# Contraception Updates

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## LEARNING OBJECTIVES

1. Evaluate legislative updates related to contraception access and pharmacists' role in contraception prescribing.
2. Assess patients for impact and scope of unintended pregnancies.
3. Compare and contrast the safety and efficacy of highly effective long-term and emergency contraception products.
4. Evaluate patients for contraception screening and assessment on the basis of CDC medical eligibility criteria and of select practice recommendations.
5. Develop a patient-specific contraception plan for long-term and emergency contraception methods based on advantages, disadvantages, patient preferences, medical eligibility criteria, and screening assessments.

### ABBREVIATIONS IN THIS CHAPTER

| | |
|---|---|
| BMD | Bone mineral density |
| CHC | Combined hormonal contraceptive |
| CPA | Collaborative practice agreement |
| DMPA | Depot medroxyprogesterone acetate |
| EC | Emergency contraception |
| EE | Ethinyl estradiol |
| HC | Hormonal contraception |
| IUD | Intrauterine device |
| LARC | Long-acting reversible contraceptive |
| LGBTQ+ | Lesbian, gay, bisexual, transgender, queer (or sometimes questioning), and others |
| LNG | Levonorgestrel |
| LNG-IUD | Levonorgestrel-releasing intrauterine device |
| MEC | Medical Eligibility Criteria for Contraceptive Use |
| POP | Progestin-only pill |
| STD | Sexually transmitted disease |
| UPA | Ulipristal acetate |

*Table of other common abbreviations.*

## INTRODUCTION

Pharmacists are not only medication experts but also universally accessible health care professionals on the front line of patient interaction. Community pharmacists are underutilized as access points to improve the use of contraceptives in the United States. With many recent changes in legislation, pharmacists will be expected to be familiar with and competent in contraception prescribing in community settings. As a result, the incorporation of contraception care into pharmacy education will be necessary to better prepare graduates. This chapter discusses legislative updates that empower pharmacists throughout the United States to prescribe contraceptives and the impact of pharmacists' contraception prescribing on unplanned pregnancy rates. It gives a brief overview of contraceptive methods, including recently approved contraceptive methods; and discusses the CDC Medical Eligibility Criteria for Contraceptive Use (MEC) for contraceptive updates and reviews recent updates in emergency contraceptive (EC) access. This chapter also provides guidance for the pharmacist's role both in states with legislatures that authorize pharmacists' contraceptive prescribing and in states that lack statewide legislation.

### Legislative Updates

The past 5 years have seen an expansion in the pharmacist's scope of practice to include prescribing of birth control (Rafie 2019). The process began in the state of Washington, which began permitting pharmacists to enter into individual collaborative practice agreements (CPAs) with physicians and other providers. In 2016, California passed the first state regulation expanding pharmacists' scope of practice to specifically permit the prescribing of hormonal contraception (HC) under statewide protocol. Soon after, interest arose in other states. The role of pharmacists in contraception-related services is rapidly expanding.

Collaborative practice agreements create formal practice relationships between pharmacists and other health care practitioners. In some states, *CPA* may stand for *collaborative drug therapy management* (CDTM). Under a CPA or under CDTM, a pharmacist assumes responsibility for specific patient care functions that are otherwise beyond the pharmacist's typical scope of practice but that are aligned with a pharmacist's education and training (NASPA 2017). Such patient care services may include initiation and modification of drug therapy. The extent of the services authorized under a collaborative agreement depends on the state's statutory and regulatory provisions as well as on the terms of the specific agreement between the pharmacist and the overseeing health care practitioner. State laws and regulations authorizing CPAs are highly variable. Some states specify the practitioners who are allowed to participate in CPAs; some states restrict the services that may be provided under a CPA; and some states raise extensive logistical barriers that limit the utility of such agreements. Pharmacists' prescriptive authority can fall into two categories: (1) collaborative prescribing, which sets forth a broad framework for the treatment of acute or chronic disease and (2) autonomous prescribing, which focuses on a limited range of medications not requiring a specific diagnosis (Adams 2016). Two models of pharmacists' autonomous prescribing are statewide protocols and unrestricted category-specific prescribing (Adams 2016). A statewide protocol is published by an empowered state body and may be followed by any pharmacist who meets the specified qualifying criteria. The protocol is the same for all qualified pharmacists in the state and thus is not site or practice specific. A statewide protocol permits a pharmacist to prescribe medications that are used for preventive care or for acute or self-limiting conditions that require no diagnosis or that are easily diagnosed. Such services are not under the direct supervision of a collaborating physician. Unrestricted category-specific prescribing authority allows the autonomous prescribing of a medication (1) without supervision by a collaborating physician, (2) for legitimate medical purposes, and (3) within the pharmacist's usual course of professional practice. Examples are pharmacists' prescribing for tobacco cessation drug therapy, for naloxone, and for immunizations.

