Adolescent Self-Screening for Contraindications to Combined Oral Contraceptive Pills

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Disclosures

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Unintended Pregnancy in the U.S.

• 3.4 million annually
  – Could be decreased by over-the-counter (OTC) access to combined oral contraceptive pills (COCPs)

• 614,000 (18%) are teen pregnancies
  – 57.4/1000 women ages 15-19
  – 30.1/1000 women ages 15–17
Global oral contraception availability

OCs OTC Working Group

OTC-Contraceptives for teens

• 86% of Mexican teens between the ages of 13 and 19 obtained contraceptives in pharmacies, the first time they had sex

• U.S. Experience with FDA approval for OTC Plan-B
  - 2006 behind the counter for ≥ 18 year olds
  - 2009 behind the counter for ≥ 17 year olds
  - April 2013 on the shelf for ≥ 15 year olds
  - June 2013 on the shelf age unrestricted

Contraindication Self-Screening

• Studies show that adults have the ability to self-screen for COCP contraindications
  - 1,271 women aged 18-49 years
  - Sensitivity 83.2%, Specificity 88.8%
    • Underidentified hypertension
    • Overidentified migraine
Objective

• To compare adolescent self-screening to health care provider reports of potential COCP contraindications

Methods

• Cross-sectional study
• Convenience sample
  – 200 participants
  – Primary care adolescent medicine clinics
  – Midwest, urban setting
• $5 gift card
• IRB approved, waiver of parental consent

Participants

• Inclusion Criteria
  – 14-21 year old females

• Exclusion criteria
  – Cognitive or linguistic inability to complete written English survey measures
  – Currently pregnant
Measures

• Prior to health care provider visit
  – Participant survey
    • Demographics
    • Reproductive health history
    • Interest in OTC access to COCPs (single item, n/y)
    • Medical History Questionnaire (20 items, n/y)

• Immediately after visit
  – Health Care Provider completes Medical History Questionnaire (20 items, n/y/not sure)

Medical History Questionnaire

1. Do you have or have you ever had breast cancer?
2. Do you have liver disease or jaundice (yellow skin or eyes)?
3. Do you take pills every day for tuberculosis, fungal infections or seizures?
4. Do you smoke cigarettes? (if no, go to question 6)
5. Do you smoke more than 15 cigarettes a day?
6. Do you get bad headaches that make you feel sick to your stomach or involve numbness, or make you lose the ability to see, or make it hard to be in light?
7. Are you breast-feeding a baby right now who is under 6 months of age?
8. Do you have high blood pressure?
9. Do you have diabetes (sugar in your blood)?
10. Do you have gallbladder disease?
11. Have you ever had a stroke, blood clot in your legs or lungs, heart attack or heart disease?
12. Has your father, mother, sister, or brother ever had blood clots?
13. Do you weight more than 200 pounds?
14. Are you in a wheelchair?
15. Are you planning to have surgery in the next 4 weeks?
16. Has a doctor or nurse ever told you not to take hormones?
17. Do you have any other medical problem or take regular medicine that could prevent you from using hormonal birth control?
18. Do you think you could be pregnant right now?
19. Do you usually get your period every month?
20. Are you on any medicines for an HIV infection?
Analysis

• Descriptive Statistics
• Concordance Analysis
• SPSS (22.0)

Results

<table>
<thead>
<tr>
<th>Participants (N=61)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (years)</td>
<td>17.3 (range)</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td>% (n)</td>
</tr>
<tr>
<td>Black</td>
<td>62 (38)</td>
</tr>
<tr>
<td>White</td>
<td>18</td>
</tr>
<tr>
<td>Latino</td>
<td>18</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
</tr>
<tr>
<td>Reproductive History</td>
<td>% (n)</td>
</tr>
<tr>
<td>Penile-Vaginal Sex</td>
<td>62 (38)</td>
</tr>
<tr>
<td>Ever use of birth control</td>
<td>62 (38)</td>
</tr>
<tr>
<td>Interest in OTC-COCPs</td>
<td>62 (38)</td>
</tr>
</tbody>
</table>

Participant v. Provider Screening

• Perfect concordance on 5 items (n= yes)
  - Diabetes (n=2)
  - Breast feeding (n=0)
  - Wheelchair use (n=0)
  - Surgery within 4 weeks (n=0)
  - HIV medications (n=0)
### Participant v. Provider Screening

<table>
<thead>
<tr>
<th>Potential Contraindication</th>
<th>Concordant % (n)</th>
<th>Participant Y/Provider N % (n)</th>
<th>Participant N/Provider Y % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast cancer (p &lt; .05)</td>
<td>98.3 (58)</td>
<td>1.7 (1)</td>
<td>0</td>
</tr>
<tr>
<td>Liver disease (p &lt; .05)</td>
<td>98.3 (57)</td>
<td>1.7 (1)</td>
<td>0</td>
</tr>
<tr>
<td>Med interaction (p &lt; .05)</td>
<td>98.3 (58)</td>
<td>1.7 (1)</td>
<td>0</td>
</tr>
<tr>
<td>Smoker (p &lt; .05)</td>
<td>98.3 (58)</td>
<td>1.7 (1)</td>
<td>0</td>
</tr>
<tr>
<td>Migraine (p &lt; .05)</td>
<td>77.6 (45)</td>
<td>19.0 (11)</td>
<td>3.4 (2)</td>
</tr>
<tr>
<td>Hypertension (p &lt; .05)</td>
<td>94.8 (55)</td>
<td>3.4 (2)</td>
<td>0</td>
</tr>
<tr>
<td>Gallbladder disease (p &lt; .05)</td>
<td>98.3 (58)</td>
<td>1.7 (1)</td>
<td>0</td>
</tr>
<tr>
<td>Thromboembolism/heart disease (p &lt; .05)</td>
<td>98.3 (58)</td>
<td>1.7 (1)</td>
<td>0</td>
</tr>
<tr>
<td>1° degree relative with thromboembolism (p &lt; .05)</td>
<td>79.7 (47)</td>
<td>13.6 (9)</td>
<td>0</td>
</tr>
</tbody>
</table>

* (1) participant endorsed history of thromboembolism or heart disease while provider did not

** (1) neither patient nor provider endorsed specific contraindications
(2) participant found to be pregnant during the visit

### Conclusions

- Adolescent women are
  - skilled at self-screening for contraindications
  - more likely than their health care providers to report potential contraindications

- These data provide preliminary support for the safety of OTC provision of COCPs to adolescents
Future research

• Assessment of self-screening in other populations
  – High prevalence of contraindications
  – Recruited from non-clinical settings
  – Diverse ethnic, linguistic backgrounds

• Assessment of capacity to use COCPs correctly

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