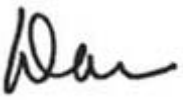
February 22, 2011

In This Update

Dear Working Group Member,

Below are several updates we thought you might be interested in, including new research articles related to over-the-counter provision of oral contraceptives, as well as information about a bill that was introduced in Washington, DC, that would allow pharmacy access to hormonal contraception. Please let me know if you have questions or comments about any of these updates.

Thanks,



Daniel Grossman
Senior Associate, Ibis Reproductive Health

Women who obtain birth control OTC in Mexico more likely to continue use

Related study suggests that pills without estrogen are most appropriate for over-the-counter status

Two papers from the Border Contraceptive Access Study appear in the March issue of *Obstetrics and Gynecology*. Below are the abstracts of the papers, followed by the press release.

Continuation of Prescribed Compared With Over-the-Counter Oral Contraceptives
Joseph E. Potter, PhD, Sarah McKinnon, PhD, Kristine Hopkins, PhD, Jon Amastae, PhD, Michele G. Shedlin, PhD, Daniel A. Powers, PhD, and Daniel Grossman, MD

Article

OBJECTIVE: To estimate differences in continuation of oral contraceptive pills (OCPs) between US resident women obtaining pills in US family planning clinics compared with over the counter in Mexican pharmacies.
METHODS: In El Paso, Texas, we recruited 514 OCP users who obtained pills over the counter from a Mexican pharmacy and 532 who obtained OCPs by prescription from a family planning clinic in El Paso. A baseline interview was followed by three consecutive surveys over nine months. We asked about date of last supply, number of pill packs obtained, how long they planned to continue use, and experience of side effects. Retention was 90%, with only 105 women lost to follow-up.
RESULTS: In a multivariable Cox proportional hazards model, discontinuation was higher for women who obtained pills in El Paso clinics compared with those who obtained their pills without a prescription in Mexico (hazard ratio 1.6, 95% confidence interval [CI] 1.1-2.3). Considering the number of pill packs dispensed to clinic users, discontinuation rates were higher (hazard ratio 1.8, 95% CI 1.2-2.7) for clinic users who received one to five pill packs. However, there was no difference in discontinuation between clinic users receiving six or more pill packs and users obtaining pills without a prescription.
CONCLUSION: Results suggest providing OCP users with more pill packs and removing the prescription requirement would lead to increased continuation.

Contraindications to Combined Oral Contraceptives Among Over-the-Counter Compared With Prescription Users
Daniel Grossman, MD, Kari White, MA, MPH, Kristine Hopkins, PhD, Jon Amastae, PhD, Michele Shedlin, PhD, and Joseph E. Potter, PhD
Article

OBJECTIVE: To compare the estimated proportion of contraindications to combined oral contraceptives between women who obtained combined oral contraceptives in US public clinics compared with women who obtained combined oral contraceptives over the counter (OTC) in Mexican pharmacies.
METHODS: We recruited a cohort of 501 women who were residents of El Paso, Texas, who obtained OTC combined oral contraceptives in Mexico and 514 women who obtained combined oral contraceptives from family planning clinics in El Paso. Based on self-report of World Health Organization category 3 and 4 contraindications and interviewer-measured blood pressure, we estimated the proportion of contraindications and, using multivariable-adjusted logistic regression, identified possible predictors of contraindications.
RESULTS: The estimated proportion of any category 3 or 4 contraindication was 18%. Relative contraindications (category 3) were more common among OTC users (13% compared with 9% among clinic users, P=.006). Absolute contraindications (category 4) were not different between the groups (5% for clinic users compared with 7% for OTC users, P=.162). Hypertension was the most prevalent contraindication (5.6% of clinic users and 9.8% of OTC users). After multivariable adjustment, OTC users had higher odds of having contraindications compared with clinic users (odds ratio [OR] 1.59, 95% confidence interval [CI] 1.11-2.29). Women aged 35 years or older (OR 5.30, 95% CI 3.59 -7.81) and those with body mass index 30.0 or more (OR 2.24, 95% CI 1.40 -3.56) also had higher odds of having contraindications.
CONCLUSION: Relative combined oral contraceptive contraindications are more common

among OTC users in this setting. Progestin-only pills might be a better candidate for the first OTC product given their fewer contraindications.

Press Release: Women Who Obtain Birth Control Over the Counter in Mexico More Likely to Continue Use, New Research Shows

Related study suggests that pills without estrogen are most appropriate for over-the-counter status

AUSTIN, Texas - Women who obtain oral contraceptives over the counter in Mexico are likely to stay on the birth control pill longer than those who obtain pills by prescription at US clinics, according to a study by researchers from two University of Texas campuses, Ibis Reproductive Health, and New York University.

The study was led by Joseph Potter, professor in the Sociology Department and Population Research Center at The University of Texas at Austin.

