Prescription of Oral Contraceptives by Licensed Pharmacists in the USA

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Aarti Sawant-Basak, PhD, Priyanka Ingle-Jadhav, BAMS, MS, PhD
On behalf of the ACCP Public Policy Committee

Oral contraceptives (OCs), a highly effective method of contraception if adherence is maintained, have been prescribed to women in the USA and globally for several decades.[1] The American College of Clinical Pharmacology (ACCP) strongly recommends the enactment of an initiative that permits licensed US pharmacists to prescribe OCs on a national basis. This position of the ACCP, based on the overall safety and well-established efficacy of estrogen- and progestin-based OCs, will provide women with easy and timely access to OCs. To ensure safe and consistent implementation of this initiative, the ACCP recommends appropriate training requirements based on the US Medical Eligibility Criteria (US MEC) for contraceptive use.

Traditionally, OCs have been prescribed by non-pharmacy healthcare providers or through a physician's office. This has enabled adherence to OCs and has encouraged women to maintain routine gynecological care visits that may otherwise not occur.[2] In addition, this practice has minimized contraindications, drug-drug interactions (DDIs), and safety issues in high-risk populations, and has enhanced face-to-face counseling on OC usage and adverse events. However, the current time and cost associated with a clinic appointment, lack of insurance, and challenges in traveling to a clinic make access to OCs difficult.[3,4] This is particularly challenging for women in socio-economic strata with limited or no healthcare access. This lack of access to effective contraception leads to a high risk of unintended pregnancies. Pharmacist-prescribed access for OCs is expected to be supported by women, pharmacists, and medical organizations involved in women's health.[5,6] A review of 4 observational studies compared the effectiveness and usage of OCs where access was provided through a pharmacy (either over the counter or as a prescription from the pharmacist), versus physician-based prescription access.[7] The review concluded that there was a higher rate of continuous OC usage when the products were available through OTC or prescription by pharmacist, relative to access through a physician's office. The review also found that women generally preferred to access OCs through a pharmacy rather than through the physician's office. Curtis and authors have provided a systematic analysis of pharmacist and patient perspectives on pharmacist-prescribed contraception: patients expressed a preference for pharmacy-prescribed OC access and pharmacists were comfortable with this method of access. Pharmacists also expressed a willingness to obtain appropriate training to support this method of OC access.[6] A national survey conducted to understand women's preferences for contraception access found that >70% of women preferred pharmacy-prescribed contraceptives because of the ease of access, affordability, and convenience of a local pharmacy.[3] Another study assessed the implementation of pharmacy access to screen and counsel women for the safe use of hormonal contraceptives. This study reported that women and pharmacists were satisfied with this method of OC access, and women were willing to continue the usage of OCs as a chronic form of birth control.[8] Another community-based survey to assess the acceptability of pharmacist-prescribed contraception in a rural Californian county suggested that there was high interest and overall community support for this method of access.[9] The American College of Obstetricians and Gynecologists (ACOG) supports increased access to hormonal contraception, as it could improve contraceptive use and reduce unintended pregnancies.[10]

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Corresponding Author:
Aarti Sawant-Basak, PhD, ACCP Public Policy Committee, PO Box 1758, Ashburn, VA 20146.
E-mail: info@accp1.org

Clinical Pharmacology of Oral Contraceptives

In the USA, OCs were first approved for clinical use in 1960.[11] Since then, the composition of OCs has evolved.[12] OCs are classified as either combined oral contraceptives (COCs), which contain both progestin and estrogen, or the progestin-only pill (POP).[13] This opinion article will focus on pharmacist-prescribed access of COCs, which is further supported by a recent US Food and Drug Administration (FDA) approval of POP as an OTC.[14] Dosing regimens of COCs include the 28-day regimen, extended regimen, and continuous regimen; each involves a certain number of days of continuous contraception followed by a short hormone-free placebo period, leading to menstruation.

