# Emergency Contraception and Adolescents





## Objectives

- Discuss the need for EC among adolescents
- Describe clinical components of EC
- Understand the challenges and opportunities for increasing EC use at the patient, provider, and health systems level



# Case: Sophie



- Sophie is a 16 yearold girl who comes to you requesting EC
- She tells you the condom broke during sex with her boyfriend

### What is Emergency Contraception (EC)?

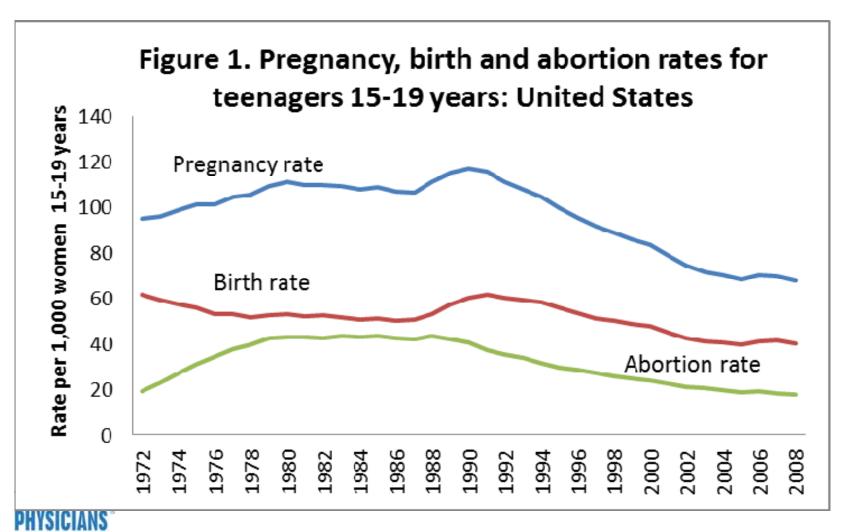
- A safe and effective way of preventing pregnancy in cases of:
  - Contraceptive failure
  - No contraceptive use
  - Unplanned or forced intercourse
  - Contraceptive sabotage
- Some methods very effective up to 120 hours after unprotected intercourse (UPI)



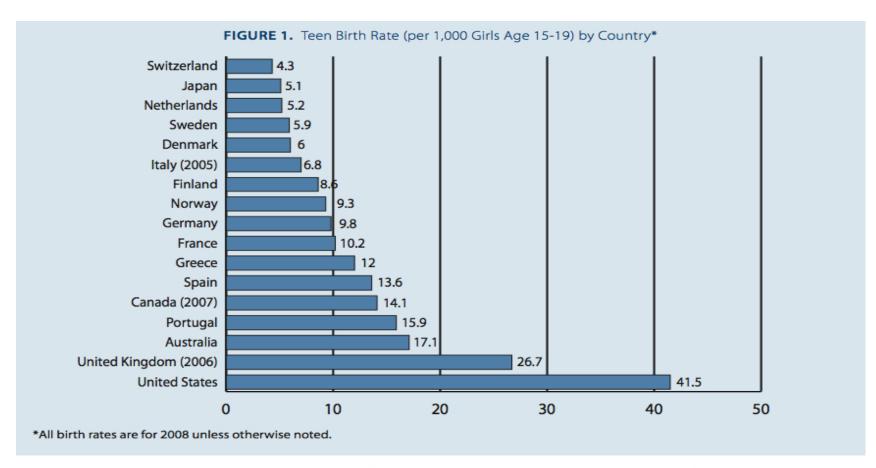
#### Adolescents need EC

- ► The U.S. has one of the highest teen pregnancy rates in the industrialized world.
- % of teen pregnancies due to contraceptive failure
  - ▶ Effectiveness of method
  - ► Consistent and correct use

## Rates are declining



# Teen Birth Rate (per 1,000 females, 15-19 years old) by Country



purce: United States: Martin, J.A., Hamilton, B.E., Sutton, P.D., Ventura, S.J., Matthews, T.J., & Osterman, M.J.K.. (2010). Births: Final data for 2008. National Vital Statistics Reports, 59 (1). Other puntries: United Nations Statistical Division. Demographic Yearbook 2008. New York: United Nations.



