



## Quick Start Contraception Now is Better

*David Turok, MD, MPH*





## Objectives & Outline

- 1) Help your clients get the method they want today.
- 2) Quickstart of all methods is supported by the CDC SPR
- 3) Menstrual cycle information helps and a pregnancy test is only rarely needed to start today

# What is Quickstart?

- People getting the method they want when present
- Regardless of where they are in the contraceptive cycle

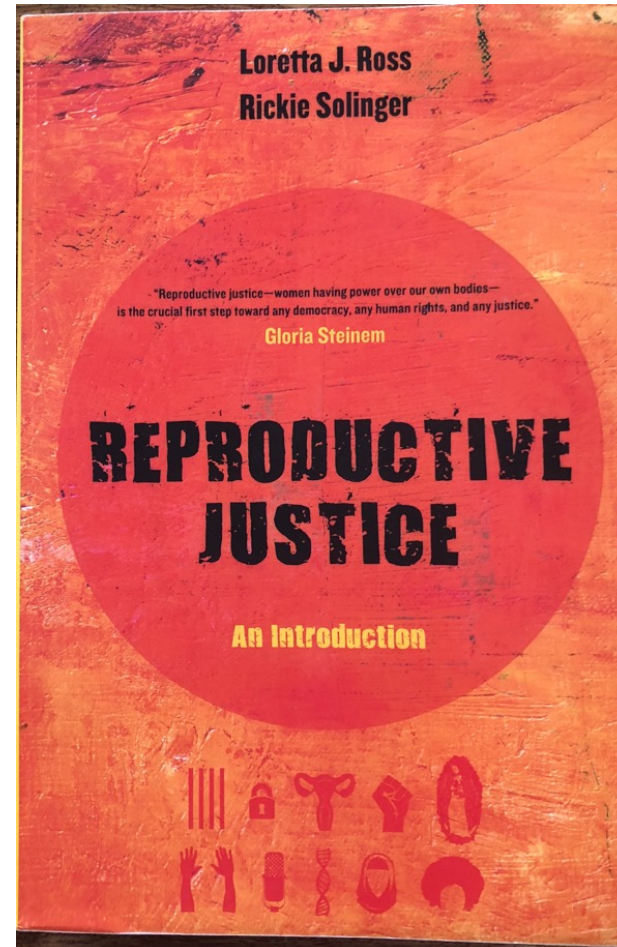


## Back in the Old Days...

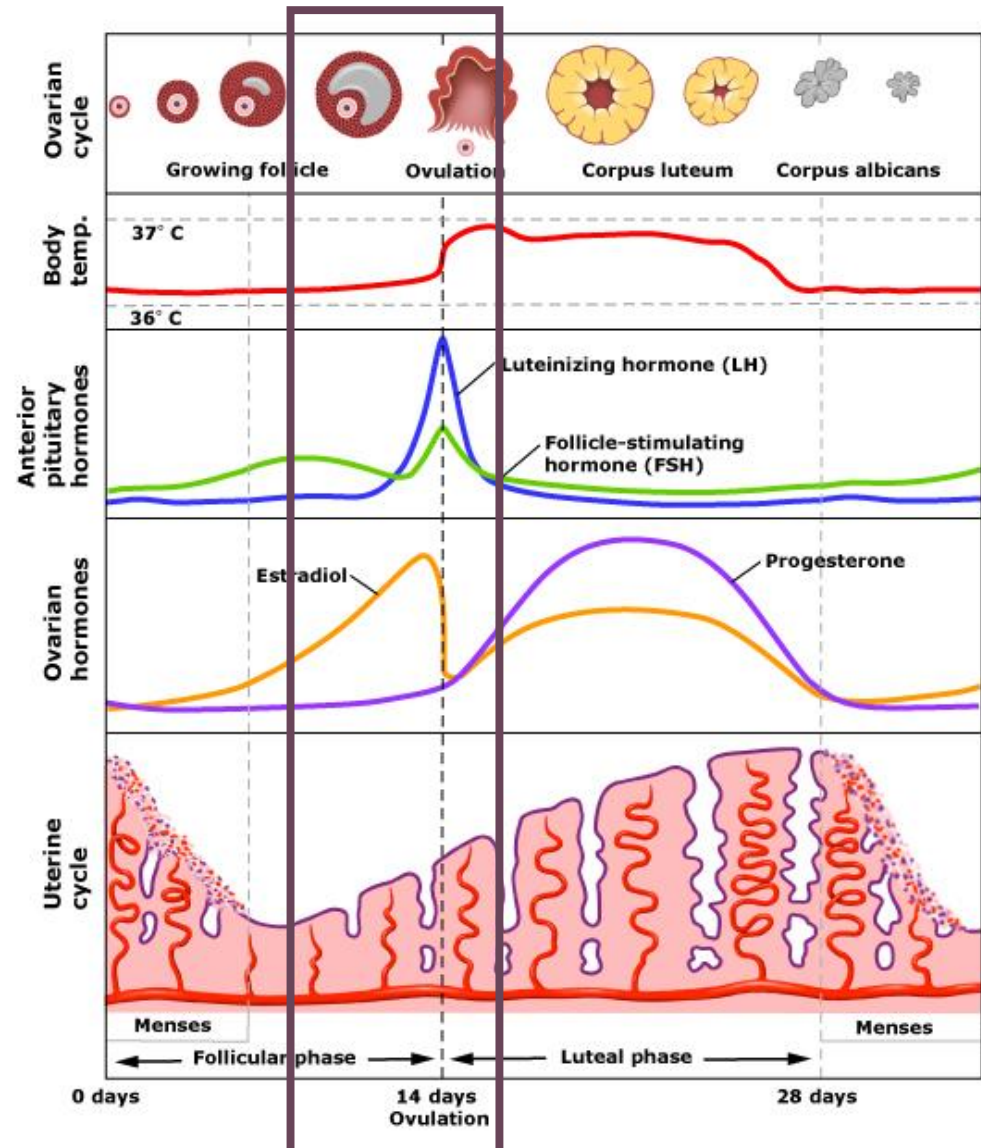
- People started new contraceptive methods Days 1-7
- Because they knew they were not pregnant
- Combined hormonal methods might interfere less
- Avoid a luteal phase pregnancy
  - And potential hormonal exposure to an early preg.



