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Dear OCs OTC Working Group Member,

Many of us are reexamining our priorities given the upcoming change in the US administration. In these challenging times, we remain resolute in our commitment to moving an OC OTC. The work ahead will be tied strongly to two of our most essential principles: affordability (in both price and insurance coverage) and availability without an age restriction. We hope to collaborate with you on both state and national levels to achieve these goals. Please let us know if you have any thoughts for ways to strengthen our work moving forward. We are proud of the momentum we have gained in this movement over the past decade with our working group partners. Now is the time to hold each other in our strength as we work to achieve an OTC OC, safeguard insurance coverage for all contraceptive methods, and strive to protect health care access for all.

In this newsletter, we would also like to share new research demonstrating that there is strong interest in OTC progestin-only pills. We hope to publish a manuscript on these findings in the coming months. In addition, the American Academy of Family Physicians has a new resolution that supports including adolescents in research for a future OTC OC. Please also let us know if there are news items or events you would like us to highlight in upcoming newsletters.

Finally, you will find an analysis of and our response to a recent study from Denmark that proposed a potential link between hormonal contraception and depression. We share a number of different perspectives on this study and highlight other research that has been done on this topic.

Have a wonderful Thanksgiving holiday!

Thank you,



Kate Grindlay Project Director/Associate Ibis Reproductive Health

New study on POP interest in the US

<u>New research</u> presented at the North American Forum on Family Planning this month finds that teens and women in the US are interested in using an OTC progestin-only pill (POP) if it were available. This is the first national survey to include teen perspectives and the first to explore interest in using an OTC POP. You can find the abstract below.

Grindlay, K, Grossman, D. Interest in over-the-counter access to a progestin-only pill among women in the United States. Contraception. 2016 Oct:94(4):406.

OBJECTIVES: There is growing interest in over-the-counter (OTC) access to oral contraceptives in the United States, and a progestin-only pill (POP) is the most likely pill to be available OTC first. However, no published data exist on women's perspectives on OTC POPs. This study aims to assess teen and adult women's interest in OTC POP use.

METHODS: In October 2015, we conducted a nationally representative survey among 2026 adult women aged 18-44 who were at risk of unintended pregnancy and a sample of 513 teen women aged 15-17. Logistic regression was used to identify characteristics associated with likely OTC POP use. We also assessed reasons for use/nonuse, anticipated duration of use and willingness to pay for a method.

RESULTS: Overall, 39% of adults and 29% of teens reported likely OTC POP use, with higher likelihood of use (46% of adults, 40% of teens) if the pill were fully covered by insurance. The median highest amount women were willing to pay per month was US\$15 among adults and US\$10 among teens. Among adults, women without insurance (vs. private insurance) and those currently using an oral contraceptive or less effective method (vs. another hormonal method or IUD) had higher odds of likely OTC POP use. Women with a high school degree (vs. college degree) had lower odds of likely use. Among teens, those who had ever had sex had higher odds of likely OTC POP use, and Black women (vs. White) had lower odds.

CONCLUSIONS: Although POP use is low in the general population, US teen and adult women are interested in using an OTC POP.

AAFP OCs OTC resolution

The American Academy of Family Physicians endorsed research on access to OTC OCs without an age restriction earlier this year. Resolution 501, "Endorse access without age restriction to over-the-counter oral contraceptive pills," recommends that "all adolescents be included in the over-the-counter (OTC) oral contraceptives studies required by the FDA (e.g., label comprehension study, actual use study) to determine whether OTC access is appropriate for this population."

Upcoming events

Do you have any upcoming events in 2017 that would be of interest the OCs OTC Working Group and that you might like to have shared with the general public? We would love to support your efforts through our future communications pushes and also share them on Free the Pill's Facebook and Twitter.

Please email Mary to let us know!

Response to Danish depression study

A recent study conducted by Skovlund and colleagues at the University of Copenhagen examining the link between depression and hormonal contraception has received considerable media attention, but much of this coverage has taken the findings out of context. This article does not contain causal evidence that hormonal birth control causes depression. The study used Danish national health registry data to follow over 1 million women aged 15-34 from 2000 to 2013. The main purpose of the study was to compare first use of an antidepressant and first diagnosis of depression at a hospital psychiatric department between women using hormonal contraceptives and non-users (including women who had stopped use over 6 months ago and never users). Although this study included a large sample of women, it was only able to control for the factors available in the national databases and may have missed important factors that influence the development of depression, especially factors that may be shared between women who take hormonal contraception and women who develop depression. For instance, women using hormonal contraception might visit the doctor more regularly and therefore have a higher awareness of the symptoms of depression than non-users of hormonal contraception. For this reason, the results should not be taken as evidence that hormonal birth control causes depression.

