A person is seen from behind, skiing down a vast, snow-covered mountain slope. The skier is wearing dark clothing and a red backpack. The snow is bright white and covers the entire foreground and middle ground. In the background, there are more snow-covered mountain peaks under a clear blue sky with a few wispy clouds. The overall scene is serene and expansive.

David Turok, MD, MPH  
FIAPAC  
October 14, 2016

# EC & IUDs

## Slow and Steady Progress to Increase Access



# Overarching Goal

To improve **access** to highly effective contraception at the time of EC





# Overview

- 1) Copper IUD EC users have lower pregnancy rates for the next year
- 2) Using the LNG IUD with EC
- 3) Expanding the limits of use- copper IUD EC



# Disclosures

- Teva
- Merck
- Bayer Women's Health
- Medicines360
- Bioceptive
- Allergan
- PharmaNest

If oral EC  
doesn't  
work....





# Copper IUD EC Efficacy: A Systematic Review

- 42 studies, 6 countries, 8 types of copper IUDs
- 7,034 women
- Pregnancy rate = 0.09%
- < 1/1000 risk of pregnancy!



# OOPS! EMERGENCY CONTRACEPTION: BIRTH CONTROL THAT WORKS AFTER SEX

Types of Emergency Contraception	How well does it work?	How soon do I have to use it?	How do I use it?	Where can I get it?
 <p>ParaGard IUD</p>	<p>Almost <b>100%</b> effective</p> 	<p>Within <b>5</b> days</p> 	<p>It's placed in the uterus by a doctor</p>  <p>Keeps working as super effective birth control.</p>	<p>From a doctor or a clinic</p>  <p>Say it's for EC so you are scheduled quickly.</p>
 <p>Ella</p>	  <p>Less effective if obese. Try an IUD.</p>	<p><b>ASAP</b></p>  <p>Works better the sooner you take it, up to 5 days.</p>	<p>Take the pill as soon as you get it</p>  <p>Remember to use it every time you have unprotected sex.</p>	<p>From a doctor or a clinic</p>  <p>Get an extra pack for future emergencies.</p>
 <p>Plan B One-Step or a generic</p>	  <p>Less effective if overweight. Try ella or an IUD.</p>	<p><b>ASAP</b></p>  <p>Works better the sooner you take it, up to 3 days.</p>	<p>Take the pill(s) as soon as you get it</p>  <p>Remember to use it every time you have unprotected sex.</p>	<p>At a pharmacy, no prescription needed</p>  <p>Get an extra pack for future emergencies.</p>