To overcome the restrictions and logistical barriers inherent in CPAs, some states authorize pharmacists to prescribe hormonal contraception under a statewide protocol. Currently, 15 U.S. jurisdictions and the District of Columbia have statutes or regulations that allow pharmacists to prescribe HC (Figure 1). Figure 2 presents a general description of pharmacists' contraception-prescribing procedures.

States' policies vary from one another with regard to contraceptive methods, age restrictions, duration of prescriptive authority, pharmacist training, documentation and reporting, professional-practice and service delivery restrictions, pharmacists' fees, models, and legislative scope of bill. Table 1 summarizes the differences between those key policy elements.

Pharmacist prescribing could help increase access to HC. Community pharmacists are accessible outside of provider and clinic hours and geographically located within most neighborhoods. The option of obtaining contraceptive methods directly from a local pharmacy decreases the time it takes for office visits with a medical provider, decreases the out-of-pocket costs of office visits with a medical provider, and decreases delays in starting contraception. In states without permissive HC prescribing legislation, pharmacists remain a resource for patient counseling so as to increase the correct and consistent use of contraceptive methods. Oral contraception is available over-the-counter (OTC) in most countries but has not yet reached that status in the United States. Table 2 summarizes drug access models in the United States.

A study of community pharmacists in the United States found that the majority (65%) want to prescribe HC, help reduce unintended pregnancies, and practice at a level that aligns with their training (Rafie 2019). The top motivator for community pharmacists is individual patient contact (94%), and the most significant safety concern is lack of health screenings by patients (76% reported to be very significant). Many studies have identified barriers to pharmacists' contraception prescribing, such as issues involving staffing, liability,

## BASELINE KNOWLEDGE STATEMENTS

Readers of this chapter are presumed to be familiar with the following:

- General physiology of the menstrual cycle
- Pharmacology and mechanisms of action of current contraceptive methods
- General knowledge of Medical Eligibility Criteria for Contraceptive Use

*Table of common laboratory reference values.*

## ADDITIONAL READINGS

The following free resources have additional background information on this topic:

- CDC. Contraceptive Guidance for Health Care Providers.
- CDC. U.S. Medical Eligibility Criteria for Contraception Use, 2016.
- CDC. U.S. Selected Practice Recommendations for Contraceptive Use, 2016.
- U.S. Department of Health & Human Services Office on Women's Health. Emergency Contraception.

