

Increasing access to care through pharmacy provision of hormonal contraceptives: A nursing perspective

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Approximately 40% of all pregnancies in the United States are unplanned, and about 50% of all unintended pregnancies occur in women who are not using contraception. In this article, the authors discuss state-based initiatives to increase access and decrease barriers to care by promoting pharmacy-provided hormonal contraceptives. The authors describe their experience in participating on a legislative commission to craft legislation to expand access.

KEY WORDS: contraceptives, over-the-counter, pharmacist-prescribed, collaborative practice, nonprescription drugs, hormonal contraceptives

Even though unintended pregnancy rates have fallen to a 30-year low,¹ 40% of all pregnancies have remained unplanned and 36% have followed an interpregnancy interval of less than 18 months.² As with most social issues, the risk for unintended pregnancy does not affect all populations equally; distinct disparities exist along racial and economic lines. Women of color as well as those of other minority groups, women of lower education and income levels, and younger women, when compared with the rest of the female adult population, are disproportionately affected by unintended pregnancy.^{1,3}

About 50% of unintended pregnancies occur in women who are not using contraception.⁴ Lack of access to healthcare, lack of information/knowledge about contraception, and cultural norms surrounding contraceptive use have been cited by women as reasons why they do not use a birth-control method.⁴ Helping women and their partners choose contraceptive methods that are most appropriate for them, as well as ensuring that they receive education and assistance regarding how to use these methods effectively and consistently, can help decrease the still-too-high rate of unintended pregnancy in this country.³



Overestimating hormonal contraceptive risks

Misconceptions regarding the safety of hormonal contraceptives (HCs) may result in lack of use, inconsistent use, or early discontinuation, any of which can lead to an unintended pregnancy. The risks associated with use of HCs, especially when prescribed appropriately, are lower than those associated with pregnancy itself, particularly unintended pregnancy.⁵ Although use of combined HCs (CHCs)—that is, contraceptives containing estrogen and a progestogen—can increase certain health risks, the overall risk to women without pre-existing risk factors or conditions is extremely low. Increased risk is more typically seen in women with co-morbid conditions such as obesity, hypertension, migraines, or clotting disorders. Studies have shown that women are able to self-screen reliably for these conditions using a safety checklist.⁶

Mørch et al.⁷ assessed for any links between HC use and the risk of invasive breast cancer in a nationwide prospective cohort study involving all women in Denmark aged 15-49 years who had not had cancer or venous thromboembolism (VTE) and who had not received treatment for infertility. Over a mean follow-up of 11 years, current and recent HC users, compared with females who had never used HCs, had a relative risk of 1.20 of developing breast cancer. This finding translated into approximately one extra case of breast cancer per 7,690 HC users, including women who used hormonal intrauterine devices.⁷

A systematic review showed that users of CHCs, compared with women who did not take hormones, had a relative risk of 1.22-1.93 for VTE, depending on the type of progestogen used in their CHC formulation.⁸ A Cochrane

Review meta-analysis showed that, compared with nonusers of hormones, users of combined oral contraceptives (COCs), some of which contained estrogen 50 mcg, had a relative risk of 1.6 for myocardial infarction (MI) or ischemic stroke.⁹ The absolute risk of these events remained low in all three studies. In another study of a cohort of Danish women without prior cardiovascular disease who were followed for 15 years, the risks for both thrombotic stroke and MI were increased by a factor of 0.9-1.7 with use of low-dose COCs (i.e., those containing ethinyl estradiol [EE] 20 mcg) and by a factor of 1.3-2.3 with use of COCs containing EE 30-40 mcg.¹⁰ Progestogen type did not appear to have a significant impact on these risks. These findings also supported the use of estrogen-free HCs such as progestin-only pills (POPs) as safe alternatives for women in whom estrogen is contraindicated.⁵

Underestimating the risks of unintended pregnancy

Unintended pregnancy, as compared with pregnancy that is planned, is associated with an increased risk for maternal and infant health problems.³ Lack of prenatal care plays a large role in the increased rates of maternal and neonatal morbidity/mortality associated with unintended pregnancy.¹¹ Lack of a basic nutritional consultation and prenatal vitamin supplementation, awareness to avoid alcohol and other teratogenic substances during the first trimester, and the inability to proactively obtain appropriate care for the mother's own health conditions, if necessary, may have a significantly adverse impact on the health of both mother and child.⁶ These increased risks have an economic cost as well: In 2010 alone, unintended pregnancies cost the U.S. healthcare system an estimated \$21 billion.¹²

