

National Reproductive Health Conference  
August 4, 2014, Orlando, FL

## Emergency Contraception (EC): Challenges and Choices



Michael Policar, MD, MPH  
Professor of Ob, Gyn, and Repro Sciences  
UCSF School of Medicine  
[policarm@obgyn.ucsf.edu](mailto:policarm@obgyn.ucsf.edu)

### Outline

- What's available for EC?
- Strategies for individual women
  - Time frame after unprotected intercourse
  - Efficacy determinants, especially body weight
  - Other clinical considerations
- Population based strategies
  - Advance provision of ECPs
- Administration and counseling
- Conclusion

- There are no relevant financial relationships with any commercial interests to disclose

### ECP Use Characteristics NSFG 2006-10

- 11% of women had ever used ECPs (from 4.2% in 2002)
  - 23% of women 20-24 years old
- Relationship status...ever use of ECPs
  - 19% of never-married women
  - 14% of cohabiting women
  - 6% of currently or formerly married women
- Reason for ECP use
  - 49% unprotected intercourse
  - 45% fear of method failure
    - More likely if college degree, non-Hispanic white

### Objectives

- Describe common considerations when recommending, prescribing and/or providing emergency postcoital contraception
- Analyze advantages & disadvantages for recommending, prescribing and/or providing a particular type of emergency postcoital contraception for selected women

### Copper IUC (Cu-IUC) as EC

- Efficacy: failure rate is 0.1%
- Can be inserted up to **5 days** after ovulation
  - Implantation occurs 6-12 days following ovulation
  - If a woman had UPI\* 3 days before ovulation, the IUD could prevent pregnancy if inserted up to 8 days afterward
  - Because of the difficulty in determining the day of ovulation, protocols allow insertion  $\leq 5$  days after UPI
- LNG-IUS has not been studied; not recommended for EC

UPI\*: unprotected intercourse

## Types of EC Pills (ECPs)

- **Combined ECPs** (estrogen and progestin)
  - The “Yuzpe” Regimen: Ovral 2+2, or equivalent
  - High rate of nausea and vomiting
  - 56-89% effective
- **Progestin-only ECPs**
  - Have largely replaced older combined ECPs because it is more effective and has fewer side effects
  - LNg is 52-100% effective
- **Antiprogesterin** (ulipristal acetate or mifepristone) ECPs
  - UPA is 62-85% effective

## Ulipristal Acetate (UPA): ella®

Glasier AF, Lancet 2010;375:555

- Comparative trial of UPA 30 mg vs LNg 1.5 mg
  - 1,696 women used with 72 hours of intercourse
    - Failure rates: UPA 1.8% vs. LNg 2.6% (OR=0.68)
  - 203 women used with 72-120 hours of intercourse
    - Failures: UPA- none vs. LNg- 3 pregnancies
  - Headache: UPA=19%, LNg=19%
- **Conclusion**
  - UPA is “not inferior” to LNg
  - UPA is effective for up to 5 days after exposure

## Levonorgestrel ECPs

- **Plan B® One-Step** (Teva)
  - Single dose tablet ; 1.5 mg levonorgestrel (LNg)
  - Plan B (2 tablet product) is no longer available
- **Next Choice®** (generic/ Watson Pharma)
  - Labeling: One 0.75 mg LNg tablet every 12 hours
  - Off label: 2 tablets at once
  - Same as the (old) two tablet Plan B® product
  - **Next Choice One Dose®** (generic 1.5 mg LNg)
- All are labeled for use up to 72 hours from last UPI, but studies support use for up to 5 days from UPI

## LNg EC Failure and Body Weight

- Compared with women of normal weight (BMI <25)
  - Overweight women (BMI 25–30) had a risk of pregnancy 1.5 times greater
  - Obese women (BMI ≥30) had a risk of pregnancy more 3-4 times greater

### Why?

- Two recent have demonstrated that OC hormone absorption is slower in obese women than it is in women of normal weight

Rapkin RB, Creinin M, OBG Management 2011; 23(8): 16-24

## Ulipristal Acetate (UPA): ella®

- Approved for up to 5 days (120 hours) after UPI
- Taken orally in single 30 mg dose
- Mechanism of action
  - Prevents ovulation, with follicles up to 18-20 mm
  - Inhibits implantation, but higher dose required
- Failure rate vs. LNg (meta-analysis 0-120 hours after last sex)
  - UPA 1.3% vs. LNg 2.2%; odds ratio = 0.55 (0.32-0.93)
- If initiating OCs after use, condoms advised for 1-2 weeks
- No data regarding secretion in breast milk; effect on newborn