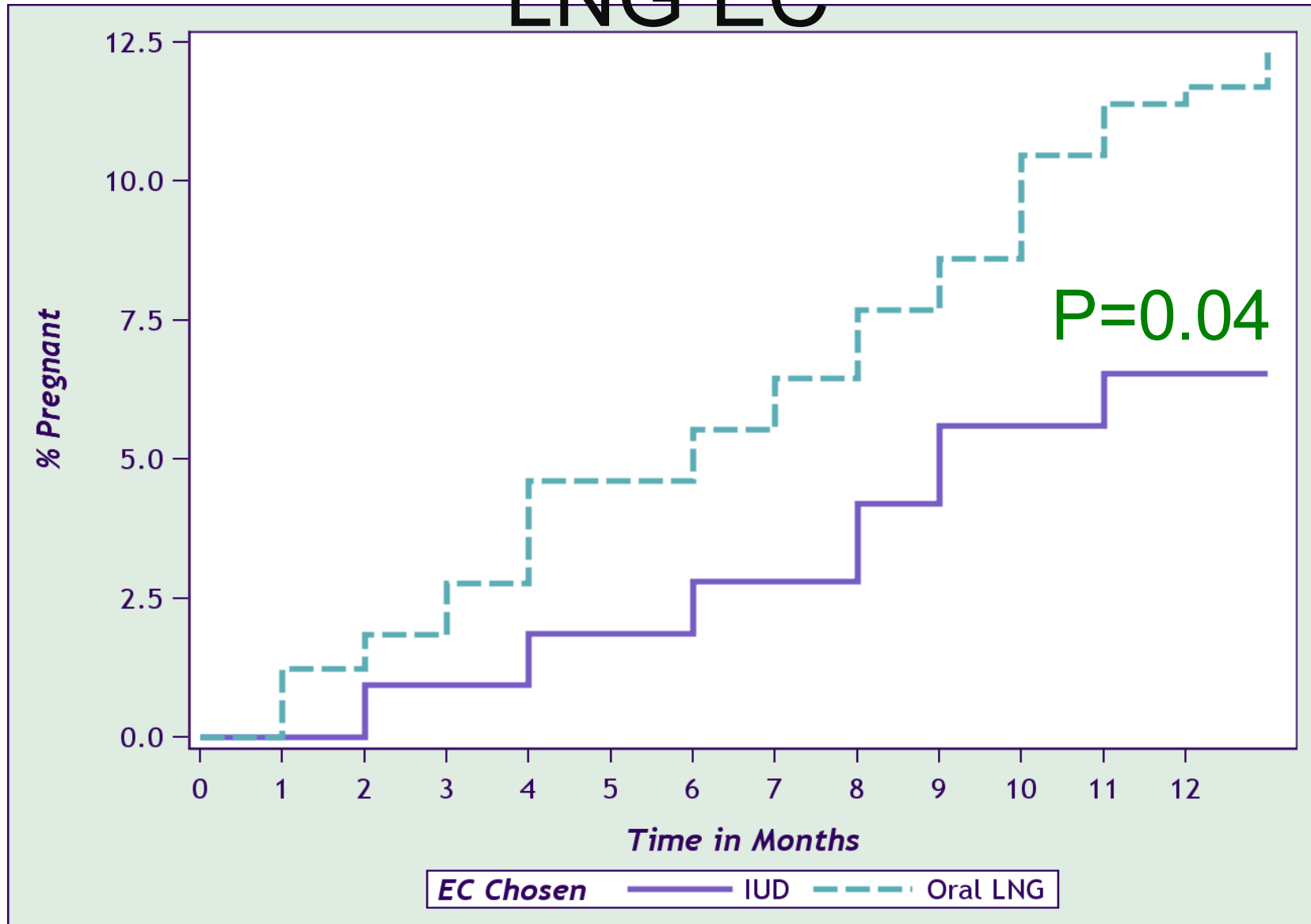


# 1) Copper IUD EC Clinical Trial: Documenting the Long Term Benefits

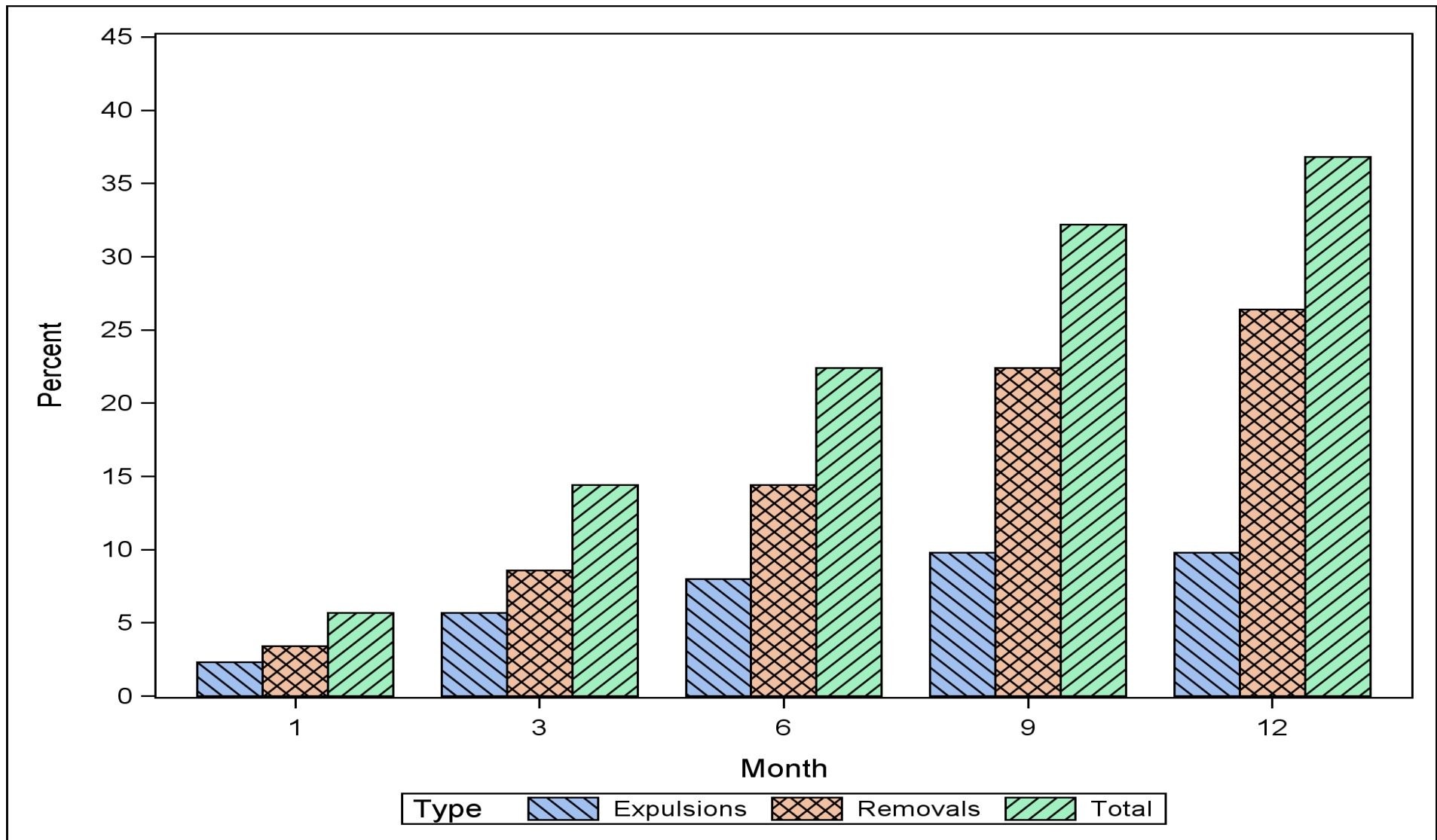
- EC users select oral LNG or the copper IUD
- 1<sup>o</sup> outcome: unplanned pregnancy at 1 year
- 2<sup>o</sup> outcomes:
  - IUD expulsion/removal rates
  - Use of an effective method of contraception



# Pregnancy for CuT380 IUD vs Oral LNG EC



# IUD for EC Expulsion & Removal





“I don’t want a long-term  
method of contraception; I’m  
not in a long-term  
relationship.”



## 2) So, the LNG IUD for EC?

COLIEC = Copper Or Lng Iud for EC

- Prospective trial offering EC users
- Participants select:  
Oral LNG & LNG IUD or Copper IUD for EC
- 1° outcome: pregnancies within 2 weeks
- 2° outcome: IUD continuation for 12 months

# Methods

- Prospective observational study
- EC users at a single clinic in Utah
- From June 2013 to September 2014
- Interested in an IUD
- 18-35 years of age
- Unprotected intercourse < 120 hours
- Fluent in Spanish or English
- No charge for chosen EC treatment

# Exclusions

- + Urine pregnancy test
- Breastfeeding
- Sterilization
- IUD or implant in place
- Usual contra-indications per package inserts

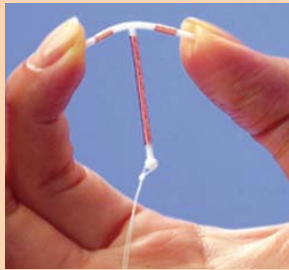


## Are you here for the Morning After Pill / Emergency Contraception (EC)?

### 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 best 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. There are two IUDs.

1.



