Emergency Contraception and Adolescents

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University of Vermont Children’s Hospital
Objectives

- Discuss the need for emergency contraception (EC) among adolescents
- Describe the 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-year-old 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.
  - 2008 Comparative:
    - U.S. 41.5 births per 1,000 girls 15-19yo
    - Japan & Netherlands 5 per 1,000

- 5% of teen pregnancies due to contraceptive failure
  - Effectiveness of method
  - Consistent and correct use

Santelli et al., 2006
US, High School YRBS, 2013

American Indian/Alaska Native Students

- Ever had Sex: 41%
- Sex in Last 3 months: 30%
- Sex with 4+ partners: 15%
- Sex before age 13: 10%
## Youth Risk Behavior Survey, 2013

<table>
<thead>
<tr>
<th>YRBS Question</th>
<th>U.S.</th>
</tr>
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<tbody>
<tr>
<td>% students who used a condom at last sex</td>
<td>59%</td>
</tr>
<tr>
<td>% students who used birth control pills at last sex</td>
<td>19%</td>
</tr>
<tr>
<td>% students who used Depo-Provera, NuvaRing®, Implanon®, or any IUD before last sex</td>
<td>5%</td>
</tr>
</tbody>
</table>
Indications for Immediate EC
Human Error

- No contraceptive use
- Failure of contraception
- Incorrect contraceptive use
- Inconsistent contraceptive use
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 females and males any age

ella®
- Single dose
- 30 mg Ulipristal acetate (UPA)
- Label: Up to 120 hrs after unprotected sex
- Prescription Only for females
- Can order online at www.ella-kwikmed.com
Generic EC Products in the U.S.

Next Choice™ and My Way® One Dose LNG
- Generic
- Label: 1 dose of 1.5 mg levonorgestrel up to 72 hrs after unprotected sex
- Recommend: Up to 120 hrs
- OTC for females and males any age

LNG Two Dose Tablets
- Generic
- Label: 2 doses of 0.75 mg levonorgestrel up to 72 hrs after unprotected sex
- Recommend: 2 tablets at once up to 120 hrs
- OTC for ages 17 & older
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?
Emergency Contraception Decision Tree

Unprotected Sex

When?

Up to 72 hours

BMI

≤ 30 kg/m²

Preferred

ella

> 30 kg/m²

Plan B

ella

Cu-T380A IUD

Most effective

72 to 120 hours

Unable to have a Cu-IUD inserted?

ella not available?

ella

Plan B

Created by Physicians For Reproductive Health: Anne R. Davis, MD, MPH
FDA approved August 2010 and entered market November 2010

Rx-only for all ages; NOT OTC

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

www.kwikmed.com/ella.asp
KwikMed is the exclusive online provider of ella®

Buy Ella® Online

Emergency contraception available by online prescription:

1. Order from the privacy of your home
2. Effective up to 5 days after intercourse
3. Confidential ordering, discreet packaging
4. FedEx Next Day delivery

<table>
<thead>
<tr>
<th>Potency</th>
<th>Quantity</th>
<th>U.S. Price</th>
<th>Order</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 mg</td>
<td>01 Tablet</td>
<td>$59.00</td>
<td></td>
</tr>
</tbody>
</table>

Upon checkout, your order will be reviewed by a KwikMed Physician. If approved, your credit card will be charged and your ella® will be shipped in confidential packaging via FedEx. A signature is required upon delivery.

Online ella® orders are typically reviewed within 4 hours.
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
Mechanism of Action
Dispelling Myths

- EC is not the abortion pill and does not cause an abortion
- EC does not harm an existing pregnancy
- UPA: No adequate large 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%

Relative Effectiveness of EC by Method

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

UPA vs. 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)

UPA: Efficacy Decreases Over Time
*but still more effective than LNg

Failure Rate of ella®

<table>
<thead>
<tr>
<th>Time Elapsed after UPI (hours)</th>
<th>Failure Rate (Percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>48-72</td>
<td>1.3</td>
</tr>
<tr>
<td>72-96</td>
<td>2.1</td>
</tr>
<tr>
<td>96-120</td>
<td>2.3</td>
</tr>
</tbody>
</table>

Fine et al 2010
EC Effectiveness Decreases with Repeated UPI

**Pregnancy Rates**

<table>
<thead>
<tr>
<th>Repeated UPI in same cycle</th>
<th>Ulipristal</th>
<th>LNG</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>1.0%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Yes</td>
<td>5.6%</td>
<td>7.3%</td>
</tr>
</tbody>
</table>

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

BMI and Its Efficacy on EC
Special Population
Obese and Overweight Women

- Higher oral EC failure rate in overweight and obese women

- Greater risk of pregnancy when UPI around ovulation regardless of EC type:
  - >3× for obese women (BMI ≥30)
  - >1.5× for overweight women (BMI 25–30)