# Youth Risk Behavior Survey, 2013

YRBS Question	US
% students ever had sex	47%
% students who used a condom at last sex	59%
% students who used birth control pills at last sex	19%
% students who used Depo-Provera, Nuva Ring, Implanon or any IUD before last sex	5%







#### **Indications for EC**

#### Human error

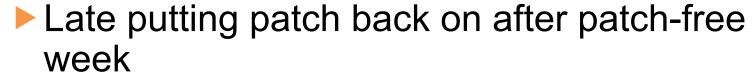
- Inconsistent contraceptive use
- Incorrect contraceptive use
- Unplanned intercourse



#### Method failure: Patch

Patch off for 24 hours or more during patchon weeks











# Method failure: Ring

Taken out for more than three hours during ring-in weeks

Same ring left in more than five weeks in a row



Late putting ring back after ring-out week



#### Method failure: Others

- Condom breaks or slips
- ▶ Two or more missed active OCPs
- ► DMPA shot 14 or more weeks ago
- Expelled IUD
- Three or more hours late taking a POP
- Diaphragm or cervical cap dislodges







#### Methods of EC





# Branded EC products in the U.S.





#### Plan B OneStep®

- Single dose
- 1.5 mg levonorgestrel
- Label: Up to 72 hrs after unprotected sex
- Recommend: Up to 120 hrs
- OTC for men and women of

#### ella®

- Single dose
- 30 mg Ulipristal acetate (UPA)
- Label: Up to 120 hrs after unprotected sex
- Prescription Only
- Can order online at www.ella-



### Generic EC products in the U.S.





# Next Choice One Dose<sup>TM</sup> and My Way<sup>TM</sup>

- Generic
- Label: 1 dose of 1.5 mg levonorgestrel up to 72 hrs after unprotected sex
- Recommend: Up to 120 hrs

# Levonorgestrel Tablets<sup>TM</sup>

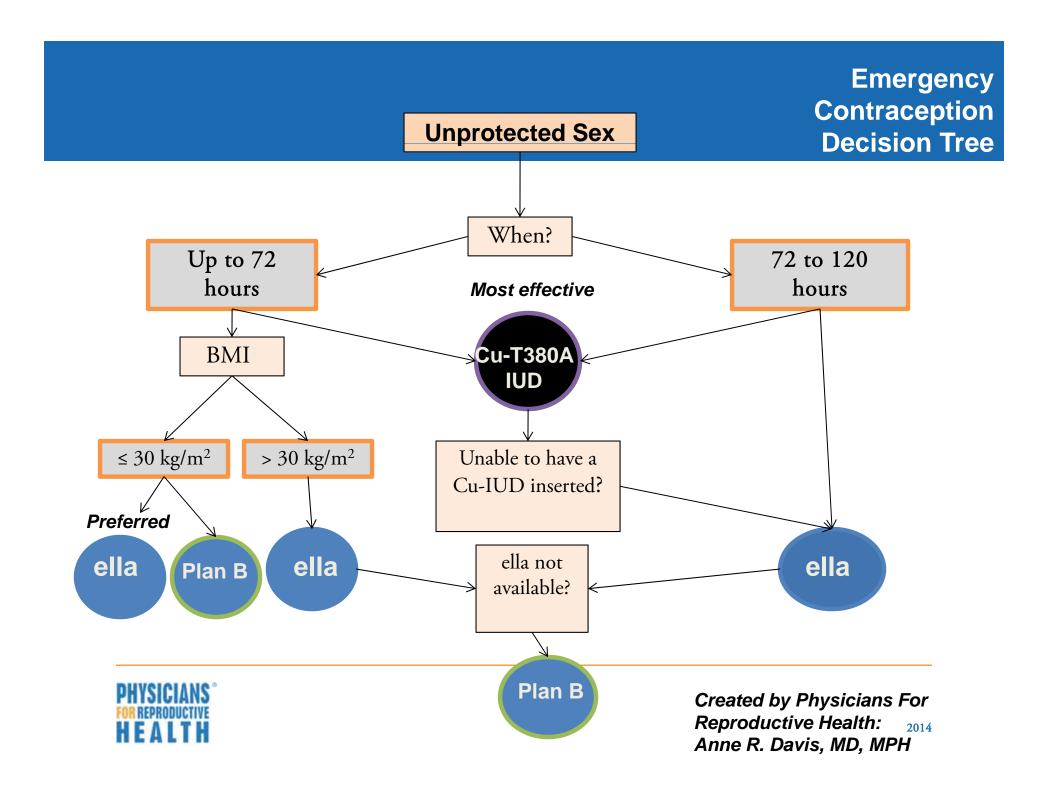
- Generic
- Label: 2 doses of 0.75 mg levonorgestrel up to 72 hrs after unprotected sex
- Recommend: 2 tablets at once



## Case: Sophie

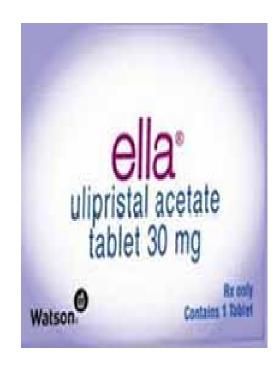


- Sophie tells you that it has been four days since the condom broke
- Her medical history also indicates that her BMI is 30
- Which EC options would you discuss with Sophie?



