Oral emergency contraception: an efficacy and regulatory update

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Disclosures/Conflict of Interest

• The speakers declare no conflicts of interest, real or apparent, and no financial interests in any company, product or service mentioned in this program, including grants, employment, gifts, stock holdings and honoraria.
Objectives
Pharmacists

At the conclusion of this program, the pharmacist will be able to:

• Explain the mechanism of action for available oral emergency contraception (EC) products as supported by current research.

• Describe the recent changes in levonorgestrel (LNG) EC labeling in the international setting and implications in the US.

• Interpret the evidence available regarding oral EC efficacy, including LNG and ulipristal acetate (UPA).

• Explain the legal regulations surrounding patient purchase of oral LNG EC and UPA EC, and recommend appropriate EC for a patient.
Objectives
Pharmacy Technicians

At the conclusion of this program, the pharmacy technician will be able to:

• Describe the appropriate time period for patients to utilize oral EC methods.

• Explain the legal regulations surrounding patient purchase of oral LNG EC and UPA EC.

• Describe where different types of EC products may be stocked in the pharmacy.
BACKGROUND
Unintended pregnancy in the United States

6.7 million pregnancies

Intended Pregnancy 51%

Unintended Pregnancy 49%

Birth 22%
Abortion 20%
Miscarriage 7%

Physiology definitions

• Ovulation
  • Lutenizing hormone (LH) increases and triggers the release of an oocyte (egg) from the ovary

• Pregnancy
  • Zygote (fertilized egg) successfully implants into the endometrium (uterine lining)
Conception

• Sperm must fertilize oocyte within 24 hours of ovulation
  • Oocyte survival is 24 hrs
  • Sperm can survive in the female reproductive tract for 5 days
• Fertile window
  • 5 days before ovulation to 1 day after

Probability of conception on specific days near the day of ovulation

Conception

- Assessing time of ovulation is difficult
  - Discrepancy
    - Patient reported stage of menstrual cycle
    - Dating based on endocrine data
  - Unprotected intercourse outside of the supposed fertile period may still result in pregnancy

Probability of clinical pregnancy with one act of intercourse relative to day of the menstrual cycle

EC should be administered regardless of cycle day to prevent an unwanted pregnancy

Allen et al. Contraception. 2001
Conception probability

<table>
<thead>
<tr>
<th>Days prior to Ovulation</th>
<th>Probability of Conception</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>3.6%</td>
</tr>
<tr>
<td>4</td>
<td>13.6%</td>
</tr>
<tr>
<td>3</td>
<td>15.5%</td>
</tr>
<tr>
<td>2</td>
<td>27.7%</td>
</tr>
<tr>
<td>1</td>
<td>29.8%</td>
</tr>
<tr>
<td>0</td>
<td>12.3%</td>
</tr>
</tbody>
</table>

- Overall pregnancy rate expected in absence of EC is 5.6%
- FDA and European Medicines Agency (EMA) established a pregnancy rate of < 4% as the EC efficacy benchmark.

Percentage of sexually experienced women aged 15-44 who have ever used emergency contraception

Daniels et al. NCHS Data Brief. 2013
EMERGENCY CONTRACEPTIVE AGENTS
EC products in the US

Copper-T IUD

UPA EC

LNG EC
Copper-T IUD

- Paragard®
  - Placed within 5 days after intercourse
  - Efficacy
    - Most effective method
    - Effectiveness does not decline with delay
    - Failure rate < 1%
  - Prescription only

Copper-T IUD: MOA

• Enhances the inflammatory response, reaching levels that are toxic for sperm
  • Diminishes sperm penetration, impairs motility

• Emergency contraception is off label use
  • Placed by trained clinician
  • More barriers to access
  • Provides long term contraception

UPA EC

• Ella®
  • Dose
    • 30 mg x 1 dose
  • Administration
    • Take within 5 days after intercourse
  • Efficacy
    • Approved for a longer window than LNG EC
    • More effective than LNG EC
  • Prescription only
UPA EC: MOA

