomized controlled trial to inform a World Health Organization family planning handbook. *Am J Obstet Gynecol* 2006;195(1):85–91.

World Health Organization/Department of Reproductive Health and Research (WHO/RHR), Johns Hopkins Bloomberg School of Public Health (JHSPH)/Center for Communication Programs (CCP). *Family Planning: A Global Handbook for Providers*. Baltimore, MD and Geneva: CCP and WHO, 2007.

Trussell J. Choosing a contraceptive: efficacy, safety, and personal considerations. In: Hatcher RA, Trussell J, Stewart F, Nelson AL, Cates W Jr., Guest F, Kowal D, eds. *Contraceptive Technology, Nineteenth Revised Edition*. New York: Ardent Media, Inc., in press.

2007

US Medical Eligibility Criterion for Contraceptive Use 2016

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Age		Menarche to <20 yrs:2		Menarche to <20 yrs:2		Menarche to <18 yrs:1		Menarche to <18 yrs:2		Menarche to <18 yrs:1		Menarche to <40 yrs:1	
		≥20 yrs:1		≥20 yrs:1		18-45 yrs:1		18-45 yrs:1		18-45 yrs:1		≥40 yrs:2	
						>45 yrs:1		>45 yrs:2		>45 yrs:1			
Anatomical abnormalities	a) Distorted uterine cavity	4		4									
	b) Other abnormalities	2		2									
Anemias	a) Thalassemia	2		1		1		1		1		1	
	b) Sickle cell disease‡	2		1		1		1		1		2	
	c) Iron-deficiency anemia	2		1		1		1		1		1	
Benign ovarian tumors	(*including cysts*)	1		1		1		1		1		1	
Breast disease	a) Undiagnosed mass	1		2		2*		2*		2*		2*	
	b) Benign breast disease	1		1		1		1		1		1	
	c) Family history of cancer	1		1		1		1		1		1	
	d) Breast cancer‡												
	i) Current	1		4		4		4		4		4	
	ii) Past and no evidence of current disease for 5 years	1		3		3		3		3		3	
Breastfeeding	a) <21 days postpartum					2*		2*		2*		4*	
	b) 21 to <30 days postpartum												
	i) With other risk factors for VTE					2*		2*		2*		3*	
	ii) Without other risk factors for VTE					2*		2*		2*		3*	
	c) 30-42 days postpartum												
	i) With other risk factors for VTE					1*		1*		1*		3*	
	ii) Without other risk factors for VTE					1*		1*		1*		2*	
	d) >42 days postpartum					1*		1*		1*		2*	
Cervical cancer	Awaiting treatment	4	2	4	2	2		2		1		2	
Cervical ectropion		1		1		1		1		1		1	
Cervical intraepithelial neoplasia		1		2		2		2		1		2	
Cirrhosis	a) Mild (*compensated*)	1		1		1		1		1		1	
	b) Severe‡ (*decompensated*)	1		3		3		3		3		4	

The Real Risk – OC vs pregnancy

Combined hormonal contraceptives are safer than pregnancy

Absolute risk of contraceptive related death is extremely low

- Nonsmoker ages 15-34 1/1,667,000[1]
- Nonsmoker ages 34-45 1/33,3000

Pregnancy death rate 1/6,900 [2]

[1]Schwingl Estimates of the risk of cardiovascular death attributable to low dose oral contraceptive in the US Am J Ob Gyn 1999

2Berg et al Pregnancy related mortality in the US, 1998 to 2005 Ob Gyn 2010;116:1302-9

Vascular Thrombotic Risk- OC

- Agree that there is a risk of VTE in OC users compared with non users[1]
- Risk increases with estrogen dosing; 3rd generation progestins
- This risk decreases over time

Incidence rates of VTE and other cardiovascular events are low in women of reproductive age, regardless of OC use

[1]Shapiro et al Risk of venous thromboembolism among users of oral contraceptives: a review of two recently published studies. J Fam Plann Reprod Health Care 2010:36:33-8

Benefit of Combined OC (CHC)

- Reduced risk of ovarian /colon cancer
- Reduction in risk relative to duration of use
- Protection extended for up to 30 years after discontinuation
- OCs prevent approx 30,000 cases of ovarian cancer worldwide /year

Benefit of Combined OC (CHC)

