A COMPREHENSIVE REVIEW OF CONTRACEPTIVE METHODS USING CASE STUDY TO FOCUS ON PHARMACY SETTINGS

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OBJECTIVES

- Review combined contraceptive methods and progestin injection prescribed by pharmacists
- Discuss the latest evidence on emergency contraception
- Review counseling around LARC methods

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DISCLOSURES

Jen Robinson, CNP, CNM, MS (*she, her*) has the following financial relationships to disclose:

- Merck Nexplanon trainer

Anna White MSN, CNM*(she, her)*

- No financial relationships to disclose.

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THE UNIVERSITY OF NEW MEXICO'S
LARC MENTORING PROGRAM

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REPRODUCTIVE JUSTICE

Why is this important?

The ability to make personal decisions about whether and when to have a child is a human right regardless of income, race or ethnicity.

Delicate balance between protecting unfettered access to contraceptive options and preventing abuse, and being encouraging versus coercing.

SisterSong LARC Statement Principles
https://docs.google.com/document/d/1ID4cEuaV1oSAXSWdJmSi4YMs5TLCGhnomjOX0InSodU/edit

5

Special thanks to

Alexandra Herman, PharmD
&
Amy Bachyrycz, PharmD

of UNM College of Pharmacy.

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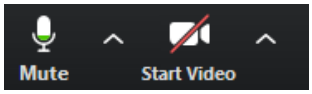
Basic Zoom Settings



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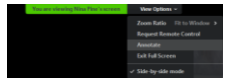
How to Annotate

- Navigate to the "View Options" pull down menu at the top of the screen.
- Select "Annotate" and a tool bar will open.
- We will be using the "Stamp" and "Text" options the most.



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Map from elizon.com

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CASE STUDY

Margaret is a 16 y/o nulliparous cis gender female at your pharmacy and is interested in contraception

She has no prior health concerns

BMI 32

Smoking 1 pack/day

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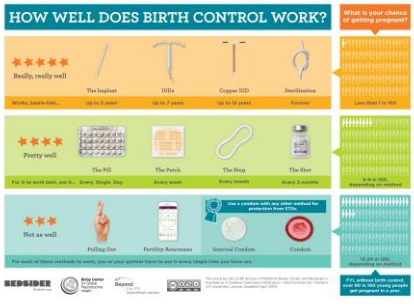
Beyond the Pill

Bixby Center for Global Reproductive Health

UCSF University of California San Francisco



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GUIDANCE FOR CONTRACEPTIVE CARE

United States Medical Eligibility Criteria for Contraceptive Use — US MEC — CDC — **2016**

United States Selected Practice Recommendations for Contraceptive Use — US SPR — CDC — **2016**

Quality Family Planning — QFP — CDC — **2015**

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CDC MEDICAL ELIGIBILITY CRITERIA

Search: "CDC Contraception"

CDC Medical Eligibility for Initiating Contraception	
Method can be used without restriction	1
Advantages generally outweigh risks	2
Method not recommended unless more appropriate methods not acceptable	3
Absolute contraindication, avoid use	4

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Injection (DMPA)

- Depot Medroxyprogesterone Acetate
- Intra-muscular or subcutaneous injection every 3 months
- 70% experience amenorrhea by 12 months
- Less PID, fibroids, endometrial cancer

Trussell J. Contraceptive Technology. 2011.
Cromer BA. Am J Obstet Gynecol. 2005.
Trussell J. Contraception. 2004.
Westhoff C. Contraception. 2003. et al.

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Vaginal Ring

- Contains estrogen and progestin
- Flexible ring that is placed in the vagina
  - Used 3 weeks/out 1 week
  - 4 weeks of medication in each ring
- Continuous use: Can be changed once every 4 weeks

NuvaRing Prescribing Information. Organon. 2001
Timmer CJ. Clin Pharmacokinet. 2000
Herndon EJ. Am Fam Physician. 2004
Diebert T O. Obstet Gynecol. 2002
Linn ES. Int J Fertil. 2003

15

The Patch

- Contains estrogen and progestin
- Applied once a week
- Use 3 weeks, off 1 week

Abrams LS. Fertil Steril. 2002.
Ortho Evra Prescribing Information.
Archer DF. Fertil Steril. 2002.
Zacur HA. et al. Fertil Steril. 2002.
Zieman M. Fertil Steril. 2002.
Archer DF. Contraception. 2004.
Audet MC. JAMA. 2001.

