

## CLINICAL COMMENTARY

# Over-the-Counter Hormonal Contraception

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In recent years, more and more women across the United States of America have been able to obtain hormonal contraception including pills, patch, ring, or injection without the need for a physician's prescription. Washington D.C., California, Colorado, Hawaii, Idaho, Maryland, New Hampshire, New Mexico, Oregon, Tennessee, Utah, Washington, and West Virginia allow women to obtain their birth control prescription directly from a pharmacist. This access is endorsed by the American College of Obstetricians and Gynecologists, which supports over-the-counter access to hormonal contraception without age restrictions.<sup>1</sup>

The California law (SB-493), which allows pharmacists to dispense hormonal contraception, was passed in 2013, but was held in regulatory discussions until April 2016.<sup>2</sup> Pharmacies in California are not required to provide birth control prescriptions, nor are pharmacists obligated to provide prescriptions for contraceptives. In addition, pharmacists who would like the authority to do so must undergo training.<sup>2</sup>

Pharmacists are generally supportive of pharmacist prescribing and behind-the-counter models for hormonal contraception. A

majority (65%) are interested in prescribing hormonal contraception. The main reason for prescribing contraception is enjoying increased individual patient contact (94%). Safety concerns e.g., patients not obtaining health screenings remained the most important barrier for pharmacist implementation, followed by cost, e.g., lack of payment for pharmacists' services, and practice impact with additional time constraints and liability issues.<sup>3</sup>

Large pharmacy chains routinely provide this service.<sup>4</sup> Under the Affordable Care Act, all prescription birth control is covered by the patient's medical insurance. Pharmacies may charge an additional fee for the assessment services provided by the pharmacist, and insurers have no obligation to pay for a pharmacist's consultation with a patient. That means that the pharmacist's fee of \$25-\$50 will likely be covered by the patient.

The California State Board of Pharmacy developed a hormonal contraception protocol.<sup>5</sup> When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

Table 1

A. Ask the patient to use and complete the self-screening tool (Appendix 1)
B. Review the self-screening answers and clarify responses if needed
C. Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended
D. Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is appropriately trained in administration of the requested or recommended contraceptive medication.
E. When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including: <ol style="list-style-type: none"><li>1. Dosage</li><li>2. Effectiveness</li><li>3. Potential side effects</li><li>4. Safety</li><li>5. The importance of receiving recommended preventative health screenings</li><li>6. That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs)</li></ol>

Appendix 1: Self Screening Tool

Self-Screening Tool:
1. What was the date of the first day of your last menstrual period?
2a. Have you ever taken birth control pills or used a birth control patch, ring or shot/injection? If no, go to question 3.
2b. Did you ever experience a bad reaction to using hormonal birth control?
2c. Are you currently using birth control pills, or a birth control patch, ring or a shot/injection?
3. Have you ever been told by a medical professional not to take hormones?
4. Do you smoke cigarettes?
5. Do you think you might be pregnant now?
6. Have you given birth within the past 6 weeks?
7. Are you currently breastfeeding an infant who is less than one month of age?
8. Do you have diabetes?
9. Do you get migraine headaches or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or involves numbness?
10. Do you have high blood pressure, hypertension, or high cholesterol?
11. Have you ever had a heart attack or stroke or been told you had any heart disease?
12. Have you ever had a blood clot in your leg or in your lung?
13. Have you ever been told by a medical professional that you are at high risk of developing a blood clot in your leg or your lung?
14. Have you had bariatric surgery, or stomach reduction surgery?
15. Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?
16. Do you have or have you ever had breast cancer?
17. Do you have or have you ever had hepatitis, liver disease, liver cancer, or gallbladder disease, or do you have jaundice (yellow skin or eyes)?
18. Do you have lupus, rheumatoid arthritis or any blood disorders?
19a. Do you take medications for seizures, tuberculosis (TB), fungal infections or human immunodeficiency virus (HIV)?
19b. If yes, list them here:
20a. Do you have any other medical problems or take regular medication?
20b. if yes, list them here:

The pharmacist uses the answers in the self-screening tool to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the Centers for Disease Control and Prevention (CDC). The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC for individuals identified as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist).

The patient completes the self-screening tool annually, or whenever the patient indicates a major health change. If it is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist refers the patient for appropriate follow-up care to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics.

Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a *minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception*. An equivalent, curriculum-based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.

Pharmacists report that many patients seeking birth control at pharmacies have been women in their twenties, who like the convenience of being able to get a birth control refill after work, or on weekends, without having to schedule a doctor's appointment. In California, pharmacists can prescribe to women younger than 18.

Lu et al<sup>6</sup> described hormonal contraception services provided by pharmacists at 391 pharmacies in California and Oregon

within a supermarket-based pharmacy chain, and characterized patient populations who utilized those services between August 2016 and February 2017. A total of 2117 visits were completed and 1970 hormonal contraception prescriptions were issued and dispensed during the study period. Patients from various age groups (13-55 years old) and geographical locations (22 states total) utilized the service. Most had health insurance (74%), most 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%).

Oregon pharmacists wrote 10% of all birth control prescriptions since the landmark law passed in 2016. Nearly 74% of all prescriptions written by pharmacists were to people who had not used the pill, patch or ring in the month prior. A majority of those had not been using birth control within six months prior, either. About 3% of women in Oregon used a pharmacist for access to birth control.<sup>7</sup>

Stone et al<sup>8</sup> researched pharmacist self-perception of readiness to prescribe hormonal contraception. Of the 823 participating US pharmacists, 58% felt they received adequate training to prescribe hormonal contraception. Having experience with prescribing any medications within the last five years, or completion of residency training were significantly associated with more participants feeling adequately trained. Of those who indicated that hormonal contraception was not covered in their pharmacy school curriculum, most (78%) felt they were either not adequately trained or unsure. Only 36% were aware of the Centers for Disease Control and Prevention US Medical Eligibility Criteria for Contraceptive Use (CDC MEC). Residency-trained pharmacists were more likely to have used the CDC MEC, and feel comfortable prescribing for adolescents. Most participants desired more training about switching between products (80%) and patient specific product selection (72%).

Mody et al<sup>9</sup> conducted a survey of pharmacies to explore emergency contraceptive prescribing by pharmacists in California. Although 95% of respondents were aware of the statewide protocol allowing pharmacists to prescribe emergency contraception, only 36% of respondents reported prescribing emergency contraception in the previous year. The most commonly reported barriers to prescribing emergency contraception were lack of payment for pharmacist patient care services by insurers, increased responsibility or liability concerns, and time constraints.

There are online digital ventures (NURX, Pandia Health, Lemonaid Health, etc), which provide hormonal contraception without requiring a visit to a health care provider. NURX is available in 18 states. It is popular in states where women live in places that lack easy access to women's health services, "contraception deserts".

The process of obtaining online hormonal contraception involves answering a screening questionnaire, which is then reviewed by a medical provider contracted with the online platform, who generates a prescription, which is filled delivered to the patient's home. Insurance covers the cost of the contraceptives but there is a delivery charge, for example \$39 for mail delivery. For uninsured women the cost of the contraceptive is an out-of-pocket expense.

### Discussion

It is important for primary care providers to be aware that many of their patients elect to obtain hormonal birth control directly from a pharmacy, including on-line pharmacies, often because of convenience and after-hours availability. In California, the State Board of Pharmacy developed a hormonal contraception protocol, and requires pharmacists to undergo special training in order to be able to provide hormonal contraceptives to women. The required training consists of a *minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception*. An equivalent, curriculum-based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol. While this minimal amount of training ensures basic knowledge about the USMEC and CDC guidance on hormonal contraception, and use of the hormonal contraception protocol, it is far less than the level of training required for primary care providers who provide similar services. It is important that pharmacists identify patients who benefit from additional expertise, and refer them. The pharmacists do not have adequate training in managing problems related to hormonal contraception, such as intermenstrual spotting, nausea, mood changes, etc., and these patients will need to seek medical advice from their primary care providers, or from their gynecologists. For low-risk women, the availability of pharmacist prescribed hormonal contraception improves access to hormonal birth control, and better family planning, and it is expected to continue to gain in popularity in the future. For higher risk women, it is important for the pharmacists to recognize the risk and refer them to providers who are trained in managing more complex issues related to hormonal contraception.

In summary, the addition of the pharmacist to the healthcare team has been instrumental in providing increased access to contraception, but also carries with it the added responsibility of knowing when to refer patients for further management.

### REFERENCES

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