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

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

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

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 ≤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 ≤7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeding),* amenorrheic, and <6 months postpartum

“...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).”
This is All About Avoiding Luteal Phase Pregnancy

How many people have to wait to start their contraceptive method so that we avoid one?
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\textsuperscript{nd} pill pack
- 115/156 (74%) of those starting later began the 2\textsuperscript{nd} pill pack
- \textbf{Getting to the 2\textsuperscript{nd} 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 injection
- 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**

**BOX 1. How To Be Sure Your Partner Is Not Pregnant**

A pregnancy test is a simple test that a woman can do at home. It is based on the hormone that is present in the urine of a pregnant woman. The presence of this hormone indicates that a woman is pregnant. The test can be done at any time after a woman has missed at least two weeks of menstruation. The test is usually done in the morning when the urine is most concentrated.

**Luteal phase pregnancy N=36**

<table>
<thead>
<tr>
<th>Results of Pregnancy Checklist</th>
<th>Pregnant</th>
<th>Not Pregnant</th>
<th>Total (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Pregnancy Not Excluded”</td>
<td>28</td>
<td>2,130</td>
<td>2,158</td>
</tr>
<tr>
<td>“Pregnancy Excluded”</td>
<td>8</td>
<td>4,763</td>
<td>4,771</td>
</tr>
<tr>
<td>Total</td>
<td>36</td>
<td>6,893</td>
<td>6,929</td>
</tr>
</tbody>
</table>

- Sensitivity = 0.78
- Specificity = 0.69
- Positive predictive value = 0.013
- Negative predictive value = 0.998

**Pregnancy Risk 1.3%**

Min, Contraception 2015;91(1):80–84
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%)

<table>
<thead>
<tr>
<th>Pregnancy Checklist</th>
<th>Pregnant</th>
<th>Not Pregnant</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy NOT Excluded</td>
<td>10</td>
<td>1056</td>
<td>1066</td>
</tr>
<tr>
<td>Pregnancy Excluded</td>
<td>2</td>
<td>658</td>
<td>660</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>1714</td>
<td>1726</td>
</tr>
</tbody>
</table>

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)

Gawron et al., AJOG 2010;82:491-96
Sanders et al., AJPH 2018;108(4):550-556
If We Start With IUDs For EC
The Pregnancy Checklist Looks Too Restrictive

- Copper IUD EC Systematic Review:
  - 7,034 women ≤ 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
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

Distribution of Days Since Last Menstrual Period to Insertion

Days Since Last Menstrual Period to Insertion

Percent

Human Reproduction 2013; 28(10):2672-6
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

- University of Utah HER Salt Lake study*  
  n=39
- University of Utah RAPID EC study*  
  n=27
- University of Utah COLIEC study*  
  n=19
- University of Utah Shared Protocol  
  n=22
- Pittsburgh Shared Protocol  
  n=14
- Minnesota Shared Protocol  
  n=13

Cu IUD placed 6-14 days after UPI with neg UPT  
(n=39)

Cu IUD placed 6-14 days after UPI with neg UPT  
(n=27)

Cu IUD placed 6-14 days after UPI with neg UPT  
(n=68)

Completed serial phone or electronic follow up at:  
1 month (n=35)**  
3 months (n=35)**  
6 months (n=35)**

Completed 4 week UPT  
(n=27)

Completed 2 week UPT  
(n=68)

95 completed UPTs 2-4 weeks after IUD insert

134 negative pregnancy assessments (0%, 97.5% CI 2.7%)

Thompson, Contraception 2019; 100(3):219-221
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.
Methods & Interventions

- Participant-blinded non-inferiority RCT
- August 2016 – December 2019 @ 6 PPAU sites
- ≥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 = 356

\[\text{Did not receive Tx} \quad 8\%\]

n = 328

n = 327

n = 355
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=311
Per-protocol analysis (n=311)
Urine pregnancy test (n=300)
Clinical & survey data (n=21)

n=321

n=305
Urine pregnancy test (n=290)
Clinical & survey data (n=27)
RESULTS - NONINFERIORITY

<table>
<thead>
<tr>
<th>Analysis Approach</th>
<th>Pregnancy Incidence Copper vs LNG</th>
<th>Incidence Difference (LNG minus Copper) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Modified intention-to-treat</td>
<td>0/321 vs 1/317</td>
<td>0.3% (-0.9% to 1.8%)</td>
</tr>
<tr>
<td>(2) Per Protocol</td>
<td>0/311 vs 1/305</td>
<td>0.3% (-0.9% to 1.8%)</td>
</tr>
<tr>
<td>(3) Sensitivity Analysis</td>
<td>0/300 vs 1/290</td>
<td>0.3% (-0.9% to 1.9%)</td>
</tr>
</tbody>
</table>

Note: LNG Better vs Copper Better
<table>
<thead>
<tr>
<th>Outcome</th>
<th>CuT380A IUD N=328</th>
<th>LNG 52 mg IUD N=327</th>
</tr>
</thead>
<tbody>
<tr>
<td>IUD removals</td>
<td>8 (2.5%)</td>
<td>10 (3.1%)</td>
</tr>
<tr>
<td>IUD expulsions</td>
<td>3 (0.9%)</td>
<td>2 (0.6%)</td>
</tr>
<tr>
<td>Cramping since insert</td>
<td>$66.6 \pm 1.8$</td>
<td>$59.5 \pm 1.9$</td>
</tr>
<tr>
<td>Sharp pain since insert</td>
<td>$72.5 \pm 1.3$</td>
<td>$66.6 \pm 1.4$</td>
</tr>
<tr>
<td># Bleeding days</td>
<td>$7.2 \pm 0.3$</td>
<td>$10.8 \pm 0.5$</td>
</tr>
<tr>
<td># Spotting days</td>
<td>$5.7 \pm 0.3$</td>
<td>$11.0 \pm 0.6$</td>
</tr>
</tbody>
</table>
### SECONDARY OUTCOMES

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

<table>
<thead>
<tr>
<th>EC Method</th>
<th>Ongoing Contraception</th>
</tr>
</thead>
<tbody>
<tr>
<td>Copper IUD</td>
<td>Easy, ready to go</td>
</tr>
<tr>
<td>Oral LNG</td>
<td>Start, Abstain or backup x 1 week</td>
</tr>
<tr>
<td>UPA</td>
<td>Hold hormones for 5 days</td>
</tr>
</tbody>
</table>

Approach to selection of emergency contraception after unprotected intercourse

1. Perform pregnancy test (home or clinic).
2. If patient presenting within 72 hours of unprotected intercourse:
   - Single dose of levonorgestrel 1.5 mg (Plan B One-Step™)
3. If pregnancy test is positive:
   - Counsel patient on options for continuation of pregnancy.

EC Method Ongoing Contraception

- Copper IUD
- Oral LNG
- UPA

For more information, visit UpToDate® 2021.
Desires IUD?

- Insert IUD
- Assess risk of pregnancy

High Risk:
- multiple &/or mid-cycle UPI

Low Risk:
- UPI outside fertile window, contraception failure

Offer UPA*
- Use back up. Delay hormonal contraception for 5 days
Prefers more effective EC or ongoing contraception?

More effective EC

Offer UPA*
Delay hormonal contraception for 5 days, continue abstain/backup x 1 week (12 days total)

Ongoing hormonal contraception

Offer LNG
Start hormonal contraception today, continue abstain/backup x 1 week
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