### ella®

- FDA approved August 2010 and entered market Nov 2010
- Rx only for all ages
- Effective 5 days after unprotected intercourse (UPI)
- Efficacy does not diminish over time
- Average failure rate of 2.1%
- More effective for obese women than levonorgestrel



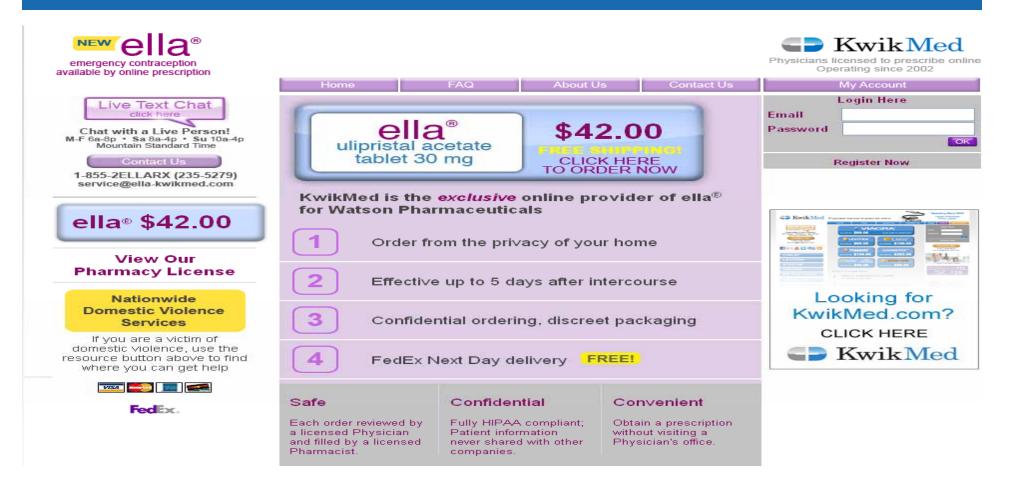
#### Ella is available online: Kwikmed

- No face-to-face is required to diagnose
- Allows patient to receive pills in a timely, discreet manner
- Resolves pharmacy access barriers
- Online physician consultation
- Highly cost efficient

KwikMed™ is the only firm licensed to prescribe online



## Ella-kwikmed.com





# ParaGard (Copper IUD): Off label use



- Insert within five days after UPI
- ► Highly effective: Reduces risk of pregnancy by more than 99%
  - Efficacy doesn't decline over time
- Historically, rarely used for EC alone but this may change
- Cannot use levonorgestrel IUS (Mirena® or Skyla®) for EC

# Yuzpe method: Not preferred

Brand	Pills per dose	Ethinyl Estradiol per dose (µg)	Lenonorge- strel per dose (mg)	
Combined progestin and estrogen pills: Take two 12 hours apart				
Altavera®; Amethia®; Camrese®; Cryselle®; Introvale®; Jolessa®; Levora®; Lo/Ovral®; Low- Ogestrel®; Nordette®; Portia®; Quasense®; Seasonale®; Seasonique®	4 pills	120	0.60	
Amethia Lo®; Aviane®; CamreseLo®; Lessina®; LoSeasonique®; Lutera®; Ogestrel®; Stronyx®	5 pills	100	0.50	
Amethyst®; Lybrel®	5 pills	120	0.54	
Enpresse®; Trivora®	4 pills	120	0.50	





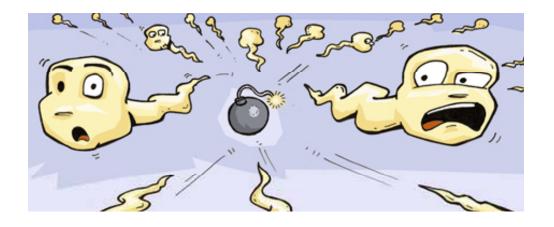


#### **Mechanism of Action**

# **Emergency Contraception**

#### **Dispelling Myths:**

- EC is not the abortion pill and does not cause an abortion
- ► EC does not harm an existing pregnancy
  - UPA: No adequate well controlled studies in pregnant women
- ► EC does not affect future fertility





#### Mechanism of action: Oral methods

- Disrupt normal follicular development by delaying or inhibiting ovulation
- DO NOT prevent fertilization or implantation
- ► ECP are not effective once fertilization occurs



# Mechanism of action: Copper IUD

Releases copper that induces an inflammatory response

Can inhibit fertilization or implantation of a fertilized egg









# How do we measure EC efficacy?

# The *reduction* in pregnancy risk after a *single* coital act



# Current estimates of EC pill (LNg) efficacy

- ► Plan B® package (LNg regimen): 88%
- ► Published literature on regimen: 52% 100%