Addressing inequities in access to contraceptives: Pharmacy provision of HCs

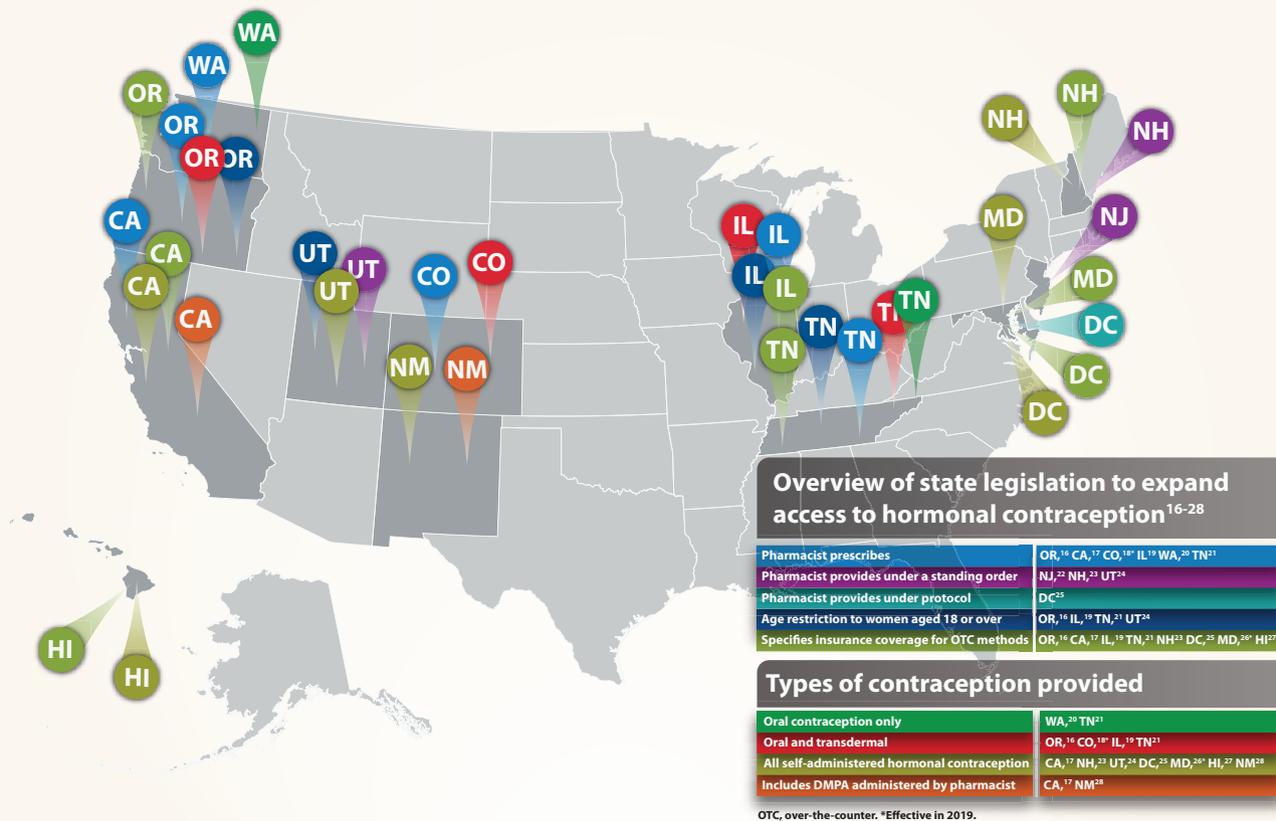
Even if women understand the low risk of HC use and the relatively higher risks associated with unintended pregnancy, they need to have physical and financial access to contraceptives—hormonal and otherwise—in order to use them. Therefore, contraception is not only a medical issue but also a public health issue and an economic issue.

Action at federal and state levels

Both state-based and national initiatives are evolving to address inequities in access to contraceptives. At the federal level, a French drug company, HRA Pharma, has initiated an actual-use study to provide important data to the FDA for over-the-counter (OTC) status of POPs. Ibis Reproductive Health, a research and advocacy group on women's health priorities, has partnered with HRA Pharma for support through the FDA application process. The application process may be streamlined for POPs because the FDA has already approved OTC status for emergency-contraceptive POPs and because POPs have fewer contraindications than do CHCs.