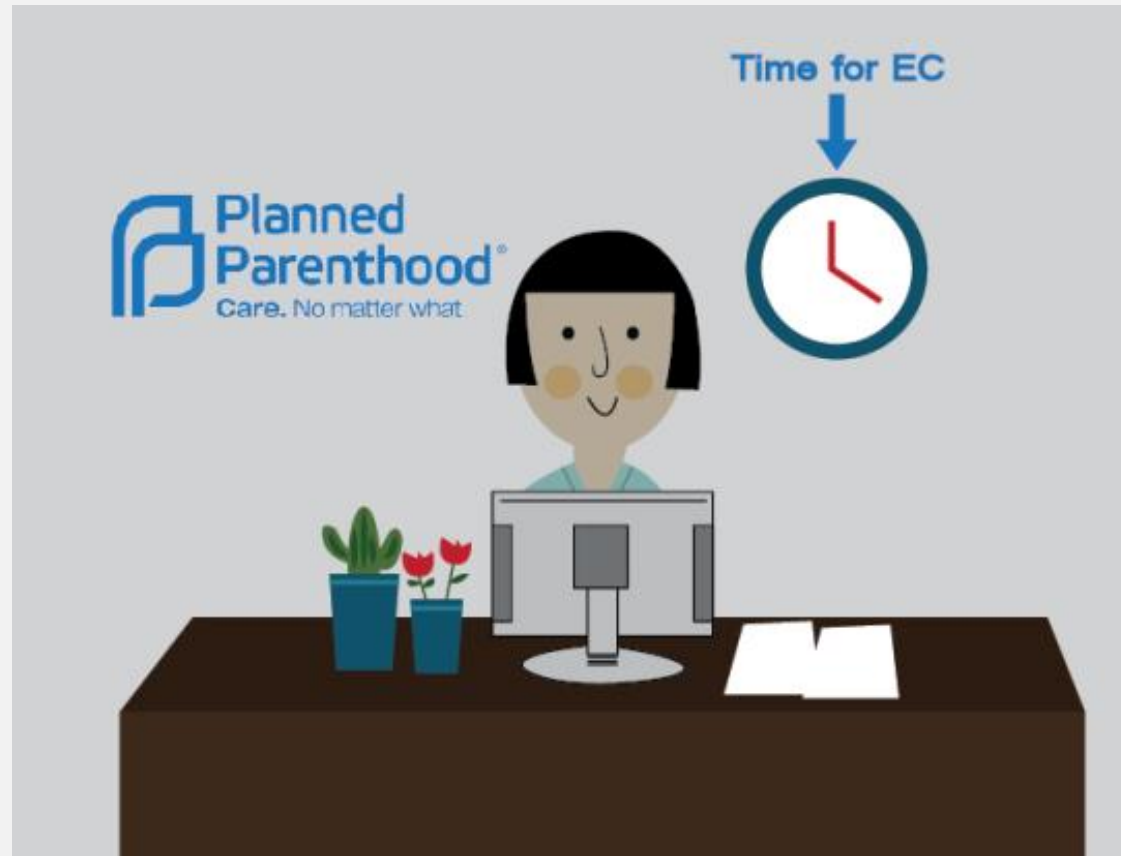
One is the ParaGard, it doesn't have hormones. It has copper, and can last up to 10 years. This IUD is also the very best to keep you from getting pregnant if you have had sex within the last 5 days without using contraception. If **1,000 women** had sex without using contraception and had a copper IUD put in, only **1** would get pregnant that month. With this IUD you'll have regular periods but they might be slightly heavier.

2.



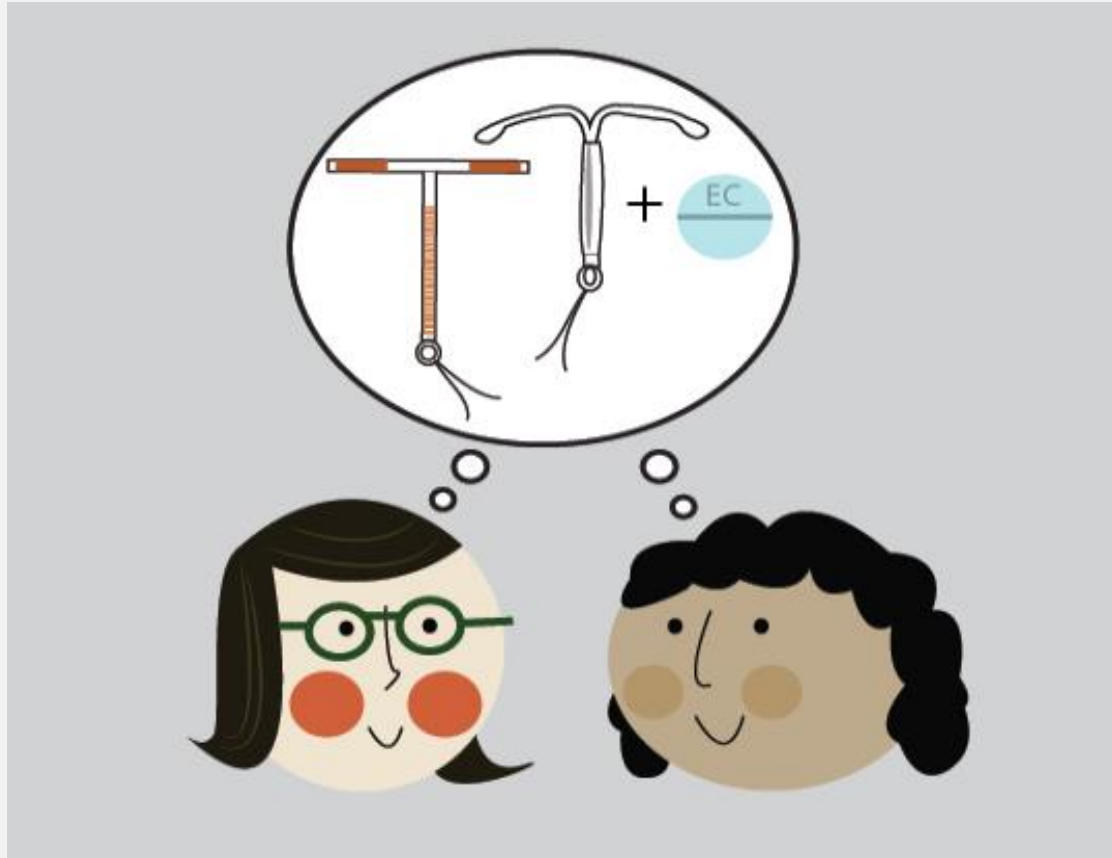
The other IUD is the Mirena. This IUD has a hormone in it (progestin) and lasts up to 5 years. In the first 3-6 months bleeding can be irregular and after that you'll have less bleeding during your period or you may not have a period at all. We do not know if this IUD works to prevent pregnancy **as Emergency Contraception**; so women coming here for EC would start this IUD with the Morning After Pill called Plan B one step. The pills work well; if 1,000 women have sex and take Plan B, about 20 will get pregnant that month.