- 2nd generation selective progesterone receptor modulator
- No effect on sperm function
- Direct inhibitory effect on follicular rupture
  - Decreased efficacy, but may still work even when luteinizing hormone (LH) has started to rise
- Likely does not effect embryo implantation

LNG EC

- Levonorgestrel
  - Dose
    - 0.75 mg x 2 doses
    - 1.5 mg x 1 dose
  - Administration
    - Take within 72 hours after intercourse
    - Off label – may take up to 5 days after intercourse
- OTC, BTC, & prescription
LNG EC: MOA

- Progestin
- No effect on sperm function
- Affects follicular development after dominant follicle selection
  - ONLY before rise in LH
- No effect on embryo implantation

In vitro model for human embryo implantation

No significant difference

Percent of embryo attached

<table>
<thead>
<tr>
<th>Treatment Groups</th>
<th>Percent of Embryo Attached</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>6/14</td>
</tr>
<tr>
<td>Levonorgestrel</td>
<td>10/17</td>
</tr>
<tr>
<td>Mifepristone</td>
<td>0/15</td>
</tr>
</tbody>
</table>

EC adverse events

Glasier et al: LNG vs UPA EC

LNG & UPA EC EFFICACY
Can we identify women at risk of pregnancy despite using emergency contraception? Data from randomized trials of ulipristal acetate and levonorgestrel

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*University of Edinburgh, Scotland
†National Institute of Child Health and Human Development, Bethesda, MD, USA
‡IKA Pharma, Paris, France

Received 3 August 2010; revised 11 February 2011; accepted 11 February 2011

Abstract

Background: Emergency contraception (EC) does not always work. Clinicians should be aware of potential risk factors for EC failure.

Study Design: Data from a meta-analysis of two randomized controlled trials comparing the efficacy of ulipristal acetate (UPA) with levonorgestrel were analyzed to identify factors associated with EC failure.

Results: The risk of pregnancy was more than threefold greater for obese women compared with women with normal body mass index (odds ratio (OR), 3.60; 95% confidence interval (CI), 1.96–6.33; p=0.001), whichever EC was taken. However, for obese women, the risk was greater for those taking levonorgestrel (OR, 4.4; 95% CI, 2.05–9.44; p=0.0002) than for UPA users (OR, 2.62; 95% CI, 0.89–7.00; ns). For both ECs, pregnancy risk was related to the cycle day of intercourse. Women who had intercourse the day before estimated day of ovulation had a fourfold increased risk of pregnancy (OR, 4.42; 95% CI, 2.33–8.20; p<0.001) compared with women having sex outside the fertile window. For both methods, women who had unprotected intercourse after using EC were more likely to get pregnant than those who did not (OR, 4.64; 95% CI, 2.22–9.96; p=0.0002).

Conclusions: Women who have intercourse around ovulation should ideally be offered a copper intrauterine device. Women with body mass index >25 kg/m² should be offered an intrauterine device or UPA. All women should be advised to start effective contraception immediately after EC.
Limited UPA data

**Published Studies**

**LNG vs UPA RCTs**
- Crenin et al, 2006
  - UPA: 7/773 pregnancies 0.91%
  - LNG: 13/773 pregnancies 1.7%
- Glasier et al, 2010
  - UPA: 15/941 pregnancies 1.59%
  - LNG: 25/958 pregnancies 2.6%

**Observational**
- Fine et al, 2010
  - UPA: 26/1241 pregnancies 2.10%

**LNG comparators**
- n = 1731

References:
Clinical trial design

<table>
<thead>
<tr>
<th>Crenin et al, 2006</th>
<th>Glasier et al, 2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 1546</td>
<td>N = 1899</td>
</tr>
<tr>
<td>UPA = 773, LNG = 773</td>
<td>UPA = 941, LNG = 958</td>
</tr>
<tr>
<td>UPA Phase II trial</td>
<td>UPA Phase III trial</td>
</tr>
<tr>
<td>Received EC within 72 hr</td>
<td>Received EC within 120 hr</td>
</tr>
<tr>
<td>0.75 mg x 2 doses</td>
<td>1.5 mg x 1 dose</td>
</tr>
<tr>
<td>Weight measured</td>
<td>Weight self reported</td>
</tr>
</tbody>
</table>
EFFICACY AND BODY WEIGHT
Question #1