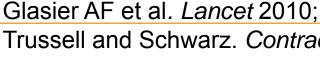


PHYSICIAT Trussell J, Raymond EG. 2011 at http://ec.princeton.edu/questions/ec-

### **UPA versus LNg effectiveness:** Time since intercourse

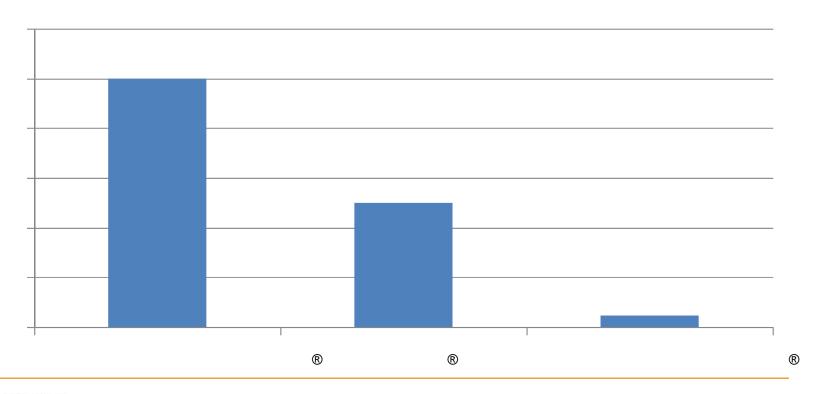
▶ In RCT, all 3 pregnancies with EC use at 73-120 hours after sex were in the LNg group

Significantly more pregnancies were prevented in the UPA group (p=0.037)





# Relative effectiveness of EC by method



PHYSI Raymond E, et al. 2004; Task Force on Postovulatory Methods of Fertility Regulation. The P, et al. 2010; Glasier AF, et al. 2010, 2014





## BMI and its efficacy on EC

# Special population: Obese & overweight women

- Risk of pregnancy when sex around ovulation regardless of EC type (UPA, LNG) taken:
  - > 3x for obese women (BMI of 30kg/m<sup>2</sup> or greater, OR=3.60, CI 1.96-6.53; P<.0001)
  - > 1.5x for overweight women (BMI 25-30kg/m<sup>2</sup>)
  - Obese & overweight women, higher oral EC failure rate
- Recommend obese and overweight women use UPA or a Copper IUD rather than LNG



### Effectiveness by method in obesity

EC Failure Among Obese (BMI 35) *versus* Non-obese (BMI 26)
Women

- LNg: OR = 4.41, 95%CI 2.05-9.44
- Ulipristal: OR = 2.62, 95%CI 0.89-7.00



# EC effectiveness decreases with repeated unprotected intercourse

Repeated UPI in same cycle	Ulipristal	LNg
No	1.0%	1.9%
Yes	5.6%	7.3%

### **Pregnancy Rates**

Copper IUD provides BEST protection because ALL future episodes of sex will be protected



## Case: Sophie



- ► This is Sophie's 4<sup>th</sup> request for EC over the past three months.
- She's used birth control pills in the past but her mom found them and threw them away
- What method would you recommend to Sophie?

## When to consider copper IUD for EC

- Interest in a long-acting method without dysmenorrhea, menorrhagia, anemia, or copper allergy
- When EC medications may be less effective
- Obese or overweight women
- When UPI occurs around ovulation
- All adolescent and adult women

The Copper IUD is a great method for patients who have privacy concerns or who have partners who try to sabotage their contraception



## What is contraceptive sabotage?

- A form of sexual coercion and control over a partner's fertility
- Hiding, withholding or destroying a partner's birth control pills
- Breaking or poking holes in a condom on purpose (or removing condom during sex)
- Not withdrawing when that was the agreed upon method of contraception
- Pulling out vaginal rings/tearing off contraceptive patches



# Take-away points on EC effectiveness:

#### **EC** works!

Effectiveness can only be estimated

EC is more effective than nothing

Copper IUD is most effective option







# Side Effects and Contraindications of EC

#### Research

- Documented studies:
  - World Health Organization states that there are no situations in which "the risks of using EC outweigh the benefits"<sup>12</sup>
  - Will not disrupt or harm an existing pregnancy<sup>13</sup>
  - Is equally safe and effective for teen and adult women<sup>14</sup>



