HORMONAL CONTRACEPTION

More Than Just Pregnancy Prevention

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WOMEN'S HEALTH COLLECTIVE

DISCLOSURES

- None

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LEARNING OBJECTIVES

- Develop comfort in counseling patients on risks, benefits and efficacy of all forms of contraception with a focus on research and FDA recommendations
- Review insertion and removal techniques for long acting reversible contraceptives as well as explain difficult insertions and removals techniques.
- Review common myths and misconceptions regarding contraception use especially in regards to age, parity and comorbidities

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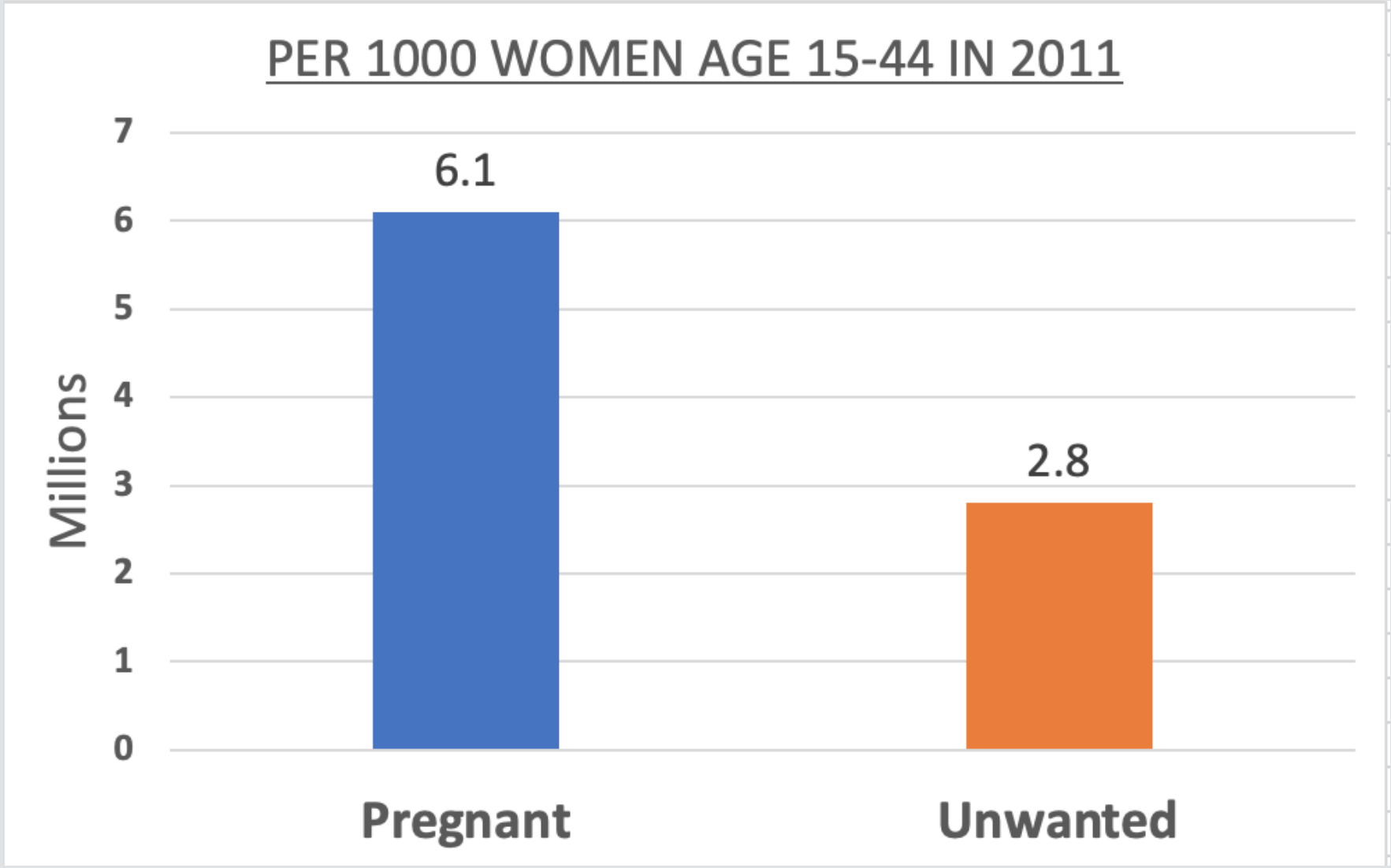
45% OF PREGNANCIES ARE UNINTENDED



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UNWANTED PREGNANCY FACTS

- 10-15% of all sexually active women use no birth control method
- 2.8 million unintended pregnancies in 2011
  - 42% ended in abortion
- Unintended pregnancies disproportionately affect low income and minority communities (up to 112/1000 women)

Finer and Zolna NEJM 2016, Guttmacher Institute 2019

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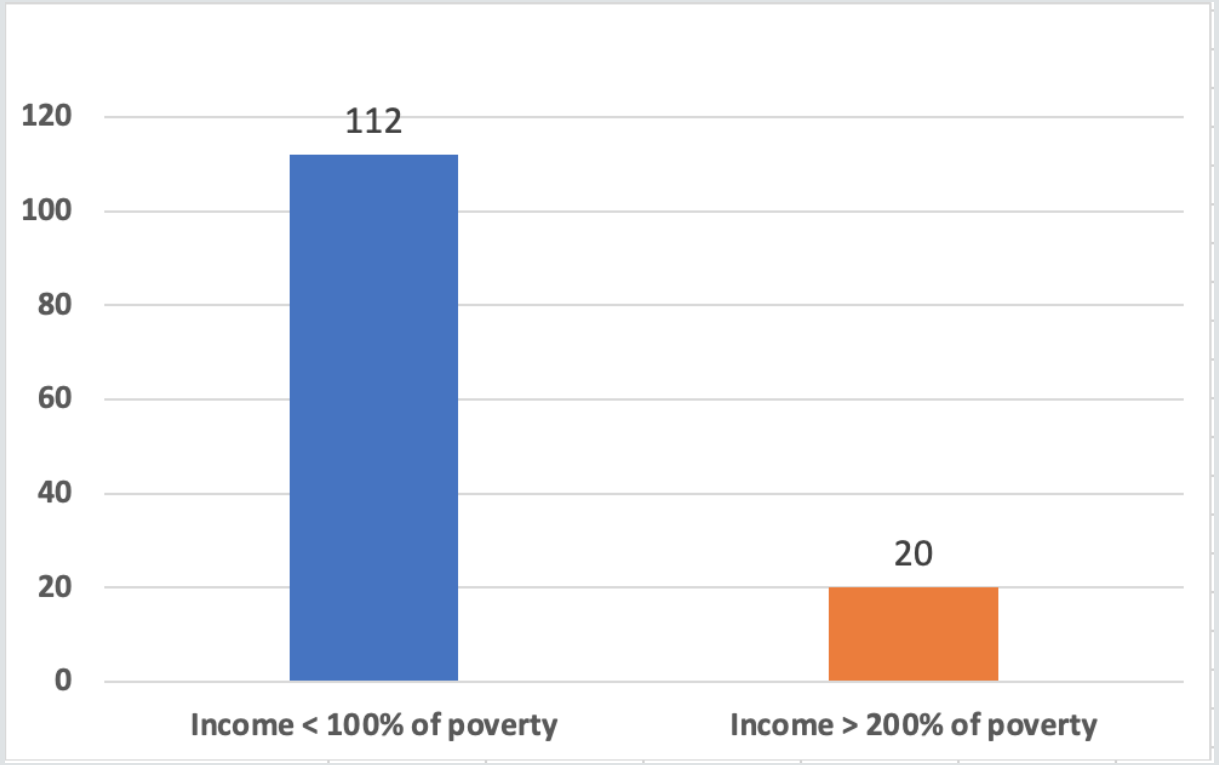
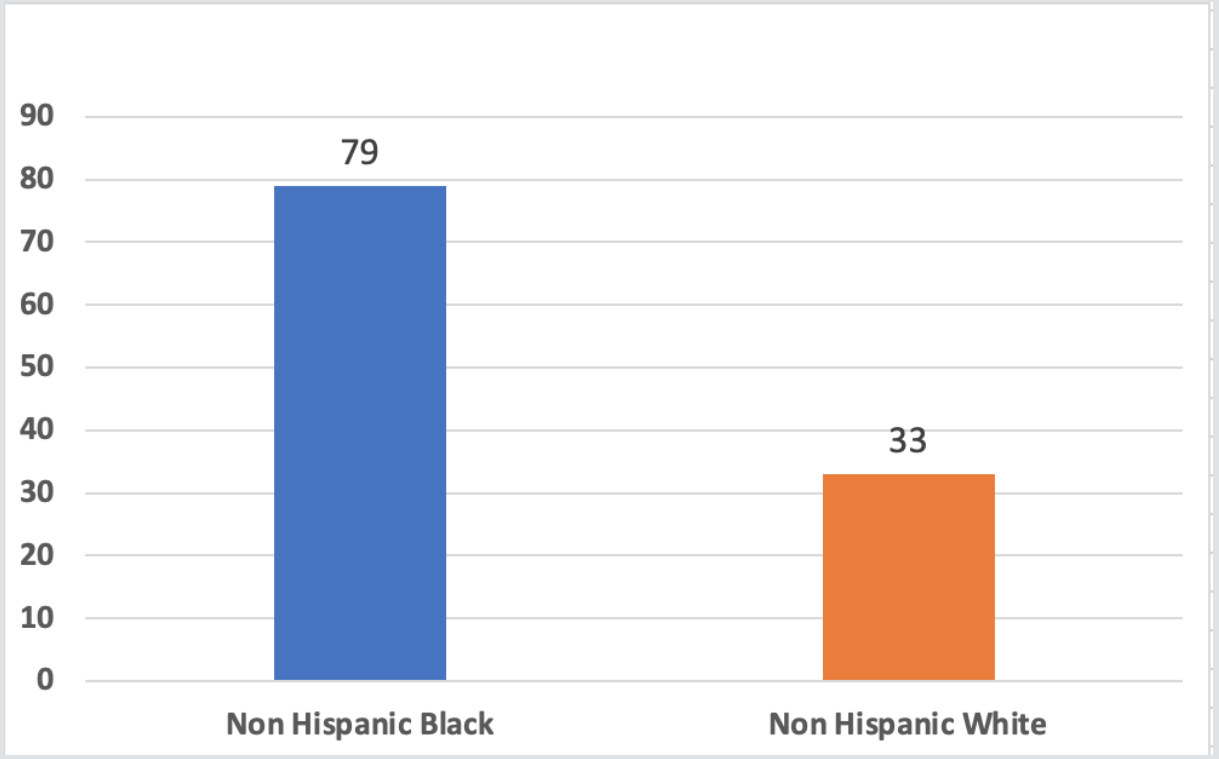
UNINTENDED PREGNANCIES/1,000 WOMEN