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After describing the patch, ring, depo and pill. Pt. Decides she wants the pill.

She states that her friend only has her period once every three months and says "can I get something like that?"

Which pill do you prescribe her?

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CDC Medical Eligibility for Initiating Contraception							
Condition		Copper IUD	LNG-IUS	Implant	DMPA	POP	Pill, patch, ring
High blood pressure	<159 / <99	1	1	1	2	1	3
	>160 / >100 or w/ vascular disease	1	2	2	3	2	3/4
Migraine with aura		1	1	1	1	1	4
Smoking	Age <35	1	1	1	1	1	2
	Age > 35, <15 cigarettes/day	1	1	1	1	1	3
	Age > 35, > 15 cigarettes/day	1	1	1	1	1	4
Blood clots	Past or current blood clot	1/2	2	2	2	2	4
Diabetes Mellitus (DM)	History of GDM	1	1	1	1	1	1
	Nonvascular NIDDM or IDDM	1	2	2	2	2	2
	DM with Vascular disease or > 20yrs	1	2	2	3	2	3/4

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MONOPHASIC VS MULTIPHASIC

MONOPHASIC are typically preferable due to:
- Ease of use
- Consistent hormone dose

Multiphasic COCs
- require more careful adherence to a specific sequential order in which to take the pills each cycle
- cannot be transitioned to continuous or extended-cycle use the way that monophasic pills can if the patient desires
- concerns that the changing hormone levels in multiphasic COCs could exacerbate mood symptoms in susceptible women (eg, those with premenstrual syndrome or premenstrual dysphoric disorder)

Madden T, Secura GM, Nease RF, et al. The role of contraceptive attributes in women's contraceptive decision making. Am J Obstet Gynecol 2015; 213:46.e1.

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CYCLIC VS EXTENDED USE

Frequency of withdrawal bleeding desired by patient is key
- monthly withdrawal bleeding
- every three months (84/7 formulations)
- no withdrawal bleeds (365 day formulations).

SEASONALE®
(0.15 mg levonorgestrel/
30 mcg ethinyl estradiol)
84 active pink pills
followed by 7 placebo pills
Teva Women's Health

SEASONIQUE®
(0.15 mg levonorgestrel/
30 mcg ethinyl estradiol)
84 active pink pills followed by
7 pills with 10 mcg ethinyl estradiol
Teva Women's Health

Edelman AB, Gallo MF, Jensen JT, et al. Continuous or extended cycle vs. cyclic use of combined oral contraceptives for contraception. Cochrane Database Syst Rev 2005; :CD004695.

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ETHINYL ESTRADIOL DOSE

Women should be prescribed a COC with 35 mcg of ethinyl estradiol or less.
- The data regarding safety of 20 mcg versus 25, 30, or 35 mcg ethinyl estradiol COCs suggest less risk with 20 mcg formulas but are not strong enough to endorse higher safety with 20 mcg pills
- COCs containing 50 mcg of ethinyl estradiol should not be used for contraception but are available for the acute treatment of uterine bleeding.

Madden T, Secura GM, Nease RF, et al. The role of contraceptive attributes in women's contraceptive decision making. Am J Obstet Gynecol 2015; 213:46.e1.

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PROGESTIN TYPE

All COCs are antiandrogenic when the effects of both estrogen and progestin are considered.
- Acne
- Heavy menses
- Dysmenorrhea
- PMS/PMDD
  - There may be a slightly increased risk with newer progestins (gestodene, desogestrel, and drospirenone) compared with levonorgestrel; however, tt absolute risk is extremely low for all COCs. The evidence is not compelling enough to change prescribing patterns.

MICRONOR® TABLETS
28-DAY REGIMEN
(0.35 mg norethindrone)
(active pills: lime green)
Ortho-McNeil

NOR-QD® TABLETS
(0.35 mg norethindrone)
(active pills: yellow)
Watson

CAMILA®
(norethindrone tablet, USP 0.35 mg)
(active pills: light pink)
Teva Pharmaceuticals USA

ERRIN®
(norethindrone tablet, USP 0.35 mg)
(active pills: yellow)
Teva Pharmaceuticals USA

de Bastos M, Stegeman BH, Rosendaal FR, et al. Combined oral contraceptives: venous thrombosis. Cochrane Database Syst Rev 2014; :CD010813.

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GENERIC VS BRAND NAME

Affordability
- Brand names are typically more expensive and have higher co-pay

Madden T, Secura GM, Nease RF, et al. The role of contraceptive attributes in women's contraceptive decision making. Am J Obstet Gynecol 2015; 213:46.e1.

