



Original research article

Characterizing pharmacist-prescribed hormonal contraception services and users in California and Oregon pharmacies^{☆,☆☆}

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ABSTRACT

Objectives: This study describes hormonal contraception services provided by pharmacists and characterizes patient populations utilizing the service at one supermarket-based pharmacy chain in California and Oregon.

Study design: This is a descriptive study of 391 pharmacies in California and Oregon within a supermarket-based pharmacy chain providing hormonal contraception services and the patients who utilized those services in a 6.5-month period between August 2016 and February 2017. Data were extracted from pharmacy prescription records and available visit documentation forms to describe services provided and patient characteristics.

Results: During the study period, 381 trained pharmacists from the pharmacy chain provided hormonal contraception services in 391 pharmacy locations in Oregon and California. A total of 2117 visits were completed and 1970 hormonal contraception prescriptions were issued and dispensed during the study period. Researchers were able to access documentation for 676 visits (32%). Patients from various age groups (range 13–55 years old) and geographical locations (22 states total) utilized the service. Most had health insurance (74%), had seen a primary care provider in the past year (89%) and were previous hormonal contraception users (91%). Contraceptive methods prescribed include pill ($n=1886$, 95.7%), patch ($n=31$, 1.6%), vaginal ring ($n=51$, 2.6%) and injectable ($n=2$, 0.1%).

Conclusion: Following scope of practice expansion, pharmacists in a community-based pharmacy setting are serving as an access point for women to obtain hormonal contraception services and supplies.

Implications: This study provides an initial look at California's and Oregon's expansion of hormonal contraception prescribing authority to pharmacists. The service was available across all pharmacy locations of a supermarket-based chain in California and select locations in Oregon and utilized by diverse populations of patients. Pharmacists effectively provided hormonal contraception services and supplies to most patients seeking hormonal contraception.

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1. Introduction

Nearly half (45%) of all pregnancies in the United States (US) are unintended [1]. Access and cost remain barriers to contraception use [2]. A survey of women in the US who were sexually active without intentions of becoming pregnant revealed that 29% experienced challenges in obtaining either a prescription or a refill for hormonal contraception [3]. Barriers to obtaining contraception from a physician's office or clinic

include difficulty obtaining an appointment, inconvenient clinic hours, high copays and not wanting to have a pelvic examination [3]. Self-administered hormonal contraceptives including combined hormonal contraceptives (i.e., oral tablet, transdermal patch, vaginal ring), progestin-only oral tablet and progestin-only injectable are widely available in pharmacies and dispensed pursuant to prescriptions issued by physicians and other prescribers. In more recent years, the Affordable Care Act has eliminated patient copayment for prescription contraception services and supplies for many insured patients [4]. A study in Washington evaluated the provision of hormonal contraception by community pharmacists through a collaborative drug therapy agreement between a physician and a pharmacist [5]. One strategy to increase access to these popular methods of contraception is expanding pharmacist scope of practice at the state level to include prescribing self-administered hormonal contraception.

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State policies expanding pharmacist scope of practice allow pharmacists to play a larger role in providing family planning services and access to hormonal contraception. California (CA) passed legislation in 2013, followed by Oregon (OR) in 2015, expanding pharmacist scope of practice to include prescribing self-administered hormonal contraceptives directly to patients pursuant to statewide protocols developed by the respective state board of pharmacy [6,7]. The statewide protocols were implemented in January 2016 in OR (protocol for pill and patch during the study period, which has since expanded to include ring and injectable) and April 2016 in CA (pill, patch, ring, injectable). Both state protocols require pharmacists to complete training, review patients' health history, measure blood pressure (BP) and refer as needed [7–9]. There is no age restriction in CA's statewide protocol, whereas OR's statewide protocol allows prescribing to all adults and to minors with evidence of a previous contraceptive prescription. Pharmacists are required to measure the patient's blood pressure to determine eligibility for all methods in OR and for estrogen-containing methods in CA. In OR, if the systolic BP ≥ 140 mmHg or diastolic BP ≥ 90 mmHg, a pharmacist is not able to prescribe any method and must refer the patient to their primary care provider (PCP) [9]. In CA, if the patient has an elevated blood pressure, progestin-only formulations may be prescribed.