# Results

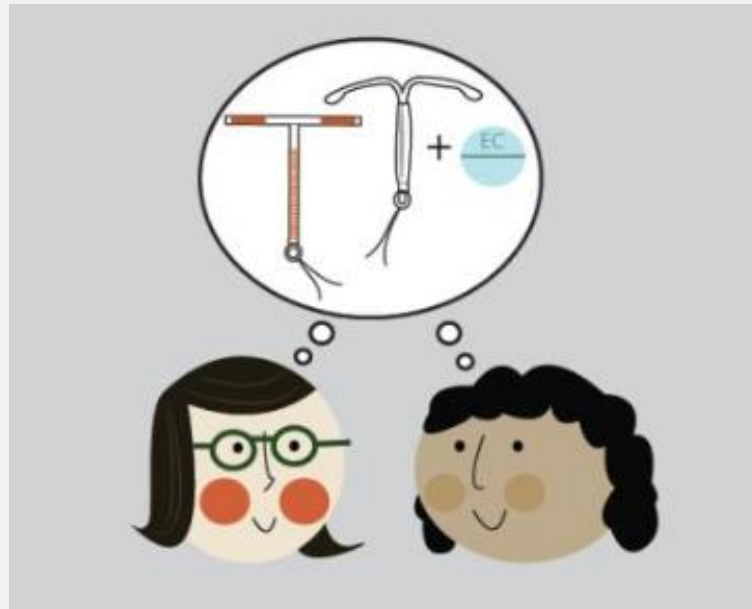


n= 1,004

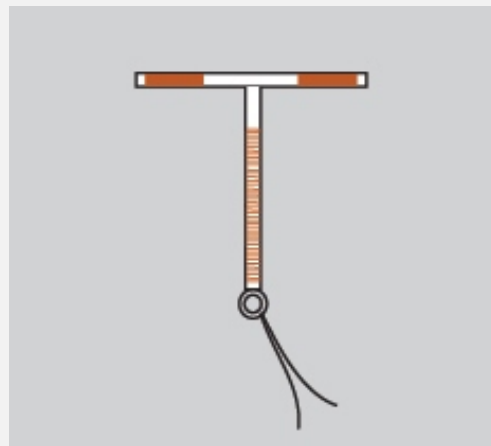




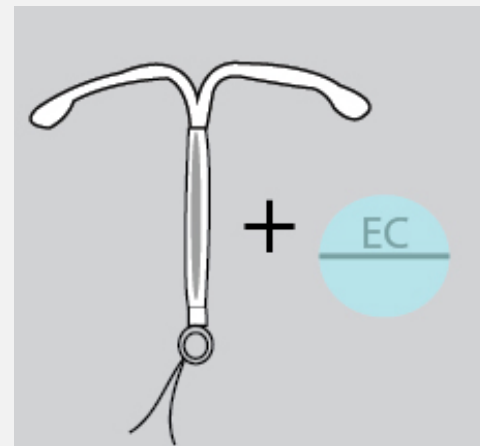
n= 188  
(18%)



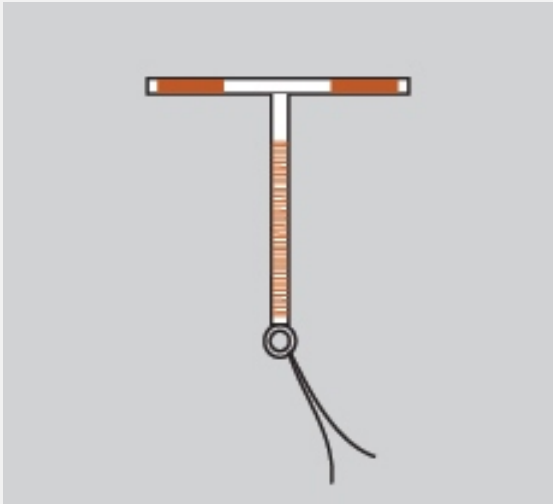
n= 188 (18%)



n= 67 (36%)



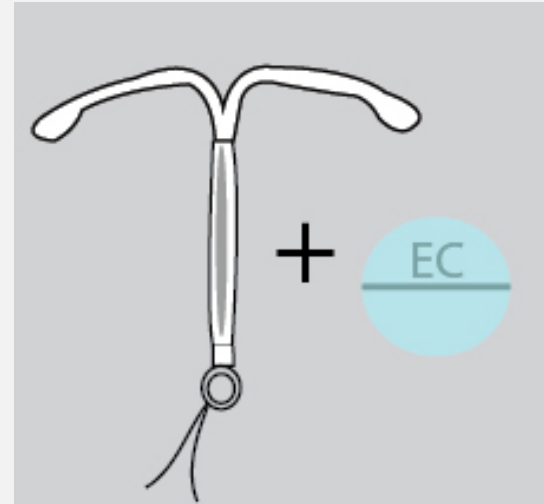
n=121 (64%)



n= 67 (36%)



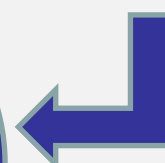
n= 66



n=121 (64%)



n= 110

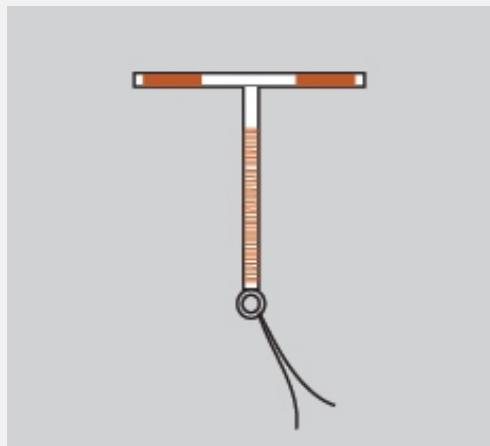
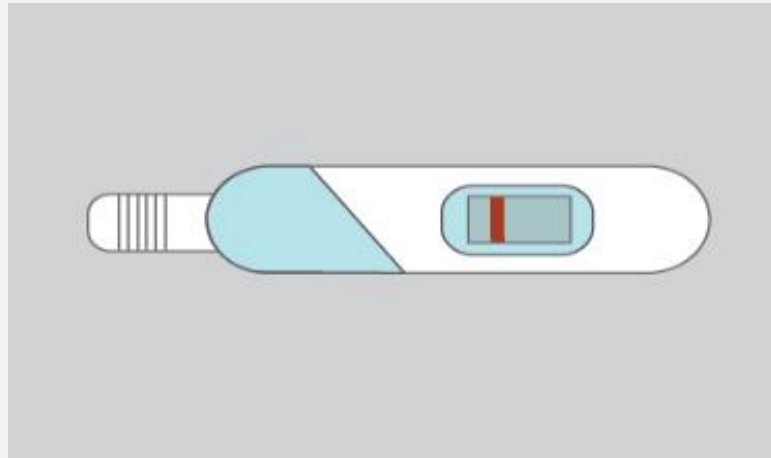


