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Dear Working Group Member,

The past six months have seen several new initiatives aimed at improving access to hormonal contraception by removing the prescription requirement and by expanding insurance coverage of over-the-counter (OTC) contraception. In this update, we highlight a new law in California that will allow pharmacists to provide hormonal contraception without a prescription, as well as an initiative aimed at reclassifying several oral contraceptives (OCs) for "behind-the-counter" sale in New Zealand.

Insurance coverage for OTC contraception without a prescription is also gaining traction in the US: Last year both the Department of Defense and the Indian Health Service issued directives to cover OTC emergency contraception (EC) without cost sharing and without a prescription. A bill has also been introduced in the California State Senate that would prohibit insurance companies from requiring a prescription as a trigger for coverage of OTC contraception.

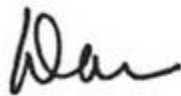
Also highlighted below are several new publications related to an OTC switch for OCs, including a recent review published in *Current Opinion in Obstetrics and Gynecology* and a policy brief published in the *Food and Drug Policy Forum*. We also include information about a study that found a high level of interest in OTC access to OCs among abortion clients, which was published in *Perspectives on Sexual and Reproductive Health*. In addition, we highlight a recent article from the Contraceptive CHOICE Project that found a very low prevalence of contraindications to combined hormonal contraception among women seeking these methods. This paper adds to the evidence on the safety of moving these methods over the counter.

On the evening of May 6, we will have an interactive presentation on the OCs OTC Working Group in Seattle. If you are interested in participating or would like to forward information about the meeting to your contacts in the Seattle area, please let me know.

Finally, I want to thank all of you who participated in the working group's meeting in New York City last October. If you would like more information about the meeting, including copies of presentations, please email [Ella Douglas-Durham](mailto:Ella.Douglas-Durham).

And please let me know if you have any questions or comments on the material in this update.

Thanks,



Daniel Grossman, MD
Vice President for Research, Ibis Reproductive Health

New California law will allow pharmacist provision of self-administered hormonal contraception

In October 2013, California passed SB 493, a new law authorizing pharmacists to prescribe self-administered hormonal contraception (pills, patch, and ring) to women of all ages, as well as nicotine replacement products and prescription medications not requiring a diagnosis that are recommended for international travelers. The bill states that a standardized procedure or protocol (developed and approved by both the Board of Pharmacy and the Medical Board of California, in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities) will require that the patient use a self-screening tool based on the US Medical Eligibility Criteria for Contraceptive Use to identify risk factors for use of self-administered hormonal contraceptives. It will also require that upon furnishing a hormonal contraceptive or if it is determined that use of a hormonal contraceptive is not recommended, the pharmacist refer the patient to her primary care provider or, if she does not have one, to a nearby clinic.

The protocol, training, and implementation plans are still under development, and it is anticipated that the new law will be rolled out over the coming year. The full text of the bill is available [here](#).

New Zealand considers reclassifying several OC formulations for pharmacy-access distribution

On April 8, the New Zealand Medicines Classification Committee will consider an

[application](#) submitted by a retail pharmacy group to reclassify several OC formulations from prescription-only to a category that would allow distribution by a pharmacist who performs required medical screening. The group is requesting reclassification of progestin-only pills (desogestrel, levonorgestrel, and norethindrone formulations), as well as second-generation combined oral contraceptives. The application refers to "a growing call internationally to remove the prescription requirement to access oral contraceptives." More information is available [here](#).

US Department of Defense and Indian Health Service expand coverage for OTC emergency contraception without a prescription

Making sure insurance covers currently available OTC contraceptives without a prescription can help lay the foundation for coverage of a future OTC OC, allowing all women to reap the benefits of OTC access. Two exciting developments happened in recent months that help us move closer to that goal. In August 2013, the Department of Defense issued a [memorandum](#) requiring all military treatment facility (MTF) pharmacies to carry OTC Plan B One-Step, and provide it to all active-duty servicewomen and female beneficiaries of child-bearing potential, without a prescription or age restrictions, at no cost. MTF pharmacists process requests for OTC Plan B One-Step in an [identical manner](#) to other pharmacy claims. Previously, OTC EC was not covered by TRICARE, the military insurance program, though some military branches made it available OTC at no extra cost. In addition, in September, the Indian Health Service issued a [verbal directive](#) ordering its facilities to provide free of charge OTC EC without a prescription for Native American women aged 17 or older. Barriers to EC access for Native American women have been [well documented](#). Both of these policy changes have promise for expanding and normalizing insurance coverage of OTC contraceptives without a prescription.