Published studies evaluating hormonal contraception services provided by community pharmacists using a statewide protocol are limited. This study evaluated the hormonal contraception services provided by a large supermarket-based pharmacy chain in CA and OR through statewide protocols. The purpose of the study was to characterize the services provided and patients utilizing the service.

2. Material and methods

This is a descriptive study from August 13, 2016, through February 28, 2017. The service was provided on a walk-in basis. Contraceptive supplies prescribed by the pharmacist were billed to the patient's insurance for payment when the patient was insured. A flat service fee was charged to patients (waived if no contraception prescribed). Pharmacists followed the company's protocols, which are in line with the respective statewide protocols, and used the US Centers for Disease Control and Prevention United States Medical Eligibility Criteria for Contraceptive Use (USMEC) to determine patient eligibility for hormonal contraception, defined as category 1 or 2 in the USMEC. Category 1 indicates no restriction, while Category 2 indicates the advantages of using the method generally outweigh the risks [10]. Pharmacists refer patients for follow-up with a PCP if found to be ineligible or for other reasons, such as preventative health screenings (e.g., well woman exam, STD/HIV testing), long-acting reversible contraception or evaluation of a health issue. This study was deemed to be nonhuman subjects research by the University of California, San Francisco, institutional review board.

Pharmacists providing the service were trained using a standardized training program that met state requirements. The training was provided to more than half of the pharmacists – all pharmacy managers and many staff pharmacists from pharmacy locations in CA and OR. In total, 812 pharmacists completed training and were able to provide the service across 391 participating locations. Pharmacy data reports at the corporate level detailing the number of contraceptive prescriptions issued, type of contraceptive prescriptions, referrals and prescribing pharmacist were used to identify trends in contraception prescribing.

Patient demographic data were collected from three documentation forms for the service that included a self-administered health history screening questionnaire, a pharmacist intake form, and a visit summary and referral form. Forms were obtained via facsimile from the pharmacies. Documentation of patient demographics included age, insurance status, PCP if established, most recent visit to a provider and medical history. Additional patient demographic data were obtained from patients' written responses in the self-administered screening

questionnaire. Data were obtained for the following number of visits: self-administered screening questionnaire ($n=676$ or 31.9% of all patients), pharmacist intake form ($n=373$, 17.6%), and visit summary and referral form ($n=51$, 2.4%).

The self-administered screening questionnaire collected information about the patient's health history (e.g., prior blood clot) and characteristics (e.g., smoking status) to identify patient characteristics or conditions that would make them ineligible for hormonal contraception (USMEC category 3 or 4) prescribed by a pharmacist. While the OR screening questionnaire includes information about pregnancy status, the CA protocol does not require an assessment of pregnancy status, as there has been no evidence stating the use of contraceptives while pregnant would increase the risk of birth defects or miscarriage [11]. However, the supermarket-based pharmacy chain elected to include "pregnancy cannot be ruled out" as a reason for referral and recommendation for follow-up with a medical professional in both states.

In addition, the screening questionnaire asked whether the patient had a PCP and health insurance, and the date of a patient's last women's health visit. It also included a section for the pharmacist to document the patient's blood pressure and birth control method prescribed, if applicable.

3. Results

3.1. Demographics of patients seeking hormonal contraception at the pharmacy

During the study period, 2117 hormonal contraception service visits were performed. Of the 676 self-administered screening questionnaires received from the pharmacies, approximately 45% of the forms were obtained from CA pharmacies and 55% from OR pharmacies. Patient demographics were captured from these 676 encounters. Patients ranging from 13 to 55 years of age presented to the pharmacies for the service (Table 1). The majority of patients were adults in their midtwenties who self-reported having health insurance (74%) and a regular PCP (57%), with 89% having seen a PCP within the past year. Ninety-one percent of patients reported using some type of hormonal contraception in the past.