LNG EC may be less effective in women weighing more than 165 lbs.

a. True
b. False
Pregnancy risk according to BMI

- UPA
- LNG

- <25 BMI: 1.1% UPA, 1.3% LNG
- 25-30 BMI: 1.1% UPA, 2.5% LNG
- >30 BMI: 2.6% UPA, 5.8% LNG

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>&lt; 55</th>
<th>55-65</th>
<th>65-75</th>
<th>75-85</th>
<th>≥85</th>
</tr>
</thead>
<tbody>
<tr>
<td>N total</td>
<td>349</td>
<td>608</td>
<td>426</td>
<td>155</td>
<td>193</td>
</tr>
<tr>
<td>N pregnancies</td>
<td>3</td>
<td>8</td>
<td>6</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Pregnancy rate</td>
<td>0.9%</td>
<td>1.3%</td>
<td>1.4%</td>
<td>6.4%</td>
<td>5.7%</td>
</tr>
<tr>
<td>95% Confidence interval</td>
<td>0.2-2.5</td>
<td>0.6-2.6</td>
<td>0.5-3.0</td>
<td>3.1-11.5</td>
<td>2.9-10.0</td>
</tr>
</tbody>
</table>
LNG EC pregnancy probability by weight

Kapp et al. *Contraception*. 2015
Clinical trial limitations

- Exploratory analyses
  - Neither trial designed to evaluate the effect of weight on the effectiveness of EC

- Weight was self reported in Glasier et al. 2010
  - ~55% of patients

- Limited number of pregnancies (n=38)
  - BMI of 30 or greater (n=242)
  - Pregnancies with BMI of 35 or greater "extremely small"

LNG EC European labeling

- NorLevo label was changed in Europe & Canada in late 2013
  - “In clinical trials, contraceptive efficacy was reduced in women weighing 75 kg or more, and LNG was not effective in women who weighed more than 80 kg”

- NorLevo® distributor
  - HRA Pharma
  - Distributes product to over 50 countries
  - Sole manufacturer of UPA
Previous clinical trial data

- Effect not reported in previous studies
  - Mean body weight much lower
  - Different demographics
    - Predominantly Asian and African population

# Previous published trial data

<table>
<thead>
<tr>
<th>Clinical Trial</th>
<th>Trial design</th>
<th>LNG EC demographic data</th>
<th>LNG EC pregnancy rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Von Hertzen et al Lancet 1998</td>
<td>• LNG vs. Yuzpe method</td>
<td>n = 976 Mean BMI 22.0</td>
<td>11/976 1.1%</td>
</tr>
<tr>
<td></td>
<td>• EC taken ≤ 72 hrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 21 study sites</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Von Hertzen et al Lancet 2002</td>
<td>• Mifepristone vs. LNG 1 dose vs. LNG 2 dose</td>
<td>n = 2712 Mean weight 56.2 kg</td>
<td>44/2712 1.62%</td>
</tr>
<tr>
<td></td>
<td>• EC taken ≤ 120 hrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 15 study sites</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dada et al Contraception 2010</td>
<td>• LNG 1 dose vs. LNG 2 dose</td>
<td>n = 2823 Mean BMI 24.2</td>
<td>17/2823 0.61%</td>
</tr>
<tr>
<td></td>
<td>• EC taken ≤ 120 hrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 7 sites (all Nigeria)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**LNG comparators n = 6511**
Data implementation

• European Medicines Agency 7/2014
  • “LNG EC can continue to be used in women of all weights as the benefits are considered to outweigh the risks”
  • EMA reviewed three WHO trials and stated they did not find reduced efficacy with increasing weight or BMI
  • Statement was removed from the label

• FDA continues to review available data
Cause of weight related decrease in LNG efficacy?