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CONTRACEPTIVE FACTS

- Between 2002 and 2012 we saw an increase in LARC use from 2 -12% (Guttmacher Institute)
- 83% of black women at risk of unintended pregnancy are currently using a contraceptive method, compared with 91% of their Hispanic and white peers, and 90% of their Asian peers (Jones J, Mosher W, Daniels K, Current contraceptive use in the United States, 2006-2010, and changes in patterns of use since 1995, *National Health Statistics Reports*, 2012, No.)
- In the US, average desired family size is 2 children. To achieve this, a woman must use contraceptives for roughly 3 decades (Sonfield A, Hasstedt K and Gold RB, *Moving Forward: Family Planning in the Era of Health Reform*: Guttmacher Institute, 2014)
- Couples who do not use any method of contraception have ~ 85% chance of experiencing a pregnancy over the course of a year (Sonfield A, Hasstedt K and Gold RB, *Moving Forward: Family Planning in the Era of Health Reform*: Guttmacher Institute, 2014)

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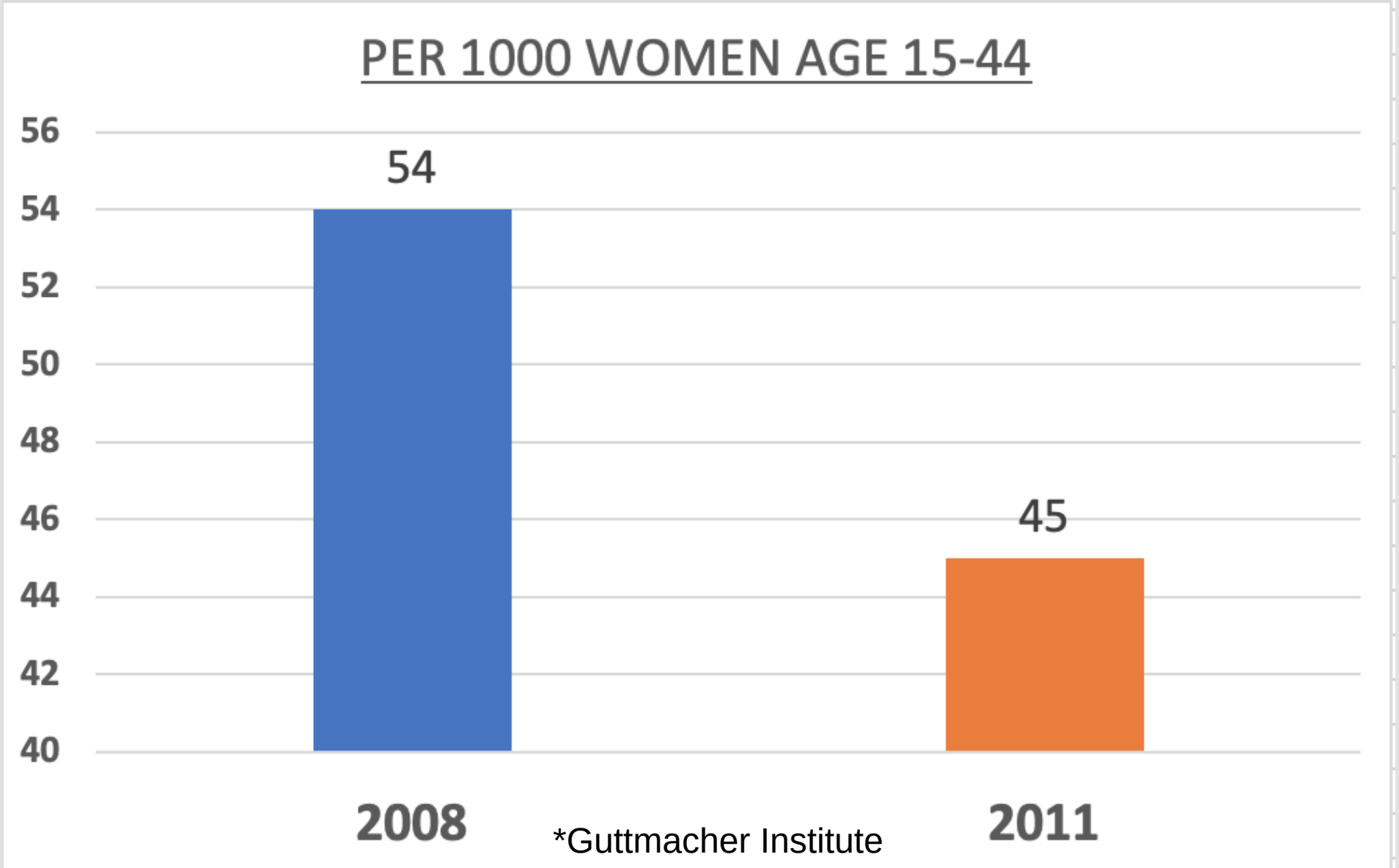
UNINTENDED PREGNANCIES PER 1,000 WOMEN



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Most effective method used in the past month by U.S. women, 2014

METHOD	No. of women	% of women aged 15–44	% of women at risk of unintended pregnancy	% of contraceptive users
Pill	9,572,477	15.6	22.7	25.3
Tubal (female) sterilization	8,225,149	13.4	19.5	21.8
Male condom	5,496,905	8.9	13.0	14.6
IUD	4,452,344	7.2	10.6	11.8
Vasectomy (male sterilization)	2,441,043	4.0	5.8	6.5
Withdrawal	3,042,724	5.0	7.2	8.1
Injectable	1,481,902	2.4	3.5	3.9
Vaginal ring	905,896	1.5	2.1	2.4
Fertility awareness–based methods	832,216	1.3	2.0	2.2
Implant	965,539	1.6	2.3	2.6
Patch	69,106	0.1	0.2	0.2
Emergency contraception	69,967	0.1	0.2	0.2
Other methods*	234,959	0.4	0.6	0.6
No method, at risk of unintended pregnancy	4,408,474	7.2	10.5	na
No method, not at risk	19,302,067	31.4	na	na
Total	**61,491,766**	**100.0**	**100.0**	**100.0**

*Includes diaphragm, female condom, foam, cervical cap, sponge, suppository, jelly/cream and other methods. NOTE: "At risk" refers to women who are sexually active; not pregnant, seeking to become pregnant or postpartum; and not noncontraceptively sterile. na=not applicable.