#### Side Effects & Contraindications

	Plan B One-Step®/ Other LNG EC pills	ella®	Paragard® T380A IUD
Possible Side Effects	Menstrual changes     Headache     Abdominal pain     Nausea     Fatigue     Dizziness	Menstrual changes     Headache     Abdominal pain     Nausea     Fatigue     Dizziness     Dysmenorrhea	<ul> <li>Irregular bleeding</li> <li>Cramps</li> <li>Pain</li> <li>Heavier menses</li> </ul>
Absolute Contraindications	Pregnancy (will not harm an existing pregnancy and medication will be ineffective)	Pregnancy (will not harm an existing pregnancy and medication will be ineffective)	<ul> <li>Pregnancy</li> <li>Mucopurulent cervicitis</li> <li>Active pelvic infection</li> <li>Postpartum/ postabortal endometritis (in past 3 months)</li> <li>Abnormalities of the uterus (distortion of uterine cavity incompatible with insertion)</li> <li>Copper allergy</li> <li>Wilson's disease</li> </ul>

Notes: Side effects usually do not occur for more than a few days after treatment and usually diminish within 24 hours; see advice below on "Nausea/Vomiting." Information retrieved from FDA product labeling. 31-33



## Side Effects: Nausea/Vomiting

More common with Yuzpe method; not common with LNG or UPA ECP

If vomiting occurs within 3 hours of taking ECP, another dose of ECP should be taken as soon as possible. (*Use of an antiemetic should be considered*)



## Contraindication: Breastfeeding

LNG ECP are NOT contraindicated during lactation

► Recommendation: women who take UPA ECP express & discard breast milk for 36 hours post UPA intake or use LNG ECP instead



## Contraindication: Pregnancy

► ECP do NOT affect an existing pregnancy

► ECP are not recommended for women with known or suspected pregnancy because it will be *ineffective*.







# Adolescent access to EC: Challenges & opportunities

## Challenges and Opportunities

- ► To utilize EC, young women must:
  - Be aware of their options
  - Locate a provider or pharmacy
  - Obtain a prescription if needed
  - Find the money to pay for EC (out of pocket/health insurance)
  - Find a pharmacy with EC in stock
  - Use EC in a timely manner after UPI



## Challenges and opportunities

Patient Level

Provider Level

Health Insurance and Pharmacy Access



## Patient level





#### Few young women are aware of EC

- ▶ 28% of teen girls have heard of EC
- ▶ 40% of teens who know about EC understand that the pills should be taken after, not before, sex
- Since ella® has recently been approved, awareness of this drug is expected to be much lower



#### Patient misconceptions create barriers to EC use

- Beliefs that EC functions as an abortifacient
- Fear that the drug would harm fetus
- Confusion over fertility cycle and timing

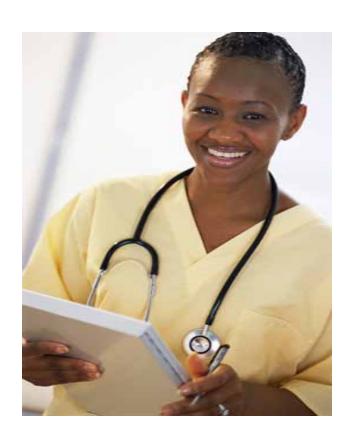


#### Other barriers

- Perceived lack of confidentiality
- Lack of money and/or insurance
- Lack of transportation
- Inability to locate a healthcare provider within the limited and effective timeframe
- Belief that pelvic examination is mandatory
- OTC exclusion of minors



## Provider level





#### AAP policy statement on EC

- Officially endorses advance provision of EC
- Reinforces safety/efficacy of EC among adolescents
- Educates pediatricians/physicians on EC
- Encourages routine counseling of EC
- Provides current data on EC methods
- Emphasizes goal to reduce teen pregnancy







#### Providers can facilitate use

#### Many providers do not discuss EC with young patients

- Of pediatricians with adolescent patients:
  - ▶20% report prescribing EC
  - ► 24% report counseling adolescents about EC



#### Providers need more training on EC

- As ella® becomes more widely available, physicians will need to learn about this option
- ► A 2001 survey of pediatricians found:
  - ► 72.9% were unable to identify any of the FDAapproved methods of EC
  - Only 27.9% correctly identified the timing for initiation
  - ▶ 31.6% felt comfortable prescribing EC



#### Provider misconceptions can discourage use

- ▶ 2001 survey of pediatricians found:
  - 22% believed that providing EC encourages adolescent risk-taking behavior
  - ► 52.4% would restrict the number of times they would dispense EC to a patient
  - ▶ 12% cited moral or religious reasons for not prescribing
  - ▶ 17% were concerned about teratogenic effects



#### Providers can remove clinical barriers to EC

- No pelvic examination or pregnancy test required by ACOG or FDA
- Pregnancy test prior to EC treatment is recommended only if:
  - Other episodes of unprotected sex occurred that cycle
  - LMP (last menstrual period) was not normal in duration, timing, or flow



