OTC vs. prescription-only oral contraceptives: Results from the Border Contraceptive Access Study

Daniel Grossman
The Border Contraceptive Access Study

- Cohort study of OC users in El Paso, Texas
- Took advantage of a natural experiment on the US-Mexico border, where women have the option of obtaining OCs in Mexican pharmacies without a prescription for about $5 per pack
- For several outcomes, we compared El Paso residents obtaining OCs at US public clinics and those obtaining OCs OTC in Ciudad Juárez
Specific Questions of BCAS

1. What motivates women to obtain OCs either OTC or at a clinic?
2. Do women who access the pill OTC have lower continuation?
3. Do women who obtain OCs OTC accurately identify contraindications to use?
4. Do OTC users have lower levels of preventive care?
5. Do women know enough to use the pill effectively without medical supervision?
The Setting: El Paso
Design & Methods

- Recruited 1,046 OC users (all EP area residents)
  - 532 who got pills at family planning clinics in EP
  - 514 who got pills from over-the-counter in Mexico

- We interviewed women four times over 9 months
  - Motivation for choosing their source of OCs
  - Knowledge about pill use
  - Medical conditions, including contraindications
  - Use of reproductive health services
  - Measured blood pressure, height and weight (Time 4)

- Women received $75 for participating.
## Characteristics of Sample

<table>
<thead>
<tr>
<th></th>
<th>Clinic in El Paso (n = 532)</th>
<th>OTC in Mexico (n = 514)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age Group</strong>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 – 24 years</td>
<td>34.4</td>
<td>23.0</td>
</tr>
<tr>
<td>25 – 34 years</td>
<td>43.4</td>
<td>41.4</td>
</tr>
<tr>
<td>35 – 44 years</td>
<td>22.2</td>
<td>35.6</td>
</tr>
<tr>
<td><strong>Parity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 or more live birth</td>
<td>81.0</td>
<td>87.1</td>
</tr>
<tr>
<td><strong>Education</strong>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High school or more</td>
<td>56.4</td>
<td>48.9</td>
</tr>
<tr>
<td><strong>Nativity/Education</strong>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>US-born</td>
<td>39.1</td>
<td>21.2</td>
</tr>
<tr>
<td>Mexican-born, US-educated</td>
<td>32.7</td>
<td>35.6</td>
</tr>
<tr>
<td>Mexican-born and educated</td>
<td>28.2</td>
<td>43.2</td>
</tr>
<tr>
<td><strong>Has health insurance</strong>*</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>23.5</td>
<td>11.1</td>
</tr>
</tbody>
</table>

* p<0.05  ** p<0.01  ***p<0.001, comparing clinic and OTC users
Main Motivation for Choosing Source

Clinic users
- Health services provided: 49.3%
- Cost of pills: 23.0%
- Trust information: 15.1%
- Convenience: 5.9%
- Other reasons: 6.9%

Pharmacy users
- Cost of pills: 39.5%
- Family/friends can pick up pills: 17.8%
- No doctor’s visit needed: 27.2%
- Convenience: 3.9%
- Other reasons: 8.8%
- Trust information: 2.7%

Other reasons included availability of preferred brand, quantity of pills provided by clinics, and other volunteered reasons.
## Discontinuation

<table>
<thead>
<tr>
<th>Reason for pill discontinuation</th>
<th>El Paso Clinic</th>
<th>Mexican pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discontinued pill use</td>
<td>23.7</td>
<td>20.8</td>
</tr>
<tr>
<td>Got pregnant</td>
<td>13.7</td>
<td>14.3</td>
</tr>
<tr>
<td>Switched methods</td>
<td>4.3</td>
<td>9.2</td>
</tr>
<tr>
<td>Wanted to get pregnant</td>
<td>18.0</td>
<td>21.4</td>
</tr>
<tr>
<td>Side effects/other reasons</td>
<td>64.1</td>
<td>55.1</td>
</tr>
<tr>
<td>(n=493)</td>
<td>(n=472)</td>
<td></td>
</tr>
</tbody>
</table>
Pill Use Duration by Source of Pill: Discontinuation Due to Pregnancy, Side Effects, or Other Reasons