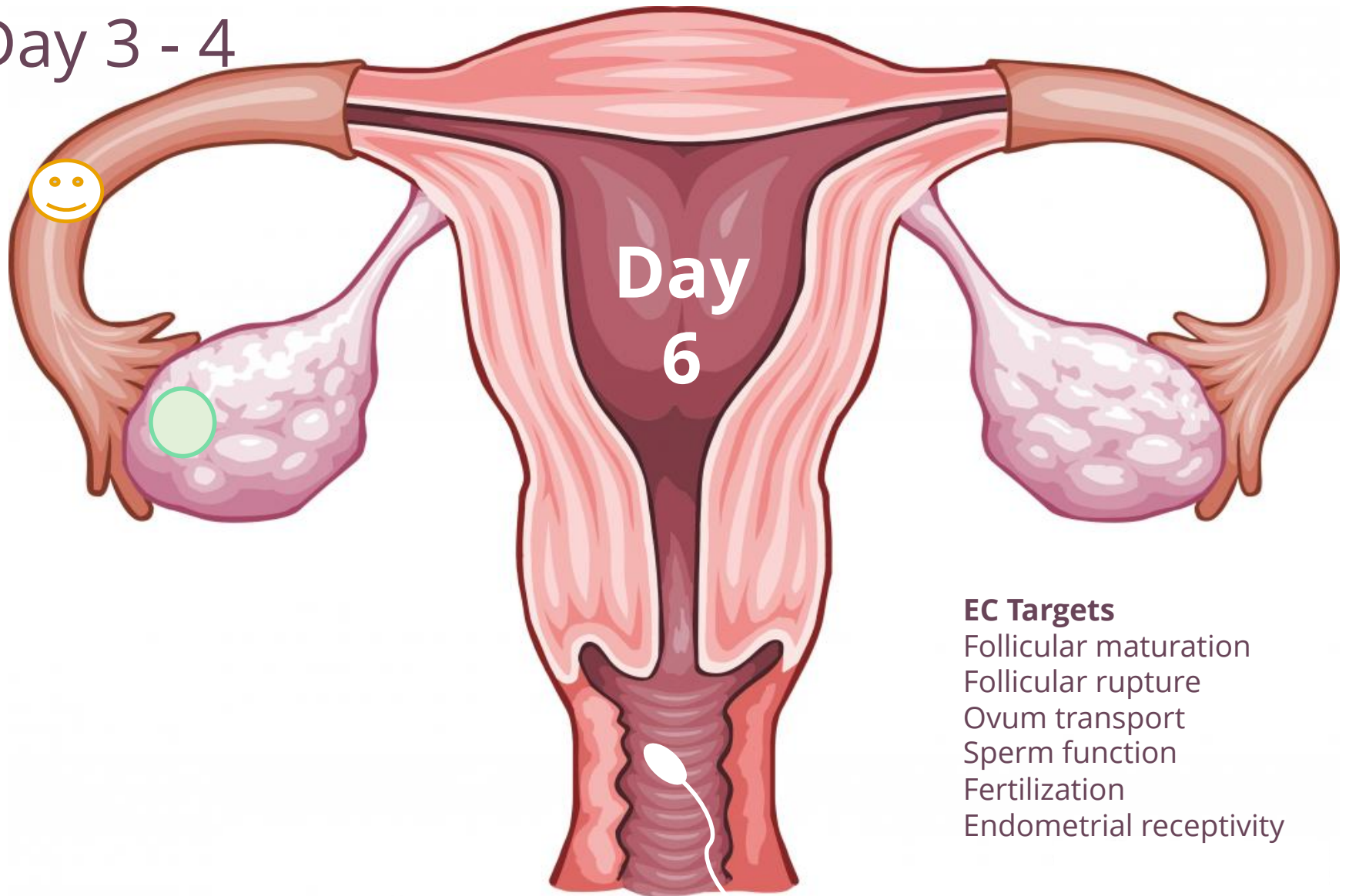
# 1) Reproductive Justice



# The Fertile Window: -5 to +1 days from ovulation



Day 3 - 4



### EC Targets

- Follicular maturation
- Follicular rupture
- Ovum transport
- Sperm function
- Fertilization
- Endometrial receptivity



## 2) Guidelines

Centers for Disease Control and Prevention  
**MMWR**

Morbidity and Mortality Weekly Report  
July 29, 2016

Recommendations and Reports / Vol. 65 / No. 3

### U.S. Medical Eligibility Criteria for Contraceptive Use, 2016

\*Except for pill, patch, ring,  
injectable, and implant users.



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

## Pregnancy Checklist\*

### BOX 1. How To Be Reasonably Certain that a Woman Is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is  $\leq 7$  days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is  $\leq 7$  days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [ $\geq 85\%$ ] of feeds are breastfeeds),\* amenorrheic, and  $< 6$  months postpartum

\*Source: Lobbok M, Perez A, Valdez V, et al. The Lactational Amenorrhea Method (LAM): a postpartum introductory family planning method with policy and program implications. *Adv Contracept* 1994;10:93–109.

CDC. MMWR. June 2013.



## Page 7 of the CDC SPR

- "...women who want to begin using an IUD (Cu-IUD or LNG-IUD), in situations in which the health care provider is **uncertain whether the woman is pregnant**, the woman **should be provided with another contraceptive method** to use until the health care provider is reasonably certain that she is not pregnant and can insert the IUD. **Pregnancies among women with IUDs are at higher risk for complications** such as spontaneous abortion, septic abortion, preterm delivery, and chorioamnionitis (41)."

# Calendar

## **This is All About Avoiding Luteal Phase Pregnancy**

How many people have to wait to start their contraceptive method so that we avoid one?

26 27 28 29 30

SUN MON TUE WED THU FRI SAT  
1 2



**Let's dig a little deeper**





# Oral Contraceptives Quick Start

- 250 people beginning OCs
- In-clinic start on the day they presented vs. other
- 50/57 (80%) of Quick Starters began the 2<sup>nd</sup> pill pack
- 115/156 (74%) of those starting later began the 2<sup>nd</sup> pill pack
- **Getting to the 2<sup>nd</sup> pack favored Quick Start (2.6 95% CI 1.1-6.1)**



# Oral Contraceptives Quick Start RCT

- 1,716 people beginning Ocs randomized to Quick Start or usual
- Followed to 6 months
- **Getting to the 2nd pack favored Quick Start (1.5, 95% CI 1.0-2.1)**
- **No difference in OCP continuation at 3 and 6 months**
- **6 month pregnancy rate less for Quick Start (0.90, 95% CI 0.64-1.25)**



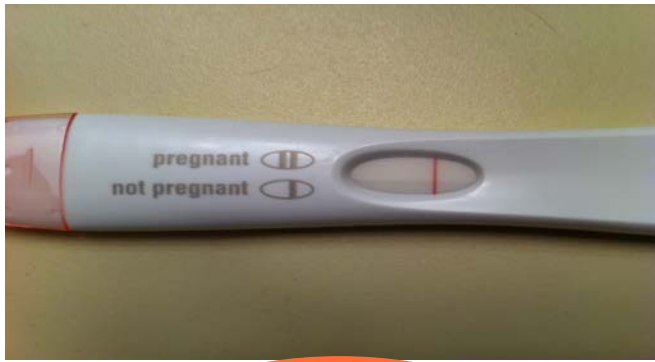
# Depo Now vs. Bridge Method RCT

- Depo Now (n=101) – Depo in clinic
- Bridge method (n=232) –Choose contraceptive method & return
- **In Bridge method group 125 (55%) returned for their first Depo**
- **3rd injection – 30% for Depo Now vs. 21% for Bridge (p=0.09)**
- **28 pregs by 6 months. Bridge group Preg risk 4.0, 95% CI 1.2-13.4)**

# Implants



# SPR Pregnancy Checklist



	Luteal phase pregnancy N=36		
Results of Pregnancy Checklist	Pregnant	Not Pregnant	Total (n)
"Pregnancy Not Excluded"	28	2,130	2,158
"Pregnancy Excluded"	8	4,763	4,771
<b>Total</b>	<b>36</b>	<b>6,893</b>	<b>6,929</b>
Sensitivity = 0.78			
Specificity = 0.69			
Positive predictive value = 0.013			
Negative predictive value = 0.998			

BOX 1. How To Be Sure a Woman Is Not Pregnant

A woman is considered to be pregnant if she meets any one of the following criteria:

- She has had intercourse since the start of normal menses.
- She has had intercourse since the start of normal menses and has not been consistently using a method of contraception.
- She has had intercourse since the start of normal menses and has not been consistently using a method of contraception and has not been fully or nearly fully protected by a condom.
- She has had intercourse since the start of normal menses and has not been consistently using a method of contraception and has not been fully or nearly fully protected by a condom and has not been fully or nearly fully protected by a condom.