Hazard ratio (95% confidence interval) for cancer by duration of use*

Type of Cancer	1-4 yrs of OC use	5-9 yrs of OC use	10+ yrs of OC use
Ovarian	0.82 (0.69-0.97)	0.72 (0.59-0.88)	0.6 (0.47-0.76)
Endometrial	0.79 (0.70-0.90)	0.84 (0.73-0.97)	0.66 (0.56-0.78)
Breast	1.04 (0.98-1.10)	1.02 (0.96-1.09)	1.04 (0.97-1.11)

* Michels et al .Modification of the association between duration of oral contraception use and ovarian, endometrial, breast and colorectal cancers .JAMA oncol.doi;1001/jamaoncol.2017.4942

How To Be Reasonably Certain a Woman Is Not Pregnant

- ✓ ≤7 days after the start of menses
- ✓ no sexual intercourse since LMP
- ✓ Consistently using a reliable method of contraception
- ✓ ≤7 days after SAB or Medical TAB
- ✓ Within 4 weeks postpartum
- ✓ Fully or nearly fully breastfeeding
  amenorrheic
  <6 months postpartum

Same Day Start

- Start using contraceptive methods at any time in the woman's menstrual cycle.
- Follow-up pregnancy test in 2–4 weeks.

U.S. Selected Practice Recommendations 2016

When to Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back up) needed	Examinations or tests needed before initiation[1]
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection[2]
Levonorgestrel-releasing IUD	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection[2]
Implant	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days.	None

Extended use OC

Standard OC formulation –

- too few hormone pills
- too many inert pills

FSH rises significantly during 7-day hormone free interval

Studies suggest :

- intermittent ovulation occurs in women who take the standard 21-day regimen

Benefit of Extended use OC

Reduced frequency of -

- Bleeding
- PMS
- Anemia

Increased OCPs efficacy -

- Simplified regimen

Kaunitz AM Contraception 2000;62:277-284

Management of Side Effects

Complaints observed in <5% of users

- Weight gain, mood changes, depression, nausea, acne, breast tenderness, headaches, low back pain

Side effects are the most common reason for discontinuation

- Characterize
- Validate
- Adjust
- Change method as needed

Grimes, Contraception , 2011

Summary OCP Start

- ✓Evaluate safety (USMEC)
- ✓Encourage continuous/extended use pills
- ✓Same day start is an option
- ✓Dispense 84 tabs (3 pack) + refills for 1yr
- ✓Triple protection
  - Condom
  - Emergency Contraception

CASE #2 - Migraine

28 y/o G2P2 with migraine headaches not sure if she has auras

- ✓ One child 2 years ago wanting a reliable BCM
- ✓ No significant PMH/FH
- ✓ Considering BC pills but not sure if they're safe

US Medical Eligibility Criterion for Contraceptive Use (2016)

	CU-IUD	LNG-IUD	Implant	DMPA	POP	CHC
Non-migraine (mild severe)	1	1	1	1	1	1
Migraine without aura	1	1	1	1	1	**2**
Migraine with aura	1	1	1	1	1	4

Headache and Contraception

- Distinguish betw migraine vs non-migraine HA
- CHC in women w migraines wo aura
  - ✓Low estrogen agents
  - ✓< 35 years of age, no stroke risk factors
  - ✓Freq follow up initially
- Migraine w aura
  - ✓Progestin options, IUD

Defining an Aura

	Atypical Aura	Typical Aura
Onset and progression	Sudden, unilateral	Slow, progressive over a few minutes
Duration	>30-60 minutes	<30-60 minutes
Headache	Present or absent	Aura precedes migraine
Visual Symptoms	Negative: Loss of vision Amaurosis fugax Visual field anomaly	Positive: Bilateral scintillating scotoma Fortification spectra Blurred vision
Sensory and motor symptoms	Including lower limbs, anesthesia, hypoesthesia	Often related to visual symptoms Upper limbs, mouth, tongue Tingling, pinching

Typical aura is associated with risk of CVA with OC use

Migraine w Aura increase CVA Risk

Do you ever have visual disturbances:

- ✓Starting ***before the headache?***
- ✓Lasting up to ***one hour?***
- ✓Resolving ***before the headache?***

If patient answers ‘yes’ to all three questions, it is likely that the symptoms are aura

CHC would be contraindicated.