## Obesity and EC Effectiveness

- If overweight (BMI 25-30)
  - With LNg =2.5% (i.e. half as good)
  - With UPA=1.1%
- If obese (BMI>30)...or weigh >150 lbs
  - With LNg=5.8% (approaches NO EFFECT)
  - With UPA=2.6% (half as good)

Glasier A et al Contraception 2011

## The Limits Of Efficacy Of EC Pills

- For LNG: Weight=70 kg (154 lb)
- For UPA: Weight=88 kg (194 lb)

*On average,  
American women now weigh 166 lbs...*

Glasier A et al Contraception 2011

## Summary: Choice of ECP Product

- **Time interval since UPI**
  - < 72 hours: products have equal efficacy
  - 72-120 hours: UPA preferred
- **Body weight (BMI)**
  - $\leq 25 \text{ kg/m}^2$  : products have equal efficacy
  - $\geq 25 \text{ kg/m}^2$  : UPA preferred
- **Availability:** LNG products stocked more widely; OTC
- **Price:** UPA 20% more expensive, but more cost effective, given greater efficacy

Patient asks for EC

Counsel for Cu- IUC

What is her BMI?

$\leq 25$

Oral EC options acceptable

26-29

Counsel that LNG may be ineffective

30-34

Oral EC failure rate 4x higher. LNG ineffective

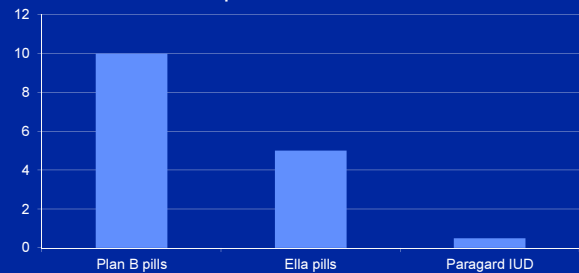
$\geq 35$

Counsel that UPA likely is ineffective, but can use if refuses Cu-IUC

Rapkin RB, Creinin M, OBG Management 2011; 23(8): 16-24

## Relative Effectiveness Of EC Options

Pregnancies expected per 1000 women who had unprotected sex in the last week



## ISSUE: Prevalence of Obesity

- Among US women aged 20-40 years
- 56% are overweight (BMI >25)
  - 74% of Black women
- 32% obese (BMI>30)
  - 56% of Black women

Flegal KM et al JAMA 2012

## What Effect Does Advance Provision Of EC Have On Clinical Outcomes?

- **The good news**
  - Increases actual EC usage with no decrease in the ongoing use of effective contraception or an increase in sexually transmitted infection rates
- **The disappointing news**
  - In a large meta-analysis, advance provision of EC does not reduce overall pregnancy rates when compared to conventional EC provision

## Advance Provision of EC: *The Hope*

- Widespread use of ECPs could prevent HALF of all unintended pregnancies and abortions in the US each year  
–Trussell, Stewart et al. 1992

Trussell et al. Fam Plann Perspect 1992

## The Fifteen Studies

- Conducted 1998-2011
- 14 randomized trials, 1 cohort study
  - Total of 12,804 women enrolled
- 1 demonstration project
  - >17,831 women given ECPs
- Followed women up to one year
- Compared increased access to standard access

## 20 Years Later – *The Reality*

- Fifteen studies have examined the impact of increased access to ECPs on pregnancy and abortion rates
- Only one has shown any benefit

Raymond et al. Obstet Gynecol 2007;  
Polis et al. Cochrane Rev 2010;  
Shaaban et al. Contraception, in press

## Fourteen Studies, No Benefit

1. Flaws in studies
  - But consistency between studies is compelling
2. Increased risk taking (reduced use of contraception)
  - Evidence mostly against
3. Low ECP efficacy
  - Precise efficacy unknown
4. Insufficient use
  - Definitely a problem: use is too late or not at all

Trussell J, Schwarz EB, *Contraceptive Technology*, Ch 6, 20<sup>th</sup> Revised Ed, 2011

## Selected Studies: EC Advance Provision

	N	Regimen	Intervention	Control
Glasier	1083	Yuzpe	5%	6%
Lo	1030	LNg	1%	2%
Hu	2000	Mifepristone	4%	3%
Raine	1228	LNg	8%	9%
Raymond	1490	LNg	9%	10%
Shaaban	1158	LNg	0.8%	5%