1.3%



# Implant and the CDC Pregnancy Checklist

- 3180 implants 1868 (59%) outside checklist
- 1726 with documented pregnancy outcomes
- 1066 (57%) outside the checklist
- 10 pregnancies 0.9% (95% CI 0.5 – 1.7%)

Pregnancy Checklist	Pregnant	Not Pregnant	Total
Pregnancy NOT Excluded	10	1056	1066
Pregnancy Excluded	2	658	660
Total	12	1714	1726

Sensitivity  $10/12 = 83\%$   
Specificity  $658/1714 = 38\%$   
PPV  $10/1056 = 0.9\%$   
NNP  $658/660 = 99.6\%$



# Implant Placement After UPI (0-14 days Ago)

- N=83 from 823 HER Salt Lake participants who received an implant (10%)
- 30 (33% who used oral EC)
- 40 UPI 0-5 days prior
- 43 UPI 6-14 days prior
- 1 pregnancy (1.6%, 95% CI, 0.04 - 8.5%)
  - after UPI 14 days prior to Implant (and took LNG EC)



# If We Start With IUDs For EC The Pregnancy Checklist Looks Too Restrictive

- Copper IUD EC Systematic Review:
  - 7,034 women  $\leq$  1/1000 risk of pregnancy
- RAPID EC Study (Copper vs. LNG IUDs for EC)
  - Rare pregnancies in 655 EC users randomized 1:1



## IUD EC Efficacy: A Systematic Review of 35 Years of Experience

- 42 of 274 studies identified in English or Chinese
- 8 types of IUD
- 7034 women
- Pregnancy rate = 0.09%





## Are There Limits on When a Copper IUD Can be Placed for EC?

The copper IUD can be placed for EC:

**IF...** within 5 days of UPI

**BUT...**if the day of ovulation can be estimated

**THEN...**it can be inserted after 5 days after UPI

**IF...**it's not more than 5 days after ovulation

A large, textured question mark is centered on a dark, textured background. The question mark is composed of a dense, granular material, possibly sand or small stones, which gives it a three-dimensional, tactile appearance. The texture is most prominent in the upper curve and the stem of the question mark.

**COULD THIS BE SIMPLER?**



## 1,963 Copper T380 IUD EC Users

- **No pregnancies**
- 1840 participants (93.7%) had usual cycle lengths of 25-35 days
- 850 (46.2%) UPI in the fertile window
- 84 (4.6%) had IUD insertion > 5 days after ovulation
- 52 (2.7%) had insertion > 5 days after UPI