- Risk of pregnancy “more pronounced’ with LNG than UPA

Glasier A, Cameron ST, Blithe D, et al., Contraception, 2011
<table>
<thead>
<tr>
<th>LNG EC Efficacy</th>
<th>UPA Efficacy</th>
</tr>
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<tbody>
<tr>
<td>▶ Less effective in overweight women (BMI 25–30)</td>
<td>▶ <strong>Equally effective in</strong> overweight women (BMI 25–30)</td>
</tr>
<tr>
<td>▶ NOT effective in obese women (BMI &gt;30)</td>
<td>▶ Less effective in obese women (BMI &gt;30)</td>
</tr>
<tr>
<td></td>
<td>▶ NOT effective in women with BMI &gt;35</td>
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</tbody>
</table>
Case: Sophie

- This is Sophie’s fourth 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 could provide EC and long acting contraception?
When to Consider Copper IUD for EC

- When EC medications may be less effective
- Obese or overweight women
- When UPI occurs around ovulation
- Interested and eligible without contraindications
- 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.
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”
  - Will not disrupt or harm an existing pregnancy
  - Is equally safe and effective for teen and adult women

## Side Effects and Contraindications

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

*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]*
Contraindication: Breastfeeding

- LNG ECP are NOT contraindicated during lactation

- Recommendation: Women who take UPA ECP express and 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 and Opportunities
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 health care provider within the limited and effective timeframe
- Belief that pelvic examination is mandatory
- OTC exclusion of minors
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

Issued by the AAP on November 26, 2012
Providers Can Facilitate Use
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
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
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.

- Know what your resources are for ensuring patient safety while in your care
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

► Only 16 states require hospitals to offer information and counseling about EC, and only 12 of those states also mandate that hospitals provide EC on-site 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.

Source: http://www.mergerwatch.org/ec-in-the-er/
Starting Contraception After LNG EC

COCs/Progestin-only Pills → Start immediately after taking EC

Vaginal Ring/Patch → Start immediately after taking EC

DMPA/Implants/IUCs → Start immediately after taking EC

*With ALL methods: abstain/use back-up protection for first 7 days

**After taking ella: Can start contraception immediately; Abstain/Use Back-Up protection for first 2 weeks
Advanced Provision of EC
Advanced Provision of EC

- Does NOT increase risk-taking behavior
  - Does not decrease condom use
  - Does not decrease contraceptive use
  - 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
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
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…”

Men less likely to know about EC

1994 International Conference On Development and Population

Wrap-Up

- Discuss all dedicated products, including UPA and copper IUD for EC
- Write advance 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 will not increase health risks for young women
EC-Specific Resources

- **www.not-2-late.com**: Provides a list of local providers and answers to the most common questions about EC
- **www.cecinfo.org**: International Consortium on EC
- **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.arhp.org/topics/emergency-contraceptionclinical-publications-and-resources**: Offers basic facts about EC; mainly intended for general public/section for providers
- National Sexual Assault Hotline 1-800-656-HOPE Provides victims of sexual assault with free, confidential, around-the-clock services
Additional EC Information

- ecotc.tumblr.com

- americansocietyforec.org/uploads/3/2/7/0/3270267/sec_ec_access_report.pdf
  - EC on the Shelf: Real-World Access in the OTC Era

- ec.princeton.edu/ASEC PricingReport.pdf
  - The Cost of EC: Results from Nationwide Survey 2013
Provider Resources and Organizational Partners

- [www.advocatesforyouth.org](http://www.advocatesforyouth.org)—Advocates for Youth
- [www.aap.org](http://www.aap.org)—American Academy of Pediatricians
- [www.aclu.org/reproductive-freedom](http://www.aclu.org/reproductive-freedom)—American Civil Liberties Union Reproductive Freedom Project
- [www.acog.org](http://www.acog.org)—American College of Obstetricians and Gynecologists
- [www.arhp.org](http://www.arhp.org)—Association of Reproductive Health Professionals
- [www.cahl.org](http://www.cahl.org)—Center for Adolescent Health and the Law
- [www.glma.org](http://www.glma.org)—Gay and Lesbian Medical Association
Provider Resources and Organizational Partners

▶ www.guttmacher.org—
Guttmacher Institute

▶ janefondacenter.emory.edu
Jane Fonda Center at Emory University

▶ www.msm.edu
Morehouse School of Medicine

▶ www.prochoiceny.org/projects-campaigns/torch.shtml
NARAL Pro-Choice New York
Teen Outreach Reproductive Challenge (TORCH)

▶ www.naspag.org
North American Society of Pediatric and Adolescent Gynecology

▶ www.prh.org—
Physicians for Reproductive Health
Provider Resources and Organizational Partners

- [www.siecus.org](http://www.siecus.org) — Sexuality Information and Education Council of the United States

- [www.adolescenthealth.org](http://www.adolescenthealth.org) — Society for Adolescent Health and Medicine

- [www.plannedparenthood.org](http://www.plannedparenthood.org) — Planned Parenthood Federation of America

- [www.reproductiveaccess.org](http://www.reproductiveaccess.org) — Reproductive Health Access Project

- [www.spence-chapin.org](http://www.spence-chapin.org) — Spence-Chapin Adoption Services
Please Complete Your Evaluations Now

Adolescent Reproductive & Sexual Health Education Program