The COCs inhibit the secretion of follicle-stimulating hormone (FSH) and luteinizing hormone (LH), during the mid-cycle surge of these hormones.[15] This inhibition of FSH and LH levels suppresses ovulation and provides contraception. The pharmacokinetics (PK), metabolism, and elimination of COCs have been extensively reviewed previously.[16–22] Cumulative analysis at a population level has suggested that age and body weight are statistically significant covariates, but are not clinically meaningful.[23] According to a retrospective analysis, women with a body mass index (BMI) of $\geq$30 kg/m^2 may be more likely to experience COC failure, compared with women with BMI of 20-25 kg/m^2; however, the authors found that a higher body weight was not associated with a higher risk of failed oral contraception.[24–26]

The risk of DDI in COC users has been discussed previously.[16,27,28] The major clearance mechanisms of COCs are cytochrome P450, family 3, subfamily A (CYP3A), CYP2C9, CYP2C19, sulfotransferase 1 (SULT1), and UDP-glucuronosyltransferase 1A1 (UGT1A1)[29,30]; recently, Zhang et al concluded that CYP3A may not be a primary pathway of the metabolism of COCs.[31] Moderate to strong inhibitors or inducers of these enzymes may cause DDIs when co-administered with COCs, affecting their safety or efficacy, respectively.[31,32] HIV antiretrovirals are generally known to interact with COCs. Co-administration of atazanavir with COCs may increase the area under the plasma drug concentration-time curve (AUC) of ethinyl estradiol (EE) by 48%, which may be associated with the dual inhibition of CYP3A and UGT1A1.[33,34] Thus, when co-administered with atazanavir, COCs require dose adjustment to 30 μg.[35] Other HIV antiretrovirals (darunavir, efavirenz, lopinavir, nelfinavir, etc.) that have also been reported to be moderate to strong inducers of CYP3A are contraindicated with COCs; in such patients, alternate contraception methods are recommended (eg, implants or intrauterine system).[36] Pharmacists should be trained to be cognizant of potential drug interactions "of COCs", and advise appropriate dose adjustments or alternate contraception methods. Such drug interactions can also be critical in women of childbearing potential (WOCBP) who may participate in investigational drug trials. This is especially significant if the investigational drug is a potential or confirmed teratogen. The FDA has recently issued final guidance for the industry to help assess COC DDIs during clinical development and labeling.[37] As licensed pharmacists are well trained to assess such drug interactions, such contraindications, dose adjustments, and suggestions of alternate contraception methods should be included as a part of routine training to licensed pharmacists. Overall, prescribing COCs through pharmacy access is not anticipated to increase risks of contraindications or adverse events associated with DDIs.

The safety profiles of COCs have been well established over more than 4 decades. The use of COCs has been associated with an increased risk of developing deep vein thromboembolism (DVT) and myocardial infarction (MI). It has been shown that use of OCs may increase the risk of MI, especially in women with pre-existing conditions such as hypertension, or with a history of smoking.[38] This risk is associated with COC formulations that have higher estrogen levels.[39] To minimize the risk of thrombotic events in COC users, a maximum daily dose of estrogen of $\leq$50 μg has been recommended.[40] Circulating concentrations of COCs have been reported to induce the production of endocrine/metabolic proteins such as sex-hormone binding globulin (SHBG), albumins, and corticosteroid binding globulins, to varying degrees.[41,42] Observational studies suggest that increased concentrations of SHBG are positively correlated with thrombin generation, and have been proposed as a marker of VTE in COC users.[43] It should be noted that COCs are contraindicated in individuals with pre-existing medical conditions, including hypertension, hepatic dysfunction, thromboembolism, diabetic nephropathy, organ transplantation, any other vascular disorders, and also in smokers that are >35 years old.[44] To minimize adverse events associated with the usage of COCs, the ACCP advises that licensed pharmacists who prescribe COCs be sufficiently trained to evaluate the patient's medical history, co-medications, and any of the contraindicated pre-existing conditions, before prescribing COCs.

In summary, COCs have well-established PK, effectiveness, and no requirement for therapeutic drug monitoring. The availability of extensive safety data that encompasses over 4 decades of usage "of COCs" has led to an excellent understanding of the

Table 1. States Permitting Pharmacist-Prescribed Contraception[48,49]

State	Year authority in effect	Prescriptive authority	Prescription duration	Pharmacist requirements			
				Receive training	Provide educational materials	Provide counseling	Provide screening tool
Washington	1979	CPA[a]	Not stated				
California	2016	SP	12 months	X	X	X	X
Oregon	2016	SP	12 months	X			X
Colorado	2017	SP	12 months	X	X	X	X
Hawaii	2017	SP	12 months	X			X
New Mexico	2017	SP	12 months	X	X	X	X
Tennessee	2018	CPA	Not stated	X	X	X	X
Utah	2018	SP	Not stated	X	X	X	X
Idaho	2019	SP	15 months				
Maryland	2019	SP	12 months	X	X		X
New Hampshire	2019	SP	Not stated				
Washington DC	2019	SP	12 months	X	X	X	X
West Virginia	2019	SP	12 months	X	X	X	X
Minnesota	2020	SP	6 months	X	X	X	X
Virginia	2020	SP	12 months	X		X	X
Arizona	[b]	SP	3 months				
Arkansas	2021	SP	6 months				
Illinois	2021	CPA	Not stated	X	X	X	X
New York	2021	CPA	12 months	X	X		X
Delaware	[b]	SP	12 months				
North Carolina	2021	SP	12 months	X	X		X
South Carolina	2022	SP	12 months	X	X	X	X
Vermont	2021	SP	12 months	X			X
New Jersey	2023	SP	12 months	X		X	X

CPA, Collaborative Practice Agreement; SP, Statewide Protocol.