Failed  
IUD  
Insertions  
6%

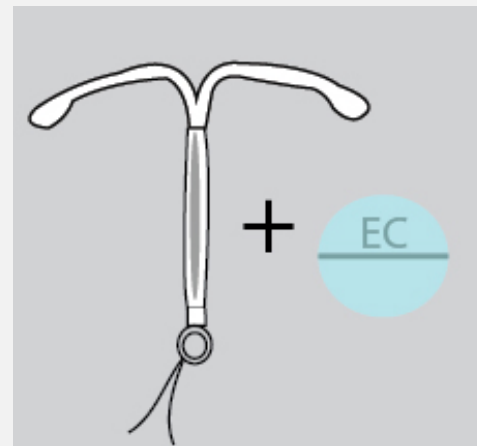
## IUD EC user Characteristics (n=176)

	Cu IUD (n=66)	LNG IUD + (n=110)	P- Value
Age 20-24	31 (48%)	55 (50%)	0.67
BMI 25-<30 kg/m <sup>2</sup>	15 (24%)	43 (41%)	.015
BMI ≥30 kg/m <sup>2</sup>	10 (16%)	25 (24%)	
White race	38 (58%)	67 (62%)	0.56
Latina	19 (29%)	33 (31%)	
Nulligravid	34 (52%)	49 (45%)	0.37
No insurance	36 (56%)	61 (56%)	0.97
>1 episode of UPI in last 2 weeks	34 (51%)	51 (40%)	0.10

## 2 Weeks



n= 63 (95%)



n=105 (95%)

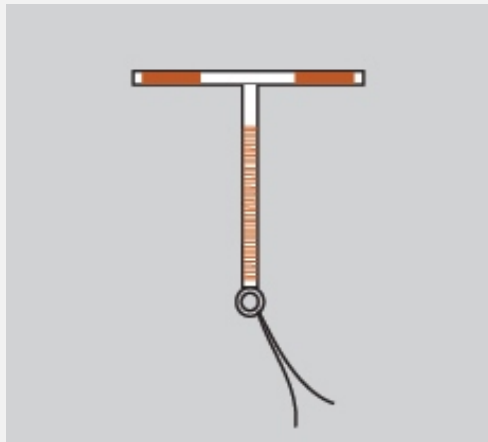
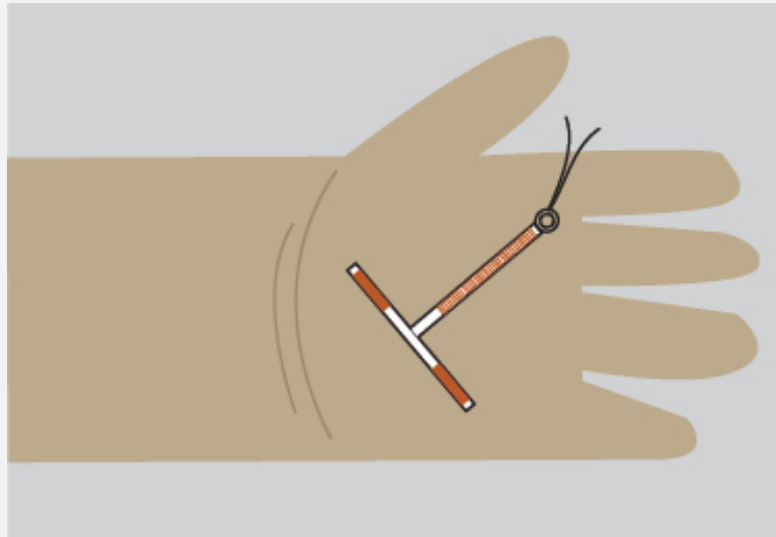
# No EC Failures

## 1 Luteal Phase Pregnancy

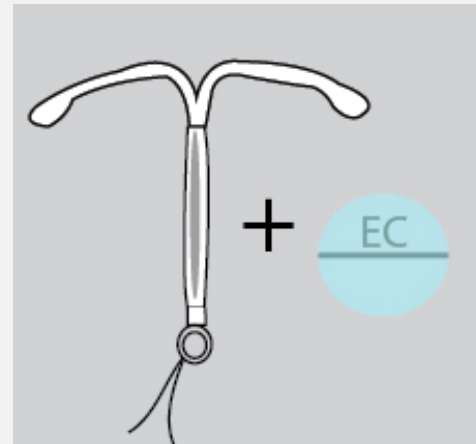
- In the LNG IUD and oral LNG group
- #1 + UCG 2 weeks post-insertion
  - Used oral EC 3 times previously that month
  - IUD inserted on day 28 of 30 day cycle
  - Luteal phase pregnancy