• Unknown if efficacy is decreased by metabolic or pharmacokinetic changes

• No data evaluating higher doses of LNG

• Decreased efficacy with other hormonals
  • Contraceptive patch (90 kg warning)
  • Combined oral contraceptives
Question #1

LNG EC may be less effective in women weighing more than 165 lbs.

a. True
b. False
Question #1

LNG EC may be less effective in women weighing more than 165 lbs.

a. True
b. False
REGIMEN TIMING AND EFFICACY
Question #2

LNG EC can be effective if taken up to 5 days after unprotected intercourse.

a. True  
b. False
Question #3

LNG EC is more effective than UPA EC when taken on day 5 following intercourse.

a. True
b. False
Timing and Efficacy

- Always give EC as soon as possible
- When stratified by time, UPA was found to have lower failure rates than LNG
  - odds ratio for pregnancy 65% lower in the first 24 hours
  - odds ratio for pregnancy 42% lower up to 72 hours
  - odds ratio for pregnancy 45% lower up to 120 hours

Glasier et al. Lancet. 2010
Timing and efficacy

• Related to MOA

• When ovulation is imminent, UPA is more effective than LNG in delaying it if administered within 5 days
  • If the follicle reaches 15–17 mm, LNG is not able to prevent follicular rupture better than placebo
  • If the leading follicle reaches 18–20 mm, UPA prevents follicular rupture in 59% of cycles compared with 0% in placebo cycles

Croxatto et al. Contraception, 2004; Brache et al. Hum Reprod 2010
Repeated acts of intercourse following EC use

• Repeated acts of intercourse following EC use increase the likelihood of pregnancy with both LNG and UPA EC
• Women should use back up with progestin containing contraceptives following use of Ella
  • Mechanism may render them ineffective
Question #2

LNG EC can be effective if taken up to 5 days after unprotected intercourse.

a. True
b. False
Question #2

LNG EC can be effective if taken up to 5 days after unprotected intercourse.

a. True
b. False
Question #3

LNG EC is more effective than UPA EC when taken on day 5 following intercourse.

a. True
b. False
Question #3

LNG EC is more effective than UPA EC when taken on day 5 following intercourse.

a. True
b. False
WHAT IS THE NEXT STEP?
Efficacy summary

• Efficacy declines over time for all oral EC
• Women are not able to reliably assess how close they are to ovulation
• “Is LNG today more effective than UPA tomorrow?”
• Currently there is no data to gauge the efficacy impact of delaying EC in order to obtain UPA
### What’s the Best Emergency Contraception for You?

<table>
<thead>
<tr>
<th></th>
<th>Copper-T (ParaGard® IUD)</th>
<th>ella®</th>
<th>Plan B One-Step® Next Choice One Dose™ and others</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effectiveness</strong></td>
<td>Best</td>
<td>Very good</td>
<td>Good</td>
</tr>
<tr>
<td><strong>When to Use</strong></td>
<td>Up to 5 days after unprotected sex.</td>
<td>Up to 5 days after unprotected sex.</td>
<td>Up to 3 days after unprotected sex. Less effective on days 4 and 5, but you can still use it.</td>
</tr>
<tr>
<td><strong>Who Can Use</strong></td>
<td>All women.</td>
<td>All women (unless breastfeeding). Less effective for women with a BMI over 35.</td>
<td>All women. Less effective for women with a BMI over 25. May not work for women with a BMI over 30.</td>
</tr>
</tbody>
</table>

My perspective

- Risk vs benefit of EC types should be discussed at well woman visits
  - Ella® script should be provided in advance
- Copper IUD is the most effective type of EC
- When using oral EC, ella® should be first choice
  - However, do not significantly delay EC administration
- LNG EC is better than no EC!
  - In absence of conclusive studies, provide information about potential relationship between weight and efficacy
LEGAL AND REGULATORY INFORMATION
History of EC dispensing in Illinois

