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Intended Consequences: Why Shared Decision Making Is Crucial to Optimizing Contraceptive Success

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Identified or perceived conflict of interest has been resolved in accordance with ACCME guidelines.

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Objectives

- Identify strategies for best practices in contraceptive counseling
- Describe the benefits of utilizing patient-centered care/shared decision making in the contraceptive counseling process
- Translate the scientific data on long-acting contraception methods into real-world patient care

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Faculty Disclosures

Dr. Shulman has the following disclosures:

- **Consulting Fees:** AMAG, Cooper Surgical, Bayer
- **Commercial Interest Speakers Bureau:** Allergan, Bayer, AMAG, Lupin
- **Contracted Research:** Bayer

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Good News for US Unintended Pregnancy Rates

- Rates of unintended pregnancy in US dropped for first time in a decade to 45%[1]
- Use of implants and IUDs increased from 8.5% in 2009 to 11.6% in 2011[2]
- Pregnancy rates declined 25% in women 15-19 years[2]
- Unintended pregnancy rates for minorities were reduced[1]
  - ↓ 51% Hispanic teens
  - ↓ 44% Black teens

1. Finer LB, et al. N Engl J Med. 2016;374(9):843-52.
2. Kavanaugh ML, et al. Obstet Gynecol. 2015;126(5):917-27.

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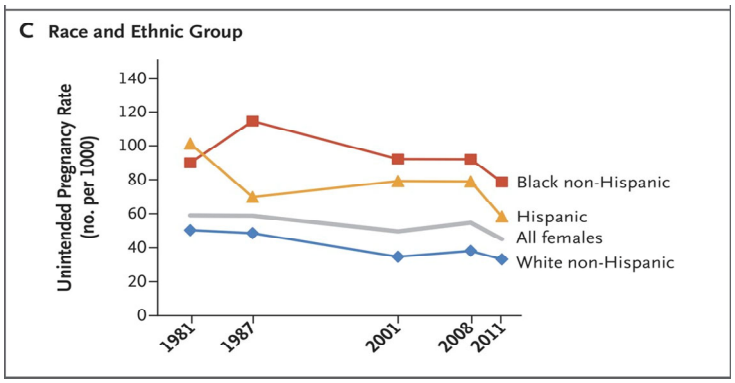
Unintended Pregnancy by Subgroups in US: Race and Ethnicity



Finer LB, et al. N Engl J Med. 2016;374(9):843-52.

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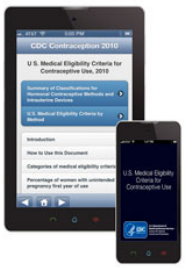
Why Improvements Now? What Changed?



- U.S. MEC 2016[1]
- U.S. Selected Practice Recommendations for Contraceptive Use, 2016[2]
- ACA: most women should have coverage without cost sharing
- Studies of LARC use in U.S.
  - Contraceptive CHOICE Study in St. Louis, MO; Teen studies in Colorado
- Medicaid coverage for postpartum placement of IUD and implants in dozen of states

1. United States Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2016. http://www.cdc.gov/reproductivehealth/contraceptive/usmec.htm.
2. Centers for Disease Control and Prevention. U.S. Selected Practice Recommendations for contraceptive Use, 2016. http://www.cdc.gov/mmwr/volumes/65/rr/rr6504a1.htm

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How Well Do Methods Work?
Newest Estimates of Failure Rates by Method

Method	Typical Use (%)	Perfect Use (%)
Condom		
Female (fc)	20	4
Male	13	2
Diaphragm	17	16
COC, POP, patch, ring	7	0.3
Depo-provera	4	0.2
Intrauterine contraceptives		
ParaGard (copper T)	0.8	0.6
Mirena (LNG)	0.7	0.5
Implanon	0.05	0.05
Female sterilization	0.5	0.5
Male sterilization	0.15	0.1

Trussell J, et al. Contraceptive Technology, 21st edition. New York, NY. Ardent Media 2018.