Table 1

Characteristics of patients seeking hormonal contraception at a supermarket-based pharmacy chain between 2016 and 2017^a ($n=676$)

Variable	Value
Age in years	
Mean \pm SD	27.5 \pm 7.4
Range	13–55
Median	26
Number of patients, n (%)	
<18 years of age	13 (2%)
18–24 years of age	258 (38%)
25–34 years of age	294 (43%)
35–44 years of age	82 (12%)
45+ years of age	29 (4%)
Patient has a PCP, n (%)	
Yes	386 (57%)
No	118 (18%)
Unknown	172 (25%)
Patient has insurance, n (%)	
Yes	502 (74%)
No	109 (16%)
Unknown	65 (10%)
Date of last PCP visit, n (%)	
≤ 1 year ago	603 (89%)
> 1 year ago	73 (11%)
Patient has used a form of hormonal contraception in the past, n (%)	
Yes	615 (91%)
No	60 (8.9%)
Unknown	1 (0.1%)

^a Patient demographics were collected from patient written responses in the Self-Administered Screening Questionnaire Form.

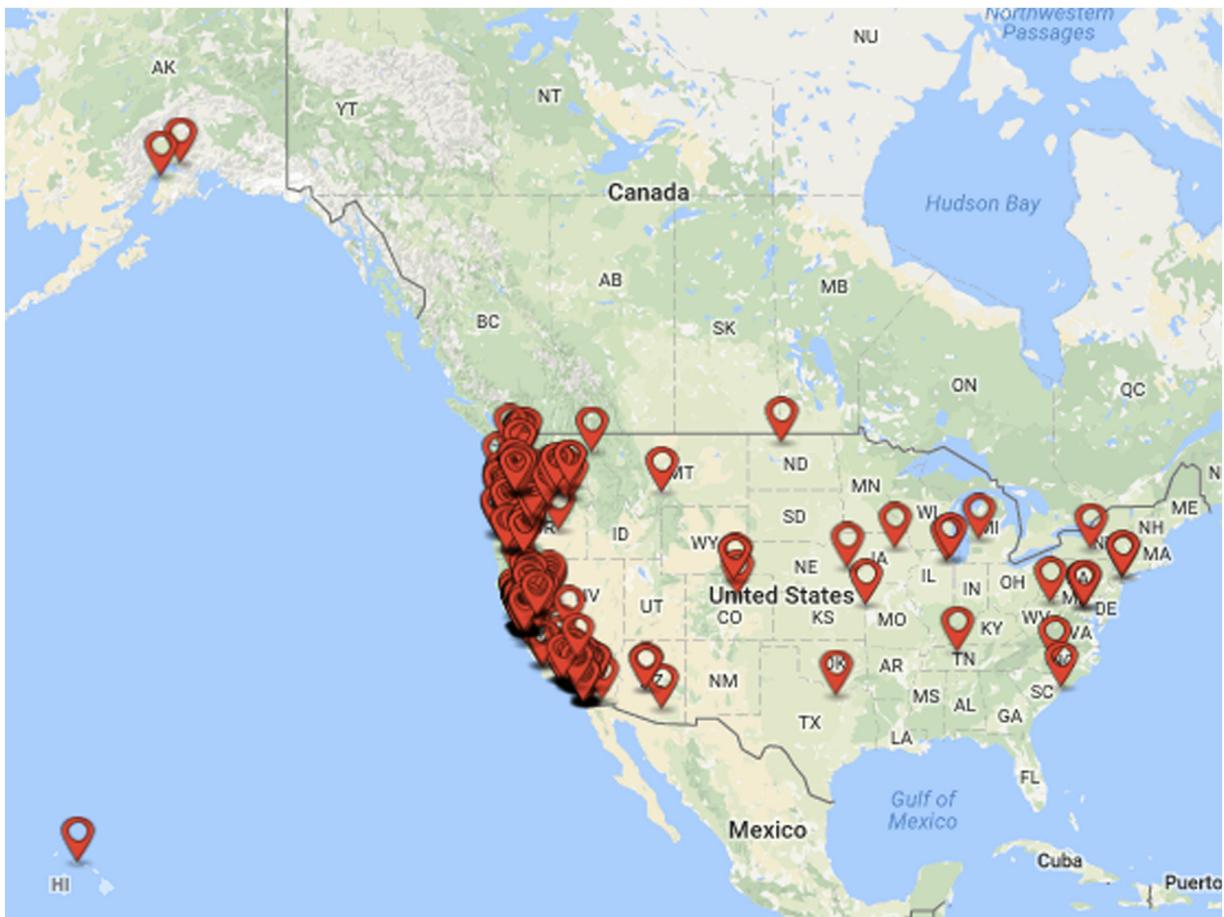


Fig. 1. Permanent residences of patients seeking hormonal contraception at California and Oregon locations of a supermarket-based pharmacy chain.^a Includes CA, OR and 20 other states.

Fig. 1 describes corporate-level data of patient-reported addresses for those who received the service. Besides CA and OR residents, 1.4% of patients ($n=29$) who utilized the service reported addresses in 20 other states.

3.2. Hormonal contraception services

Of the 2117 service visits, 93% ($n=1970$) received hormonal contraception from a pharmacist. The remaining 7% ($n=147$) did not meet USMEC for methods available from the pharmacist and were referred to their PCP (or a local PCP if they did not have one) for follow-up care. Of the 147 referrals, a documented reason for referral to a PCP was available for 51 patients (45 in OR and 6 in CA). An elevated BP ($\geq 140/90$ mmHg; see Table 2) was the most common reason for referral.