Summary- Migraine and BCM

- In the absence of other contraindications, low dose COCs are safe for women with migraines without aura
- Risk of CVA is increased in women with migraines
- Consider other risk factors—age, smoking, DM, obesity, hyperlipidemia

Neurol Clinics 2001 19 (1): 1-21

Can J Neurol Sci 1997;24 (1): 16-21

CASE #3

36 y/o G2P2 on metformin for Type 2 DM

- ✓ Regular menses
- ✓ Monogamous
- ✓ Uses condoms
- ✓ Stable BP
- ✓ Wanting to switch BCM – what's safe for her

US Medical Eligibility Criterion for Contraceptive Use (2016)

	CU-IUD	LNG-IUD	Implant	DMPA	POP	CHC	
History of Gestational DM	1	1	1	1	1	1	
Nonvascular Non-insulin dependent	1	2	2	2	2	**2**	
Nonvascular Insulin Dependent	1	2	2	2	2	2	
Nephropathy /retinopathy/ neuropathy	1	2	2	3	2	3	4
Other Vascular Dz or >20yr duration	1	2	2	3	2	3	4

Diabetes and Contraception

Combined hormones (CHC)

✓Evaluate CV risk profile

✓Use Low E (thrombosis) + Low P(glucose control)

Progestin alone

✓May cause insulin resistance, usually insignificant

✓No increase arterial thrombosis

IUC – safe, effective

CASE #4

42 y/o G4P4 married no future wishes for more kids

- ✓ Tired of taking daily pills
- ✓ Vasectomy is not an option
- ✓ What longer term options are there for her
- ✓ PMH Obese

American College of Obstetrics & Gynecology 2012

- IUDs and the contraceptive implant are the best reversible methods for preventing unintended pregnancy, rapid repeat pregnancy, and abortion in young women
- LARC methods should be first-line recommendations for all women and adolescents

American College of Obstetricians and Gynecologists. Committee Opinion No. 539, "Adolescents and Long-Acting Reversible Contraception: Implants and Intrauterine Devices," October 2012.

Increased use of LARC* has the potential to lower unintended pregnancy rates

*LARC = Long-Acting Reversible Contraception

CASE #5

- 1 out of 2 teens in 9-12th grade have sexual intercourse
- Those not using BCM have 2x odds of being a teen mom then those that do

Adolescent Unintended Pregnancies

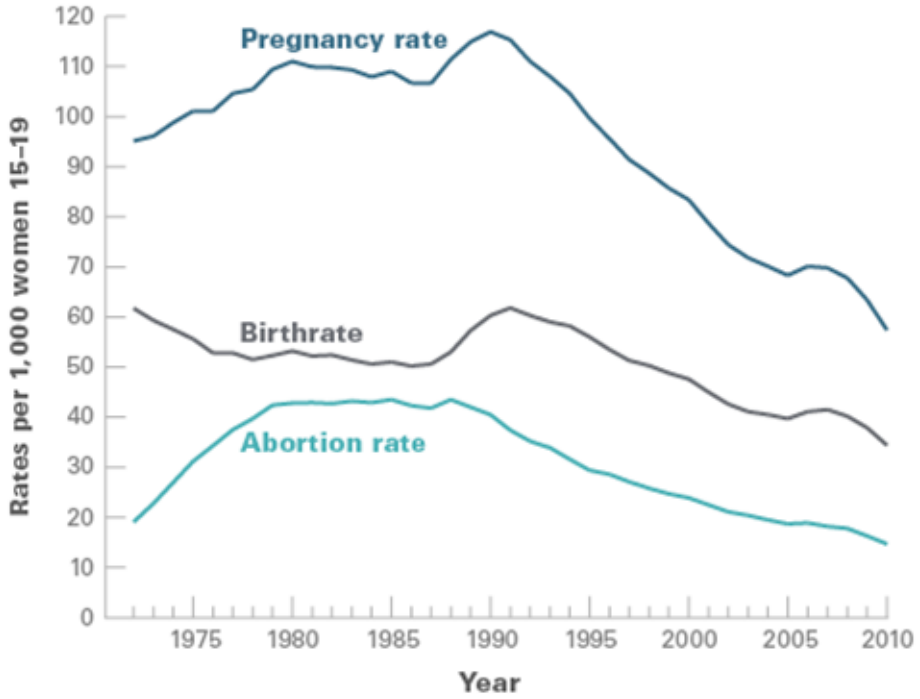
430,000

15% of all unintended pregnancies [1]

2/5 of teen mothers will have a repeat pregnancy in 2 years

[1] Finer LB, Zolna MR. 2011. Unintended pregnancy in the United States: incidence and disparities, 2006. Contraception 2011; 84:478-85.

