Should women have over-the-counter access to oral contraceptive pills?

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"…reproductive health advocates in the USA are now beginning to set their sights on the next advance in contraceptive access: over-the-counter oral contraceptive pills."

After more than a decade, the battle surrounding over-the-counter (OTC) access to emergency contraception (EC) in the USA has finally been won. Science trumped politics in the end, and women are now able to obtain OTC EC on the shelf, and not just in a pharmacy, but in other retail stores as well. Building on this victory, reproductive health advocates in the USA are now beginning to set their sights on the next advance in contraceptive access: OTC oral contraceptive pills (OCPs).

OTC access to OCPs might sound revolutionary in the USA or Western Europe, but it is the reality for most women in the world. A recent analysis of prescription requirements for OCPs in 147 countries found that women can easily obtain pills in pharmacies without a prescription in most of these countries [1]. In only 31% of countries, a prescription is required to obtain OCPs. In 24% of countries, pills are formally available OTC, while some countries (8%) require a woman to undergo health screening by a pharmacy worker before pills are provided without a prescription. In 38% of countries, OCPs are technically in a class of drug that should require a prescription, but they are generally available informally in pharmacies without a prescription.

A growing body of evidence from some of these other countries, as well as experimental research from the USA, indicate that OTC access to OCPs is both safe and effective. The main safety question is whether women can accurately identify contraindications to use without the assistance of a clinician. In two studies in the USA, women were able to accurately identify contraindications to combined OCPs using a simple checklist, although in one study, 7% of women had unrecognized hypertension that was not identified until they saw a clinician [2,3]. Women were much more accurate at identifying contraindications to progestin-only OCPs, a formulation that has fewer and rarer contraindications compared to combined OCPs [4].

OTC access to OCPs also may help women with method continuation by making it easier to get more supply. In a study from El Paso, Texas, women who obtained OCPs in Mexican pharmacies OTC were significantly less likely to discontinue their method over 9 months compared to women who obtained OCPs by prescription in clinics [5]. In another study from Kuwait, where OCPs are available without a prescription, OTC users had similar method continuation compared to women who used OCPs under the supervision of a physician [6].

Importantly, US women are interested in OTC access to OCPs. A recent nationally representative survey found that 37% of women at risk of unintended pregnancy said they would be likely to use an OTC OCP if one were available [7]. Interest was highest among current OCP users, of which 59% said they were likely to use an OTC pill. In addition, 28% of women using no method and 33% of those using a less effective method, such as condoms

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used alone, reported they would be likely to start using an OTC OCP, suggesting that uptake of the method might increase with OTC availability.

Taken together, these findings suggest that OTC access to OCPs could help to reduce unintended pregnancy, which remains persistently high in the USA [8]. Some women using less effective methods will likely begin to use the pill, while current OCP users might experience fewer gaps in use because of improved access to the method and might stay on the pill for longer periods of time. Although, the magnitude of these changes is unknowable until an OTC OCP is actually available.

So what are the risks? Given the tremendous amount of safety data about OCPs, I have no concerns about the safety of an OTC OCP. Women are able to self-identify contraindications to the method, and the populations most interested in using an OTC pill – younger women and current users – have a low prevalence of contraindications. The risks associated with contraindicated use – especially among women with relative or category three contraindications – are low. It is also important to remember that pregnancy is also risky for women with contraindications to OCPs. In addition, it is likely that the first pill to be made available without a prescription in the USA will be a progestin-only OCP given the lower prevalence of contraindications. The fact that the US FDA has already approved progestin-only EC products for OTC sale will also make it easier for this formulation to gain approval.

My primary concern about an OTC pill is that its price could be a barrier to access. In the national survey mentioned above, women reported being willing to pay on average about US$20 per cycle for an OTC pill [7]. However, this survey was conducted in 2011 before the Affordable Care Act (ACA) began to go into effect, including the provision that requires new private insurance plans to cover FDA approved contraceptive methods without cost sharing such as co-payments or deductibles [101]. It may be that as women become accustomed to this benefit that they will be willing to pay even less out of pocket for an OTC pill. Under the ACA, FDA-approved OTC contraceptives used by women, such as OTC EC and female condoms, also must be covered without cost sharing; however, the woman must have a prescription to access this benefit. In order to reap the full benefit that OTC access could offer, it is critical that this prescription requirement be removed.

Another risk is that an OTC progestin-only OCP could not take off among US women. Currently only about 4% of US OCP users are taking a progestin-only formulation [9]. How much of this is due to a true preference for a combined pill as opposed to a lack of marketing by pharmaceutical companies or bias among physicians which is unknown. A progestin-only OCP with desogestrel is among the most popular OCP formulations in some countries in Europe, suggesting there may be an untapped market in the USA. Regardless, it is clear that if a progestin-only OCP is the first OTC pill in the USA, a wide-reaching informational campaign will be needed to educate women about this formulation, including its effectiveness and expected side effects.

As the discussion about a possible OTC switch gets more serious, it is inevitable that the debate will turn again to a possible age restriction, as it did with EC. The evidence with OTC EC clearly indicates that adolescents can safely use the product, and having access to it does not increase sexual risk-taking [10,11]. More research is needed with teens to explore their interest in using an OTC OCP, as well as the safety and effectiveness of OTC access to a daily pill for this population. But the evidence collected to date does not indicate a medical reason to restrict OTC OCPs to adult women, and I hope pharmaceutical companies will include minors in any research on a product they propose to switch to nonprescription status.

A future OTC progestin-only OCP would be the most effective contraceptive method available on the shelf without a prescription. It would give women yet another option to prevent pregnancy and help to reduce gaps in contraceptive use. It could also be a revolutionary advance in contraceptive access in the USA – one that would present an opportunity to rebrand birth control as something safe, effective and immediately available.

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