Of the 1970 birth control prescriptions provided during the study period, most prescriptions were for the pill (95.7%). Among pill prescriptions with descriptive data available, most were for a combination pill ($n=632$, 98%), and a small proportion were for the progestin-only pill ($n=13$, 2%). Less commonly, pharmacists prescribed the vaginal ring ($n=51$, 2.1%), transdermal patch ($n=31$, 1.6%) and injectable ($n=2$, 0.1%) for patients. These prescriptions were issued by 381 pharmacists (average 5.2 prescriptions per pharmacist) at 391 pharmacies (average 5 prescriptions per pharmacy).

The statewide protocols allow for up to 1 year of prescription supply quantities in the form of initial quantity plus any refills. The supply quantities authorized ranged from 1 to 13 packs; the most common was for a full year's supply, written as either single pack or multiple pack refills (Table 3).

Fig. 2 depicts a heat map of the volume of services provided in different areas throughout the two states. High-volume areas (more than 20

service visits) were primarily major cities such as Portland, San Francisco, Los Angeles and San Diego. Services were also provided outside of major cities in both states.

4. Discussion

Over 2000 patients utilized pharmacist hormonal contraception services at one supermarket-based pharmacy chain in CA and OR in a 6.5-month study period. An overwhelming majority of patients obtained

Table 2

Reasons for referral due to patients' self-reported health histories when seeking hormonal contraception^a ($n=51$)

Reason for referral	Value, n (%)
Pregnancy cannot be ruled out	7 (14%)
Migraines with aura	7 (14%)
Smoker with chronic kidney disease	1 (2%)
Unspecified health condition	2 (4%)
Elevated BP	23 (45%)
Systolic ≥ 140	14 (27%)
Range	143–184
Mean	156
Diastolic ≥ 90	19 (37%)
Range	91–114
Mean	99
Systolic ≥ 140 and diastolic ≥ 90	10 (20%)
Other ^b	11 (21%)

^a Reasons for referral were collected from pharmacist written responses in the Visit Summary and Referral Form.