Although only 4% of women use POPs,¹³ results of a recent study suggested that about one-third of teenagers and women would be interested in using POPs if they were available OTC.^{13,14} The FDA-approved product information sheet lists the first-year failure rate for POPs as 0.5%, with a typical failure rate closer to 5% because of late or omitted pills.¹⁵ Action at the FDA level to approve OTC POPs could greatly expand contraceptive access to teenagers and women, although passing legislation at the state level might be accomplished in a timelier, less cumbersome manner than the lengthy and complex FDA

Box 1. Overview of state legislation to expand access to hormonal contraception¹⁶⁻²⁸



process. In fact, 12 states have already passed or proposed legislation to expand access to HCs in pharmacies—without needing to have a prescription specifically written by a healthcare provider (HCP) for a given patient (Box 1).¹⁶⁻²⁸ Pharmacies have the advantage of convenient locations, extended hours of operation, and availability of walk-in access without appointments.

In order to achieve this end—that is, provision of HCs by pharmacists—states can take one of three general routes: standing order, collaborative practice agreement (CPA), or pharmacist prescribed. A standing order is one written by a prescriber (e.g., physician, advanced practice registered nurse, physician assistant) that gives a nonprescribing clinician such as a pharmacist the authority to dispense the medication as long as predetermined conditions have been met. This route requires detailed

legislation to address all legal issues, a prescriber willing to write the standing order, and annual updates for the order.²⁹ CPAs are contracts between a pharmacist and other members of a healthcare team, including a prescribing provider, that outline and allow for certain expanded services that the pharmacist can provide within that practice under specific conditions.³⁰⁻³² This type of arrangement is seen frequently in hospital settings wherein a pharmacist takes the lead in managing complex medication regimens such as chemotherapy, chronic pain treatment, or therapy for other pharmacologically complex diseases.³⁰ In the case of pharmacist-prescribed medication, prescriptive authority comes from the state and does not depend on the medical license of a separate HCP. As with standing orders and CPAs, the pharmacist must undergo additional training and the

patient must meet certain criteria in order to obtain contraceptives.

In all three situations, patients must complete a self-screening risk assessment tool, check their blood pressure in the pharmacy, and submit the completed form to the pharmacist. The pharmacist reviews the health history and, if no contraindications are present, provides the HC. If a contraindication is identified, the pharmacist refers the woman to an HCP. Numerous studies have shown that patient self-screening is accurate and safe.³³⁻³⁵

Types of pharmacist-provided contraceptives, use of standing orders, protocols, pharmacist-prescribing roles, age restrictions, and insurance coverages vary from state to state (Box 1).¹⁶⁻²⁸ In addition, data from states that have expanded pharmacy access indicate that barriers may remain despite legislation. Barriers include the time required for pharmacist training, already-

demanding pharmacist workloads, and, most notably, a lack of insurance reimbursement for pharmacists' time spent in evaluation. Legislation in six states has addressed the lattermost barrier by expanding pharmacists' scope of practice to enable direct billing for time spent providing the service.

Action by the OCs OTC Working Group

An exhaustive search identified multiple physician groups that have issued policy statements on expanding access to contraceptives. Although no nursing organizations have issued statements of their own at this time, many of them have signed a Statement of Purpose published by the **OCs OTC Working Group^A** to expand access to OCs through OTC status (Box 2). This working group is a coalition of reproductive health, rights, and justice organizations; nonprofit research and advocacy groups; university-based researchers; and prominent clinicians who are committed to providing easier access to safe, effective, acceptable, and affordable contraceptives to all reproductive-age women.

Signing this Statement of Purpose is consistent with nursing organizations' strong history of advocating for healthcare reform to improve access to high-quality care for all populations. Nursing's history of advocacy has included support for the Affordable Care Act (ACA), which was intended to provide parity in health services and to improve access for women by requiring insurance companies to cover a standard package of essential health services. One essential benefit addressed coverage of 18 FDA-approved contraceptive methods, along with education and counseling; any and all appointments needed to initiate or discontinue a method; and follow-up visits to manage any concern related to the method. Provisions were added so

Box 2. Policy statements from professional medical organizations and signing status of nursing organizations

Organization	Link to policy statement
American College of Obstetricians and Gynecologists (ACOG)	acog.org/-/media/Departments/Government-Relations-and-Outreach/2017ACOGPositionOTC-OCandInsurance.pdf?dmc=1&ts=20190327T1227357703
American Academy of Family Physicians (AAFP)	aafp.org/about/policies/all/otc-oral-contraceptives.html
American Medical Association (AMA)	ocsotc.org/wp-content/uploads/2013/07/AMAResolution5071.pdf
OC, oral contraceptive; OTC, over-the-counter.	
Organizations that have signed on to the Statement of Purpose of the OCs OTC Working Group^A but have not yet issued a specific position statement: American Nurses Association (ANA); American College of Nurse-Midwives (ACNM); Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN); National Association of Pediatric Nurse Practitioners (NAPNAP); National Association of Nurse Practitioners in Women's Health (NPWH); Nurses for Sexual and Reproductive Health (NSRH)	
Organizations that have not signed on to the Statement of Purpose of the OCs OTC Working Group: American Academy of Nursing (AAN); American Association of Nurse Practitioners (AANP)	

that insurers cannot levy out-of-pocket charges such as deductibles or copays for any of these services.