The Border Contraceptive Access Study takes advantage of a natural experiment along the US-Mexico border, where US women have the option of obtaining oral contraceptives over the counter in Mexico, and it provides insight into what might happen if the pill were made available OTC throughout the US. The researchers interviewed more than 1,000 El Paso, Texas oral contraceptive users and followed them over nine months. Half of the women obtained their pills over the counter at pharmacies in Juarez, Mexico, while the other half obtained them from family planning clinics in El Paso. Most women in the study were low-income and uninsured.

According to the findings, women who obtained pills in El Paso clinics were 60% more likely to stop taking their pills during the nine-month study compared to those who purchased their contraceptives without a prescription in Mexico. Women who received fewer than six packs of pills at one time at the clinic were about 80% more likely to discontinue taking the pill compared to over-the-counter users.

The results suggest that access is a key determinant of contraceptive continuation. "Removing unnecessary barriers to access-such as limits on the number of pill packs dispensed or even possibly the prescription requirement-could have an important impact on reducing unintended pregnancy," Potter says.

In a related paper from the Border Contraceptive Access Study, the researchers found that women who purchased their pills over the counter in Mexico might not be making the best choice about which kind of birth control is safest for them.

The study, led by Daniel Grossman of Ibis Reproductive Health, a nonprofit research organization based in Cambridge, Mass., and Oakland, Calif., found that women who obtained combined oral contraceptives, which contain both synthetic estrogen and progesterone, in Mexico were significantly more likely than US clinic users to have health conditions such as hypertension or smoking over age 34 that may put them at risk while using this type of pill.

While there was no difference in absolute contraindications, relative contraindications were significantly more common among over-the-counter users (13%) compared to clinic users

(9%). Although no woman in the study reported a medical complication related to pill use, these contraindications may put women at higher risk of having a heart attack or stroke while using estrogen-containing pills.

The findings highlight the importance of self-screening for contraindications when pills are made available over the counter, said Grossman, who also coordinates a working group of researchers, clinicians, and advocates exploring the feasibility of an OTC switch for pills in the US.

"If combined oral contraceptives are available over the counter, we need to be sure that women have the necessary tools to determine whether they are appropriate for this kind of pill," Grossman said. "Alternatively, progestin-only pills, which don't contain estrogen, might be the best option as the first over-the-counter oral contraceptive in the US. Progestin-only pills are also very effective, but they have many fewer and rarer side effects."

The Border Contraceptive Access Study is funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development. The findings will be published in the March issue of *Obstetrics & Gynecology*.

For more information, contact: Jessica Sinn, Public Affairs Specialist, College of Liberal Arts, 512-471-2404 or sinnjessica@austin.utexas.edu; or Britt Wahlin, Director of Communications, Ibis Reproductive Health, 617-549-2852 or bwahlin@ibisreproductivehealth.org.

Study shows increased contraceptive supply linked to reduced unintended pregnancy and abortion

A new study shows that pregnancy and abortion rates decrease significantly when women receive a one-year supply of oral contraceptives, compared to women who are prescribed one- or three-month supplies.

Number of Oral Contraceptive Pill Packages Dispensed and Subsequent Unintended Pregnancies
Diana Greene Foster, PhD, Denis Hulett, Mary Bradsberry, Philip Darney, MD, MSc, and Michael Policar, MD, MPH
Article

OBJECTIVE: To estimate how number of oral contraceptive pill packages dispensed relates to subsequent pregnancies and abortions.
METHODS: We linked 84,401 women who received oral contraceptives through the California family planning program in January 2006 to Medi-Cal pregnancy events and births conceived in 2006. We compared pregnancy rates for women who received a 1-year supply of oral contraceptive pills, three packs, and one pack.
RESULTS: Women who received a 1-year supply were less likely to have a pregnancy (1.2% compared with 3.3% of women getting three cycles of pills and 2.9% of women getting one cycle of pills). Dispensing a 1-year supply is associated with a 30% reduction in the odds of conceiving an unplanned pregnancy compared with dispensing just one or three packs (confidence interval [CI] 0.57-0.87) and a 46% reduction in the odds of an abortion (95% CI 0.32-0.93), controlling for age, race or ethnicity, and previous pill use.

CONCLUSION: Making oral contraceptives more accessible may reduce the incidence of unintended pregnancy and abortion. Health insurance programs and public health programs may avert costly unintended pregnancies by increasing dispensing limits on oral contraceptives to a 1-year supply.

Bill introduced in DC for pharmacy access to hormonal contraception

On February 15, 2011, District of Columbia Council Member David Catania (I-At Large) introduced a bill that would create a pharmacy access model of dispensing hormonal contraception. An article that appeared in the *Washington Post* is available here. Below are some initial comments from the working group steering committee regarding the bill.