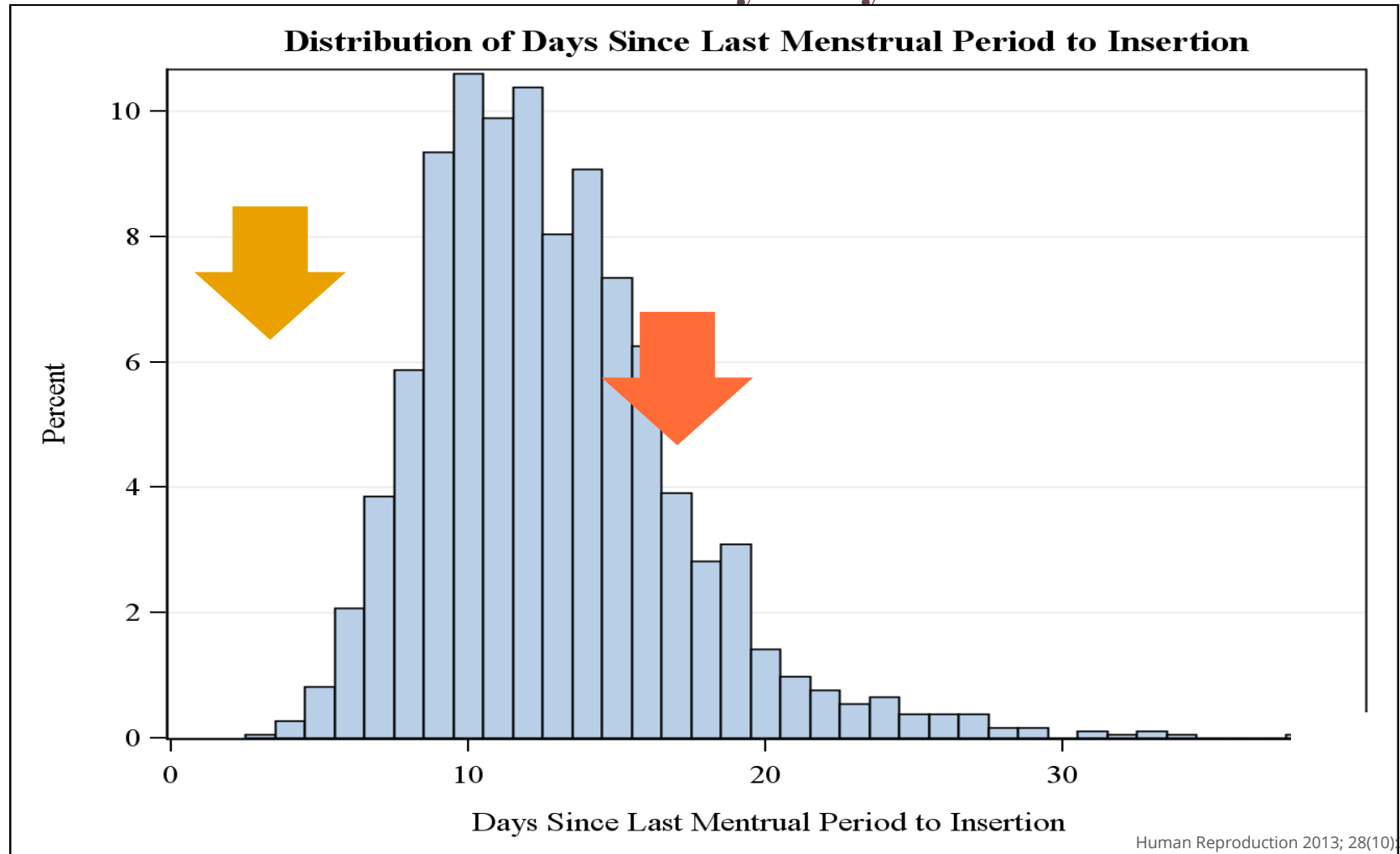


## Methods: Original Inclusion Criteria

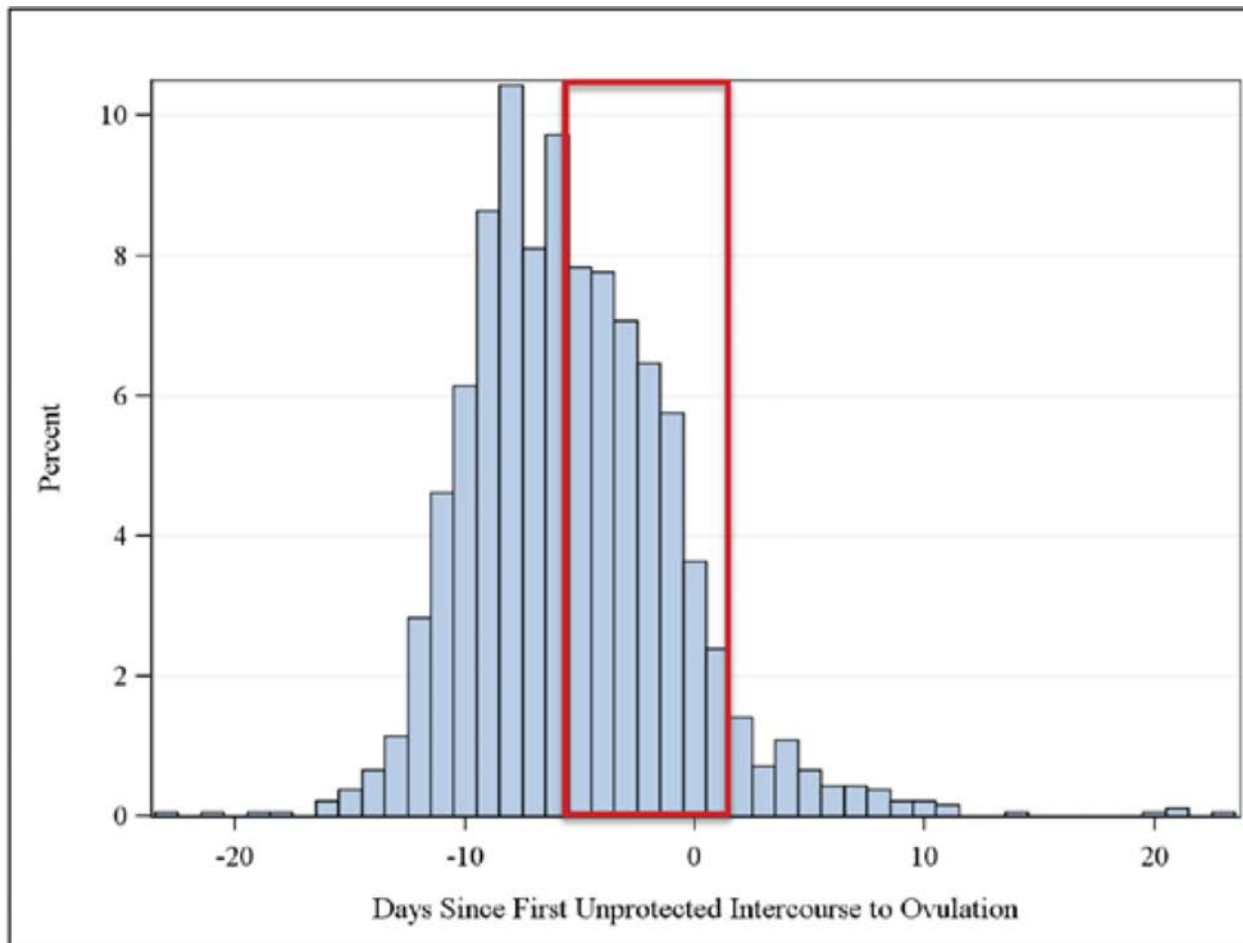
- Secondary analysis of a prospective trial of copper T380 IUD EC users in China (n=1,963)
- Age 18-44
- Regular cycles between 24-42 days
- Known last menstrual period (LMP)
- Within 5 days (120 hours) of UPI
- All participants had a negative urine pregnancy test (hcg 25 IU/L)