Persistent barriers

The ACA addressed financial barriers to acquiring contraceptives by mandating insurance coverage. However, other obstacles persist, including a need to travel long distances for prescribers' services, some prescribers' lack of evening and/or weekend hours, an inability to leave work to seek care without penalty, or a need to schedule an appointment in advance. In 2015, federal legislation, the Allowing Greater Access to Safe and Effective Contraception Act, was proposed to encourage the FDA to approve OTC status for OCs. However, no provisions in the bill ensured teenagers' access to OCs or ensured that insurance companies would cover the cost of the pills.³⁶ This legislation failed; many policy advocates saw it as an attempt by insurers to avoid providing coverage for contraceptives. State legislatures' provision for pharmacist-prescribed contraceptives would bridge this gap, increasing access to HCs, including OCs, while continuing to ensure insurance coverage for consumers.

Status of pharmacy provision of HCs in New Hampshire: A case study

In New Hampshire (NH), the NH Nurses Association (NHNA) and the NH Nurse Practitioner Association (NHNPA) share the services of a lobbyist who is tasked with monitoring all health-related bills. If commissions are developed, the lobbyist ensures that nursing is represented with membership on them. A bipartisan bill to expand pharmacy provision of HCs was introduced in 2016 and referred to a commission for further study. Three nursing organizations—the NHNA, the NHNPA, and the NH Board of Nursing (NHBN)—put out a call for volunteers to represent nursing on the commission. Members of the commission included representatives from the NH Pharmacists Association, the NH Board of Pharmacy, the NHBN, the NHNA, the NHNPA, the NH Medical Society, and the NH Board of Medicine, as well as health policy experts.

At the initial meeting, all members voiced commitment to the bill's ultimate goal: to expand contraceptive access. The commission met 6 times (continued on page 28)



Participating in the creation of new healthcare legislation can be a rewarding professional experience.

(continued from page 23)

and modified the original language of the bill so that it would now ensure teenagers' access to contraceptives and guarantee that insurers would reimburse for contraceptives provided by a pharmacist. The commission compromised on two notable areas: (1) allowing pharmacists to prescribe under their own licenses because there were no precedents for this practice in the state, and (2) removal of depot medroxyprogesterone acetate from the list of contraceptives because not all members of the commission were comfortable with its inclusion. The final decision of the commission was unanimous—a compelling statement to legislators about the healthcare community's support for the bill. Legislators needed substantial education about the goals of the bill. Ultimately, it passed with only minor changes.

Participating in the creation of new healthcare legislation can be a rewarding professional experience. In addition, serving on a collaborative healthcare commission with members from all sectors of the healthcare community and working toward one goal can be profoundly inspiring. Participation provides an opportunity to deepen understanding of healthcare policy, politics, and the law in general and to act as agents for change within the community. As the process in NH may differ from the pathway elsewhere, readers are encouraged to reach out to their own state nursing or-

ganizations to find out more about opportunities to participate within their local governments.

Recommendations for action

Various public policy approaches are needed to address the high rate of unintended pregnancy in the U.S. An ideal strategy is to make a progestogen-only contraceptive available OTC. However, this approach requires a drug company to submit an application to the FDA, a process that can take at least 4 years. An alternate strategy is to expand pharmacy access through state legislation. Either approach needs full support from professional healthcare societies. The annual Gallup poll consistently ranks nursing as the most honest and ethical profession.³⁷ As such, the public trusts nurses as leaders in healthcare. Nursing organizations are urged to develop policy statements regarding expanded contraception access. To this end, the National Association of Nurse Practitioners in Women's Health (NPWH) has written a position statement on expanding access to contraceptives via pharmacies at the state level and via granting OTC status to OCs at the federal level. The position statement appears on pages 16-19 in this issue of the journal. Nursing colleagues need to seek opportunities to get involved in their local government process to help reach the goal of increasing access to contraceptives. ●

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Web resource

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