[a] These states do not have legislation specific to hormonal contraception (HC) but allow pharmacist-prescribed HC through a broad CPA.

[b] The state enacted a pharmacy access law, but its regulations are not yet finalized.

contraindications or dose modifications that may be necessary in individuals with pre-existing conditions. This supports COCs as suitable for prescription by licensed pharmacists at a national level. Overall, based on the well-understood pharmacology and safety of COCs, the ACCP supports pharmacy access of COCs to individuals in US Medical Eligibility Criteria for Contraceptive Use (MEC) Category 1 (no restrictions) and Category 2 (advantages generally outweigh theoretical or proven risks).

Implementation of COCs via Pharmacy Access

This practice, recommended by ACCP at a national level, already has precedence. Pharmacists in at least 21 states in the USA and in the District of Columbia (DC) are licensed to prescribe COCs. In July 2015, Oregon and California passed legislation to allow pharmacists to prescribe hormonal contraceptives to women over 18 years of age without the need for a physician's visit.[45] Later in the same year, the Oregon Board of Pharmacy drafted a new protocol to allow pharmacies to provide preventive contraception.[46] This protocol involves a patient screening form, a medical assessment form filled out by the pharmacist, and an algorithm that determines the best method of contraception based on the patient's screening information, in conjunction with the US MEC guidelines.[46] Additionally, the protocol requires pharmacists to complete education and training accredited by the Board for Contraceptive Prescription. Similar measures have been adapted by New Hampshire to ensure compliance and consistency of practice.[47]

In the USA, pharmacists are now licensed to prescribe contraceptives in the following states: Arizona, Arkansas, California, Colorado, Delaware, Hawaii, Idaho, Illinois, Maryland, Minnesota, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, Oregon, South Carolina, Utah, Vermont, Virginia, West Virginia, and DC.[48] Table 1 provides a summary of prescriptive authority, prescription duration, and training to be imparted for consistent and safe usage of pharmacy access to contraception in these states. It is important to note that although pharmacy access is designed to make contraception more accessible, this should not be used as a substitute for regular health check-ups, such as physical and gynecological

examinations. Although a recent meta-analysis suggests that women using COCs may be at an increased risk of breast cancer,[49] it should also be noted that no evidence has been found so far to suggest any increase in women's health issues related to the use of COCs in any of the 21 states or in DC. In general, pharmacists encourage and inform women seeking pharmacy access to COCs to continue routine screening and physician visits.

Conclusions

According to the collective knowledge available from the Centers for Disease Control and Prevention (CDC), the FDA, and the World Health Organization (WHO), as well as the reviews and published literature reports, the safety, efficacy, and benefits/risk of COCs are well understood. Prescribing COCs through pharmacy access, by licensed pharmacists, is not expected to increase the incidences of adverse events associated with COC usage. Therefore, the ACCP strongly supports pharmacy access for COCs by licensed pharmacists. This will reduce the financial, logistical, and economic barriers to contraception for women with low incomes, women without health insurance, and women with limited healthcare coverage. To ensure the safe and consistent usage of COCs, the ACCP recommends that pharmacists prescribing COCs be adequately trained to: (i) understand US MEC prescription guidelines; (ii) evaluate an individual's medical history and pre-existing conditions; and (iii) assess concomitant medications, dose adjustments, and contraindications before prescribing COCs.

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Mark Rogge, Peter Bonate, Janelle Burnham, Mohit Gandhi, Sindura Gollamudi, Jean-Michel Gries, Amandeep Gupta, Priyanka Ingle, Mark Kirstein, Parag Kumar, Tao Long, Suresh Mallikaarjun, Kenneth T. Moore, Ken Ogasawara, Sudhakar M. Pai, Alex Prokopienko, Sreedharan Sabarinath, Aarti Sawant-Basak, Jinshan Shen, Suneet Shukla, and Karthik Venkatakrishnan.

Conflicts of Interest

The authors declare no conflict of interest.

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