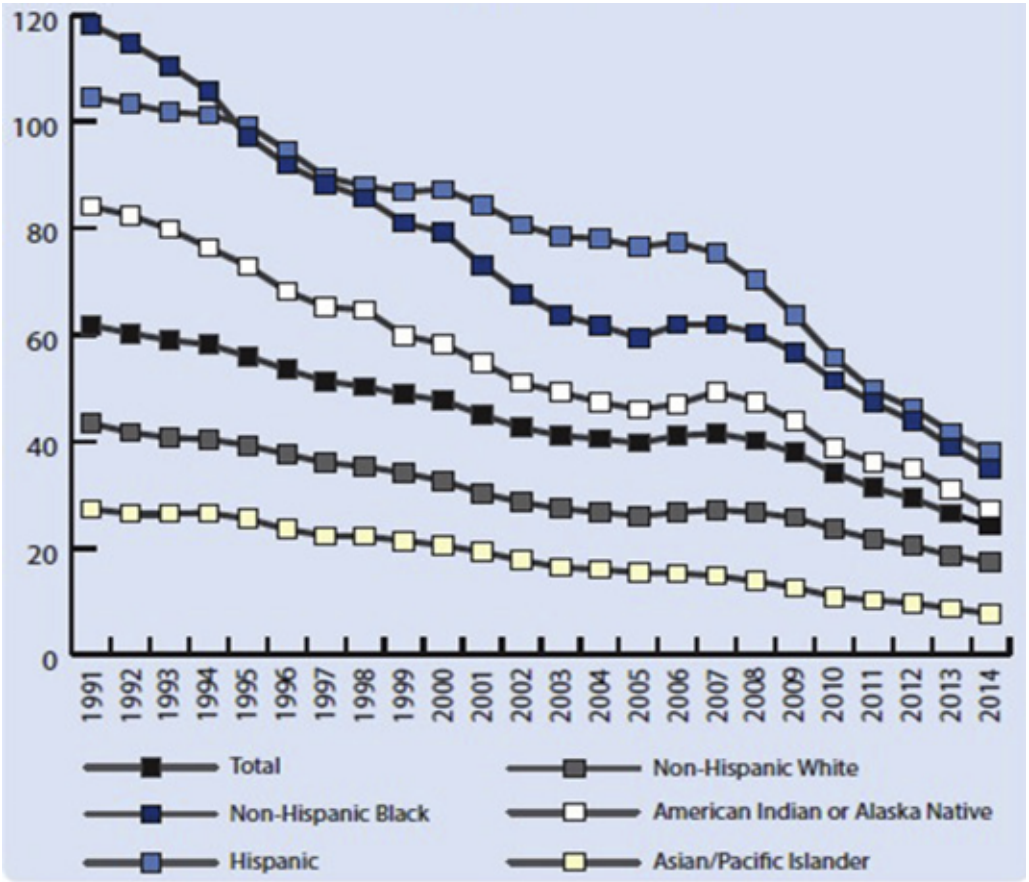
U.S. teen pregnancy, birth and abortion rates have **reached historic lows**



http://www.guttmacher.org/media/nr/2014/05/05/. Retrieved November 30, 2015.

Health Disparities – Teen Birth Rate

(per 1000 girls aged 15-19 yrs) 1991-2014



From the National Campaign to Prevent Teen and Unplanned pregnancy Parks et a; Eliminating health disparities in unintended pregnancy with LARC Am J Ob Gyn 2016

Counseling Adolescents about LARC

Adolescents should be encouraged to consider LARC methods

- Less than 1% failure rate
- High rates of satisfaction AND continuation
- No need for daily adherence

Advise consistent condom use

FACTS about IUD

1. IUD increases risk of STD/PID

FALSE

2. IUD should be inserted during menses

FALSE

3. IUD should be placed after STD results are confirmed

FALSE

4. Insertion of IUDs is technically more difficult w adolescents

FALSE

Copper vs. LNG IUD

Copper IUD

- Initial increased bleeding and cramping
- Treat with nonsteroidal anti-inflammatory drugs (NSAIDs)
- Decreases over time

LNG-IUDs

- Bleeding duration and amount decreases initially and over time
- 70% of patients experience oligomenorrhea or amenorrhea within 2 years of insertion

Implant Summary

The Implant:

- Is one of the most effective reversible contraceptives
- Allows for short insertion and removal time
- Provide anticipatory guidance regarding bleeding pattern