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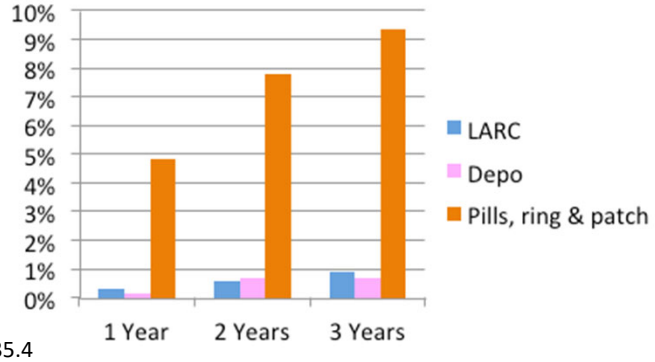
Unintended Pregnancy by Contraceptive Method: Twenty-Fold Difference in Effectiveness



HR_{adj} = 22.3, 95% CI 14.0, 35.4

Winner B, et al. New Engl J Med 2012.

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Streamlining Contraceptive Initiation: Same Day Placement if Not Pregnant

Method	Exams/Tests Needed	Back-Up Needed
Copper IUD	Bimanual exam & cervical inspection	None
LNG-IUSs	Bimanual exam & cervical inspection	7 days**
Implant	None	7 days*
Injection	None	7 days**
Combined hormonal contraceptives	BP	7 days*
Progestin-only pills	None	2 days*

* If >5 days since LMP ** If >7 days since LMP

MMWR Recomm Rep. 2013;62(RR-05):1-60.

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IUD Placement and STI Testing

- No routine STI screening needed for low-risk women
- If clinical evidence of infection, delay placement until infection is treated
- If no evidence of current infection but history suggests she is at risk, test and place same day
  - Recall for treatment <7 days if positive
- No additional requirements for cervical cytology testing
  - May be done on day of placement

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Low Risk of PID with IUD

- Kaiser study of 57,728 women:[1]
  - Overall risk of PID within 90 days was 0.0054
  - In women <26 yo
    - Same-day screening had equivalent PID risk to prior screening within 8 weeks or 1 year
  - In women ≥26 yo
    - Same day screening = prior screening
    - NO screening was just as good as ANY screening
- If PID is diagnosed in woman with IUD – try treatment with IUD in place[2]

1. Sufrin C et al. Obstet Gynecol 2012;120:1314-21.
2. https://www.cdc.gov/std/tg2015/default.htm

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Why Immediate Postpartum Initiation?

- Women often fail to return for postpartum care[1]
  - 42% of women wanting IUD and scheduled for delayed placement never returned
- 25% of non-lactating women ovulated between 25-39 days postpartum[2]
  - Before they would be seen in typical six-week postpartum visit
- Pregnancy rates higher when initiation delayed[3]

12 Month Outcomes		
	Immediate	Delayed
Pregnancy	15%	27.3%
Repeat abortion	9.9%	17.7%

1. Gillett PG, et al. Fertil Steril. 1980;34(2):121-4.
2. Jackson E, Glasier A. Obstet Gynecol. 2011;(117):657-62.
3. Langston AM, et al. Contraception. 2014;89(2):103-8.

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What Are the Upsides to Starting IUDs or Implants During Hospitalization for Delivery?

- Implants and IUDs
  - No interference with breastfeeding
  - Provider and patient both present without anyone making a special trip
- IUDs only
  - Negligible time investment for insertion
  - Cervix is open
  - Fewer "accessories" than for interval insertion
  - Many side effects in the early post-insertion period masked by postpartum status

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Are There Any Downsides to Starting IUDs or Implants During Hospitalization for Delivery?

- IUDs
  - Higher expulsion rates (10-25%) than interval insertion

BUT

- IUDs and implant
  - Reimbursement issues for device in context of global fee for delivery
  - Many states (including DC) have published guidance regarding Medicaid reimbursement for immediate postpartum LARC
  - ACOG sponsoring programs to local hospitals to implement all aspects of postpartum IUD placement

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Contraception for Adolescents

- AAP Committee on Adolescence 2014[1]
  - . . . "Given the efficacy, safety, and ease of use, LARC methods should be considered first-line contraceptive choices for adolescents. . ."
- ACOG[2]
  - "Encourage implants and IUDs for all appropriate candidates, including nulliparous women and adolescents"
  - "Adopt same day insertion protocol"

1. Committee on Adolescents. Pediatrics. 2014;134(4):1244-56.
2. ACOG Committee Opinion. Obstet Gynecol. 2009;114(6):1434-8.