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Contraindications: Combined Hormonal Contraceptives

- Clotting disorders
- History of deep vein thrombosis or pulmonary embolism
- Migraine with aura or focal neurological deficit
- Uncontrolled hypertension
- Ischemic heart disease
- Active liver disease

USMEC 2016

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21/7 VS 24/4

24/4
- emerging evidence about increased efficacy (especially for obese women)
- decreased hormone withdrawal side effects during the hormone-free interval

London A, Jensen JT. Rationale for eliminating the hormone-free interval in modern oral contraceptives. Int J Gynaecol Obstet 2016; 134:8.

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ACHES – WARNING SIGNS/SIDE EFFECTS

Abdominal pain	Blood clot in pelvis or liver
Chest pain	Pulmonary embolism/heart attack/angina
Headaches	Stroke/retinal vein thrombosis
Eye problems	Thrombophlebitis/deep vein thrombosis
Severe leg pain	

http://www.contraceptivetechnology.org/wp-content/uploads/2015/06/ACHES-Figure.pdf

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WHEN AND WHY TO SWITCH TO A DIFFERENT OCP

If the patient has been referred for additional evaluation with a health provider, it may be reasonable to change medication until appointment takes place.
- Consider increasing dose of ethinyl estradiol to 35 mcg pills
- Consider use of 24/4 formulation, if not already in use
- Consider progesterone only options (such as Norethindrone acetate 5 mg and Provera 10 mg) as short term courses to manage bleeding complications
  - Important to assess need for contraception and possible need for barrier methods

UpToDate

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WHEN TO REFER TO A CLINICIAN/CLINIC

Heavy or prolonged vaginal bleeding
- Pregnancy
- STIs
- Anemia
- Cancer

Patient experiencing undesired side effects

Difficulty with adherence to medication

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HTTPS://WWW.REPRODUCTIVEACCESS.ORG/RESOURCE/PILL-USER-GUIDE/

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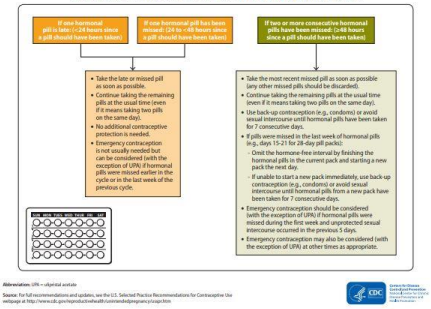

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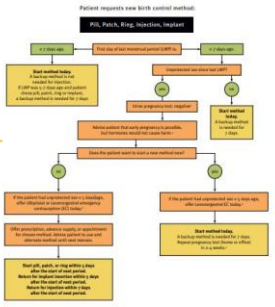
QUICK START



CDC SPR 2016
https://www.reproductiveaccess.org/resource/quick-start-algorithm/

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After describing all of the different aspects of the pill, you suddenly realized that you didnt ask her LMP or last episode of unprotected intercourse

Pt. States that she had unprotected intercourse 3 days ago

Again, her BMI is 32

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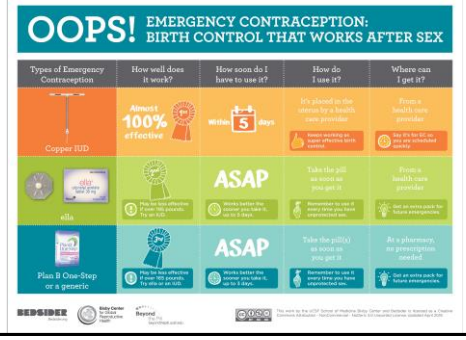

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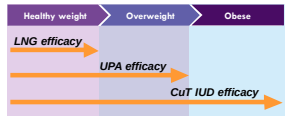
ECP loses efficacy with increased BMI



Copper T IUD remains nearly 100% effective for these patients

Glasier A et al. *Contraception*. 2011.

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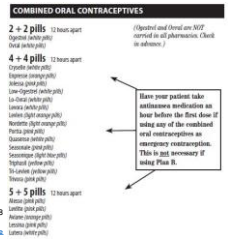
USING OCPs AS EMERGENCY CONTRACEPTION



Hatcher et al, 2018
https://ec.princeton.edu/questions/dose.html#dose

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COST OF EC VS COC

EC lower cost with online coupon
- LNG 1.5 mg as low as $10
- UA 30 mg as low as $43
- OTC vs. with prescription

COC lower cost with online coupon
- 28 pill pack as low as $8.45
- Extended OC pack (91 tab) lowest $47

ACA - Mandated coverage with no cost-sharing

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Which form of EC do you prescribe patient?