^b Other reasons for referral include the following: patient was waiting for initiation of insurance coverage, patient preferred the vaginal ring but the OR pharmacist could not prescribe, >1 year since the patient had seen a provider and unspecified reasons.

Table 3
Characteristics of pharmacist-prescribed hormonal contraception services

Service provided (n=2117) ^a	Value, n (%)
Hormonal contraception prescribed	1970 (93%)
Patient referred	147 (7%)
Type of hormonal contraception prescribed (n=1970) ^b	Value, n (%)
Pill	1886 (95.7%)
Vaginal ring	51 (2.6%)
Transdermal patch	31 (1.6%)
Injectable depot	2 (0.1%)
Number of refills given with prescription (n=241)	Value
Range	1–16
Average	8
Median	11
Standard deviation	4
Total packs authorized	Value (n total packs)
2–6 packs	25
7–11 packs	6
12 packs	160
13 packs	50

^a Hormonal contraception services were collected from a corporate-level monthly metrics report (n=2117).

^b Type of hormonal contraception prescribed was collected from a corporate-level monthly metrics report (n=1970).

birth control during their visit with a pharmacist. Among the patients seeking hormonal contraception at the pharmacy, 7% did not meet eligibility criteria, including 3% with elevated BP. The prevalence of medical contraindications was slightly higher than a previous study of women seeking combined hormonal contraception in a traditional clinic setting where 2.4% of women had a medical contraindication, including 1.7% with hypertension [12]. The prevalence of hypertension among patients seeking contraception at the pharmacy since the availability of state-wide protocols has not been described in the literature to date.

Within the service protocol, pharmacists were able to apply their clinical judgment. The majority of pharmacists took a repeat BP reading if the patient's initial reading was elevated. In one case, the patient's BP was elevated, and the CA pharmacist prescribed the progestin-only-pill for which the patient was eligible, and notified the patient's PCP.

Patients of various ages and geographical locations utilized the service. A prior study found that women from diverse demographic backgrounds and ages would utilize contraception if it were more accessible over-the-counter [13]. The pharmacist prescribing service allowed women to obtain direct access to hormonal contraception but differs from over-the-counter access in that it includes pharmacist screening and counseling [14].

This study has several limitations. Some data were collected from handwritten, patient self-administered forms that could potentially have incomplete information. Patient demographic data depended on the responses of OR and CA pharmacies to submit the documentation forms for study purposes. While company policy requires completion of all documentation forms, submitting the forms to researchers was optional. Thus, our summary of patient demographics may not be reflective of the actual demographics of all patients using the service. Furthermore, intentionally or unintentionally, patients may not have provided accurate health history on the self-administered screening questionnaire. Given the straightforward nature of the hormonal contraception protocol, we did not include an evaluation of pharmacists' adherence to the protocol. This study describes services from one pharmacy chain in CA and OR and may not reflect the services of all pharmacies across these or other states with this pharmacist authority. Although all pharmacists completed the same training, pharmacists may have different comfort levels and readiness when providing the service. The flat service fee, which is comparable to a physician office visit copay, was an out-of-pocket expense during the study period which could have influenced the patient population accessing the service. Finally, all forms were available in English language only during the study period, though verbal language translation services were

