Moving oral contraceptives over the counter

Daniel Grossman, MD

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Unintended pregnancy in US

- Unintended pregnancy rate stable over time
- Disparities by race, ethnicity, income
- Variation across states
  - 36%-69%

Finer and Zolna, 2011; Finer and Kost, 2011
Factors contributing to non-use, discontinuation and gaps in use

- Side effects (feared and experienced)
- Health concerns
- Not liking (any) method
- Personal/religious reasons
- Access issues
  - Difficulty getting prescription/method
  - Cost

Frost et al., 2007; Grossman et al., 2010; Potter et al. 2011
Obstacles to obtaining prescription contraception

Among women who had used or wanted to use a prescription contraceptive (N=725)

<table>
<thead>
<tr>
<th>Obstacle</th>
<th>% reporting it as a problem</th>
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<tbody>
<tr>
<td>Long wait to get appointment</td>
<td>27%</td>
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<tr>
<td>Doctor office hours not convenient</td>
<td>23%</td>
</tr>
<tr>
<td>Doctor visit costs too much</td>
<td>20%</td>
</tr>
<tr>
<td>No time off from work or school</td>
<td>19%</td>
</tr>
<tr>
<td>Doctor visit takes a long time</td>
<td>17%</td>
</tr>
<tr>
<td>Didn’t want pelvic exam</td>
<td>12%</td>
</tr>
</tbody>
</table>
30% of women who had ever tried reported difficulty obtaining Rx or refill

18% reported running out of method and had difficulties resupplying

Grindlay, et al., unpublished data
Could removing the prescription barrier to oral contraceptives improve access to contraception?

Increase contraceptive uptake?

Improve continuation?

Reduce unintended pregnancy?

Reduce disparities in contraceptive use and unintended pregnancy?
Global OC prescription requirements

Grindlay et al., 2013
Women’s interest in accessing OCs without a prescription

- Pharmacy Access Partnership survey (n=811)
  - 41% of non-users reported they would start pill, patch or ring if directly available in pharmacy
  - Interest in obtaining hormonal methods at pharmacy was significantly associated with
    - Prior difficulty obtaining prescription contraception
    - Lack insurance, income below 200% federal poverty level
    - Latina, African-American race

Contraceptive features important to women

- Survey among abortion clients (N=574)
- Rated the importance of 18 features of contraceptive methods
- Women’s preferences then matched to features of existing or potential new methods
- OTC OCs matched 71% of features considered extremely important—more than any existing or potential new method

Lessard et al., 2012
National survey (n=2,046)

- 62% supported OTC access to OCs
- 37% reported being likely to use OTC OC
  - 59% of current OC users
  - 33% of women using a method less effective than OCs
  - 28% of women using no method
- Interest highest among younger women, living with partner, private or no insurance

Grossman et al., 2013
<table>
<thead>
<tr>
<th>FDA criteria</th>
<th>Oral contraceptives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug has no significant toxicity if overdosed</td>
<td>True</td>
</tr>
<tr>
<td>Drug is not addictive</td>
<td>True</td>
</tr>
<tr>
<td>Users can self-diagnose conditions for appropriate use</td>
<td>Women determine if they are at risk of unintended pregnancy</td>
</tr>
<tr>
<td>Users can safely take the medication without a clinician’s screening</td>
<td>Research suggests that women can self-screen for contraindications without involving a clinician</td>
</tr>
<tr>
<td>Users can take the medication as indicated without a clinician’s explanation</td>
<td>Research suggests that continuation is similar/higher among women obtaining pills OTC compared to in a clinic</td>
</tr>
</tbody>
</table>
US MEC Category 3 & 4
Contraindications to use

**Combined OCs**
- Pregnancy
- MI/stroke
- Lupus with + Antiphospholipid antibodies
- Breast cancer
- Severe cirrhosis/acute hepatitis
- Liver tumor
- Certain drugs (TB, epilepsy, HIV)
- History of malabsorptive bariatric surgery
- Allergy
- Breastfeeding < 1mo postpartum
- < 21 days postpartum
- Smoking at age ≥ 35 years
- Hypertension
- Complicated valvular heart disease
- Peripartum cardiomyopathy
- Diabetes (severe)
- DVT/PE (acute or history)
- Major surgery with prolonged immobilization
- Migraine with aura
- Known hyperlipidemias
- Known thrombogenic mutations
- Gall bladder disease
- Complicated solid organ transplant

**Progestin-only OCs**
- Pregnancy
- MI/stroke while on OCs
- Lupus with + Antiphospholipid antibodies
- Breast cancer
- Severe cirrhosis
- Liver tumor
- Certain drugs (TB, epilepsy, HIV)
- History of malabsorptive bariatric surgery
- Allergy

2010 US Medical Eligibility Criteria for Contraceptive Use
How common are these contraindications?

- The most prevalent COC contraindications were:
  - Migraine with aura (18%)
  - Hypertension $\geq 140/90$ mm Hg (15%)
  - Hypertension $\geq 160/100$ mm Hg (7%)

- The prevalence of specific POP contraindications was:
  - Medications for TB/seizure (0.9%)
  - Liver disease/cancer (0.4%)
  - Breast cancer (0.3%)

Grossman et al., 2008; White et al. 2012
Accuracy of Self-Screening Checklist Compared to Provider Screening for Contraindications to Use of OCs

<table>
<thead>
<tr>
<th>% (95% C.I.)</th>
<th>Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Contraindicated</td>
</tr>
<tr>
<td>Respondent Contraindicated</td>
<td>32.7 (30.1-35.3)</td>
</tr>
<tr>
<td>Eligible for pill use</td>
<td>6.6 (5.2-8.0)</td>
</tr>
<tr>
<td>Total</td>
<td>39.3 (36.6-42.0)</td>
</tr>
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</table>