ABORTION FACTS

- At 2014 abortion rates, about 1:4 (24%) women will have an abortion by age 45 (Jones RK and Jerman J, Population group abortion rates and lifetime incidence of abortion: United States, 2008-204, *American Journal of Public Health*, 2017)
- In 2014, 51% of abortion patients were using a contraceptive method at the time they became pregnant, most commonly condoms (24%) or a short acting hormonal method (13%) (Jones RK, Reported contraceptive use in the month of becoming pregnant among US abortion patients in 2000 and 2014, *Contraception*, 2018)
- ~75% of women who had abortions in 2014 were poor or low-income (below poverty level or 100-199% of federal poverty level) (Jerman J, Jones RK and Onda T, *Characteristics of U.S. Abortion Patients in 2014 and Changes since 2008*, New York: Guttmacher Institute, 2016)

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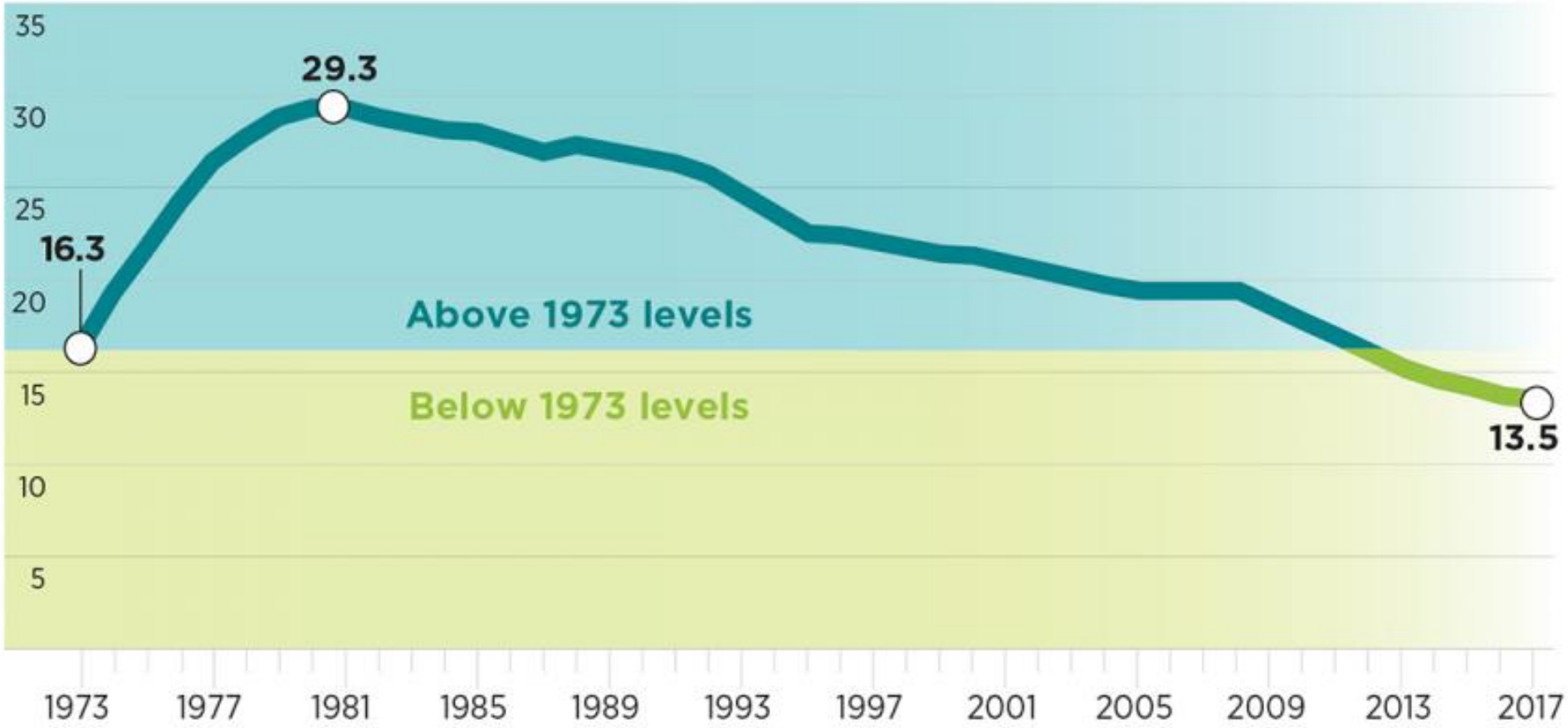
TRENDS IN ABORTION

The U.S. abortion rate reached a historic low in 2017.



No. of abortions per 1,000 women aged 15–44

www.guttmacher.org

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Investing in sexual and reproductive health care would dramatically reduce unintended pregnancies, unsafe abortions and maternal deaths

	Annual number			
	At current levels of care	− If all needs are met	= Averted if all needs are met	% change if all needs are met
Unintended pregnancies	111M	35M	76M	–68%
Unsafe abortions	35M	10M	26M	–72%
Maternal deaths	299K	113K	186K	–62%

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WHO IS A CANDIDATE FOR A LARC?

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IUD PROS AND CONS

YAY

- Highly effective and easily reversible
- Very few CIs to placement (think uterine anomaly)
- Appropriate for nulliparous women, adolescents, and peri/postmeno
- Higher rates of satisfaction and compliance vs short acting contraceptives
- Low expulsion rates
  - LNG IUD 3.3%
  - Cu IUD 9.2%
- No increased risk of PID
- Local effect, not systemic (will not decrease systemic T)

NAY

- Requires office visit to insert and remove
- Pain with insertion
- Limited data re: sexual side effects
  - CHOICE Project: no difference in desire
- LNG is androgenic, targets the AR
- Several reports/studies showing increased vaginal complaints/vaginitis with IUDs
- CU IUD shows increased in uterine bleeding and dysmenorrhea

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IMPLANT PROS AND CONS

YAY

- Prospective studies x 2 show improvement in FSFI/sexual function
- Low doses of circulating progestin suppresses ovulation
- Ease of placement (think pts with vaginismus or h/o abuse)

NAY

- Does not have a significant impact on suppression of systemic estradiol
  - Explaining AUB (11%)
- Mood swings (2.3%)
- Weight gain (2.3%) (2.8lbs after 1yr, 3.7lbs after 2 yrs)
- Acne (1.3%)
- Requires training by Merck prior to ordering

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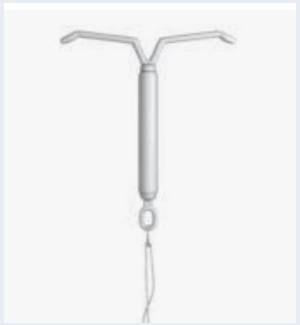
Product	Device	FDA Approved Duration	FDA Approved Indication	Mechanism of Action
Etonogestrel Subdermal Implant • Nexplanon 68mg		• 3 yrs	Contraception	Suppresses ovulation, increases viscosity of cervical mucous, alters endometrial lining
Levonorgestrel IUD • Skyla 13.5mg (28x30mm) • Kyleena 19.5mg • Liletta 52mg (32x32mm) • **Mirena 52mg**	 	• 3 years • 5 years • 6 years • 5 years	• Contraception • Contraception • Contraception • Contraception/ **Menorrhagia**	Thickens cervical mucous, alters endometrial lining impairing implantation, may inhibit binding of sperm and egg
Copper IUD • Paragard		• 10 years	Contraception (off label emergency contraception)	Copper ions toxic to sperm

LARC CONTINUATION RATES FROM THE CHOICE PROJECT

Method	1 Year	2 Year	3 Year
LNG IUD	87.3	76.7	69.8
Copper IUD	84.3	76.2	69.7
Implant	81.7	68.7	56.2
LARC methods overall	85.8	75.2	67.2
Non-LARC methods overall	55.8	39.5	31.0

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NON CONTRACEPTIVE HEALTH BENEFITS

- Menorrhagia/Heavy menstrual bleeding/Anemia
  - 40% decrease in blood loss after 3 months of use
- Dysmenorrhea
  - 66% decreased cramping
  - Low-dose pills improve menstrual pain over time
- Regulates bleeding pattern
- Ovarian cysts
- Cancer prevention
  - Ovarian, endometrial, colon