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LOW KNOWLEDGE OF IUDS AND THE IMPLANT

Less than half of young women have heard of LARC

Two-thirds do not know safety or effectiveness

Health care providers are primary source of information on LARC

Many providers have not integrated these methods into counseling, especially in primary care settings

Kaye K et al. The Fog Zone. 2009
Fleming KL et al. *Contraception* 2010
Barrett M et al. *J Pediatr Adolesc Gynecol* 2012
Harper C et al. *Family Medicine* 2012

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COPPER IUD IS THE MOST EFFECTIVE EMERGENCY CONTRACEPTIVE (EC)

Nearly 100% effective as emergency contraception

More effective than EC pills for longer

Effective for patients >165 lbs.

Provides ongoing contraception when desired -- *No back-up needed!*

Cleland K et al. *Human Reproduction*. 2012
Glasier A et al. *Contraception*. 2011
Envall N, *Acta Ob/Gyn Scan*. 2016

40

COPPER T 380A IUD, PARAGARD®

Works for at least 12 years

Nearly 100% effective

Only highly effective non-hormonal method

FDA label for ParaGard. Revised 9/1/2005.

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EMERGENCY CONTRACEPTION (EC) TYPES

IUD

- Cu IUD
- LNG 52 mg IUD +/- LNG ECP

EC Pills

- Progestin (LNG) "Plan B"
- Ulipristal Acetate (UPA) "Ella"

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IUD MECHANISM OF ACTION

Primary: prevention of fertilization
- Decreasing sperm motility and capacitation
- Decreasing sperm and egg survival

Secondary (LNG IUDs)
- Thickening of cervical mucous

IUDs are not an abortifacient (won't disrupt implanted pregnancy)
- Tubal flush studies find no fertilized eggs
- No transient elevations in hCG
- IUD users have low rates of intrauterine and ectopic pregnancies

UpToDate. 2015
Stanford & Mikolajczyk. *Am J Obstet Gynecol*. 2002
Ortiz & Croxatto. *Contraception*. 2007

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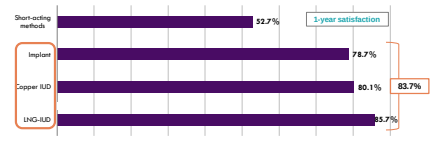
METHOD SATISFACTION



% of respondents indicating that they were either "*very satisfied*" or "*somewhat satisfied*" with their method.

Peipert J et al. Obstet Gynecol. 2011

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IUD SELECTION AND INDIVIDUAL PREFERENCES

Cu-T Paragard®	LNG 52 mg Mirena® / Liletta®	LNG 13.5-19.5 mg Skyla® / Kyleena®
• Want regular menses • Don't want hormones • Want EC	• Want light menstrual flow • Amenorrhea 30% • Want non-contraceptive benefits (for painful or heavy menses; uterine protection) • Want EC (w/ LNG ECP)	• Want less menstrual flow • Amenorrhea 10% • Want low-dose LNG IUD • Need smaller IUD

Madden T et al. *UpToDate*. 2018

45

CAN ADOLESCENTS AND PATIENTS WHO HAVE NO CHILDREN USE AN IUD?

Yes

High satisfaction and continuation rates

Veldhuis H. *Eur J Gen Pract*. 2004.
Suhonen S et al. *Contraception*. 2004.
Thonneau P et al. *Human Reprod*. 2006.
ACOG Committee Opinion 539. *Obstet Gynecol*. 2012.

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CONFIDENTIAL SERVICES IN NM FOR MINORS

- Are her services confidential?
- Can she consent for her reproductive health services?
- Where can patients obtain confidential services?

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

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SUMMARY

1. Keep individual patient priorities at the forefront during contraceptive counseling.
2. Focus on building rapport and the *process* of counseling rather than on a specific outcome or specific method.
3. Emergency contraception pills lose efficacy with increasing BMI

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One thing you learned

One thing you felt

One thing you will do after today

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THANK YOU!

LARC Mentoring Program

Questions? Please contact us:

Andrea Andersen, Program Manager

aanderse@salud.unm.edu

SCHOOL OF MEDICINE
DEPARTMENT OF PEDIATRICS

NEW MEXICO DEPARTMENT OF HEALTH

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