# 1 Year

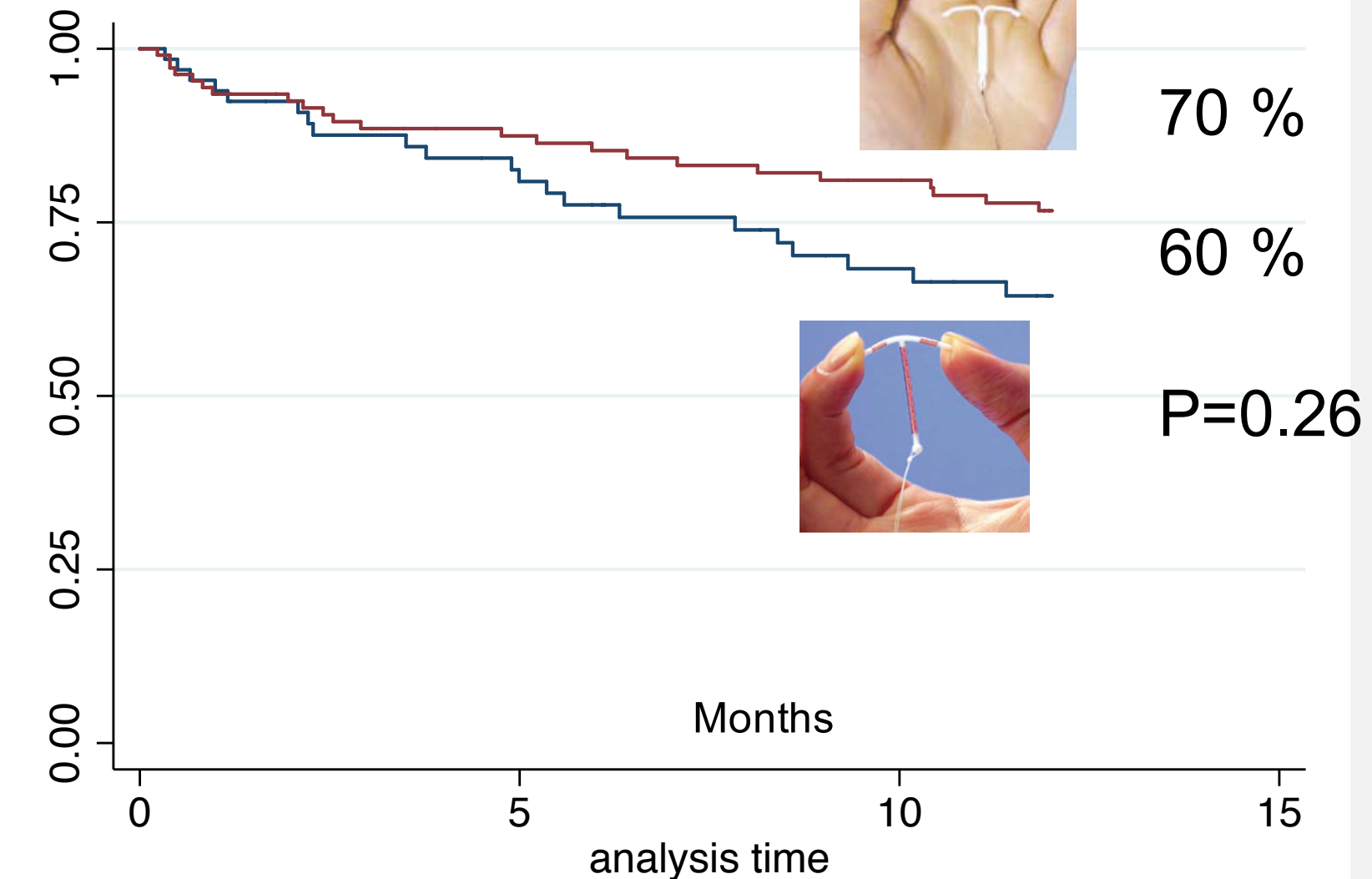


n= 53 (80%)



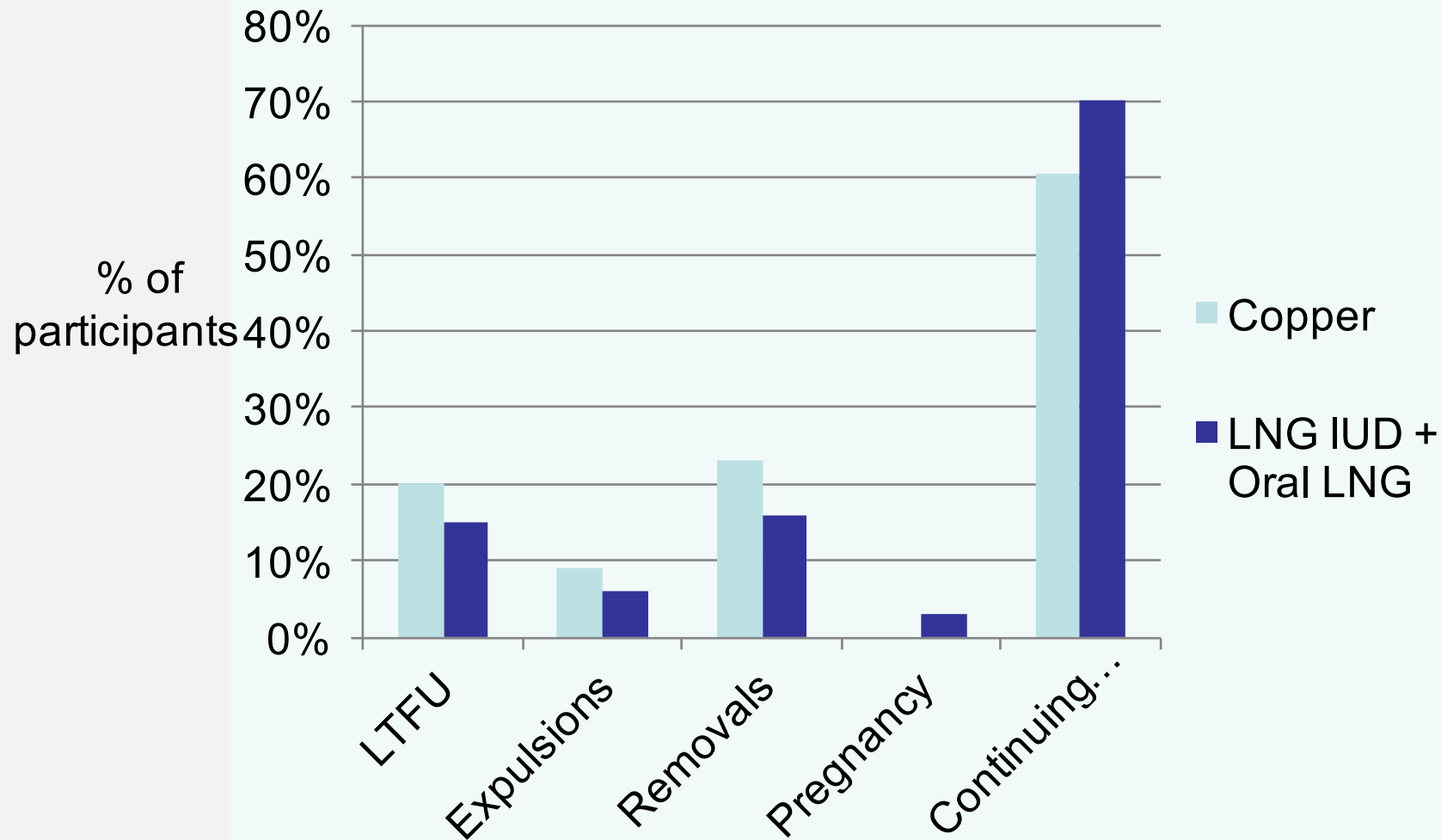
n=94 (85%)

# 1 year IUD continuation by IUD type



Unpublished Data

# 12 Month Outcomes



Unpublished Data

# 12 Months: 3 Pregnancies

- All in the LNG IUD and oral LNG group
- #1 + UCG 2 weeks post-insertion
  - Used oral EC 3 times previously that month
  - IUD inserted on day 28 of 30 day cycle
  - Luteal phase pregnancy
- #2 +UCG 10 weeks post-insertion
  - Unrecognized expulsion
- #3 + UCG 7 months post-insertion
  - IUD failure

# EC: Is it just once? NO!

- N= 176
- 76 (43%) reported multiple UPI in the last 14 days
- 1 UPI episode - 0 pregs of 97 (0%; 95% CI, 0-3.7%)
- Multiple UPI - 1 preg of 75 (1.3%; 95 CI, 0-7.2%)
- Including 1 of 40 (2.5%; 95% CI, 0-13.2%) UPI 6-14 days prior to IUD insertion

# Next up: RAPID EC

- **RCT Assessing Pregnancy with IUDs (RAPID) for EC**
- Women interested in the an IUD for EC
- Randomly assigned to copper or LNG IUD
- Primary outcome: non-inferiority pregnancy at 4 weeks
- Secondary outcome: IUD continuation continuation
- Recruitment goal = 706





### **3) 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



Could this be Simpler?