Maguire K, et al AJOG 2011

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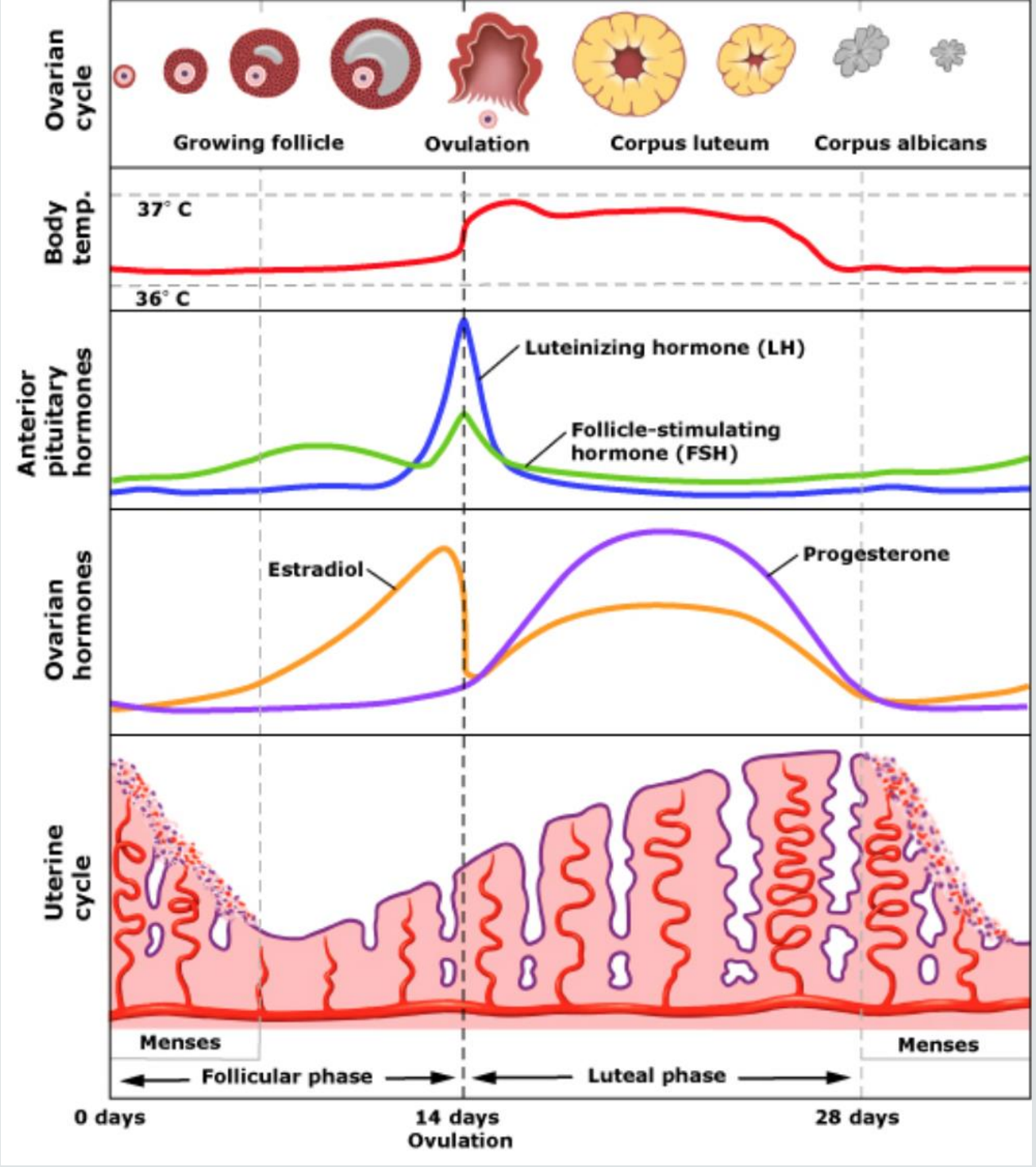
NON CONTRACEPTIVE HEALTH BENEFITS

- Bone
  - Women in their 40s show a 25% decrease in hip fractures later in life
  - Dose related effect on BMD
- Fibroids
  - Pain management and control of AUB related to leiomyoma
- PMDD
  - Most data on drospirenone containing OCPs
- Acne
  - Increased SHBG resulting in decreased free testosterone
  - 50% decrease in inflammatory lesions

Maguire K et al AJOG 2011

WOMEN'S HEALTH COLLECTIVE



MENSTRUAL CYCLE

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The Takeaway: Know your OCP type

ISSWSH
International Society for the Study of Women's Sexual Health

- Almost all OCPs comprised of ethinyl estradiol
  - Stronger effect on hepatic (inc SHBG, HDL VLDL, Angiotensinogen)
  - more potent than estradiol, longer half life
  - 10, 20, 30, 35 mcg

Estrogen	FSH	HDL-C	SHBG	CBG	Angio
E_2	100	100	100	100	100
Estriol	30	20			
Estrone sulfate	90	50	90	70	150
CEE	110	150	300	150	500
Equilin sulfate		600	750	600	750
EE	**12,000**	**40,000**	**50,000**	**60,000**	**35,000**

Legend: Angio = angiotensinogen; CBG = cortisol-binding globulin;
CEE = conjugugated estrogens; EE = ethinyl estradiol; HDL-C = high density lipoprotein-cholesterol;
HF = hot flushes; SHBG = sex hormone-binding globulin.

WWW.ISSWSH.ORG

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SHARED DECISION MAKING

- Individualize
  - Sexual history
  - Co-morbidities
  - Complex psychosocial and contextual factors
    - Stress, relationships, culture, interpersonal, body image, schedule, etc
  - Reproductive health goals
  - h/o tampon use?
  - Comfort with route of administration
  - Logistical and cost barriers
- ACOG has good video resources for shared decision making
- Address any misconceptions

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MAIVE, 16 YEARS OLD

- Menarche at 12 years old
- Heavy menstrual bleeding and dysmenorrhea
- Frequency q 27-30 days, Duration 5-7 days
- Accompanied by her mom to today's visit
- Misses 2-3 days of school per month due to HMB and dysmenorrhea
- Denies being sexually active
- Hgb/Hct 12/36 (nml adolescent range 12-15/37-43)

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PEDIATRIC LARC RECOMMENDATIONS

- ACOG
  - “LARCs have higher efficacy, higher continuation rates, and higher satisfaction rates compared with short-acting contraceptives among **adolescents** who choose to use them. Complications of intrauterine devices and contraceptive implants are rare and differ little between **adolescents** and women, which **makes these methods safe for adolescents**”
- AAP
  - “Pediatricians should counsel about and ensure access to a **broad range of contraceptive services for their adolescent patients**. This includes educating patients about all contraceptive methods that are safe and appropriate for them and describing the **most effective methods first**.”

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CAN MINORS IN YOUR AREA CONSENT TO CONTRACEPTION?

MOST STATES ALLOW MINORS TO CONSENT WITHOUT PARENTAL INVOLVEMENT

- 27 states and the District of Columbia explicitly allow all individuals to consent to contraceptive services or those at a specified age (such as 12 or 14) and older to consent to such care.
- 19 states allow only certain categories of people younger than 18 to consent to contraceptive services
- 4 states have no explicit policy or relevant case law

*https://www.guttmacher.org/state-policy/explore/overview-minors-consent-law

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MAIVE

- Full discussion of risks, benefits and efficacy of each method as well as contraindications
- Maive and her mom participated in shared decision making and decided to proceed with oral contraceptives
- It is important to have discussion re: dosing/timing, expectations, potential side effects and what to do if she misses a pill
- Always use these opportunities to discuss safer sex and STI screening
- Follow up is scheduled for 3 months

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Effectiveness of Family Planning Methods

Most Effective

Less than 1 pregnancy per 100 women in a year

6-12 pregnancies per 100 women in a year

18 or more pregnancies per 100 women in a year

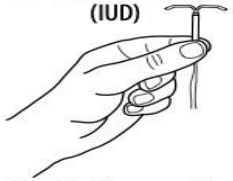
Least Effective

Reversible

Implant

0.05 %*

Intrauterine Device (IUD)



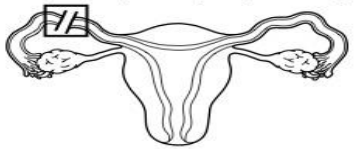
LNG - 0.2 % Copper T - 0.8 %

Permanent

Male Sterilization (Vasectomy)

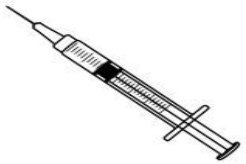
0.15 %

Female Sterilization (Abdominal, Laparoscopic, Hysteroscopic)



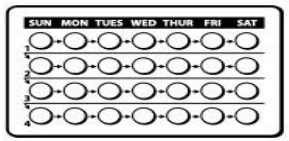
0.5 %

Injectable



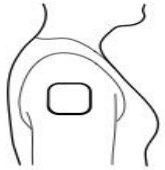
6 %

Pill



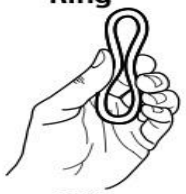
9 %

Patch



9 %

Ring

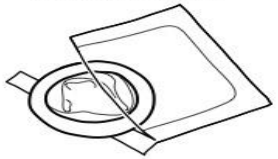


9 %

Diaphragm

12 %

Male Condom



18 %

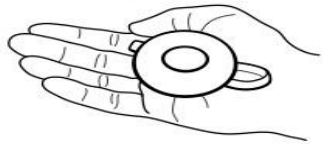
Female Condom

21 %

Withdrawal

22 %

Sponge



24 % parous women
12 % nulliparous women

Fertility-Awareness Based Methods

24 %

Spermicide

28 %

* The percentages indicate the number out of every 100 women who experienced an unintended pregnancy within the first year of typical use of each contraceptive method.