## Advance Provision of ECPs



- An advance supply of ECPs may be provided so that ECPs will be available when needed and can be taken as soon as possible after unprotected sexual intercourse
- Any use of ECPs was two to seven times greater among women who received an advance supply of ECPs
- A summary estimate (relative risk = 0.97; 95% CI = 0.77–1.22) of five RCTs did not indicate a significant reduction in unintended pregnancies at 12 months

## Emergency Contraception Q and A

### Management of Clients in Office Setting?

- Health history or exam are unnecessary
  - The only contraindication to EC is a known pregnancy
  - A history of MI, angina, stroke, VTE, migraine, and severe liver disease are listed as US-MEC 2
- Pregnancy test only if  $\geq 10$  days from the date of UPI
- Provide contraceptive counseling
  - EC is not recommended as a sole method
  - Do not have intercourse until another method started
  - If your menses doesn't start in 3 weeks, see your clinician

### Does The Use Of EC Cause Abortion?

- EC does not cause an abortion because it works before implantation occurs
- If a woman already is pregnant, EC will not cause a miscarriage or birth defects
- By preventing pregnancy, EC reduces the need for induced abortion

### What Are The Specific Indications For EC?

- When requested within 5 days of an episode(s) of UPI
- As a component of a "quick start" regimen, if a woman has had UPI in the past five days

### Are There Any Women Who Should Not Be Given EC?



- The US Medical Eligibility Criteria (US-MEC) states that the only contraindication to ECPs is a known pregnancy
- A history of heart attack, angina, stroke, thromboembolic conditions, migraine, and severe liver disease are listed as US-MEC Category 2

### When Should EC Use Be Considered By A Woman Already Using Contraception?

- Women who have had intercourse in the past 5 days should use a barrier back-up for the next 7 days **and consider the use of EC**
  - When a woman misses 1 or more days of OCs in week one or 3 or more days in week two or three of cyclic OC use
  - After removal of the ring for 3 or more hours in week one or longer than 72 hours in week two or three
  - After detachment of the patch for 24 hours or longer in week one or longer than 72 hours in week two or three
  - When progestin-only pill-taking is delayed for longer than 3 hours OR after missing 1 or more POP

## Initiation of Contraception After Use of ECPs



- **UPA**
  - Any contraceptive method can be started immediately
  - Abstain from UPI or use barrier contraception for 14 days or until her next menses, whichever comes first
- **Levonorgestrel and Combined OC ECPs**
  - Any contraceptive method can be started immediately
  - Abstain from UPI or use barrier contraception for 7 days
- Advise the woman to have a pregnancy test if she does not have a withdrawal bleed within 3 weeks

## What Are the Age Restrictions Regarding The Use Of ECP?

- UPA requires a prescription at all ages
- Plan B One Step (only) can be sold to women and men of any age
- Other ECPs can be obtained without a prescription by women and men  $\geq 15$  years of age at most pharmacies
  - Remind clients that proof of age will be requested
  - Minors have the legal right to self-consent for pregnancy-related services, including the use of EC

## Vomiting < 3 Hours of Taking ECPs?



- Another dose of ECP should be taken asap
- Use of an antiemetic should be considered
- **Comments and Evidence Summary**
  - Routine antiemetic use is not recommended
  - Women taking E+P ECPs are more likely to experience nausea and vomiting than LNG or UPA ECPs
  - Antiemetics reduce the occurrence of nausea and vomiting in women taking E+P ECPs;

## EC Case Study #1

- A 25 year old student is seen with a request for EC because a condom broke during intercourse 2 days ago
- She is not currently in a relationship, but occasionally “hooks up” with a limited number of classmates
- She relies on condoms, but breakage occurs on occasion
- Her past medical history is unremarkable
- Her stated weight is 175 pounds and she is 5’ 8” tall
- She is counseled regarding copper IUC insertion and ECPs

## Vomiting < 3 Hours of Taking ECPs?



- LNG is associated with significantly less nausea than a nonstandard dose of UPA (50 mg) and the E+P regimen
- Two trials of anti-nausea drugs, meclizine and metoclopramide, taken before E+P ECPs, reduced the severity of nausea

## EC Case Study #1

- If she is not interested in IUC insertion, which product will you recommend to her?
- Given her sexual history, what STI screening tests would you recommend?
- How would you code this visit?