• In 2005, former governor Blagojevich signed "emergency rule" which required pharmacists to dispense EC with a valid prescription without delay
  • Pharmacists could be fined or lose their license if they refused to fill
• Challenged by 2 pharmacists citing the Conscience Act and the Freedom of Religion Act

"Emergency Contraception: Law and Ethics" http://www.uspharmacist.com/content/d/pharmacy_law/c/37747/
History of EC dispensing in Illinois

• In 2009 the circuit court granted an injunction to the pharmacists prohibiting the state from enforcing the law
• The rule was amended in April 2010 stating pharmacies had a “duty to deliver lawfully prescribed drugs to patients and distribute nonprescription drugs”
  • EC not mentioned, neither was conscience- or religious-based objections
Pharmacy organization stance

• APhA
  • Added a conscience clause to the Code of Ethics in 1998

• ACCP
  • Position statement in 2005

• Both recognize that a pharmacist has the right to conscientiously refuse to dispense certain medications, but encourages that policies be developed to ensure medication delivery to the patient in a timely manner

"Prerogative of a Pharmacist to Decline to Provide Professional Services Based on Conscience"
http://www.accp.com/docs/positions/positionStatements/pos33_200508.pdf
<table>
<thead>
<tr>
<th>State</th>
<th>Emergency Rooms Required To:</th>
<th>Expanding Access Pharmacist May Dispense EC Without Prescription Under:</th>
<th>Restricting Access State Law Excludes EC From:</th>
<th>State Law Allows Refusal to Dispense EC By:</th>
<th>Requires Prescription 16 and Younger</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alaska</td>
<td></td>
<td>Provide Information About EC</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Arizona</td>
<td></td>
<td>Disperse EC Upon Request</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Arkansas</td>
<td>X</td>
<td>Collaborative Practice Agreement</td>
<td>X</td>
<td>X</td>
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<tr>
<td>California</td>
<td>X   X       X</td>
<td>State Approved Protocol</td>
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<td>Pharmacists</td>
<td>X</td>
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<tr>
<td>Dist. of Columbia</td>
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<td>Medicaid Family Planning Expansion</td>
<td>X</td>
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<td>X</td>
</tr>
<tr>
<td>Florida</td>
<td></td>
<td>Contraceptive Coverage Mandate</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Georgia</td>
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<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Hawaii</td>
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<td>X</td>
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<tr>
<td>Idaho</td>
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<tr>
<td>Illinois</td>
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</tr>
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<td>Maine</td>
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<td>X</td>
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</tr>
<tr>
<td>Massachusetts</td>
<td>X   X</td>
<td>Medicaid Family Planning Expansion</td>
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<td>Minnesota</td>
<td>X</td>
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<tr>
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<td>New Hampshire</td>
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<td>X</td>
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<tr>
<td>New Jersey</td>
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<td>New Mexico</td>
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<tr>
<td>North Carolina</td>
<td></td>
<td>Pharmacists</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Laws surrounding EC dispensing

- Pharmacies must fill valid prescriptions for EC
  - Unless they refuse
- Illinois law allows for refusal to dispense EC by pharmacists and pharmacies
  - Broadly worded--refusal may apply to either but does not specifically include them
A brief legal history of LNG

• May 1999 – Plan B approved as Rx drug by FDA
• August 2006 – Plan B approved as OTC for consumers 18 and older (Rx for 17 and younger)
• April 2009 – Plan B approved for sale OTC to women and men 17 and older
• December 2011 – FDA was to approve Plan B with no age restriction—overruled by HHS Secretary Kathleen Sebelius

“History of Plan B OTC” http://ec.princeton.edu/pills/planbhistory.html
A brief legal history of LNG

- 2012 – Teva files amended application to the FDA to make Plan B One Step available OTC to consumers 15 and over and not BTC
- April 2013 – Amendment approved by FDA
- June 2013 – Plan B One Step approved by FDA for unrestricted sale OTC
- February 2014 – FDA approves generic one-pill EC products for unrestricted sale OTC