How to make your method most effective

After procedure, little or nothing to do or remember.

Vasectomy and hysteroscopic sterilization: Use another method for first 3 months.

Injectable: Get repeat injections on time.

Pills: Take a pill each day.

Patch, Ring: Keep in place, change on time.

Diaphragm: Use correctly every time you have sex.

Condoms, sponge, withdrawal, spermicides: Use correctly every time you have sex.

Fertility awareness-based methods: Abstain or use condoms on fertile days. Newest methods (Standard Days Method and TwoDay Method) may be the easiest to use and consequently more effective.

CS 242797

CONDOMS SHOULD ALWAYS BE USED TO REDUCE THE RISK OF SEXUALLY TRANSMITTED INFECTIONS.

Other Methods of Contraception

Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception.

Emergency Contraception: Emergency contraceptive pills or a copper IUD after unprotected intercourse substantially reduces risk of pregnancy.

Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP). Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD; Geneva, Switzerland: CCP and WHO; 2011; and Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397–404.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

MAIVE FOLLOW UP

- **3 months**
  - B/P WNL
  - Forgetting to take pill at same time every day – leading to breakthrough bleeding
  - Is now sexually active
    - Counsel regarding STIs
  - Discuss apps or reminders in phone to take pill at the same time
  - Also discuss other methods of contraception and bleeding control
  - She decided she would like to try a new app and work on taking it at the same time daily over the next few months

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MAIVE FOLLOW UP

- **6 months**
  - B/P WNL
  - No longer having BTB, but still forgetting her pill often
  - Using condoms most of the time
    - Counsel regarding STIs
  - Discuss decreased efficacy with irregular use of the pill
  - Since she was forgetting so often, she stopped taking the pill completely about a month ago

WOMEN'S HEALTH COLLECTIVE

POINTS TO CONSIDER

- Comfort with pelvic exam
  - Can patient use a tampon?
- Common side effects with each LARC
- History of keloid formation?
- Contraindications:
  - Pregnancy
  - Known or suspected breast cancer
  - Abnormal uterine morphology (IUD)
  - Acute pelvic inflammatory disease (IUD)
  - Hypersensitivity

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HEAVY MENSTRUAL BLEEDING

- Ovulatory (cyclic) uterine bleeding
- Treatment indicated when it interferes with quality of life or causes anemia
  - “do you use pads or tampons?” “regular or super?” “how often do you need to change those on heavy days?” “do you avoid activities/work due to bleeding?”
- Estrogen-progestin contraceptives or the LNG 52mg IUD are 1st line therapy

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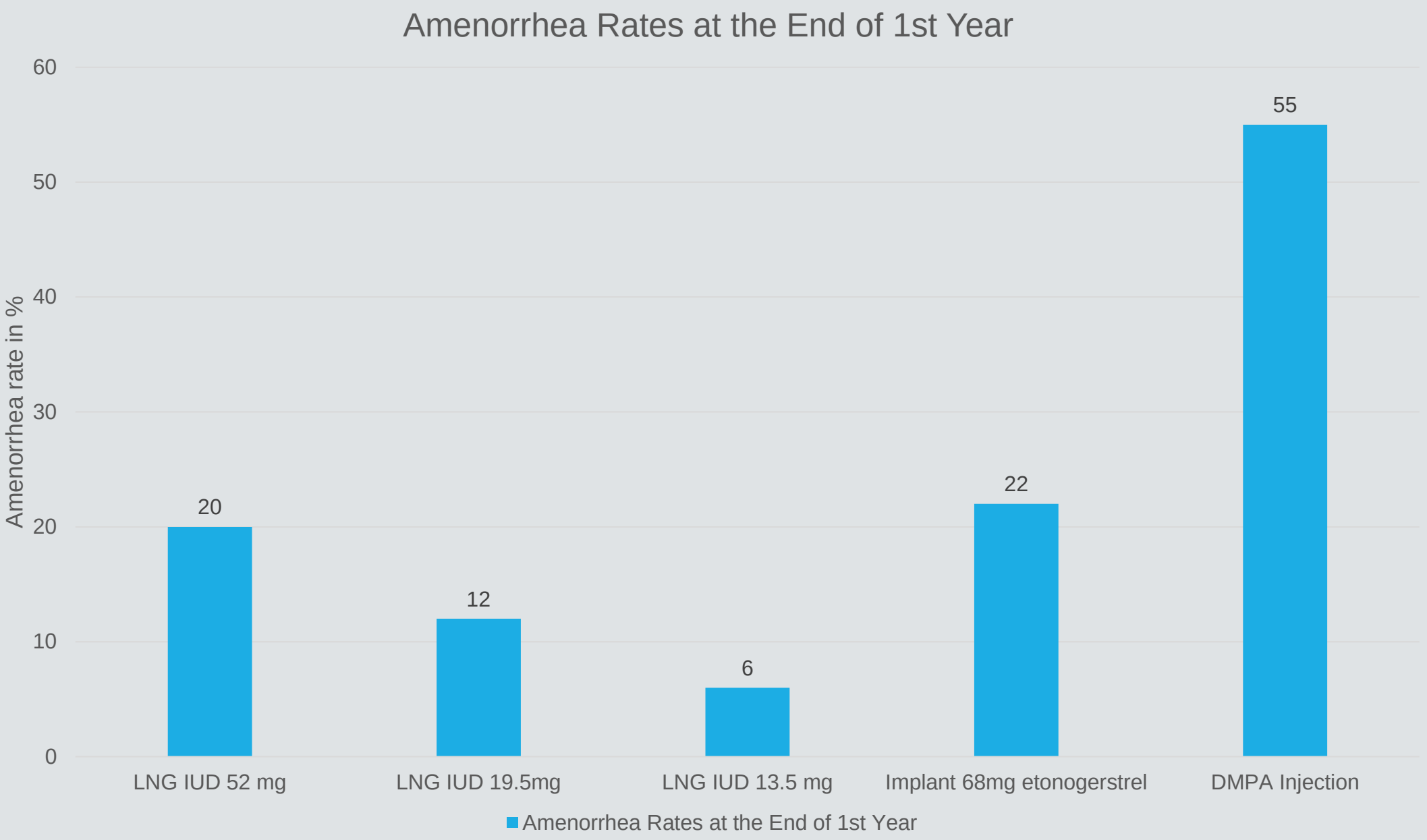

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- Maive’s LMP was about 2 weeks ago
- She has not had unprotected sex since her LMP
- She would like to proceed with the implant
- Does she need back up contraception after implant?