# IUD EC Insertion by Days Since LMP



## Day of UPI Relative to Ovulation



Turok et al. Human Reproduction 2103



# Risk of Pregnancy with **Copper T380 IUD** Placement **6-14 days** after UPI

**134 People**

**0 Pregnancies**

**(97.5% CI 0– 2.7%)**

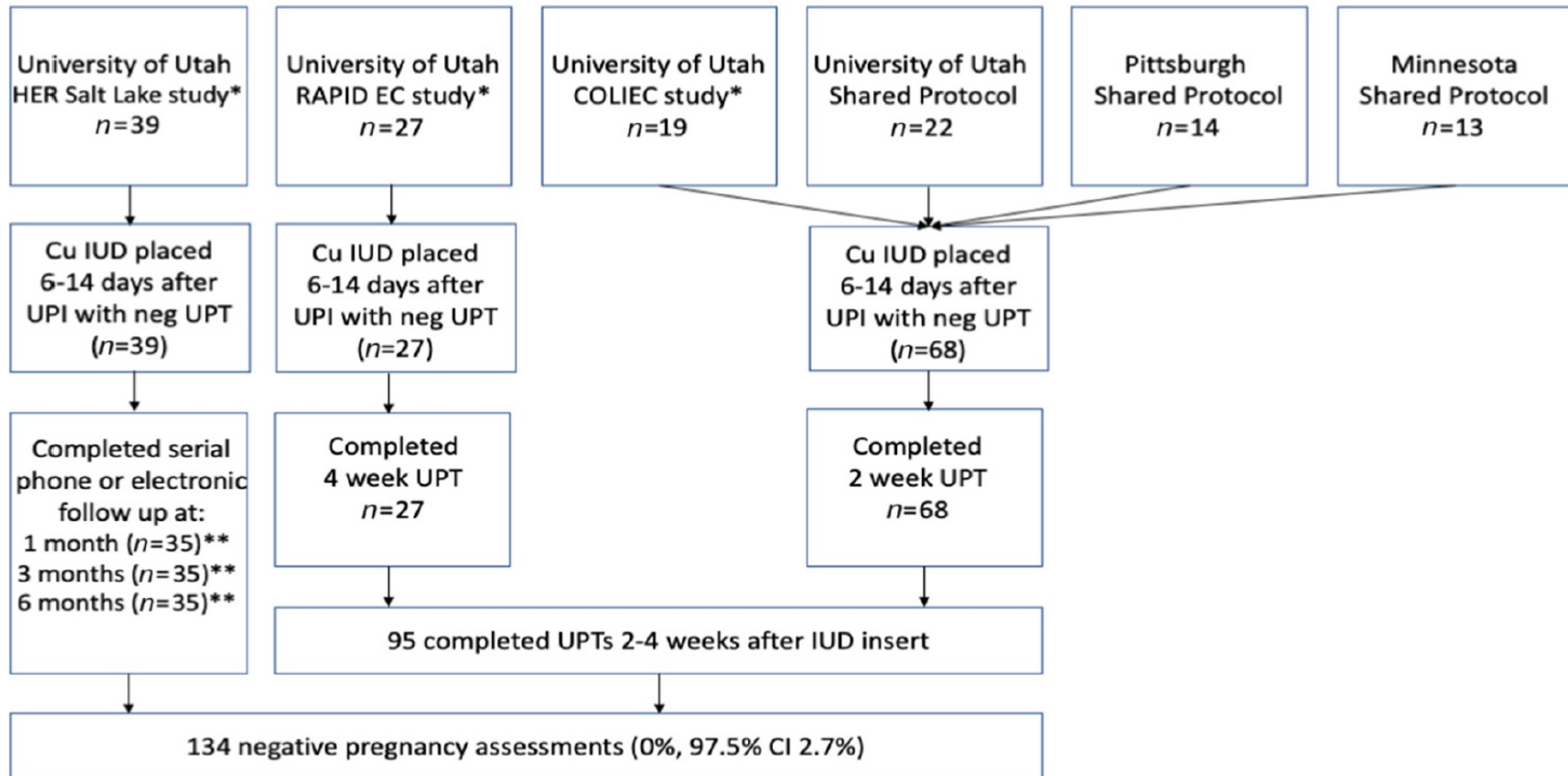
**+52 (WU) + 64 (Goldstuck)**

**= 250 (0%, 97.5% CI 0 – 1.5%)**

Thompson, Contraception 2019; 100(3):219-221



# Copper IUD Placement 6-14 Days After UPI





# Risk of Pregnancy with LNG 52 MG IUD Placement 6-14 days after UPI

**187 People**

**1 Pregnancy**

**(95% CI 0.01 – 2.9%)**



# SPR Emergency Contraception Opportunities For Change

- 1) Add LNG-IUD as an acceptable method of EC
- 2) Use of Copper & LNG IUDs for EC to at least 7 days
- 3) Placing IUDs if not meeting the Pregnancy Checklist Criteria AND has a negative urine pregnancy test



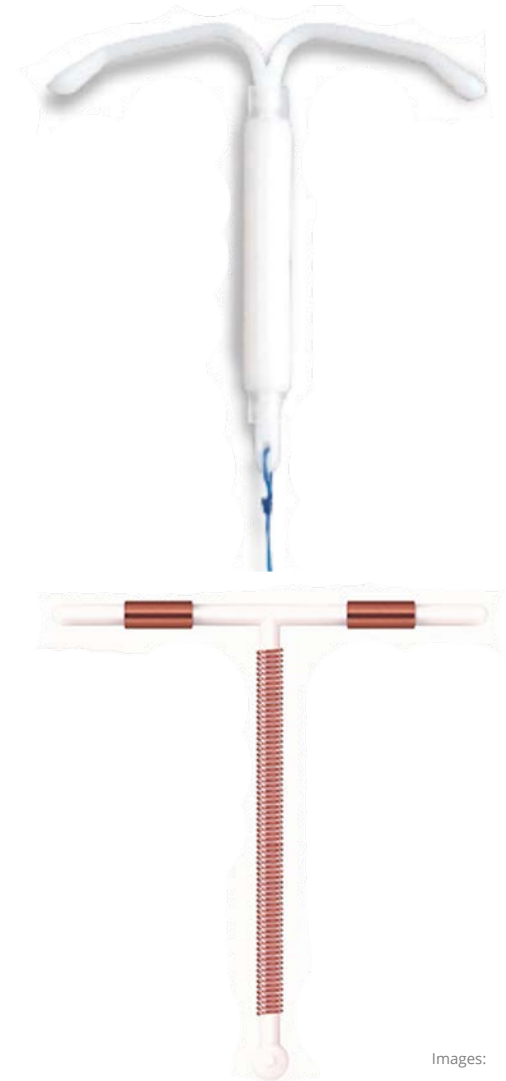
## Objectives

- LNG IUD > Copper IUD selection
- Copper IUD for EC highly effective
- No LNG IUD EC data

We compared EC pregnancy risk between the LNG and copper IUD.



FAMILY PLANNING ELEVATED | MYFPE.ORG | FACEBOOK.COM/FPEUT | TWITTER.COM/FPEUTAH



Images:

<https://www.lilettahcp.com/iud-product-features##>

<https://www.coopersurgical.com/our-brands/paragard/>



## Methods & Interventions

- Participant-blinded non-inferiority RCT
- August 2016 – December 2019 @ 6 PPAU sites
- $\geq 1$  episode of unprotected intercourse within five days and desired an IUD
- Randomized 1:1
- LNG 52 mg IUD
- or copper T380A IUD





# Inclusion Criteria

- Presented for EC (UPI within 120 hours)
- Fluent in English or Spanish
- Age 18-35
- Desire to initiate an IUD
- Desired to prevent pregnancy for 1 year
- Regular menstrual cycle (21-35 days)
- Known LMP (+/-3 days)
- **Negative UPT**



# Exclusion Criteria

- Breastfeeding
- Current use of sterilization, IUD or implant
- Use of oral EC in the preceding 5 days
- Vaginal bleeding of unknown etiology
- Allergy to copper
- Known uterine cavity anomalies
- Intrauterine infection in the last 3 months
- Untreated GC or Chlamydia in the last 30 days



# Primary Outcome

- 1°Outcome 1 month pregnancy by UPT
  - (By modified ITT and per protocol)
- 1) Text message reminder to complete UPT with link to upload UPT photo
- 2) REDCap survey including UPT results on the following day
- 3) In-person clinic UPT
- If none of the above (n=48), review 1,3, & 6-month survey follow up & EHR review



## Power & Sample Size

- Estimated 1% pregnancy risk for LNG IUD and 0.1% for CuT380A
- 80% power
- 2.5% non-inferiority margin
  - requires 335 per arm + 5%
- Recruitment goal  $(670 + 36) = 706$



# 1° OUTCOME

## 1-MONTH PREGNANCY

(1) Modified ITT (UPT, survey, and EHR review)

321 Copper / 317 LNG

(2) Per protocol (UPT, survey, and EHR review)

311 Copper / 305 LNG

(3) Sensitivity Analysis - only those with UPT results

300 Copper / 290 LNG



# Secondary Outcomes

- IUD continuation
- Satisfaction (5 point Likert Scale)
  - IUD related pain and bleeding outcomes
- Spotting & bleeding
- Cramping & pain
- Adverse Events
  - Open-ended query of receipt of medical care

Time for EC



Planned Parenthood Association of Utah



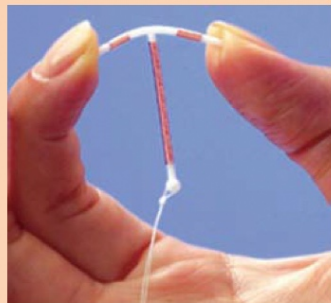
N = 10,317

## Are you here for the Morning After Pill / Emergency Contraception (EC)?

### You might be interested in a study offering EC users the most effective type of contraception.

We would like to be sure women coming to this clinic for emergency contraception (EC) also know about some of the most effective birth control methods. These methods include the intrauterine device (the IUD). IUDs are placed in the uterus by a doctor or nurse practitioner. When they are taken out, you can get pregnant again right away. We are offering participation in a study that gives EC users one of two IUDs.

1.



One IUD is the copper IUD

- It doesn't have hormones and can last up to 12 years.
- This IUD is the very best to keep you from getting pregnant if you have had sex within the last 5 days without using contraception: if 1,000 women have sex and have this IUD placed, we expect that about 0-1 will get pregnant (0.1%).
- You'll have regular periods but they may be heavier and you may experience more cramping.