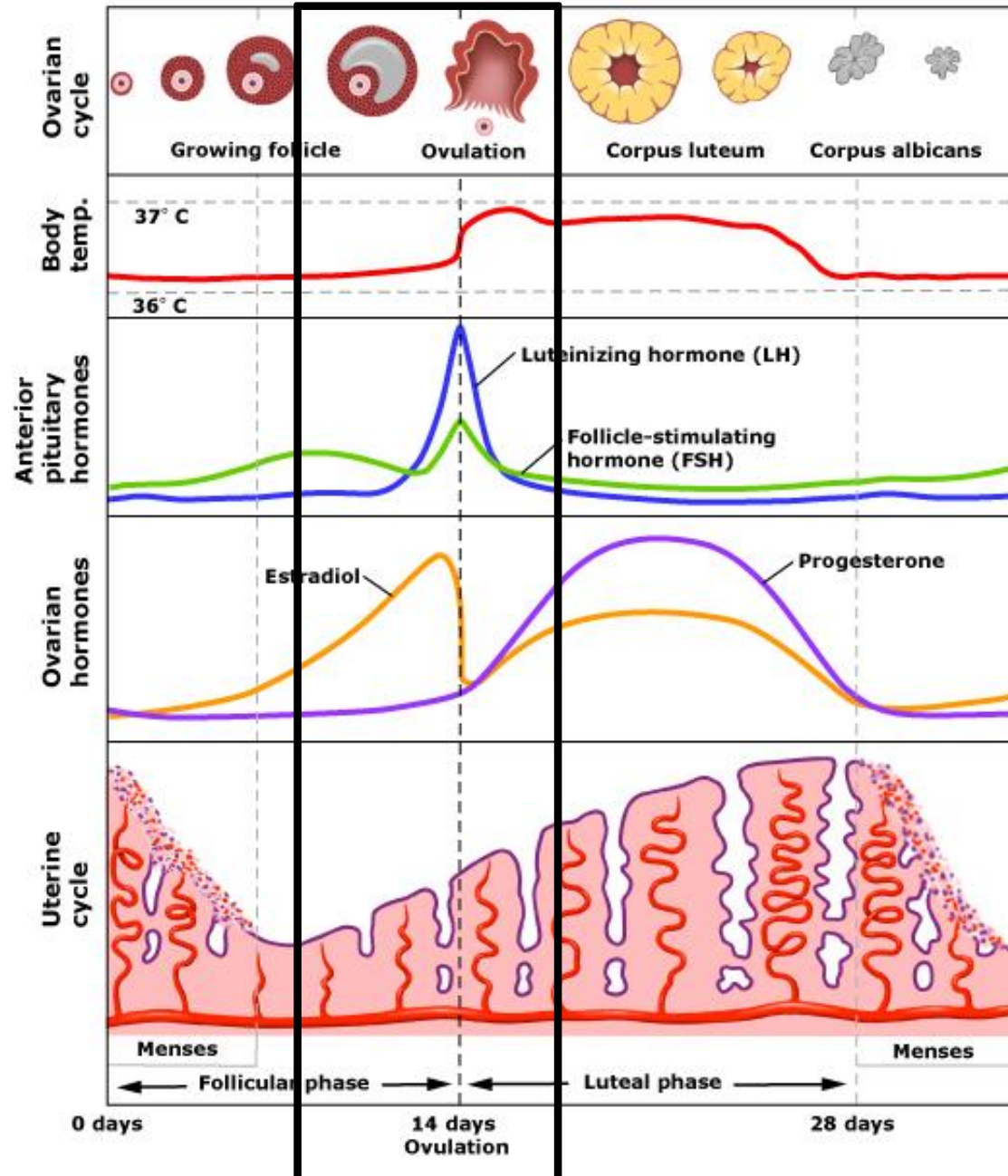


Let's go back to the  
beginning...