## Prescribing EC

- ▶ Plan B One-Step is OTC for men and women of any age
- Ella available for patients of all ages with a prescription
- Some states allow people 16 years and younger to obtain Next Choice One Dose and My Way without an Rx





## Training office staff

- ► Train office staff on EC
  - Importance of timely appointments
  - Lack of required exam for prescriptions
  - If provider is uncomfortable counseling/providing EC, must make appropriate referral







## **Counseling and Education**

#### Provide supportive counseling

- > EC is responsible behavior
- If using a two-dose product, taking both doses at once may improve compliance without additional side effects or decreasing efficacy
- Counsel on other methods of birth control
- Provide STI/HIV counseling/testing if possible
- Provide condoms and review use
- Provide return appointment





#### Addressing concerns about STI risk

- While EC does NOT protect against STIs or HIV:
  - ► 2005 study: Young women obtaining EC from pharmacist were no more likely to get an STI
  - Product's label clearly states that regimen does not protect against STIs or HIV



#### Individual patient needs

- Providers must take into account patient's:
  - Knowledge of reproductive physiology
  - Ability to understand the regimen
  - Moral perceptions of contraception
  - Misconceptions about the drug's mechanism of action
  - ► Barriers that may restrict access



#### Instruct patient on use

- More effective the sooner it is taken (LNG EC)
- ▶ To be effective, EC must be used each and every time a woman has UPI
- Having unprotected sex after EC use can increase pregnancy risk
- Call provider if no menstrual period within 3 weeks after taking EC



# Opportunities for bridging contraceptive services

- Cost of EC may prohibit multiple use within a cycle (~\$25–\$50)
  - Cost of ella® expected to be higher
- During visit, discuss alternative and ongoing methods of contraception that are more effective and less expensive



#### Counseling teens about contraception method

- Have you tried anything to prevent pregnancy in past?
- Any problems with a previous method?
  - Trouble remembering to take the pill?
  - Concerns over privacy with the pill/patch?
  - Difficulty using condoms consistently?
  - Cost barriers?



## Be adolescent friendly

- Display posters and materials about EC
- Work with teen patients to establish a "plan" in the event of contraceptive failure, including identifying:
  - A pharmacy that will fill prescription
  - A method of transportation to pharmacy
  - A means of locating or borrowing funds for pills



## Providing resources

- List yourself as an EC provider on www.not-2-late.com
- Compile list of pharmacists in area that dispense EC
- Refer patients to www.not-2-late.com







Crisis Management

## Intimate Partner Violence and Emergency Contraception

- Repeated requests for EC may indicate pregnancy coercion or birth control sabotage
  - Adolescent girls in physically abusive relationships were 3.5 times more likely to become pregnant than non-abused girls
  - Among teen mothers on public assistance who experienced recent abuse, 66% experienced birth control sabotage by a dating partner.



## Screening for IPV

- Make sure to explain confidentiality and mandatory reporting
- Now what your resources are for ensuring patient safety while in your care
- ▶ Be prepared to offer referral information for follow-up



### Sexual Assault and EC

>50% of all rapes occur in young women under 18 years old

► For teens, 5.3% of rapes lead to a pregnancy

Emergency contraception should be offered to all survivors of sexual assault



# EC and sexual assault survivors

- Most states have no requirements to provide EC to survivors of sexual assault
- Only 16 states require hospitals to offer information and counseling about EC, and only 12 of those states also mandate that hospitals provide EC <u>on-site</u> to victims

### EC in the ER

- ► Each year, approximately 25,000 American women become pregnant as a result of sexual violence
- As many as 22,000 of those pregnancies could be prevented by using EC





## Sample Questions

- ► Was the sex you had something you wanted to do?
- Are you at all concerned that a partner may be trying to get you pregnant when you don't want to be?
- Sometimes women have to worry about someone else finding their emergency contraception and throwing it away. If that is an issue for you, you might want to think about some other forms of birth control."







**Quick Start** 

## Starting contraception after LNG EC

COCs/Progestin-only Pills

Start *immediately* after taking EC

Vaginal Ring/Patch

>> Start *immediately* after taking EC

DMPA/Implants/IUC's

Start *immediately* after taking EC

\*With ALL methods: Abstain/Use Back-Up protection for first 7 days



## Case: Sophie



Sophie has private health insurance and wants to know if it covers the IUD.

How would you respond to her questions?