2.



The other IUD is the hormonal IUD.

- This IUD has a hormone in it (progestin) and lasts up to 5 years.
- This IUD should work for EC. If 1,000 women have sex and have this IUD inserted we expect about 20 will get pregnant that month.
- In the first 3-6 months bleeding can be irregular and after that you'll have less bleeding during your period or you may not have a period at all. After 3 months women with this IUD have little or no bleeding.



# ENROLLED

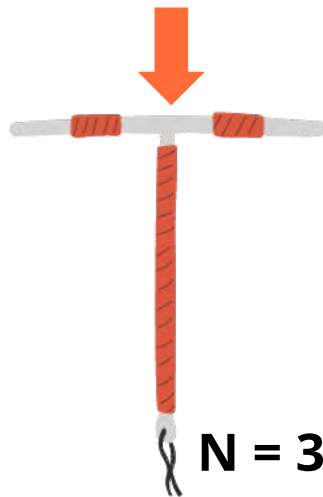


N = 718 (7%)

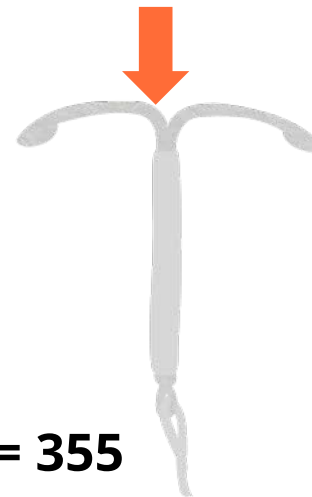
# RANDOMIZED



N = 711

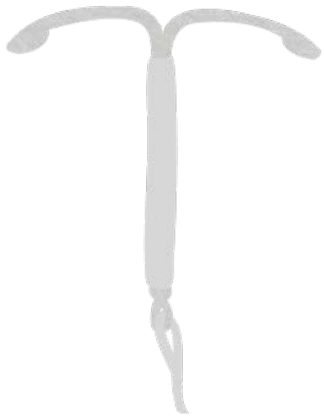


N = 356



N = 355

**n=355**



**n= 327**



**Did not  
receive Tx  
8%**

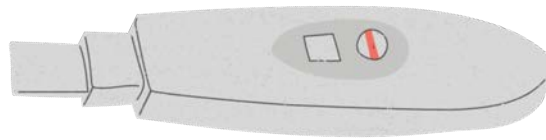


**n=328**

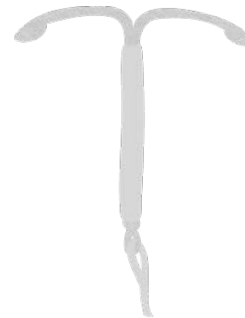


**n= 356**

# 1-MONTH PREGNANCIES



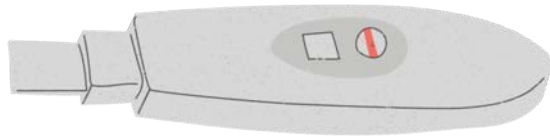
n= 321



n=317

# 1-MONTH PREGNANCIES

## MODIFIED ITT



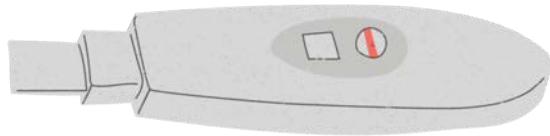
n=317  
1/317, 0.3%  
(95%CI 0.1%-1.7%)



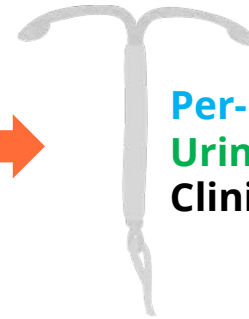
n= 321  
0/321, 0%  
(95%CI 0%-1.1%)

# 1-MONTH PREGNANCIES

## PER PROTOCOL SENSITIVITY ANALYSIS



**n=317**



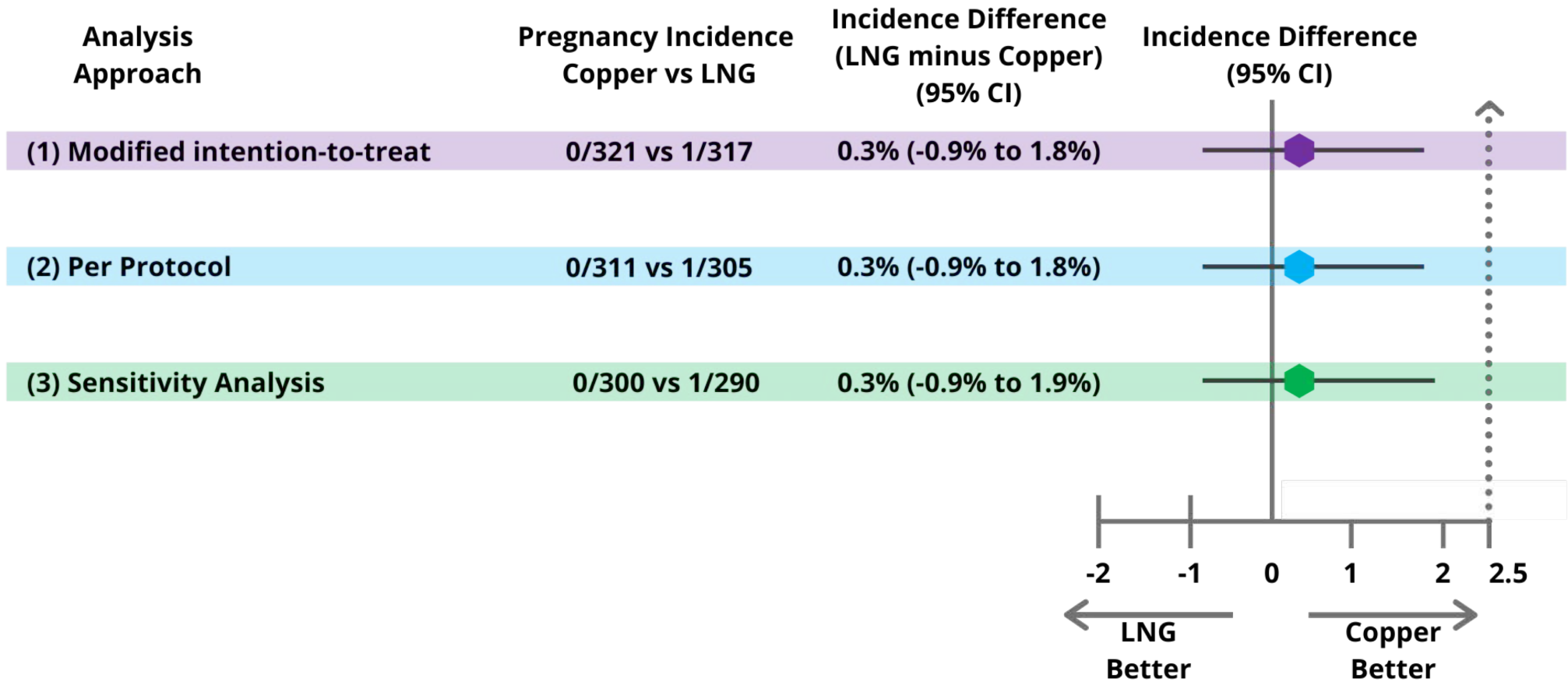
**Per-protocol analysis (n=305)**  
**Urine pregnancy test (n=290)**  
**Clinical & survey data (n=27)**