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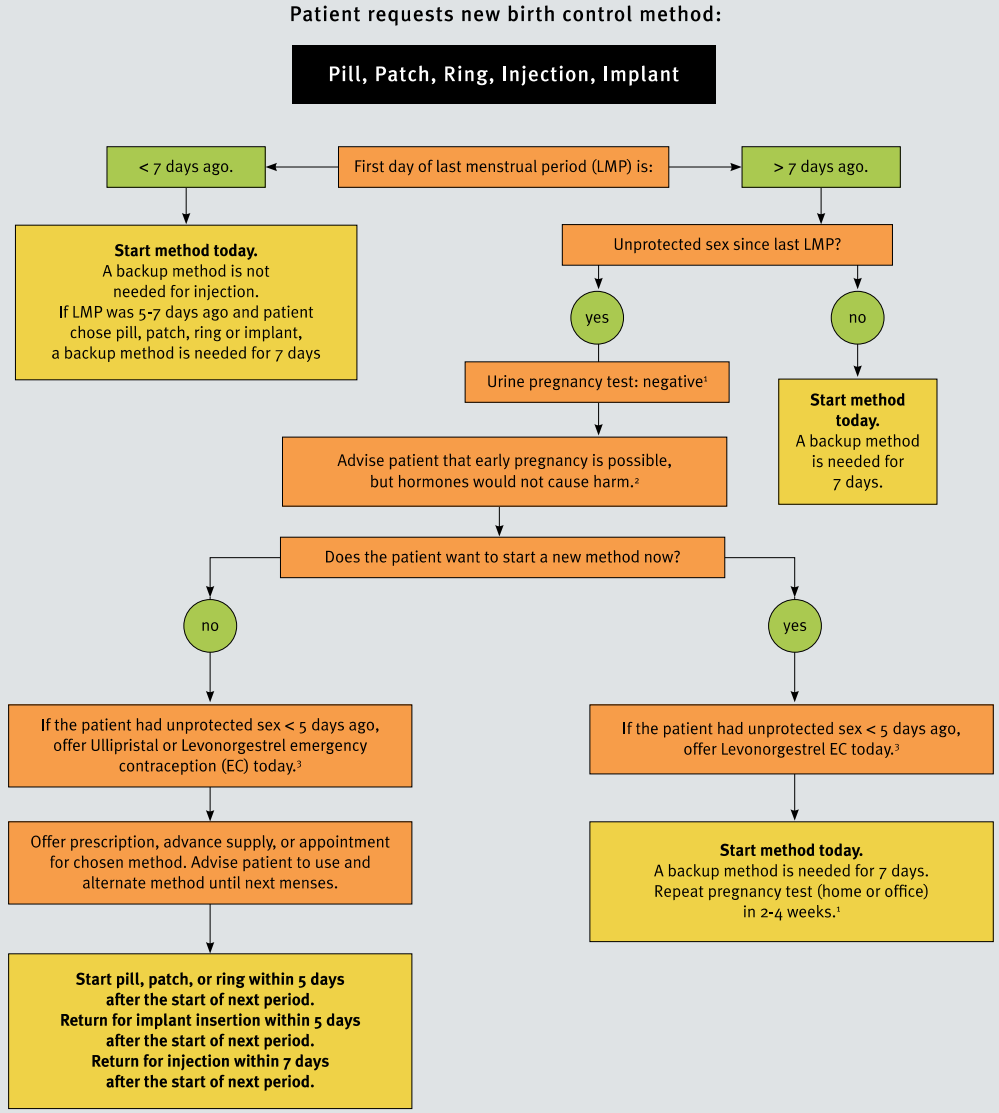
Quick Start Algorithm for Hormonal Contraception[2]



1 If pregnancy test is positive, provide options counseling.

2 CDC advises that benefits of starting contraceptive likely exceed risk of early pregnancy.

3 For patients with body mass index over 25, levonorgestrel EC works no better than placebo. Ulipristal EC has higher efficacy than levonorgestrel EC for those who had unprotected sex 3-5 days ago. Because hormones may decrease the efficacy of ulipristal, the new method should be started no sooner than 5 days after ulipristal. Consider starting injection/IUD/implant sooner if benefit outweighs risk.

REPRODUCTIVE HEALTH ACCESS PROJECT – QUICK START ALGORITHM

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COMPARING LARCS

LARC	Size	FDA Approved length of use	FDA Approved for HMB
Nexplanon (68 mg subdermal etonogestrel implant)	4 cm long, 2 mm diameter	3 years	
Paragard (Cu-IUD)	32 mm x 36 mm	10 years	
Mirena (LNG-IUD, 52 mg)	32 mm x 32 mm	5 years	✔
Liletta (LNG-IUD, 52 mg)	32 mm x 32 mm	6 years	
Kyleena (LNG-IUD, 19.5 mg)	28 mm x 30 mm	5 years	
Skyla (LNG-IUD, 13.5 mg)	28 mm x 30 mm	3 years	

FDA: https:/www.accessdata.fda.gov

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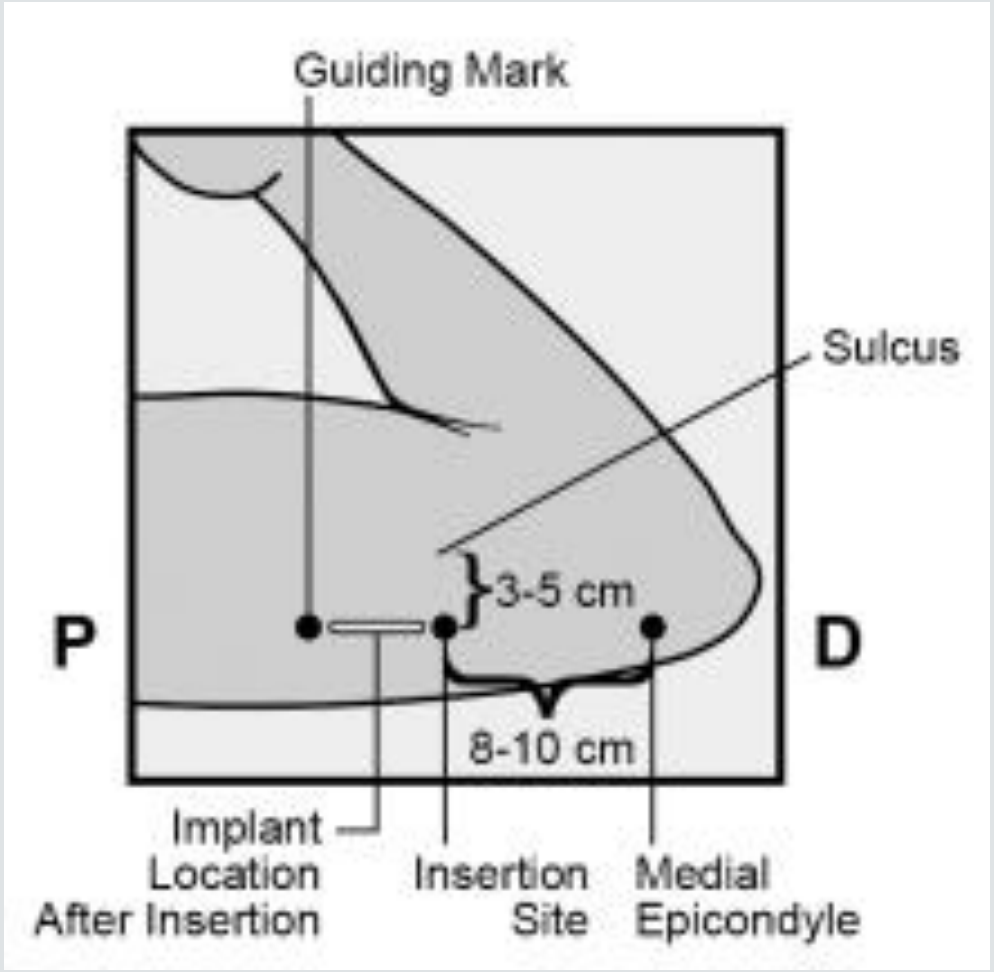
IMPLANTING NEXPLANON

1: Lying on back with non-dominant arm flexed at elbow and externally rotated so hand is under head

2: ID insertion site 8-10 cm proximal to medial epicondyle and 3-5 cm posterior to (below) sulcus between biceps and triceps (so overlying triceps)

3: Use surgical marker to mark insertion site at a spot 5cm proximal for guide



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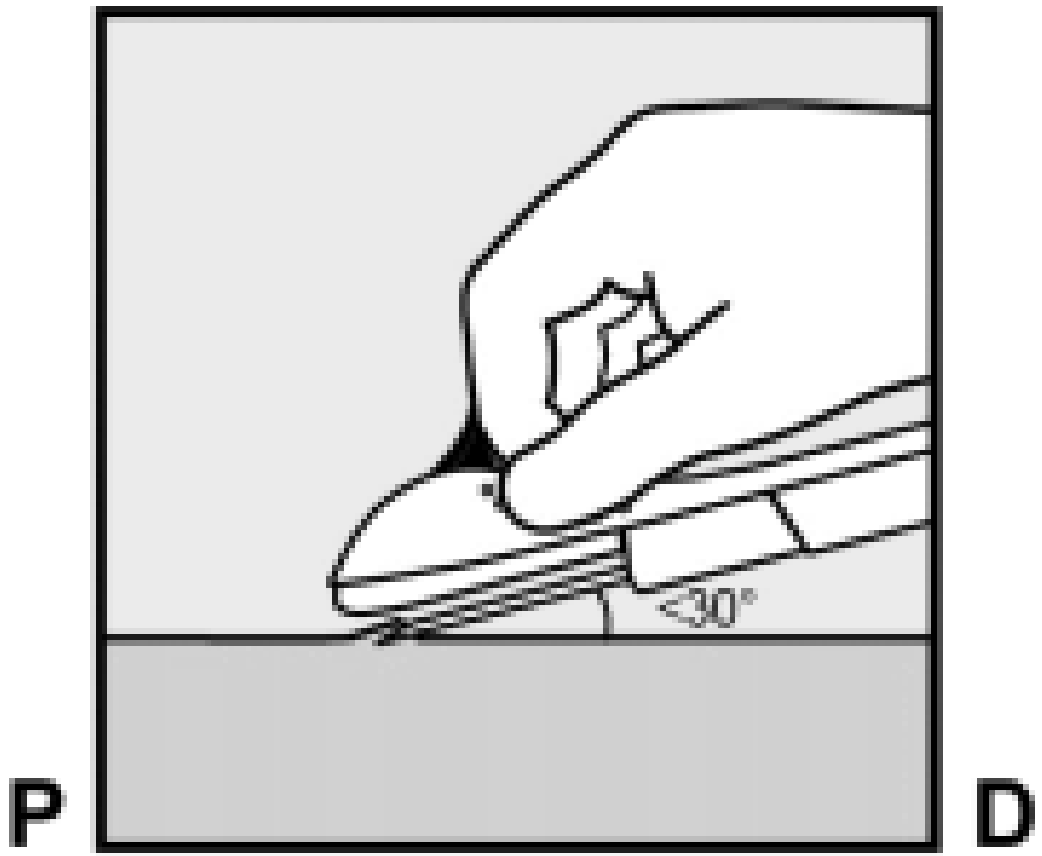
IMPLANTING NEXPLANON