		Weight in Pounds															
		120	130	140	150	160	170	180	190	200	210	220	230	240	250		
29	31	34	36	39	41	43	46	48	51	53	56	58	60				
27	29	31	34	36	38	40	43	45	47	49	52	54	56				
25	27	29	31	34	36	38	40	42	44	46	48	50	52				
23	25	27	29	31	33	35	37	39	41	43	45	47	49				
22	24	26	27	29	31	33	35	37	38	40	42	44	46				
21	22	24	26	28	29	31	33	34	36	38	40	41	43				
19	21	23	24	26	27	29	31	32	34	36	37	39	40				
18	20	21	23	24	26	27	29	30	32	34	35	37	38				
17	19	20	22	23	24	26	27	29	30	32	33	35	36				
16	18	19	20	22	23	24	26	27	28	30	31	33	34				
15	17	18	19	21	22	23	24	26	27	28	30	31	32				
15	16	17	18	20	21	22	23	24	26	27	28	29	30				
14	15	16	17	19	20	21	22	23	24	25	27	28	29				
13	14	15	17	18	19	20	21	22	23	24	25	26	28				
		Underweight Healthy Weight Overweight Obese															

## Women's BMI Table

### ACOG on CPT + E/M Visit

- If clinician and patient discuss a number of contraceptive options, decide on a method, and then an implant or IUD is inserted during the visit, an E/M service may be reported, depending on the documentation
- If the patient comes into the office and states, "I want an IUD," followed by a brief discussion of the benefits and risks and the insertion, an E/M service is not reported
- If the patient comes in for another reason and, during the same visit, a procedure is performed, then both the E/M services code and procedure may be reported

ACOG; LARC Quick Coding Guide

### EC Case Study #1

- If she is not interested in IUC insertion, which product will you recommend to her?
  - BMI: 27, therefore UPA preferred
- Given her sexual history, what STI screening tests would you recommend?
  - Gonorrhea, chlamydia, and HIV
  - Syphilis test, depending on local prevalence
- How would you code this visit?
  - 9921x, based on time
  - V25.03 Encounter for EC counseling and prescription

### ACOG on CPT + E/M Visit

- If reporting both an E/M service and a procedure, the documentation must indicate a significant, separately identifiable E/M service. Documentation must indicate either the key components or time spent counseling
- Modifier 25 (significant, separately identifiable E/M service on the same day as a procedure or other service) is added to the E/M code.
  - This indicates that two distinct services were provided: an E/M service and a procedure

ACOG; LARC Quick Coding Guide

### EC Case Study 2

- Mr. L is 29 year-old established client who presents with concerns about STI and wants to be tested
- Two episodes of UPI; one last night and one 4 days ago
- EC + contraceptive counseling (15 minutes)
- Offered ECP or IUC: requested insertion of copper IUC
- Office urine pregnancy test negative
- Samples sent for GC/CT NAAT, HIV serology
- Bimanual exam performed; IUC then inserted easily

### ACOG on Ultrasound with IUD Insertion

- An ultrasound to check IUD placement is not bundled into the IUD insertion (code 58300), and it is not common practice to use ultrasound to confirm placement. This should not be billed.
- Ultrasonography may be used to confirm the location when the clinician incurs a difficult IUD placement (e.g., severe pain)
  - Code 76857 Ultrasound, pelvic, limited or follow-up, or
  - Code 76830 Ultrasound, transvaginal
- Occasionally, ultrasound is needed to guide IUD insertion. Code 76998 (Ultrasonic guidance, intraoperative)

ACOG; LARC Quick Coding Guide

### Case Study 2: Answer

	CPT/ HCPCS II Code	ICD-CM Code
Procedure	58300 Insert IUD	V25.11 Insertion of IUC
Supply	none	
Drug	J7300 Intrauterine copper contraceptive	V25.11 Insertion of IUC
Lab	81025 UPT	V72.41 Preg exam or test, negative
E/M	99213	V 25.09 Other FP advice
Modifier	99213-25	

- -25 indicates that a significant and separately identifiable E/M was provided on the same date of service as a procedure

### EC Summary: Take it Home

- ECPs are a “last chance” to prevent pregnancy
  - UPA is preferred for exposure  $\geq 72$  hours ago and for women who have a BMI  $>25$  kg/m<sup>2</sup>
  - LNG and UPA probably equivalent in other cases
  - “The earlier the better” to maximize efficacy
- The copper IUC provides superior EC
  - Within 5 days of unprotected intercourse
  - In women who *also* desire long term contraception
- Advance provision of ECP *does not* impact pregnancy rates
  - Not cost-effective as a public health measure
  - If requested, provide undated written prescription