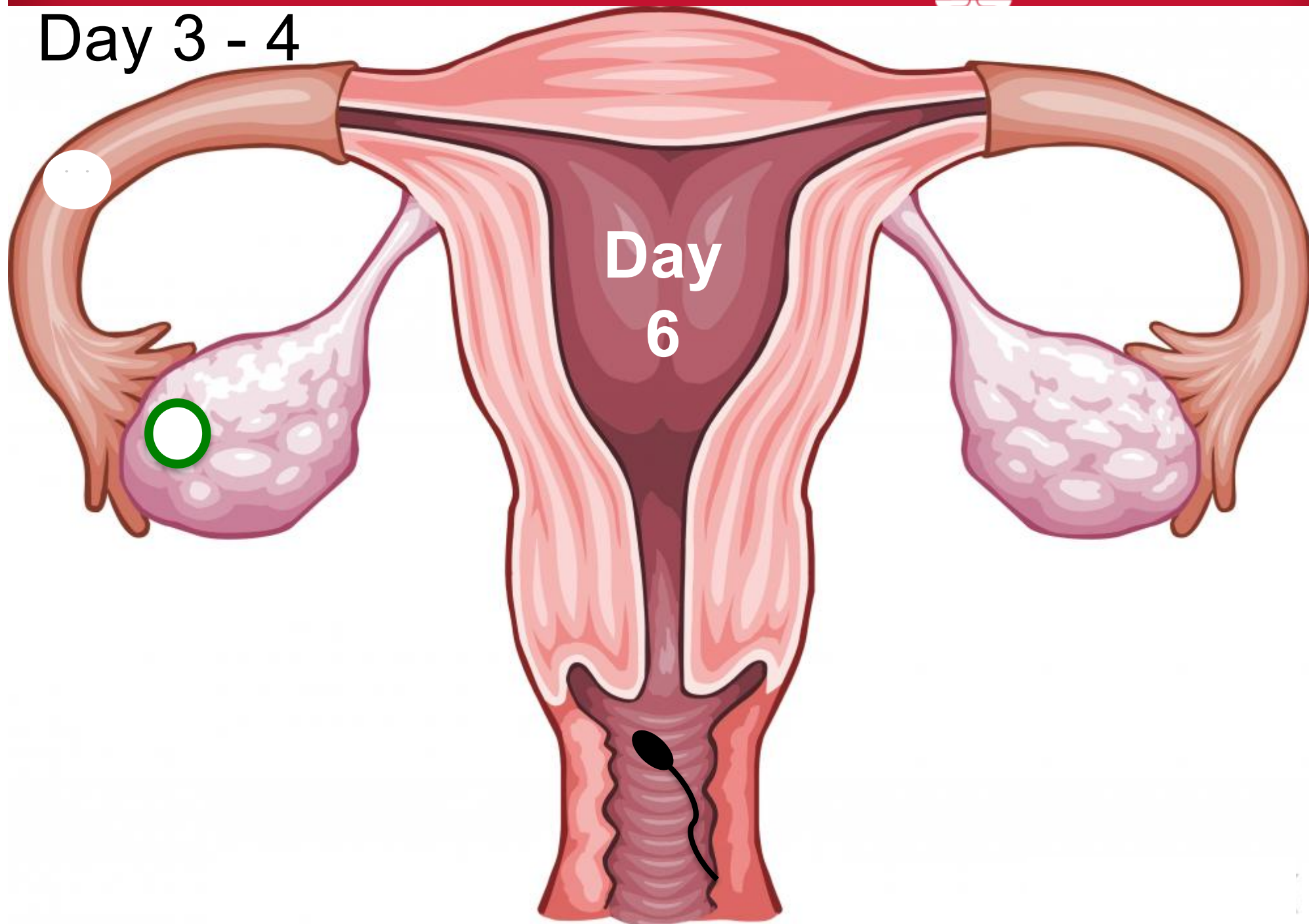
Fertilization



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



Day 3 - 4



Day  
6



# 1963 Copper T380 IUD EC Users

- 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)



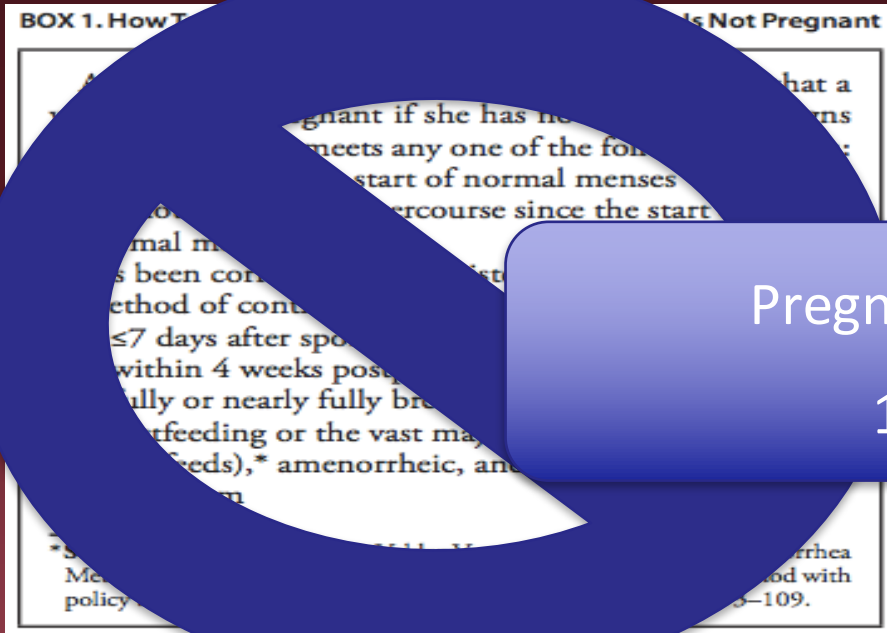


## Secondary Analysis

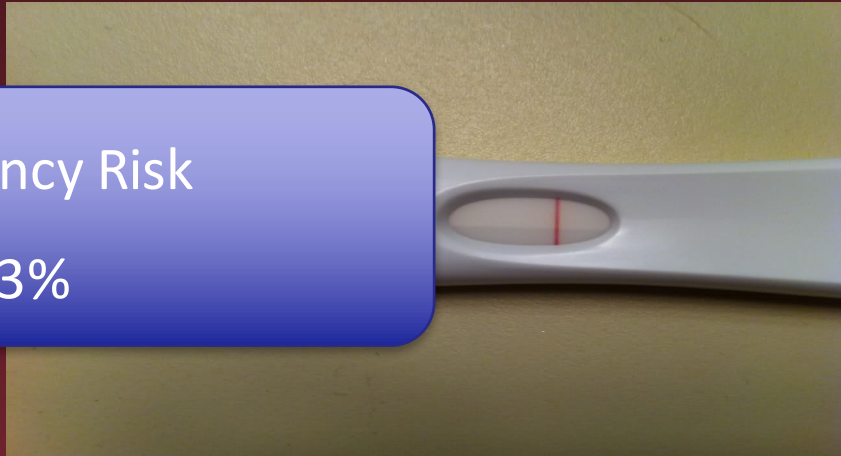
- **No pregnancies**
- 1840 participants (93.7%) had usual cycle lengths of 25-35 days
- 850 (46.2%) UPI in the fertile window
- 84 (4.6%) had IUD insertion > 5 days after ovulation
- 52 (2.7%) had insertion > 5 days after UPI



# Evidence



Pregnancy Risk  
1.3%





# Expanding the EC Window

- 62 Copper IUD users
  - with UPI 6-14 days prior to presenting
  - No pregnancies
- 72 LNG IUD users
  - with UPI 6-14 days prior to presenting
  - 1 pregnancy
- Etonorgestrel implant?



# Conclusions

- 1) Copper IUD EC users have lower pregnancy rates for the next year
- 2) Consider the LNG IUD with EC
- 3) Expanding the limits of use- copper IUD EC



# Questions



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# Gratitude

- Planned Parenthood Association of Utah
- Kathy Burke & Penny Davies
- University of Utah OGRN
- Jessica Sanders
- Holly Bullock & Utah Fam Plan Fellows
- Bimla Schwarz & external collaborators