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US Contraceptive CHOICE Study

- Longitudinal, observational study in St. Louis
  - 9,256 women given free contraception with counseling
  - Choices: IUD, implant, DMPA, pill, patch, ring
- 75% of women chose IUDs or implants

	1st Year	
	Continuation Rate	Pregnancy Rate
IUD, Implant	86%	0.27%
DMPA, Pill, patch, ring	55%	4.55%

- Pill, patch, and ring have a 20 times higher pregnancy risk

Peipert LB et al. Obstet Gynecol. 2012;120(6):1291-7.
Rosenstock JR et al. Obstet Gynecol. 2012;120(6):1298-305.
Winner B et al. New Engl J Med. 2012;366(21):1998-2007.

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Shared Decision Making

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Counseling Lessons from Teens and Young Women

Insight	Recommendation
Most women are unaware of the wide range of birth control options out there.	Offer IUDs and the Implant first—inform young women of these most effective methods without overwhelming them with the wide array of options all at once.
Effectiveness is expected.	Emphasize *not only* effectiveness, but *more importantly,* other attributes and benefits of IUDs and the Implant.
Side effects can be more important to young women than effectiveness.	Explain how IUDs and the Implant are made to work with young women's bodies–by highlighting both low and no hormone IUD options and the hormonal associated benefits of the Implant.

http://thenationalcampaign.org/sites/default/files/resource-primary-download/whoops_proof_insights.pdf.

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Counseling Lessons from Teens and Young Women (con't)

Insight	Recommendation
The concept of "long-acting" as a desirable attribute of IUDs and the Implant does not resonate with young women.	Describe IUDs and the Implant as *"low maintenance"* methods made to fit this "now" generation of young women vs. using the term "LARCs."
Women confuse IUDs and the Implant, but there are differences and strong personal preferences attached to each.	Highlight the distinct attributes, placement, and benefits of IUDs and the Implant individually to guide women at pivotal points in their decision-making process.
Communicating *how it will feel* for both women and their partners is vital.	Engage women in an honest conversation about *how it will feel* during the entire experience—for both themselves and their partners.

http://thenationalcampaign.org/sites/default/files/resource-primary-download/whoops_proof_insights.pdf.

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Counseling Lessons from Teens and Young Women (con't)

Insight	Recommendation
Women want to hear from other women.	Share experiences that other women have had with these methods—the good and the bad—using everyday language to provide them with the confidence and comfort they're seeking.
Birth control is a journey full of troubleshooting.	Frame the birth control conversation on what matters most to each individual woman's needs, concerns, and preferences—from side effects to adherence issues.
It's not birth control versus pregnancy.	Speak to women's future aspirations about having children by explaining how IUDs and the Implant are safe for young women and their future fertility.

http://thenationalcampaign.org/sites/default/files/resource-primary-download/whoops_proof_insights.pdf.

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Continuing Barriers to Use of Implants and IUDs

- Lack of training/experience in placement/removal
- Insurance/ACA challenges
  - Plans excluding some FDA-approved methods
  - Some plans only covering generics without cost sharing
  - Charging for services associated with birth control
  - Not all IUDs covered
- Upfront cost to women/stocking price to practice
- Patient misinformation/hesitancy in delivery method
  - Trust medical system?
- Clinician misinformation about safety, acceptability, and mechanisms of action

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Bottom Line Messages 2019

- IUDs and implants provide top-tier contraception
  - Pills, patches, rings, and injective have a 20 times higher pregnancy risk
- Offer a method to all candidates who are not actively seeking pregnancy within 12 months
- Use US MEC Eligibility Criteria as basis for offering methods
- Eliminate all barriers to access
  - Start method same day as visit
- Counsel effectively

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What Has Changed in the Last Several Years?

- Success and enthusiasm
  - Enthusiasm interpreted as possible coercion
- Counseling not to be in order of efficacy, but based on a more comprehensive patient-centered process with patient as informed consumer
- Incorporates pregnancy intention in place of reproductive life planning

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Clinical Attitude – ARS Polling Question #1

In your practice, who does the majority of implanting contraceptive LARC methods?