**n= 321**

**Per-protocol analysis (n=311)**  
**Urine pregnancy test (n=300)**  
**Clinical & survey data (n=21)**

# RESULTS - NONINFERIORITY



# SECONDARY OUTCOMES

Outcome	CuT380A IUD N=328	LNG 52 mg IUD N=327
<b>IUD removals</b>	8 (2.5%)	10 (3.1)
<b>IUD expulsions</b>	3 (0.9%)	2 (0.6%)
Cramping since insert	66.6 ± 1.8	59.5 ± 1.9
Sharp pain since insert	72.5 ± 1.3	66.6 ± 1.4
# Bleeding days	7.2 ± 0.3	10.8 ± 0.5
# Spotting days	5.7 ± 0.3	11.0 ± 0.6



# SECONDARY OUTCOMES

Outcome	CuT380A IUD	LNG 52 mg IUD
<b>Satisfaction</b>		
Very Satisfied	50 (16.3%)	42 (13.7%)
Satisfied	119 (38.8%)	115 (37.5%)
Neutral	88 (28.7%)	107 (34.9%)
Unsatisfied	22 (7.2%)	23 (7.5%)
Very Unsatisfied	28 (9.1%)	20 (6.5%)
<b>Adverse Events</b>	16 (4.9%)	17 (5.2%)



## CONCLUSION

The LNG 52 mg IUD is noninferior to the Copper T380A IUD for EC





## CONCLUSION

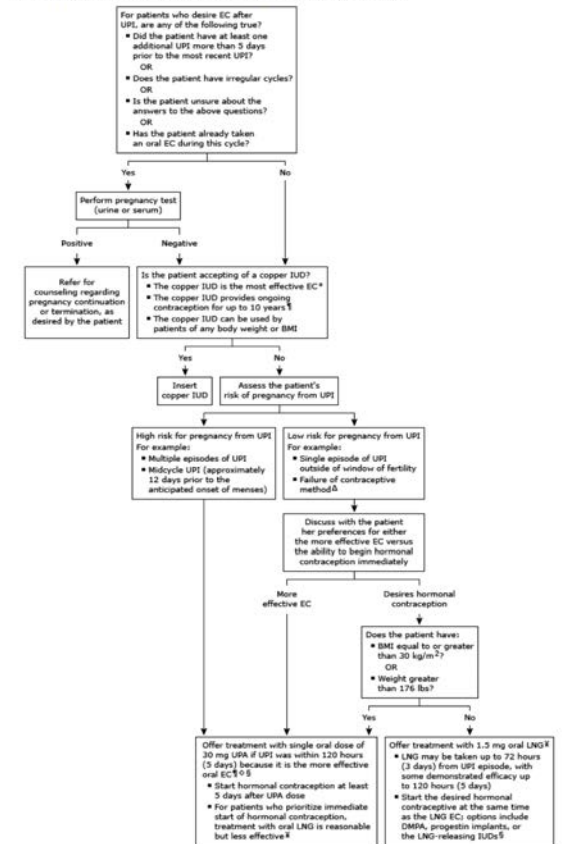
- 1) Nearly all clients can get the method they want today.
- 2) Quickstart of all methods is supported by the CDC SPR
- 3) Menstrual cycle information helps and a pregnancy test is only rarely needed to start today



# Ongoing Contraception

EC Method	Ongoing Contraception
Copper IUD	Easy, ready to go
Oral LNG	Start, Abstain or backup x 1 week
UPA	Hold hormones for 5 days

Approach to selection of emergency contraception after unprotected intercourse



UPI includes instances in which no contraception was used, a method was used imperfectly, or intercourse was forced without use of contraception.

UPI: unprotected intercourse; EC: emergency contraception; IUD: intrauterine device; BMI: body mass index; LNG: levonorgestrel; DMPA: depot medroxyprogesterone acetate; UPA: ulipristal acetate.

\* Pregnancy rates are 0.1% for the copper IUD, up to 1.8% for UPA, and up to 2.6% for LNG.

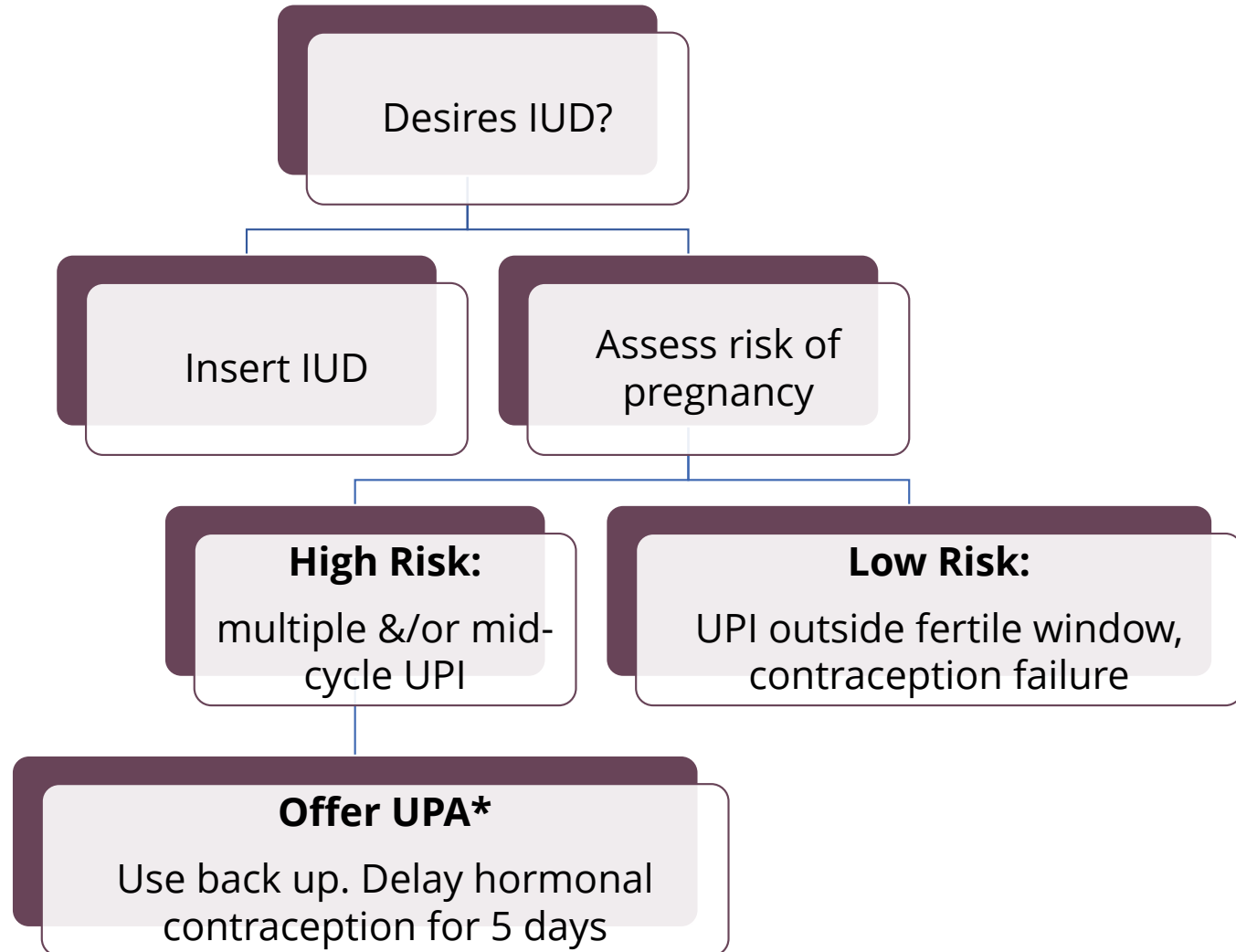
† Information on IUD device types, candidates, and device selection can be found in related UpToDate content. Δ Contraceptive failure can include missing more than one dose of oral contraceptive pills; failure to resume the DMPA injection, patch, or vaginal ring at the correct time; having a diaphragm, cervical cap, or contraceptive sponge slip; or having a condom break.