Hormonal contraception, which encompasses methods such as oral contraceptives (the birth control pill), the patch, and the vaginal ring, is a popular and effective form of birth control. In particular, oral contraceptives (OCs) are among the safest, best studied medications on the market and the most widely used contraceptive method in the United States. But barriers to accessing this highly effective method of birth control can be a deterrent to use, leading to unintended pregnancy. Removing barriers such as the prescription requirement and making OCs available over the counter or through pharmacists could make it easier for women to access and consistently use the method.

A pharmacy access program could help to improve access to OCs and other hormonal methods for thousands of women in the District. Research on pharmacy access to hormonal contraception in Washington State showed pharmacists can safely provide hormonal methods to women and women are satisfied with this provision model.

It is important to keep in mind that pharmacy access, in which women would consult with a pharmacist and undergo a screening process before obtaining their birth control, is different from over-the-counter access, in which individuals could directly purchase their method from pharmacies just like they do condoms and spermacides. Some of the press surrounding the DC bill confused pharmacy access with true OTC provision.

As plans for the pharmacy program in Washington, DC, are implemented, questions regarding pharmacist training and reimbursement will need to be addressed, as well as whether women's insurance--especially Medicaid--will cover hormonal contraception dispensed in this manner.

While pharmacy access is an important step to reducing barriers to accessing contraception, the OCs OTC Working Group believes that true over-the-counter status should be the goal for at least some kinds of OCs, such as progestin-only pills.

No evidence of increased risk of heart attack with progestin-only contraceptives, new review shows

As noted above, there is growing interest in the possibility of a progestin-only pill (POP) to be the first OTC oral contraceptive in the US since there are many fewer--and rarer--contraindications compared to combined oral contraceptives. This review adds to our knowledge about the safety of POPs.

Progestogen-Only Contraceptives and the Risk of Acute Myocardial Infarction: A Meta-Analysis
Zeina Chakhtoura, Marianne Canonico, Anne Gompel, Pierre-Yves Scarabin, and Geneviève Plu-Bureau
Abstract

CONTEXT: The association between combined oral contraceptives (OC) and the risk of myocardial infarction (MI) has been intensively studied, and conclusions are controversial. While progestogen-only contraceptives (POC) are commonly used worldwide, their impact on cardiovascular diseases is poorly investigated and remains unclear.
OBJECTIVE: We carried out a meta-analysis based on EMBASE- and MEDLINE-referenced literature corresponding to OC marketed since 1960.
METHODS: Eligible articles published in English language describing OC or POC use and MI outcome were reviewed, and relevant ones were extracted. All types of POC and route of administration were considered.
RESULTS: Six case-control studies were identified. The combined odds ratio showed no increase in the MI risk with POC use (odds ratio = 1.07; 95% confidence interval, 0.62-1.84). This result was similar according to the route of administration, including implant, injectable, and oral POC.
CONCLUSION: Data from observational studies suggest no increase in risk of MI with POC use. However, these results are based on limited data. Further investigations are needed, especially among women at high MI risk.

Commentary questions whether women should be counseled about side effects of oral contraceptives

A provocative commentary in last month's issue of *Contraception* reviews the limited evidence from placebo-controlled trials of combined oral contraceptives and finds that there is no evidence that nonspecific side effects are more common among pill users compared to those taking inert pills. Should we change how we counsel women about pill use, and how does this affect what information should be in the pill labeling? The abstract of the article is below.

Nonspecific Side Effects of Oral Contraceptives: Nocebo or Noise?
David A. Grimes, Kenneth F. Schulz

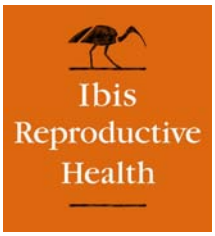
Side effects of combined oral contraceptives are the most common reason why women discontinue them. Over the past half century, an elaborate mythology about these ill effects has evolved, fueled by rumor, gossip and poor-quality research. In contrast, placebo-controlled randomized trials document that nonspecific side effects are not significantly more common with combined oral contraceptives than with inert pills. These reported nonspecific side effects may reflect the nocebo phenomenon (the inverse of a placebo): if women are told to expect noxious side effects, these complaints occur because of the power of suggestion. Alternatively, nonspecific complaints may simply reflect their background prevalence in the population. Because Level I evidence documents no important increase in nonspecific side effects with oral contraceptives, counseling about these side effects or including them in package labeling is unwarranted and probably unethical. When in doubt, clinicians should err on the side of

optimism.

About Us

The Oral Contraceptives (OCs) Over-the-Counter (OTC) Working Group is an informal coalition of reproductive health and rights organizations, nonprofit research and advocacy groups, university-based researchers, and prominent clinicians who share an interest in women's health and access to contraception. Our goal is to evaluate objectively the risks and benefits of demedicalizing contraceptive care, with an eye toward improving access to OCs and potentially other hormonal contraceptive methods by making them available without a prescription.

The working group is coordinated by Ibis Reproductive Health.



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