1. MD
2. PA
3. NP
4. Divided equally between MD and NP and/or PA
5. Other
6. We do not prescribe contraceptive LARC methods.

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ARS Polling Question #2

According to the US MEC, which of the following medical conditions represent category 4 conditions (contraindications) to the use of the contraceptive implant?

1. Seizure disorder
2. Anticardiolipin antibodies
3. Smoking over age 35
4. Breast cancer in the last 5 years
5. All of the above

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Important Updates in Recent Years: Implant

- Extended life to 4 years off-label
- Placement change: Put over triceps
  - AVOID BICEPTS SUICUS
- Postpartum placement prior to discharge home
- New insights into bleeding patterns and possible treatments
- Ongoing implementation of safety net (Centers of Experience) for different removals
- Effective in women with BMI >30 kg/m^2

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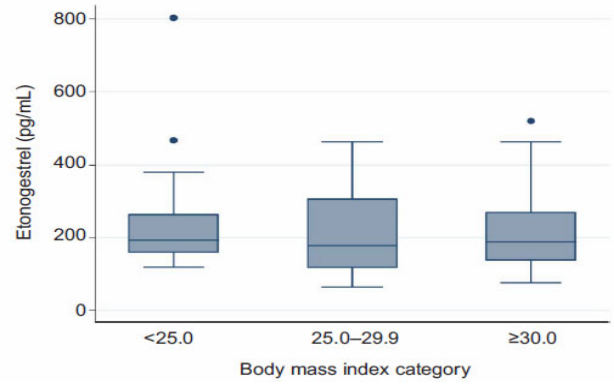
Etonogestrel Level at End of Third-Year Implant Use: *Minimal Decline of ENG Levels That Do Not Vary by BMI*



McNicholas C, et al. Obstet Gynecol. 2015;125(3):599-604.

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Bleeding Patterns on ENG Implant

- Only 13% of women in U.S. trials discontinued implant use due to bleeding complaints over 3-year period
- Women with favorable bleeding in first 3 cycles generally do not later discontinue due to bleeding irregularities although bleeding may increase over time
- 50% of women with unfavorable patterns in first 3 cycles will improve with time
- Counseling critical to long-term continuation
- Dysmenorrhea decreased
  - 77% complete resolution

Masour D, et al. Eur J Contracept Reprod Health Care. 2008;(1):13-28.

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Treatments for Unscheduled Bleeding with Progestin-Only Method

- First line
- NSAIDs
  - Ibuprofen 800mg PO TID for up to 5 days PRN bleeding
  - Naproxyn 500mg PO BID for up to 5 days PRN bleeding
- Alternative: Lysteda (or generic) 650mg TT PO TID for up to 5 days PRN bleeding
- If those fail, try one of following:
  - COC cyclically or continuously for 3 + months
  - Vaginal contraceptive ring for 35+ days continuously for 3 months
  - MPA 10mg or NETA 5mg BID X 21 days

Masour D, et al. Contraception. 2010;(3):202-10.

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Extended Use of Implant Beyond FDA-Approved Duration

- Initial Report (2015)[1]
  - 237 women
    - Extended use range 5.1 - 40.5 month extra
    - 123 women ≥1 extra year
  - 0 pregnancies during extension period
- New Report (2017)[2]
  - 291 women contributing 444.0 women-years of follow-up
    - 0 pregnancies/failures
    - Failure rate in Year 4 = 0 (1-sided 97.5% confidence interval: 0 - 1.48) per 100 women-years
    - Failure rate in Year 5 = 0 (1-sided 97.5% confidence interval: 0 - 2.65) per 100 women-years
- ACOG endorsed routine use for 4 years in November 2017[3]

1. McNicholas C, et al. Obstet Gynecol. 2015;125(3):599-604.
2. McNicholas et al. Am J Obstet Gynecol. 2017.216(6):586.e1-586.e6.
3. ACOG Practice Bulletin 186. Obstet Gynecol. 2017.130(5):e251-e269.