4: Clean with antiseptic solution from insertion site to guide mark

5: Anesthetize insertion area

6: Remove protection cap and view white implant inside tip of needle

7: Puncture skin with tip of needle slightly angled < 30 degrees



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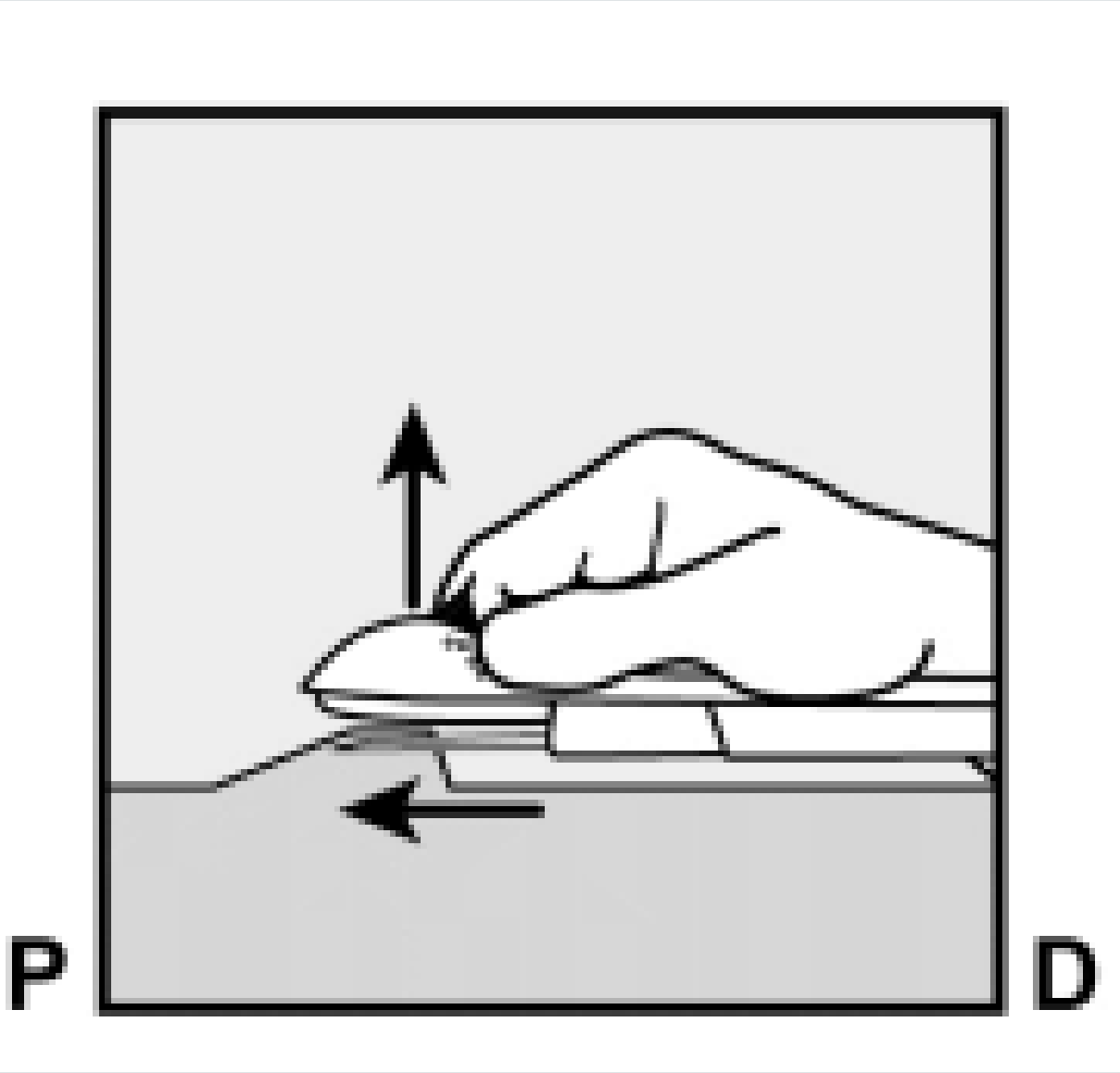
IMPLANTING NEXPLANON

8: Insert until bevel is just beneath skin, then lower applicator to horizontal position and lift

9: Unlock the purple slider by pushing it slightly down and pulling it fully back

10: Apply butterfly bandaid or steri-strip

11: apply pressure bandage to be left in place clean and dry for 24 hours



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MAIVE FOLLOW UP

- **1 year**
  - Very happy with her choice of the implant
  - Over the past 6 months she has been diagnosed with Bipolar II Disorder
  - She was started on Lamotrigine
- Can she continue this method of contraception?
- Are there any new recommendations based on the addition of this new medication?

WOMEN'S HEALTH COLLECTIVE

MEDICAL ELIGIBILITY CRITERIA FOR INITIATING CONTRACEPTION

Condition	Sub-Condition	Cu-IUD	LNG-IUD	Implant	DMPA	POP	CHC
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	1	1	2*	1*	3*	3*
	b) Lamotrigine	1	1	1	1	1	3*

Key:	
1 No restriction (method can be used)	3 Theoretical or proven risks usually outweigh the advantages
2 Advantages generally outweigh theoretical or proven risks	4 Unacceptable health risk (method not to be used)

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

WOMEN'S HEALTH COLLECTIVE

MEC APP

WOMEN'S HEALTH COLLECTIVE

ZURI, 42 YEARS OLD

Patient History	▪ **42 and recently single** ▪ **Previous husband had a vasectomy** ▪ **Cycles becoming variable – frequency ranging every 3-6 weeks** ▪ **She considers her flow to be normal** ▪ **HTN controlled (124/78)** ▪ **12 pack year history – quit smoking 10 years ago** ▪ **Migraines with aura** ▪ **G2P2** ▪ **BMI 31kg/m^2**
Current medications	▪ Lisinopril 10mg qd ▪ M=Ca 600mg with Vitamin Dr 1000 IUs
Contraceptive history	▪ Infertility – conceived twice with IUI ▪ Used OCPs x 5 yrs prior to trying to conceive

WOMEN'S HEALTH COLLECTIVE

ZURI

- **Shared decision making**
  - Decrease risk of unintended pregnancy
  - Not interested in a permanent option
  - Discuss hormonal impact on blood pressure
  - Variable cycle length
  - Discuss risks of hormone use with migraines
  - STI counseling/testing
  - Previous infertility – dispel myths

- Zuri is very interested in a LARC
  - Discuss differences, common side effects (copper vs LNG), and implant
  - Remind increased risk of IUD displacement with use of menstrual cup