## Health Insurance Coverage and EC

### Affordable Care Act (ACA): August 2012

- New health plans must provide contraceptives and contraceptive counseling without a co-pay
- For many plans, this new benefit starts January 1, 2013; for others it may not be until "new" changes are made
- Guidelines are unclear about coverage of generic versus brand name products and how to implement over time



## Things to Know about the ACA and EC

- All FDA-approved birth control methods should be covered without a co-pay
  - Unclear if every brand of EC will be covered
  - No FDA guidelines about limitation regarding how many times EC is covered in one year/month?
  - More guidance needed



## ACA: Contraceptive Coverage

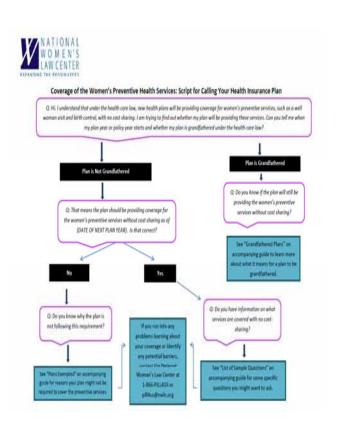
- Has potential to eliminate cost barriers for highly effective/more expensive EC methods
  - e.g., ella® and the copper IUD







# What questions should you ask your health insurance?



- State that you're aware of the new contraceptive coverage with ACA
- Ask when your plan year or policy year starts
- Ask whether your plan is "grandfathered" under the health care law

# National Women's Law Center: Tools for EC Access

► The "Contacting your Insurance Guide" Flowchart can be found and downloaded from the National Women's Law Center website at:

http://www.nwlc.org/resource/how-find-out-if-and-when-your-health-plan-will-begin-covering-women%E2%80%99s-preventive-services-n



## Clinicians with prescribing privileges

- Clinicians recommended to provide patients with written prescriptions for insurance purposes
- Rx helpful when seeking reimbursement
- Easier for patients without government issued ID, embarrassed to request from pharmacist/be asked additional questions

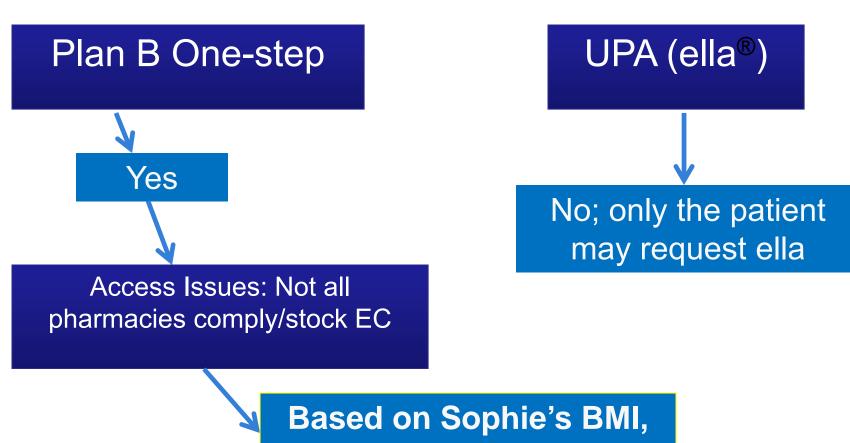


## Case: Sophie



- Sophie says she will call her health plan about IUD coverage but requests EC pills today and for the future "just in case"
- She asks you if her 18 year-old boyfriend can pick them up for her from the pharmacy

### Can Sophie's boyfriend get EC without an Rx?









### **Advanced Provision**

### **Advanced Provision**

- ► Does NOT increase risk taking behavior

  - Does not increase number of sexual partners or increase risk for STIs
- DOES increase use of EC and increases earlier use when EC more effective
  - ▶ Risks are reduced from episodes of unprotected sex and/or contraceptive failure that occur



# Advanced Provision: No Increase in Risk Behavior

Receive EC in advance

2004 study of young women randomized to:

Receive instructions on how to get EC

Advance Rx: ~twice as much EC use as control (15% vs. 8%)

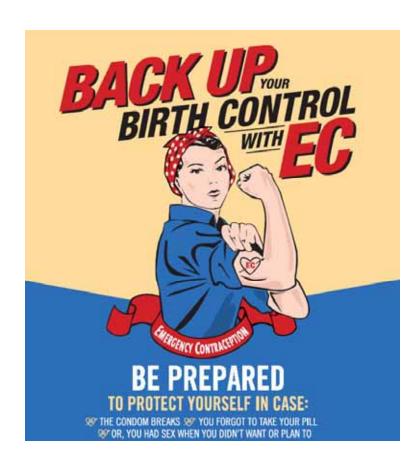
No decrease in condom or contraceptive use

No increase in unprotected sex

Advance Rx: used EC sooner than control group (10 vs. 21 hrs)