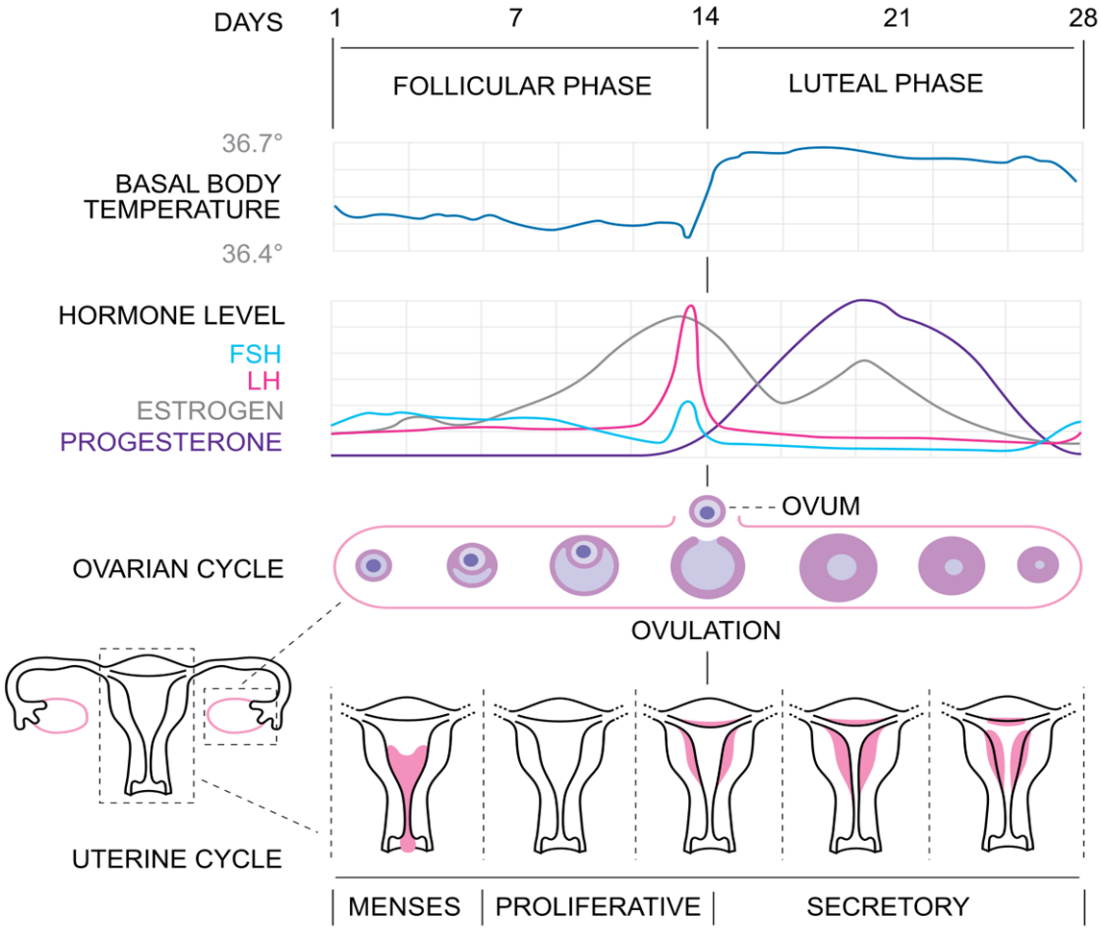
Birth Control Summary

- ✓Shared decision making is key
    1. What do you want in a BCM?
    2. Review efficacy/ease of use
- ✓Review Medical Eligibility
- ✓Encourage LARC as 1st line
- ✓Know side effects

Committed to giving women
and their partners
effective options for birth control

The Fertile Window

-5 to -1
Days from ovulation



Wilcox, et al *New Engl J Med* 1995; 33(23): 1517-1521

Types of Intrauterine Devices

3-Year LNG-IUD	5-Year LNG-IUD	Copper IUD
• 3-year IUS releases 6 mcg of levonorgestrel per day • Approved for use up to 3 years • Causes endometrial suppression and changes in cervical mucus • All effects occur before implantation	• 5-year IUS releases 20 mcg of levonorgestrel per day • Approved for use up to 5 years • Causes endometrial suppression and changes in cervical mucus • All effects occur before implantation	• 10-year IUD polyethylene wrapped with copper wire • Approved for use up to 10 years • Inhibition of sperm migration and viability • Change in ovum transport speed • Damage to or destruction of ovum • All effects occur before implantation

Abbreviations: IUS, intrauterine system; LNG, levonorgestrel; mcg, micrograms.