Question #4

Plan B One Step ® can be purchased by a 15 year old male, without proof of age, as an over-the-counter item.

a. True
b. False
Definitions

• Behind the Counter
  • Purchaser must be 17 years and older with valid ID
  • Can be male or female
  • Purchased from the pharmacy (not available on the shelves)

• Over the Counter
  • Anyone of any age can purchase
    • No ID required for purchase
  • Available in the “Family Planning” aisle instead of behind the pharmacy counter
Prescription status

• The 2-pill regimens (LNG 0.75mg tabs) are prescription only
  • Mostly manufacturer discontinued at this point
• Patients can talk to the pharmacist about running the OTC EC as a prescription to get coverage through insurance (i.e. IHFS)
Which products are truly OTC?

<table>
<thead>
<tr>
<th>Product name (levonorgestrel 1.5mg)</th>
<th>Label</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plan B One Step</td>
<td>Available OTC unrestricted</td>
<td>~$50</td>
</tr>
<tr>
<td>Take Action</td>
<td>Available OTC unrestricted</td>
<td>~$40</td>
</tr>
<tr>
<td>MyWay</td>
<td>Available OTC for 17 and older*</td>
<td>~$30</td>
</tr>
<tr>
<td>Next Choice One Dose</td>
<td>Available OTC for 17 and older*</td>
<td>~$40</td>
</tr>
<tr>
<td>Fallback Solo</td>
<td>Available OTC for 17 and older*</td>
<td>~$50</td>
</tr>
<tr>
<td>Opcicon One-Step</td>
<td>Available OTC for 17 and older*</td>
<td>~$30</td>
</tr>
<tr>
<td>AfterPill</td>
<td><a href="http://www.afterpill.com">www.afterpill.com</a></td>
<td>$20 + $5 shipping</td>
</tr>
</tbody>
</table>

*Labeled as such; ID not required to purchase*
Why is this important?

ACCESS!
Access issues

• Study done in 2013 illustrated the barriers and false information given by pharmacists to females seeking EC
  • 943 pharmacies were called, 57% gave correct information about EC access
• Survey done in 2014 demonstrated that young men have a 1 in 5 chance of not being able to obtain EC
  • 158 pharmacies, 22 required a female at the time of purchase
• Study done in 2005 looked at EC use in adolescents when it was readily available
  • No difference in use of routine contraception; no increase in risky sexual behavior
Why are there barriers to access?

- Ethics
- Education
- Safety
- Cost
ella®

• Requires prescription for all ages
• Can get through some websites (don't have to see a physician)
• ~$60

https://pharma.afaxys.com/afaxys/afcor_web_hcp_ella.html
http://www.ella-kwikmed.com/
ella® availability

- Distributed by Afaxys
  - Previous distributor dropped ella® in early 2014
- OTC status for Ella®?
  - Recommended for OTC availability by European Medicines Agency in 2014
- Widely available to order through McKesson, Cardinal, Smith, ANDA

Accessed 6/2/14
Afaxys Full Line Product Catalog
Paragard®

- Requires prescription for all ages
- Must be inserted by a specially trained provider
- ~$800

EC availability summary

- PlanB One-Step and Take Action available OTC for all ages
- Some one dose branded generics still BTC/Rx
  - No ID verification required
- Two dose generics are BTC/Rx
  - Manufacturer discontinue
- ella® and Paragard® available only by prescription
Question #4

Plan B One Step ® can be purchased by a 15 year old male, without proof of age, as an over-the-counter item.

a. True
b. False
Plan B One Step ® can be purchased by a 15 year old male, without proof of age, as an over-the-counter item.

a. True
b. False
Questions?
References

- Croxatto HB, Brache V, Pavez M, et al. Pituitary-ovarian function following the standard levonorgestrel emergency contraceptive dose or a single 0.75-mg dose given on the days preceding ovulation. Contraception. 2004 Dec;70(6):442-50
References


References