The study found an increased relative risk of first use of an antidepressant (ranging from 1.1 to 2.0) and of first depression diagnosis at a hospital (ranging from 1.1-1.9)* among almost all users of hormonal contraception compared to non-users; however, the overall incidences of first antidepressant use and first depression diagnosis were low. The overall crude incidence rate of first use of antidepressants was 2.2 per 100 person-years among users of any hormonal contraceptive compared to 1.7 per 100 person-years among non-users, and the crude incidence rate of first depression diagnosis was 0.3 per 100 person-years among users of hormonal contraception compared to 0.28 per 100 person-years among non-users.

Putting this in perspective, this means among women who were not taking hormonal birth control in a given year, 1.7 out of 100 women would been given a prescription for antidepressants while among those women using any form of hormonal contraception, 2.2 out of 100 women would have been prescribed antidepressants for the first time.

Looking at oral contraceptives specifically, women taking combined pills (COCs) had an increased risk of first use of antidepressants of 20% (95% CI 22%-25%) compared to non-users of any hormonal contraception, while women taking progestin only pills (POPs) had an increased risk of 30% (95% CI 27%-40%) compared to non-users of hormonal contraception. In comparing COCs to POPs, it is important to note that only a small proportion of Danish women (4% of market share in 2010) used POPs as a method of hormonal birth control and use increased with age. Because POPs are more likely to be prescribed after birth while breastfeeding, the increased risk in depression may be partially due to a larger proportion of women in this group experiencing postpartum depression.** Researchers also found the highest relative risk for adolescents aged 15-19 with estimates of relative risk ranging from 1.4

to 3.1 for different types of hormonal contraception for first use of antidepressant and 1.2 to 3.2 for diagnosis of depression, with the highest risk amongst adolescents using the patch, ring, and IUD. In explaining this relationship, the researchers may have missed an important confounder: prior research has shown that adolescents who become sexually active are at a higher risk of depression and <u>anxiety</u>. Risks increased up to the first three to six months of use for all women and decreased thereafter.

These results must also be weighed against other studies. A study by O'Connell et al. in 2007 randomized 76 adolescent women to oral contraception or placebo for three months and found no significant difference in depressive symptoms. A study published in 1995 randomized 150 women who were sterilized or had partners that were sterilized to receive COCs, POPs, or placebo for four months and found POP users reported fewer depressive symptoms than those taking COCs or placebo pills. We highlight some of the higher quality studies, but they are part of a larger body of evidence that is conflicting and non-conclusive about the link between hormonal contraception and depression, as many of the studies conducted have been observational.

The recent study by Skovlund and colleagues does highlight that responses to hormonal contraception vary from person to person and emphasizes the need for all people to weigh the pros and cons of using any type of hormonal contraception and to consult a clinician if they have questions about certain side effects or risks. Physician and expert responses to this article highlight that women should not change their choice in contraception because of this study, and they should consider the benefits of each method of contraception alongside the potential risks of each option. Many thoughtful critiques and analyses have been written about this study that highlight many of the points raised here as well as others (e.g., Boston Magazine, The Establishment, Jezebel, and NPR).

*The estimated relative risk for one type of COC was less than one, but was not found to be statistically significant.

**The authors did exclude women during pregnancy and 6 months after.

About us

The Oral Contraceptives (OCs) Over-the-Counter (OTC) Working Group is a coalition of reproductive health, rights, and justice organizations, nonprofit research and advocacy groups, university-based researchers, and prominent clinicians who share a commitment to providing all women of reproductive age easier access to safe, effective, acceptable, and affordable contraceptives. The working group was established in 2004 to explore the potential of over-the-counter access to oral contraceptives to reduce disparities in reproductive health care access and outcomes, and to increase opportunities for women to access a safe, effective method of contraception, free of unnecessary control, as part of a healthy sexual and reproductive life.

The working group is coordinated by Ibis Reproductive Health.



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