Discontinuation 60% higher for those obtaining pills in clinics.
Hazard Ratios for Pill Discontinuation Due to Pregnancy, Side Effects, or Other Reasons

* p<0.05   ** p<0.01

Source of Pill/Number of Pill Packs

Cd. Juarez Pharmacy  El Paso Clinic/ 1-5 packs**  El Paso Clinic/=6 packs
Category 3-4 contraindications to COCs: WHO MEC

- Pregnancy
- Hypertension
- Smoking age 35 or over
- Migraine with aura
- Known hyperlipidemia
- Gall bladder disease
- Breast cancer
- Diabetes (severe)
- MI/stroke
- Complicated valvular heart disease
- DVT/PE (acute or history)
- Known thrombogenic mutation
- Major surgery with prolonged immobilization
- History of peripartum cardiomyopathy
- Lupus with +APA
- Breastfeeding <1 month postpartum
- <3 weeks postpartum
- Liver tumor (hepatocellular adenoma or hepatoma)
- Severe cirrhosis/acute hepatitis
- Complicated solid organ transplant
- Certain drugs (TB, epilepsy, HIV)
- History of malabsorptive bariatric surgery
- Allergy to pill components
Screening for COC Contraindications

- In Mexico, women who obtained OCs from CBD program had similar health profiles to those who visited physicians\(^1\).

- Mexican National Health Survey\(^2\):
  - Women who obtained OCs from pharmacies and from clinics had similar prevalence of contraindications.

- In Washington, women at FP clinic were able to use a checklist to self-identify contraindications\(^3\).

- Accuracy of self-screening using a checklist of WHO MEC category 3 and 4 contraindications\(^4\):
  - Sensitivity 83%, specificity 89%, PPV 83%, NPV 89%.

1. Zavala et al, SFP 1987
• Among 1,015 women in the original sample using COCs, we examined the prevalence of:
  - Specific contraindications
  - Any Category 3 or 4 contraindication

• Using logistic regression, we assessed factors associated with having any Category 3 or Category 4 contraindication:
  - Women’s sociodemographic characteristics
  - Body Mass Index (35% were overweight and 33% were obese)
Most common contraindications among COC users

- Hypertension ($\geq 140/90$ mm Hg): 7.7%
- Smoking, over age 35: 4.9%
- Migraine with aura: 4.1%

(n = 1,015)
Frequency of WHO Category 3 and 4 Contraindications by source of COCs

(n = 1,015)

- Clinic users
- OTC users

* p < 0.05, comparing clinic and OTC users
Odds Ratios of having at least one Category 3 or 4 Contraindication

- **OTC users** (vs clinic users): 1.59 (1.11 – 2.29)
- **Age 35 – 44** (vs Age 18 – 34): 5.30 (3.59 – 7.81)
- **BMI 25.0 – 29.9 kg/m²** (vs BMI < 25.0): 1.03 (0.63 – 1.68)
- **BMI ≥ 30 kg/m²** (vs BMI < 25.0): 2.24 (1.40 – 3.56)

Regression model also adjusted for parity, education, country of birth and education, and US health insurance coverage. All $p > 0.05$
What Women Don’t Know

El Paso Clinic Users

Cd. Juarez Pharmacy Users

% Correct

0 10 20 30 40 50 60 70 80 90 100

= 35 & smoking**

Thrombosis

Take a break

30.4 22.5

50.6 48.7

55.2 45.6

* p<0.05   ** p<0.01
Use of Reproductive Health Services

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<tr>
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<th>Cd. Juarez Pharmacy Users</th>
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<tbody>
<tr>
<td>Ever had a pap screening**</td>
<td>99.6%</td>
<td>96.9%</td>
</tr>
<tr>
<td>Had a pap screening in the last 3 years**</td>
<td>98.7%</td>
<td>89.3%</td>
</tr>
</tbody>
</table>

* p<0.05  ** p<0.01
Conclusions

• There is a lot women like about OTC access
• Continuation is better among OTC users
• High prevalence of COC contraindications in this population—and even higher among OTC users
• Research supports moving forward with OTC OC in US
• Progestin-only pills might be best option as first OTC OC given fewer and rarer contraindications