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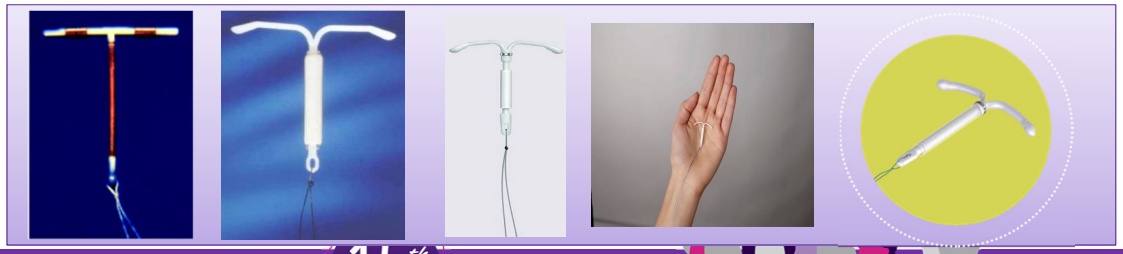
Available Intrauterine Methods

Generic	Brand	Reservoir
T380A Copper IUD	ParaGard	380 mm^2 Cu
LNG IUD 20 mcg/24 hr	Mirena	52 mg LNG
LNG IUD 18.6 mcg/24 hr	Liletta	52 mg LNG
LNG IUD 17.5 mcg/24 hr	Kyleena	19.5 mg LNG
LNG IUD 13.5 mg	Skyla	13.5 mg LNG

Cu = copper
LNG = levonorgestrel



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Cu-T380A IUD Placement Timing

- Systematic review: 8 studies identified
- Timing (within menstrual cycle) of Cu-IUD insertion has little impact on:
  - Continuation rates, safety, and efficacy
  - Expulsion (immediate or long term)
  - Pregnancy
  - Pain or bleeding at time of placement
- Place same day as visit, during elective C-section, post partum, post-abortal[1-6]
- No benefits for placement on menses

1. Grimes DA, et al. Obstet Gynecol. 2012;120(6):1477-8.
2. Nelson AL, et al. Contraception. 2009;80(1):81-3.
3. Levi E, et al. Contraception. 2012;86(2):102-5.
4. Knapp N, et al. Contraception. 2009;80(4):327-36.
5. Bednarck PH, et al. N Engl J Med. 2011;364(23):2208-17.
6. Whiteman MK, et al. Contraception. 2013;87(5):666-73.

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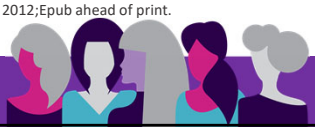
Copper IUD Updates

- Most effective emergency contraceptive
- Very appropriate for nulliparous women[1,2]
  - 30% clinicians have misconceptions[3]
- Pain with placement – no treatment effective for general use[4,5,6]
- NSAIDs reduces cramping and bleeding after placement with Copper IUD use[7]
- IUDs may be retained during PID treatment[8]

1. ACOG Committee Opinion 539. Obstet Gynecol. 2012;120(4):983-8.
2. Bayer LL, et al. Contraception. 2012;86(5):443-51.
3. Tyler CP, et al. Obstet Gynecol. 2012;119(4):762-71.
4. Hubacher D, et al. Am J Obstet Gynecol. 2006;195(5):1272-7.
5. Dijkhuizen K, et al. Hum Reprod. 2011;26(2):323-9.
6. Chor J, et al. Contraception. 2012;85(6):558-62.
7. Godfrey EM, et al. Contraception. 2012;Epub ahead of print.
8. Tepper NK, et al. Contraception. 2012;Epub ahead of print.



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Is There a Difference in Efficacy?

- Unintended pregnancy in 1 year
  - LNG-IUS: 26 pregnancies: 0.06 (95% CI 0.04-0.09)
    - 13 unrecognized expulsions
    - 1 dislocated
    - 7 ectopic (27%)
  - Copper IUDs: 92 pregnancies: 0.52 (95% CI 0.42-0.64) – all different doses
    - 16 unrecognized expulsions
    - 26 dislocated
    - 14 ectopic (15%)
  - ParaGard slightly less effective

Heinemann K, et al. Contraception. 2015;S0010-7824(15):00012-8.