California bill would eliminate the prescription requirement to trigger insurance coverage of FDA-approved OTC contraception

Last year the US Department of Health and Human Services (HHS) [clarified](#) that FDA-approved OTC contraceptives used by women must be covered by new private insurance policies without cost sharing under the Affordable Care Act (ACA). However, HHS also stipulated that insurance companies could require women to have a prescription in order to have the OTC method covered. While this was an important step in codifying insurance coverage of OTC contraceptives, the prescription requirement works against the improvement in access that motivates our interest in OTC availability.

Now a bill introduced in the California State Senate would prohibit insurance companies from requiring a prescription to trigger insurance coverage. The Contraceptive Equity Act of 2014 ([SB 1053](#)) was introduced last month by Senator Holly Mitchell and aims to improve access to all FDA-approved contraceptives by building on federal and state law, including the ACA. SB 1053 would place clear limits on medical management techniques used by insurers in the context of contraceptive coverage, including the prescription requirement for OTC contraceptives. The bill also creates equity in the contraceptive coverage mandate by making it gender neutral and including contraceptive methods used by men. SB 1053 is co-sponsored by the California Family Health Council and the National Health Law Program; more information is available [here](#). We will be following the bill closely as it moves through the state legislature.

New published papers related to OCs OTC

Grossman D. Should women have over-the-counter access to oral contraceptive pills? *Expert Review of Obstetrics and Gynecology*. 2013; 8(5):389-391. Article available [here](#).

Grossman D, Fuentes L. Over-the-counter access to oral contraceptives as a reproductive healthcare strategy. *Curr Opin Obstet Gynecol*. 2013;25(6):500-5. Abstract available [here](#).

PURPOSE OF REVIEW: The aim of this review is to summarize the current evidence on the safety and effectiveness of moving oral contraceptives from prescription-only to over-the-counter (OTC) status. The review also examines women's interest in OTC access to oral contraceptives, as well as potential barriers and facilitators to an OTC switch.

RECENT FINDINGS: Studies show that women can safely self-screen for contraindications to oral contraceptives - especially progestin-only pills - without the aid of a clinician. One study in Texas found that women using pills obtained OTC in Mexico were significantly less likely to discontinue compared to women obtaining pills at US clinics by prescription. A national representative survey of US women at risk of unintended pregnancy found widespread interest in using OTC pills, and many women worldwide already have access to pills without a prescription. On average, the most US women report being willing to pay for an OTC pill is \$20.

SUMMARY: OTC access to oral contraceptives could help to reduce unintended pregnancy by increasing the number of pill users, improve continuation and reduce gaps in use. It is critical that a future OTC pill be made available at an accessible price, and it should be covered by insurance without a prescription. Research suggests that common concerns about the safety of oral contraceptives OTC and a potential negative effect on women's use of preventive services are largely unsupported.

Wahlin B, Grindlay K, Grossman D. Should oral contraceptives be available over the counter? *Food and Drug Policy Forum*. March 2014; 4(3). Article available [here](#).

Oral contraceptives (OCs), popularly known as the birth control pill, have been on the US market for over 50 years and used by more than 80% of sexually active American women, making them women's top contraceptive choice. But research shows that the prescription may be a barrier to women's access to and consistent use of OCs. Moving OCs over the counter (OTC) in the United States could help more women obtain their method of choice and reduce unintended pregnancy. This policy brief reviews current evidence on OCs OTC, showing that the safety of OCs outweighs the risks of making OCs available over the counter and that women are able to use a simple checklist to determine whether they have any medical conditions that would make it unsafe for them to use OCs. In addition, over two-thirds of women support moving OCs OTC, and one-third of women not currently using a method report they would be likely to use an OTC OC. Major professional medical associations, such as the American College of Obstetricians and Gynecologists (ACOG), also support moving OCs OTC. But policy solutions are needed to ensure that a future OTC OC is covered by both public and private insurance plans, ideally without a prescription. In addition, the manufacturer of a future OTC OC will need to price its product affordably, keeping in mind that women will not likely pay more than \$10-20 for a single pack of OCs.