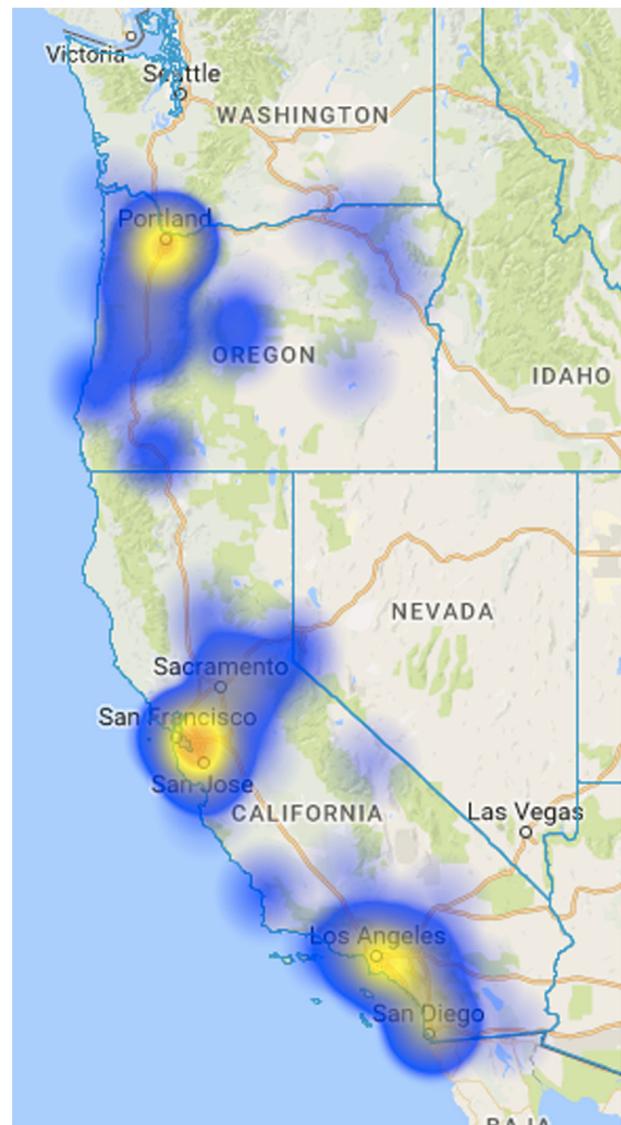


Fig. 2. Volume and distribution of hormonal contraception services provided at California and Oregon locations of a supermarket-based pharmacy chain.^a Orange: >20 services provided, yellow: >10 services provided, blue: ≥1 service provided.

available. With many non-English-speaking patients in these states, there is an opportunity to expand to other languages in the future.

During the study period, health insurance reimbursement for the service was not available. Since completion of this study, this pharmacy chain implemented billing for the service to the OR state Medicaid program (Oregon Health Authority). In CA, legislation was passed and is being implemented whereby the state Medicaid program (Medi-Cal) will reimburse pharmacies for hormonal contraception services. Health plan payment for pharmacist services is anticipated to increase patient access and pharmacist participation. A key barrier to expanding pharmacist scope of practice is additional supportive legislation regarding reimbursement for pharmacist services [15].

As of 2017, CA health plans upon plan renewal must cover up to a 12-month supply of a self-administered hormonal contraception dispensed at one time upon patient request [16]. In previous studies, women who received a 12-month supply of oral contraceptives showed increased adherence and a 30% reduction in unintended pregnancies compared to patients who received a 1-month or 3-month supply [17, 18]. Pharmacist prescribing services may further help reduce the incidence of unintended pregnancy and abortion when pharmacists can

prescribe and dispense a 1-year supply of self-administered hormonal contraception for a patient with health insurance.

Future studies should evaluate patients' experiences with the service as well as pharmacy implementation. Less patients in rural areas utilized the service, likely due to the smaller population of residents located within southeastern OR and northern CA. The roles of health insurance and geographical settings (urban vs. rural) on pharmacist prescribing service utilization or method selection would be worthwhile to explore.

The study did not identify any referrals for an intrauterine device or implant. Since 91% of patients had used some type of hormonal contraception in the past, they may have been seeking a familiar self-administered method at the pharmacy. In addition, patients may have presented to the pharmacy because they desired a self-administered method available at the pharmacy. Finally, pharmacist counseling practices may have guided patients towards the contraceptive methods readily available. These topics warrant further future investigation.

During this study period, Colorado became the third state to expand pharmacists' scope of practice to include prescribing hormonal contraception under statewide protocol and more have followed. Further study in additional states and type of pharmacy settings (e.g., independent, chain, supermarket or big-box pharmacies) will be valuable.

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