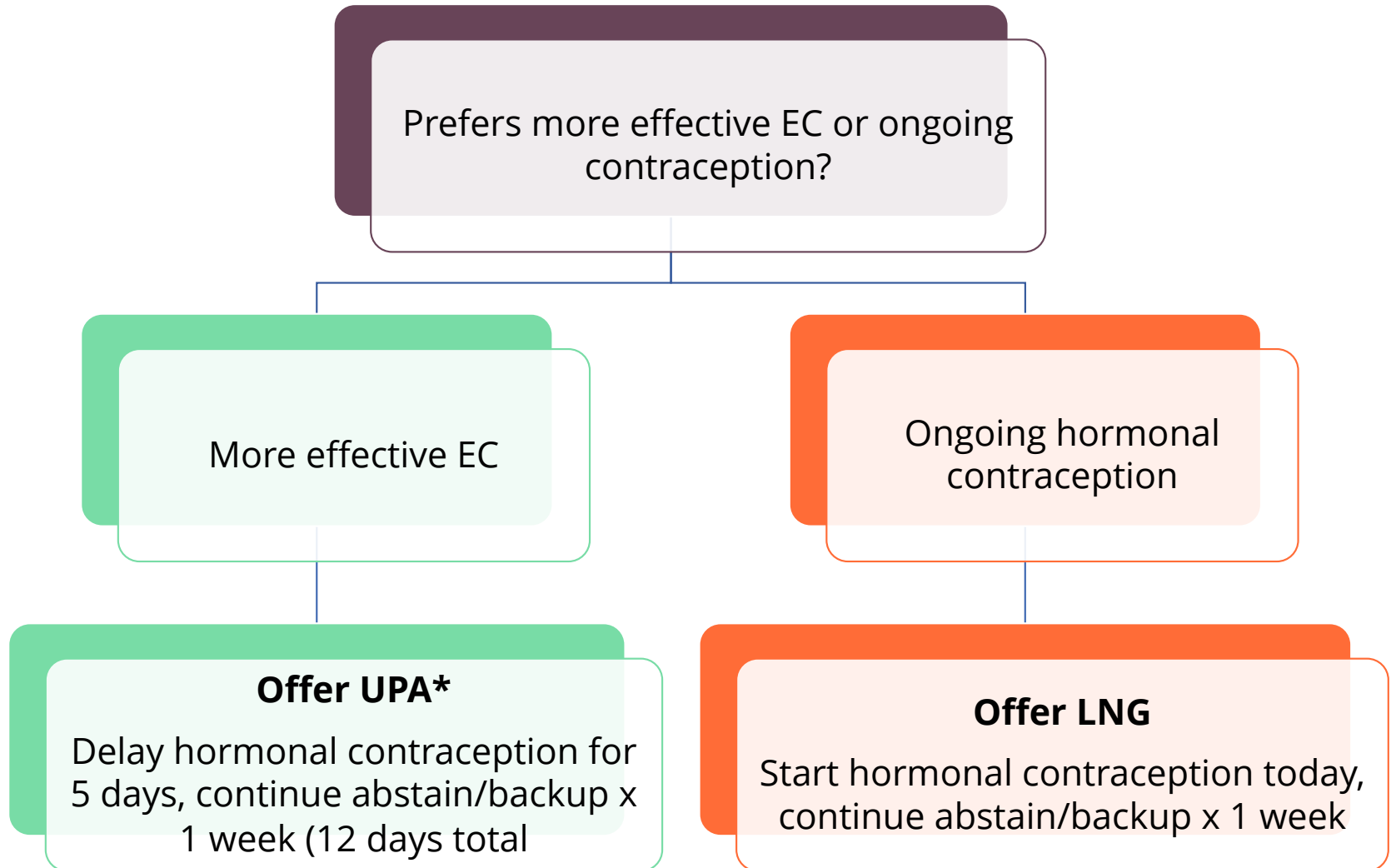
◊ Treatment with UPA requires a prescription.

§ After receiving EC, the patient can expect her period within three weeks. Patients who do not have a period after three weeks should perform a pregnancy test.

¶ For United States patients, oral LNG is available over-the-counter for individuals ages 17 and older. Individuals younger than age 17 may require a prescription, which varies by state.

Courtesy of David Turok, MD.

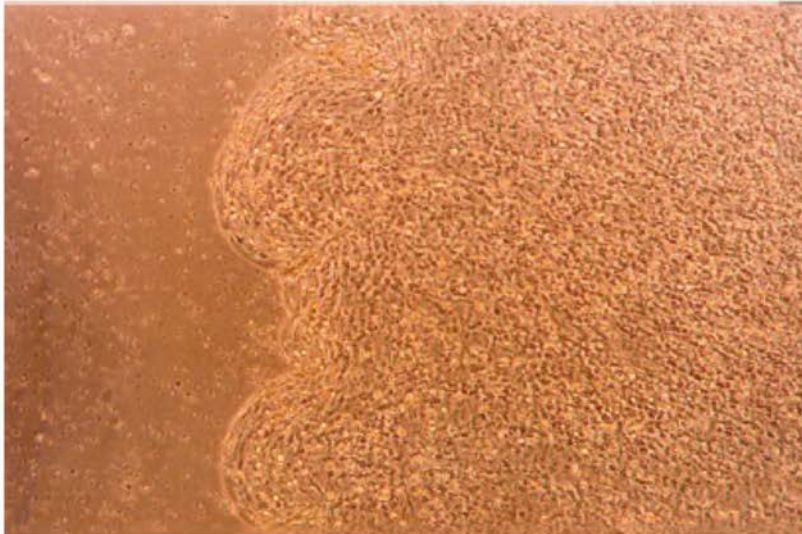




# 7-Day Backup with Initiation of LNG-IUD

1. If placement > 7 days since LMP then abstain or use a backup method for 7 days

**LNG IUD Great Wall of Mucus**



**Normal Mucus  
without exogenous hormones**