Sensitivity = 32.7 / 39.3 = 83.2%; 95% CI: (79.5-86.3)

Specificity = 53.9 / 60.7 = 88.8%; 95% CI: (86.3-90.9)

Grossman et al., 2008
Ongoing use of OCs

- Even with current prescription requirement, adherence to OCs is poor
- Kuwait: continuation was similar between women who consulted a physician and those who did not

Shah et al., 2001
Discontinuation 60% higher for those obtaining pills in clinics

Discontinuation 80% higher for those who obtained 1-5 packs in a clinic

Potter et al., 2011
Which pill? POP vs. COC

- Consensus around POP as first OTC pill in US
- FDA has indicated that OTC approval of estrogen-containing product very unlikely
- Fewer and rarer contraindications for POP
- Incremental step from OTC LNG EC to OTC daily POP
Progestin-only pills (POPs)

- Only about 4% of US OC users use POPs
  - Postpartum, women with contraindications to combined OCs
- Only 1 formulation of POP registered and marketed in US: norethindrone
- Norgestrel POP also registered but no longer marketed
- Levonorgestrel and desogestrel POPs registered and marketed elsewhere

Liang et al., 2012
POP challenges

- Formulation not well-known by women
- Some providers believe that POP less effective than COC
  - Recent Cochrane review found insufficient evidence to compare efficacy
- More breakthrough bleeding than COC
  - But women generally more familiar with bleeding changes with progestin-only methods

Grimes et al., 2010
## Concerns related to an OTC switch for OCs

<table>
<thead>
<tr>
<th>From women and/or general public</th>
<th>From providers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preventive screening</td>
<td>Lost opportunity to counsel about LARC</td>
</tr>
<tr>
<td>Choosing pill</td>
<td>Screening for eligibility</td>
</tr>
<tr>
<td>Cost/insurance coverage</td>
<td>Cost</td>
</tr>
<tr>
<td>Teens might have more (unprotected) sex</td>
<td>Concerns about a POP</td>
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</table>
Cervical cancer screening

Reasons for not having a Pap in last 3 years

- Too expensive
- Too inconvenient
- Keep putting it off
- Don’t know where to get it

Hopkins et al., 2012
Lost opportunity for LARC

- In a study of 1,287 women age 15-24 getting FP at clinics in SF Bay Area, only 10% reported their provider discussed IUDs.
- In a pilot study in London, pharmacists dispensing OCs without a prescription were trained to counsel about LARC and refer those interested.
  - Of 741 consultations, 9 (1.2%) referred for LARC.

Harper et al., 2010; Parsons et al., 2013
Adolescents and OCs OTC

- Evidence from EC indicates that OTC access does not increase sexual risk-taking
- Teens are interested in OTC access
  - 47% of abortion clients age 15-17 reported being likely to use an OTC pill if available
  - Data from focus groups with teens indicate interest but also concerns about cost and use among younger girls, first-time users

“[A girl’s] mom [might say], ‘You better not be having sex. You ain’t getting no birth control.’ But when you can go on your own and get it, you know you’re safer.”

Harper et al., 2005; Grindlay et al., 2014; Baum et al., unpublished data
Willingness to pay for OTC OC

- Highest amount willing to pay for OTC OC (2011)
  - Mean $20.75
  - Median $20.00
  - →~$5 more than current monthly expenses for contraception
- Only 12% willing to spend more than $30
- Likely lower since ACA implementation

Grossman et al., 2013
HMOs covering any OTC product

McIntosh et al., 2013
Coverage of OTC EC

- Medicaid generally requires a prescription to receive federal matching funds
- Most state Medicaid programs cover OTC EC but require a prescription
  - ~7 states have developed work-arounds to cover OTC EC without Rx
- 2013: Department of Defense and Indian Health Service issued directives to fully cover OTC EC without a Rx
Percentage change in the number of unintended pregnancies to low income women in the US

Change in the number of unintended pregnancies

Out of pocket cost of a pack of pills

Foster et al., Contraception 2015
Is there a need for OTC access to OCs in the era of no-copay FP?

- Not everyone will benefit from ACA
- CHOICE: Users of short-term methods who reported difficulty obtaining the method more likely to discontinue (HR 2.43)
- There has been interest in pharmacy access model in London, where NHS covers clinic-based FP

Stuart et al., 2013; Parsons et al., 2013
OTC contraception and ACA

- HHS clarified that OTC FDA approved methods must be covered without cost sharing by plans subject to Women’s Preventive Services Guidelines of ACA—
  *but insurance company may require woman to have prescription*

- Advocacy focus on obtaining insurance coverage of OTC contraception without a prescription
Support among professional organizations

- APHA policy in support of insurance coverage for OTC contraception – 2011
- ACOG Committee Opinion – 2012, 2015
- AMA resolution recommending FDA to encourage pharma – 2013
- AAFP resolution in support of OCs OTC with insurance coverage - 2014
- Outreach to SAHM, AAP
Pharmacy access to hormonal contraception

- “Behind-the-counter” status
- Pharmacist screens women for eligibility
- Washington State: pharmacy access model found to be safe, effective and acceptable to women
- CA, DC, New Zealand
- Concerns: reimbursement and refusals—and must be done state by state

Gardner et al, 2008
Where are we now?

- Considerable evidence base
  - Safety and effectiveness of OTC OCs
  - Women’s demand for OTC access
- No apparent risk of women losing insurance coverage for OCs if go OTC
- Decision to focus on POP
- More voices in support of OTC switch
- No pharmaceutical company clearly moving forward
- Focus on creating enabling environment and making case for pharma investment
Thank you!

Ibis Reproductive Health

dgrossman@ibisreproductivehealth.org