## Advanced Provision Does Increase Use!



#### Women who receive

#### **LNG EC in advance:**

- Twice as likely to use EC when they needed it (44% vs. 29%- Harper, 15% vs. 8%- Gold)
- Twice as likely to use it more than once
- ► Used EC sooner when more effective (Gold)

Gold MA, et al. *Journal of Pediatric and Adolescent Gynecology* 2004;17:87-96 Harper CC, et al. Obstetrics and Gynecology 2005

## Who supports advance EC?

- ► American Academy of Pediatrics
- Society for Adolescent Health and Medicine
- ► The American Medical Association
- ► American Academy of Family Physicians
- ► American Congress of Obstetricians and Gynecologists







**EC:** Pharmacy Access

### Pharmacy access does not increase risk behavior

- A 2005 study of 2117 young women
- Improved access group no more likely to:
  - ► Miss a pill
  - Switch birth control methods
  - Forgo using a condom
- Frequency of intercourse, amount of unprotected sex, and number of sexual partners similar among the study groups







Males and EC

### What has been said about male involvement?

"Special efforts should be made to emphasize men's shared responsibility and promote their active involvement in responsible parenthood; sexual and reproductive behavior, including family planning; prenatal, maternal and child health; prevention of STDs, including HIV; prevention of unwanted and high-risk pregnancies..."

1994 International Conference On Development & Population



## Comparing men and women on EC

- ► Men less likely to know about EC
- Rates of purchase not different statistically
  - ► (10.8% vs 18.3%)

## Attitudes on buying and using EC

- Many men felt that:
  - they should offer to buy EC if needed (56.1%),
  - their purchases would prevent unplanned pregnancies (67.6%)
  - the decision to use EC was a woman's (75.4%);
- > 73.8% of women agreed that men should always have EC access.

# 2012 review on young men and EC

- Young men's knowledge of EC
  - Equated with awareness or familiarity
  - ▶ 38% of teenagers knew about EC
  - ▶ 65-100% of adults knew about EC
- Previous use or discussion
  - ▶ 13-30% had used or discussed EC
- Previous purchase
  - ▶ 11% previously purchased EC
- Attitudes
  - Supportive of use



## Males and Emergency Contraception



- Plan B One Step OTC for males
- ► Ella, Rx for patient only
- Pharmacies have not been 100% compliant in dispensing EC to males
  - ACLU has documented several cases over the years
- Can still counsel males

## **Implications**

## Availability \neq Access



## Wrap Up

- Discuss all dedicated products, including UPA and copper IUD for EC
- Write advanced prescription for EC or provide instructions on OTC access with all teens
- Check local pharmacies for available products and EC access policies for youth 16 and under
- Offer women with a BMI > 30 kg/m² UPA or copper IUD and offer those having UPI around time of ovulation a copper IUD



### **Conclusions**

- EC: safe and effective method of preventing pregnancy
- Can prevent pregnancies when taken within indicated window
- Should be readily available to all women, especially adolescents
- Advanced provision and pharmacy access will not increase health risks for young women



## EC specific resources

- http://prh.org/resources/emergency-contraception-apractitioners-guide/: Physicians for Reproductive Health, Emergency Contraception: A Practitioner's Guide
- www.not-2-late.com: Provides a list of local providers and answers to the most common questions about EC
- <u>www.cecinfo.org</u>: International Consortium on EC: produces research and info on EC
- www.ec.princeton.edu : EC at Princeton University: a site aimed at patients with credible research sources
- www.rhtp.org : The Reproductive Health Technologies Project
- www.backupyourbirthcontrol.org: Offers basic facts about EC; mainly intended for general public/section for providers
- www.aed.org/Publications/upload/ECtoolkit3283.pdf
- National Sexual Assault Hotline 1-800-656-HOPE Provides victims of sexual assault with free, confidential, around-the-clock services



### Resources

- www.prh.org—Physicians for Reproductive Health
- www.aap.org—The American Academy of Pediatrics
- <u>www.acog.org</u>—The American College of Obstetricians and Gynecologists
- <u>www.adolescenthealth.org</u>—The Society for Adolescent Health and Medicine
- <u>http://www.aclu.org/reproductiverights</u>—The Reproductive Freedom Project of the American Civil Liberties Union
- www.advocatesforyouth.org—Advocates for Youth
- www.guttmacher.org—Guttmacher Institute
- www.cahl.org—Center for Adolescent Health and the Law
- <u>www.gynob.emory.edu/centers/jfc.html</u>—The Jane Fonda Center of Emory University
- <u>www.siecus.org</u>—The Sexuality Information and Education Council of the United States
- <u>www.arhp.org</u>—The Association of Reproductive Health Professionals



# Please Complete Your Evaluations Now