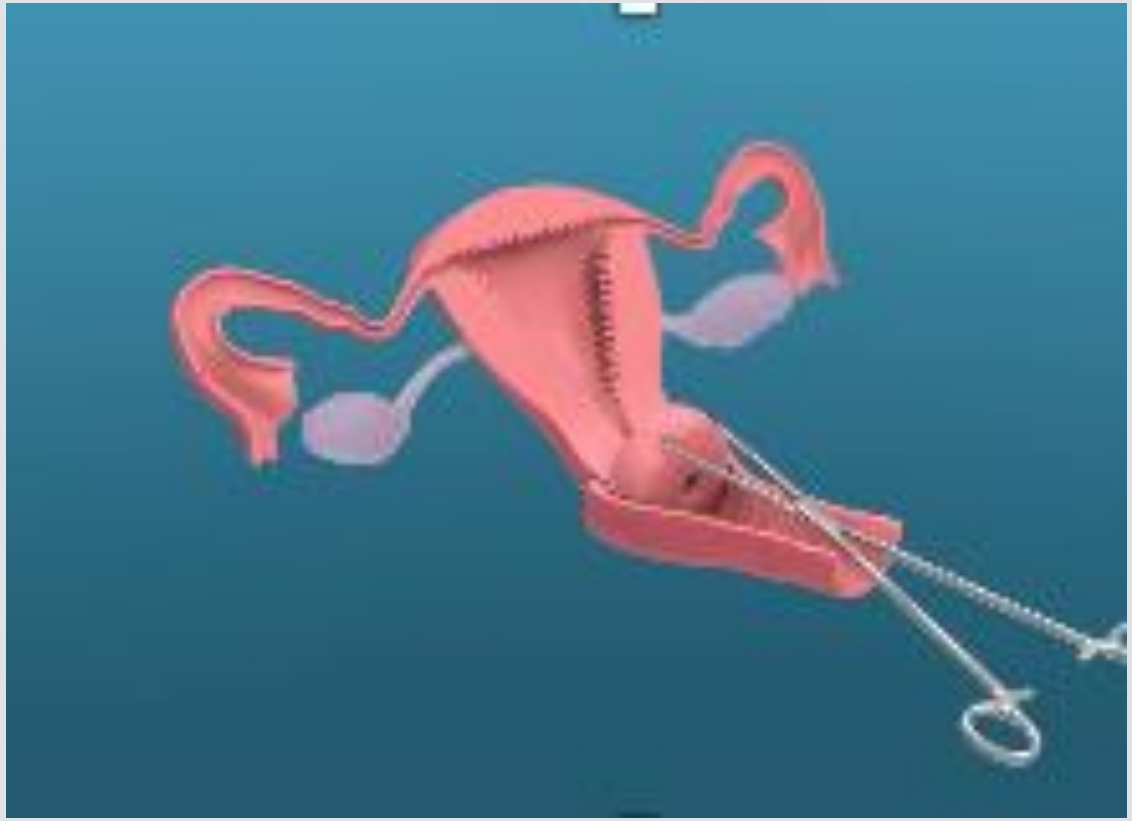
WOMEN'S+ HEALTH COLLECTIVE

MEDICAL ELIGIBILITY CRITERIA

Condition	Sub-Condition	Cu-IUD		LNG-IUD		Implant		DMPA		POP		CHC	
		I	C	I	C	I	C	I	C	I	C	I	C
Hypertension	a) Adequately controlled hypertension	1*		1*		1*		2*		1*		3*	
	b) Elevated blood pressure levels (*properly taken measurements*)												
	i) Systolic 140-159 or diastolic 90-99	1*		1*		1*		2*		1*		3*	
	ii) Systolic ≥160 or diastolic ≥100‡	1*		2*		2*		3*		2*		4*	
	c) Vascular disease	1*		2*		2*		3*		2*		4*	
Headaches	a) Nonmigraine (mild or severe)	1		1		1		1		1		1*	
	b) Migraine												
	i) Without aura (includes menstrual migraine)	1		1		1		1		1		2*	
	ii) With aura	1		1		1		1		1		4*	

WOMEN'S HEALTH COLLECTIVE

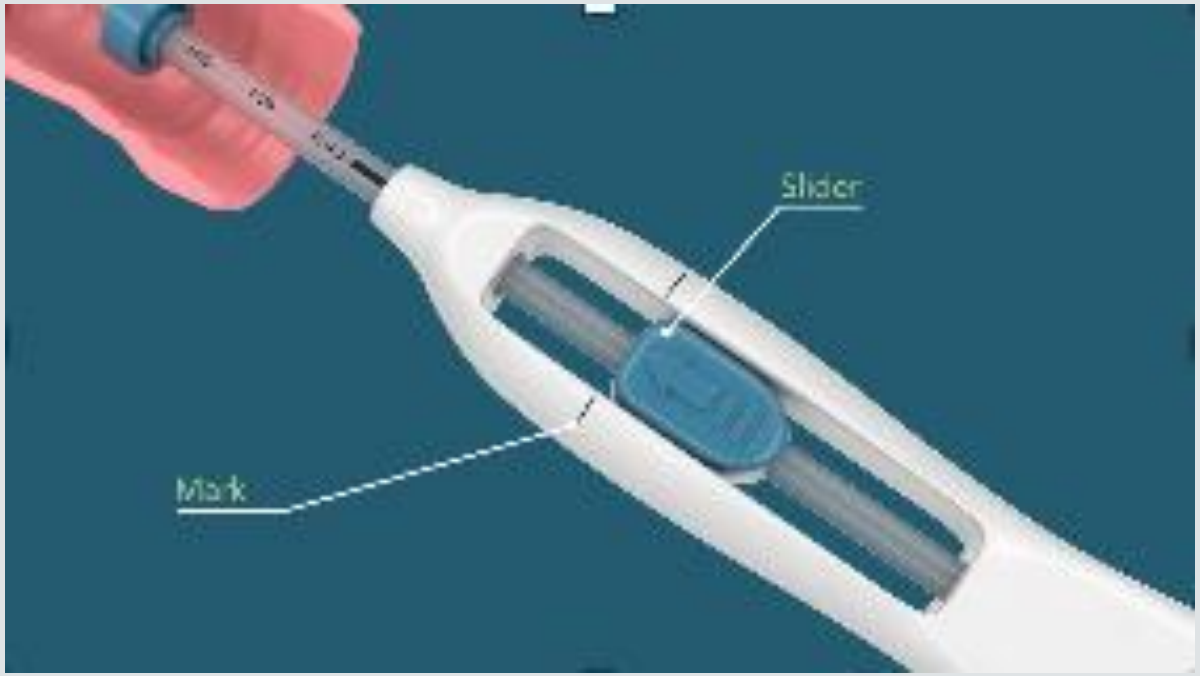
IUD INSERTION TECHNIQUE



- Insert appropriately sized speculum (gracious use of lube)
- Apply antiseptic to cervix
- Tenaculum gently placed at anterior or posterior lip of cervix
- Gentle traction to align uterine cavity
- Sound to note uterine depth with metal or plastic sound
- Maintain sterility of portion to enter uterine cavity (use packaging to move flange)

WOMEN'S+ HEALTH COLLECTIVE

IUD INSERTION TECHNIQUE



- Insert IUD to either:
  - 2cm prior to depth set on flange
  - To fundus, then withdraw 2cm
- Pull back slider to marks on the insertion device deploying arms into cavity
- Advance device to fundus as noted on flange
- Then pull slider entirely back to the bottom of the window
- Slowly remove insertion device
- Cut strings to 3-4 cm

WOMEN'S HEALTH COLLECTIVE

CHALLENGING IUD INSERTION TIPS

- Consider repositioning – farther down on table, larger speculum, moving light
- Use tenaculum – may also reposition based on angle of uterus
- Use dilators
- Consider misoprostol, NSAIDs, anxiolytics, nitrous oxide
- Consider referral and insertion under sedation/imaging
- Consider ultrasound, MRI, CT after difficult insertion if concerns for perforation

WOMEN'S+ HEALTH COLLECTIVE

ZURI RECOMMENDATIONS AND MONITORING

- Zuri proceeded with LNG 52mg IUD insertion
- Recommend follow up within 1-3 months
  - Assess response/satisfaction
  - Check strings
  - Assess B/P, migraines
  - Address sexuality/STI testing again
- Check strings at home after each bleed or prn
- Annual strings checks in the clinic

WOMEN'S+ HEALTH COLLECTIVE

ZURI FOLLOW UP

- Zuri returns 6 years after insertion (now 48 yrs old)
- No concerns with IUD – has been happy with her response – rare and light bleeding only
- New male partner – he has also had a vasectomy
- Migraines and B/P still well controlled
- Is she a candidate for another LNG IUD?

WOMEN'S+ HEALTH COLLECTIVE

KEY MESSAGES

- Hormonal contraception is instrumental in Women's Health Care and utilized for more than just contraception
- LARCs are safe and highly effective methods for most women, including adolescents, regardless of parity
- It is important to engage in shared decision making
- Thoroughly discuss expectations and provide anticipatory counseling about expected changes in bleeding
- Review needs for backup contraception and follow up/monitoring
- Assess all comorbid conditions and related medications
  - Utilize CDCs MEC

WOMEN'S HEALTH COLLECTIVE