Grindlay K, Foster DG, Grossman D. Attitudes toward over-the-counter access to oral contraceptives among a sample of abortion clients in the United States. *Perspect Sex Reprod Health*. 2014;46(2):xx-xx, doi: 10.1363/46e0714. Abstract available [here](#).

CONTEXT: Women having abortions are at high risk for future unintended pregnancy, and removing the prescription requirement for oral contraceptives may increase continuation and adoption of this effective method.

METHODS: A survey fielded from May to July 2011 collected information from 651 women aged 15-46 seeking abortion services at six urban clinics from across the United States. Descriptive statistics, chi-square tests and logistic regression analyses were conducted to estimate women's interest in over-the-counter access to oral contraceptives.

RESULTS: Eighty-one percent of respondents supported over-the-counter access to oral contraceptives; while 42% of women planned to use the pill after their abortion, 61% said they would likely use this method if it were available over the counter. Thirty-three percent of women who planned to use no contraceptive following their abortion said they would use an over-the-counter pill, as did 38% who planned to use condoms afterward. In multivariable analysis, several subgroups had increased odds of likely over-the-counter use: women who were older than 19 (odds ratios, 1.8 for those aged 20-29 and 1.6 for those aged 30-46), were uninsured (1.5), had ever used the pill (1.4), had had difficulty obtaining a prescription refill for hormonal contraceptives (2.7) or planned to use the pill post-abortion (13.0). By contrast, compared with white respondents, women of other races or ethnicities were less likely to say they would use over-the-counter pills (0.4-0.7).

CONCLUSIONS: Interest in a hypothetical over-the-counter oral contraceptive was high in this sample, and this delivery model has the potential to reduce unintended pregnancy among abortion patients.

Xu H, Eisenberg DL, Madden T, Secura GM, Peipert JF. Medical contraindications in women seeking combined hormonal contraception. *Am J Obstet Gynecol*. 2014;210(3):210.e1-5. Article available [here](#).

OBJECTIVE: The objective of the study was to evaluate the prevalence of medical contraindications in a large group of women seeking combined hormonal contraception (CHC).

STUDY DESIGN: The Contraceptive CHOICE Project is a prospective cohort study designed to promote the use of long-acting reversible contraceptive methods to reduce unintended pregnancies in the St Louis region. During baseline enrollment, participants were asked about their desired methods of contraception and medical history. Potential medical contraindications were defined as self-reported history of hypertension, myocardial infarction, cerebral vascular accidents, migraines with aura, any migraine and age 35 years or older, smoking in women older than 35 years, venous thromboembolism, or liver disease. We reviewed all research charts of women with self-reported medical contraindications to verify all conditions. Binomial 95% confidence intervals (CIs) were calculated around percentages.

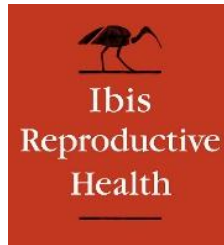
RESULTS: Between August 2007 and December 2009, 5087 women who enrolled in the CHOICE Project provided information about their medical history and 1010 women (19.9%) desired CHC at baseline. Seventy women (6.93%; 95% CI, 5.44-8.68%) were defined as having a potential medical contraindication to CHC at baseline. After chart review, only 24 of 1010 participants desiring CHC (2.38%; 95% CI, 1.53-3.52%) were found to have true

medical contraindications to CHC including 17 with hypertension, 2 with migraines with aura, 2 with a history of venous thromboembolism, and 3 smokers aged 35 years or older.
CONCLUSION: The prevalence of medical contraindications to CHC was very low in this large sample of reproductive-aged women. This low prevalence supports provision of CHC without a prescription.

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.



www.ibisreproductivehealth.org

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