

Original research article

Prescription requirements and over-the-counter access to oral contraceptives: a global review

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Abstract

Background: Since the prescription requirement for oral contraceptives (OCs) can act as a barrier for some women, over-the-counter (OTC) access may improve uptake and continuation. The goal of this study was to ascertain the prescription requirements and informal OTC availability of OCs worldwide.

Study Design: From April 2011 to September 2012, we researched official documentation and conducted an online survey with government officials and pharmaceutical and reproductive health specialists on OC availability in countries worldwide. Results were compiled in a database and entered into a map for analysis of regional patterns.

Results: Data were obtained for 147 countries. OCs were informally available without prescription in 38% of countries, legally available without prescription (no screening by a health professional required) in 24% of countries, legally available without prescription (screening required) in 8% of countries and available only by prescription in 31% of countries. Notable regional patterns in OC prescription requirements emerged.

Conclusions: OCs are available without prescription in the majority of countries. Country experiences with OTC provision may provide evidence about the safety and effectiveness of OTC provision as a strategy to improve access to effective family planning.

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1. Introduction

Oral contraceptives (OCs) are the most commonly used form of contraception in Africa, Europe and Oceania (Australia, New Zealand and the South Pacific islands) and the most commonly used reversible contraception in the Americas among women who are married or in a union [1]. Ensuring easy access to this widely used and effective method is critical for women electing to use OCs for pregnancy prevention, as well as for other important noncontraceptive reasons, including reducing menstrual pain and cramping, reducing heavy bleeding or menorrhagia, normalizing irregular periods and treating pelvic pain associated with endometriosis, among others [2].

There is evidence that prescription requirements for OCs can serve as a barrier for some women [3–5] and that over-

the-counter (OTC) access may lead to higher rates of use, especially for women who lack health insurance or easy access to a provider. In a 2004 national survey of US women aged 18–44 years, almost half of women at risk of unintended pregnancy and not using contraception, including uninsured and low-income women, said they would begin using a hormonal method if it were available directly in a pharmacy without a prescription [3]. In addition to increasing method initiation, research indicates that OTC access may also increase method continuation. A study among women living in El Paso, Texas, on the US–Mexico border, found that women who obtained OCs in US clinics had significantly higher discontinuation rates compared to those who obtained pills OTC in Mexican pharmacies (hazard ratio, 1.58; 95% confidence interval, 1.11–2.26) [6].

One important consideration for countries considering removing the prescription requirement for OCs is whether women can use them safely if obtained without a prescription. In the United States, Food and Drug

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Administration approval of OTC status requires a drug to meet certain safety criteria: first, that it is not habit forming and, second, that it can be used safely without the supervision of a licensed health care practitioner. A component of the second condition is the ability of the user to self-diagnose for the proper condition for use and recognize warnings and contraindications [7]. Registration authorities in other countries likely have similar criteria. OCs meet the first condition of not being habit forming, and research suggests they may meet the second as well. Most contraindications to OC use, with the exception of high blood pressure, can be detected with women's health history alone and can therefore be identified by women themselves. Research from Mexico, where OCs are available informally in pharmacies without a prescription, has shown that women who get OCs OTC are no more likely to have a contraindication than those who get them from a clinic [8,9]. Research from the US–Mexico border, on the other hand, found that women living in El Paso who obtain OCs in Mexican pharmacies were more likely to have relative contraindications [WHO Medical Eligibility Criteria (MEC) category 3] than women who get OCs from clinics in the United States (13% versus 9%, $p=0.006$); however, there was no difference in absolute contraindications (MEC category 4, 5% versus 7%; $p=0.162$) [10]. One way for women to determine if OCs are safe for them to take is by using a simple checklist. Two studies from the United States comparing the accuracy of self-administered checklists to clinicians' assessments indicate that women are able to self-screen for the rare but potentially serious contraindications to OCs [11,12], although in one study, women over the age of 35 years were more likely to have unrecognized hypertension compared to younger women [11]. Alternatively, pharmacists could screen women for contraindications to OCs using a checklist combined with a blood pressure measurement in a model often referred to as "pharmacy access" [13].

For these reasons and others, reproductive health practitioners and advocates have been debating whether existing prescription requirements for OCs should be maintained [14–18]. In many countries, OCs are already available in commercial outlets without prescription, either as a recognized OTC drug or informally in practice. However, the extent of OTC availability worldwide is not known. A 1974 survey of 45 developing countries found OCs to be available OTC in 41 (despite legal prescription requirements in 22 of them) [19]. While several recently published studies have documented OTC availability of OCs in various countries, including Jamaica, Kuwait, Mexico and Thailand [20–23], there is no current review of the global prescription requirements. This study was conducted to ascertain the prescription requirements and informal OTC availability of OCs worldwide. Country experiences with OTC provision may provide evidence about the safety and effectiveness of this model and serve as an example for other countries considering removing the prescription barrier to OCs.

2. Methods

From April 2011 to September 2012, we collected data on the prescription requirements and informal OTC availability of OCs in countries worldwide. We conducted a short online survey, which was administered via e-mail and Survey Monkey (SurveyMonkey.com, LLC, Palo Alto, CA, USA) and sent to ministries of health, pharmacy boards, family planning associations, pharmaceutical companies and other reproductive health or pharmaceutical specialists, including health care providers and staff from nongovernmental organizations with reproductive health and pharmaceutical expertise. Reproductive health and pharmaceutical specialists were selected because they were internationally recognized family planning specialists or because they were affiliated with organizations known to be working in the reproductive health or pharmaceutical field.

The survey inquired about countries' prescription requirements and informal commercial availability of OCs, about health screening requirements for obtaining OCs without a prescription (such as asking questions about health history or measuring blood pressure) and whether the participants knew of any published sources supporting their responses. In addition to the survey, we also researched peer-reviewed journal articles, country drug registries and other government websites for official documentation of countries' OC prescription requirements. We compiled responses in Microsoft Excel and conducted follow-up communication with survey respondents to clarify information as needed. Countries with conflicting responses were classified on the basis of the most reliable data source. Registered drug lists or databases, other government sources (e.g., official documents, correspondence with a ministry of health), peer-reviewed journal articles and correspondence with a pharmaceutical company were considered to be of high reliability. Correspondence with in-country contacts, including individuals from pharmacy boards, family planning associations and other reproductive health specialists, was considered to be of lower reliability. Data conflicts were only observed between high- and lower-reliability sources, and among lower-reliability sources. We did not find conflicting reports between multiple high-reliability sources, such as a pharmaceutical company and ministry of health. In the case of conflicting reports among lower-reliability sources, we sought corroboration from additional sources. We did not seek approval from an institutional review board as the data we collected were about public policies and did not contain any information about human subjects.

Countries were assigned to one of four classification groups:

1. OCs informally available without prescription — Legally, a prescription is required for OCs, but women typically can get them without a prescription in pharmacies or other retail outlets.
2. OCs legally available without prescription (no screening required) — OCs are legally available without a

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