

Is it time to bring OCs over the counter?

Research recently conducted in the area around El Paso, TX, and Juarez, Mexico, suggests there is demand in the United States for over-the-counter birth control pills.¹

As part of the study, researchers interviewed more than 1,000 El Paso women, about half of whom obtained their birth control pills across the border at Mexican pharmacies and half of whom

went to U.S. clinics to get their pills. Researchers report that women of different ages, parities, and educational levels likely would take advantage of an OTC option were oral contraceptives available at low cost.¹

One group already is working on the possibility of such access, says study co-author **Daniel Grossman, MD**, senior associate at Ibis Reproductive Health, a non-profit research organization based in Cambridge, MA, and Oakland, CA. Since 2004, the Working Group on Oral Contraceptives Over-the-Counter has brought together researchers, advocates and clinicians to review existing data and identify information gaps, reached out to provider organizations, synthesized existing data and conducted new analyses to establish the rationale for an over-the counter (OTC) switch, states Grossman.

“Our aim is to ensure that all these efforts move forward with a clear focus on providing more options to women who currently face barriers accessing contraception,” Grossman observes. “The cost of an OTC OC [oral contraceptive] product is a critical piece of this.”

Convenience key factor

In conducting the current study, researchers found that older women and those who were born and educated in Mexico were more likely to buy their pills in Mexican pharmacies. Women who received public assistance from such federal programs as Women, Infant and Children (WIC) were more likely to go to the U.S. clinics.

Among both groups, most of the women said they believed the facility where they obtained the pills was cheaper and more convenient than the options on the other side of the border. About 90% of the women who obtained oral contraceptives on the U.S. side say they trusted their clinic to give them good information (compared to 46% of Mexican pharmacy consumers), and that they liked the other health services provided there. About 90% of the women who bought pills from the Mexican pharmacies said they wanted to bypass a doctor’s prescription and be able to send family or friends to pick up the pills.

Lead author **Joseph Potter, PhD**, professor in the Sociology Department and Population Research Center at the University of Texas at Austin, said, “Our team’s next steps will be to further analyze the experience of the women enrolled in the El Paso study to see how well the OTC pharmacy

EXECUTIVE SUMMARY

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- Researchers interviewed more than 1,000 women, about half of whom obtained their birth control pills across the border at Mexican pharmacies and half of whom went to U.S. clinics to get their pills. Women of different ages, parities, and educational levels would likely take advantage of an OTC option were oral contraceptives available at low cost, researchers report.
- The Working Group on Oral Contraceptives Over-the-Counter is focusing its efforts on establishing the rationale for an OTC switch. It is looking to first take a progestin-only pill over the counter.

users compare to the family planning clinic users with respect to A, continuation, B, screening for contraindications, and C, use of preventive health services.”

POP to come first

Are oral contraceptives suitable for over-the-counter status? According to the working group, the substantial literature available on the Pill confirms it meets most of the Food and Drug Administration’s (FDA) criteria for OTC status:

- the drug’s benefits outweigh the risk for women of reproductive age;
- the potential for misuse or abuse is low;
- a consumer can easily self-diagnose the condition for which the pills are indicated;
- directions for use are straightforward.²

Because the FDA officials also want to know that health care practitioners are not needed for the safe and effective use of an OTC product, the outstanding safety question is whether women can self-screen appropriately for contraindications to OC use, including hypertension, states the working group. Experience indicates that in countries where OCs already are obtainable without prescription, women use them safely without prior screening by a health care professional, the working group maintains.²

Over the past year, working group members have focused efforts on first moving a progestin-only pill (POP) over the counter, which Grossman sees as an interim step toward an eventual OTC switch for combined pills. Given the fewer and rarer contraindications for POPs, as well as the precedence of an OTC switch for a progestin-only emergency contraception product, an over-the-counter switch for POPs is likely more feasible,

says Grossman. In addition, by not affecting the much larger population of current combined Pill users, whose pills would remain on prescription, it seems less likely that many women would lose insurance coverage for an OTC POP and have to pay more after the OTC switch, says Grossman.

“Still, we are concerned about the cost of an OTC POP product, and the working group is exploring how best to ensure an accessible price,” states Grossman.

What will it take to bring over-the-counter access to combined oral contraceptives? To bring about an OTC switch, a company would need to submit an application to the FDA, says Grossman. Several types of studies would be required as part of that application, including an actual use study and a label comprehension study, he explains.

“The working group has developed a draft OTC label for an OTC POP, as well as protocols for actual use and label comprehension studies, and we are now beginning to reach out to both for-profit and non-profit pharmaceutical companies to gauge their interest in exploring the possibility of an OTC switch with the FDA and moving forward with this research,” states Grossman.

REFERENCES

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