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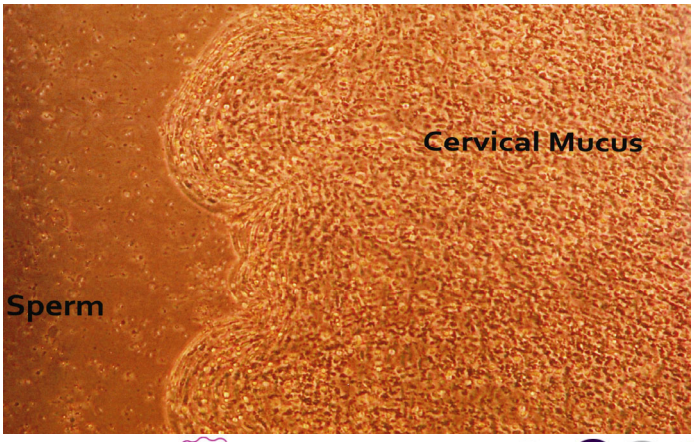
Cervical Mucus



Lewis RA, et al. Fertil Steril, 2009;92(3) Suppl: S27.

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LNG IUS-52mg Updates

- Place same day as visit, but need 7 days of backup if not on menses
- Place postpartum, post abortal[1,2]
- Can be used by nulliparous women
- Most effective medical treatment for heavy menstrual bleeding
  - 5-year follow-up HMB: LNG-IUS 20 vs. thermal balloon[3] IUS
    - Better efficacy and satisfaction

1. Hohmann HL, et al. Contraception. 2012;85(3):240-5.
2. Chen BA, et al. Obstet Gynecol. 2010;116(5):1079-87.
3. Silva-Filho AL, et al. Contraception. 2012;Epub ahead of print.

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2015 Cochrane Review
Progestin-Releasing IUDs and HMB

- LNG-IUS-20 more effective than oral medication for HMB
  - Greater reduction in HMB, improved Quality of Life (QoL)
  - More acceptance long term
  - More minor adverse effects
- LNG-IUS-20 vs. ablation similar outcomes
  - LNG-IUS more cost effective
- LNG-IUS-20 vs. hysterectomy less effective for HMB
  - Same improvements in QoL
  - LNG-IUS-20 more cost effective

Lethaby A, et al. Cochran Database Syst Rev. 2015;4:CD002126.

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Extended Use of LNG IUS-20mg
CHOICE Extended

- 263 women (33.8% ≥35 years)
  - Used range 4.7 - 36.2 months (median 11.7 months)
  - 108 women for ≥1 year extra
- 1 pregnancy (partially expelled IUD at 5.1 years) during Year 6
  - Failure rate 0.5 (95% CI 0.01 - 2.82)/100 women-years
  - Age adjusted 0.79/100 women-years
- New Report (2017)
  - 496 LNG-IUS Users (697 women-years of follow-up): 2 pregnancies
    - Failure rate in Year 6 = 0.25 (95% confidence interval: 0.04 - 1.42) per 100 women-years
    - Failure rate in Year 7 = 0.43 (95% confidence interval: 0.08 - 2.39) per 100 women-years

McNicholas C, et al. Obstet Gynecol. 2015;125(3):599-604.
McNicholas et al. Am J Obstet Gynecol. 2017. 216(6):586.e1-586.e6.

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LNG IUS-8 and LNG IUS-12

- Smaller device 30 x 28mm
- New and narrower introducer 3.8mm – easier and less painful to place
- Silver ring at top of vertical stem
- Barium sulfate in device to make radio opaque
- LNG IUS-12 approved for 5 years
- 5-year failure rate: 0.18
- 5-year amenorrhea rate: 22%
- LNG IUS-8 approved for 3 years
  - 3-year failure rate: 0.9%

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Pooled Phase II/III Data: Women Experienced Shorter, Less Frequent Menses over Time During Use of LNG IUS-13.5mg

Change in bleeding pattern by World Health Organization (WHO) criteria and 90-day reference periods

	Amenorrhea, %	Infrequent bleeding, %	Frequent bleeding, %	Prolonged bleeding, %
First 90-day reference period[a]	<1	8	31	59
Second 90-day reference period	3	19	12	17
End of Year 1	6	20	8	9
End of Year 3	12	22	4	3

- The percentage of women with amenorrhea and infrequent bleeding increased over time
- The percentage of women with prolonged and frequent bleeding decreased over time

[a]Baseline data for bleeding patterns were not captured.

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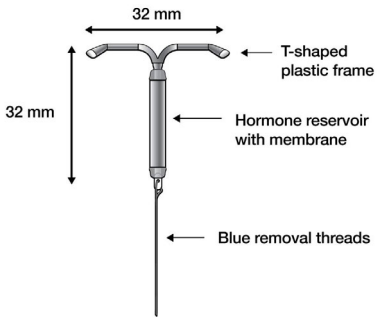
Low-Cost 52mg LNG IUD: *Liletta*

- Developed TO REMOVE BARRIERS
- LNG20 IUS
  - 3-year initial approval from FDA → ***now 4 years***
  - Phase III study continuing through 8 years
  - Same size and LNG release as Mirena®
    - 52 mg
    - 32 X 32 mm
  - Nulliparas and multiparas
  - Public sector pricing: $50



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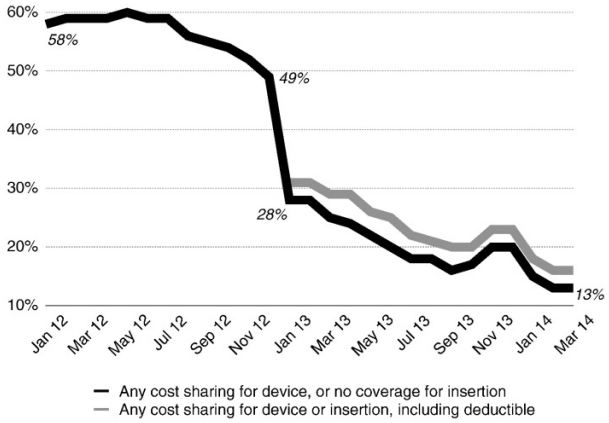
Change in Out-of-Pocket IUD Expense with ACA



Bearak JM. Contraception 2016;93:139-44.

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Comparing LNG IUS Products

	Skyla	Kyleena	Mirena	Liletta
N	1432	1452	1169	1751
U.S. Subjects	540 (38%)	563 (39%)	0	1751 (100%)
Nulliparas	556 (34%)	574 (40%)	0	1011 (58%)
Pearl Index at 1-year	0.4	0.16	0.2	0.15
Life-Table Pregnancy Rate at 3 years	0.9	NR	0.5	0.55
Life-Table Pregnancy Rate at 5 years	--	1.45	~0.7	--
Amenorrhea at 1 year	6%	12%	20%	19%
Amenorrhea at 3 years	12%	20%	NR	38%
Amenorrhea at 5 years	--	23%	NR	--

Nelson A, et al. Obstet Gynecol 2013;122:1205-13.
Eisenberg DL, et al. Contraception 2015;92:10-6.
Skyla, Kyleena, Mirena, Liletta package inserts

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Where Do We Go from Here?

- Questions about state coverage
- ACOG
- National Women's Law Center
  - Pill4Us hotline (1-866-PILL4US or pill4us@nwlc.org) which assists women having difficulty accessing contraceptive coverage
  - Coverher.org
- Liletta – continuing clinical trial
- Advocate for coverage
- Need no co-pays for as many forms as possible of each of the methods for women

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LARC Methods Meet Women's Needs

- Contraception is cost-effective, primary prevention
- Implants and IUDs are:
  - Safe
  - Highly effective
  - Convenient (forgettable is best)
  - Have high tolerability/few side effects
  - Cost effective
  - Easy to use
  - Reversible

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Important Updates in Recent Years: IUDs

- Extended life off-label: copper and LNG 52
- Increased perforation risk with breastfeeding
- Expanded choices of IUDs
  - More in pipeline
- Immediate postpartum/early postpartum placement more frequent, more effective
- Lessons learned about bleeding, pain with placement

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Remaining Widespread Misperceptions

- IUDs and implants are invasive methods
- Pills and condoms are 99% effective
- Pills are more hazardous to a woman's health than pregnancy
- Few women seek preconception care
- Mechanisms of action are not understood (abortifacients)

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Other Realities

- Challenges to women getting coverage for contraception
  - Many women seeking longer-acting methods now while their insurance provides coverage
  - Spreading influence of organizations that oppose women's rights to control their fertility
    - Clinicians often caught in the middle
  - Research is continuing to try to develop wide range of new methods

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