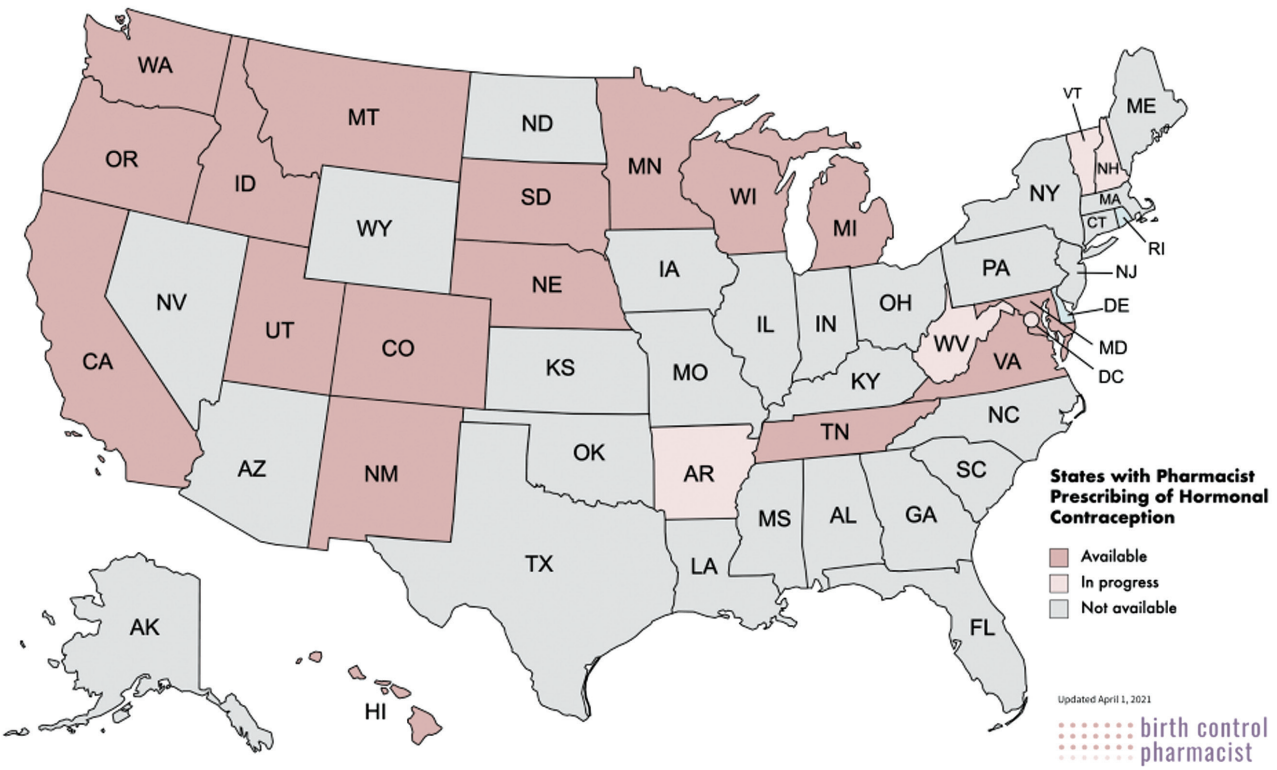


**Figure 1.** Map of pharmacists' prescribing of hormonal contraception by statewide protocol.

Information from: Rafie S, Landau S. Opening new doors to birth control: state efforts to expand access to contraception in community pharmacies. Birth Control Pharmacist, 2020.

need for training, corporate policies, reimbursement, cost, and lack of privacy (Dosea 2017, Rafie 2019, Rodriguez 2016).

In one survey of consumers, most respondents (68%) in the United States said HC should be available without prescription and that they would personally use pharmacy access (Landau 2006). Pharmacists' prescribing of HC may be associated with improved method continuation through the provision of a larger supply of medication at one time (Rodriguez 2020). Pharmacists were significantly *more* likely to prescribe a 6-month supply of contraceptives (6.9% vs. 1.5%, p< .001) and significantly *less* likely to prescribe only a 1-month supply than were other providers (42 [29.2%] vs. 118 [44.4%] prescriptions, p< .001). In women with potential contraindication to estrogen, pharmacists were as likely as other clinicians to prescribe a progestin-only method (8 [20%] vs. 6 [30%], p=0.52). Pharmacists' contraception prescribing occurred for 144 women, and 266 women obtained contraception through traditional prescribing. Compared with women who received prescriptions from other providers, women who obtained

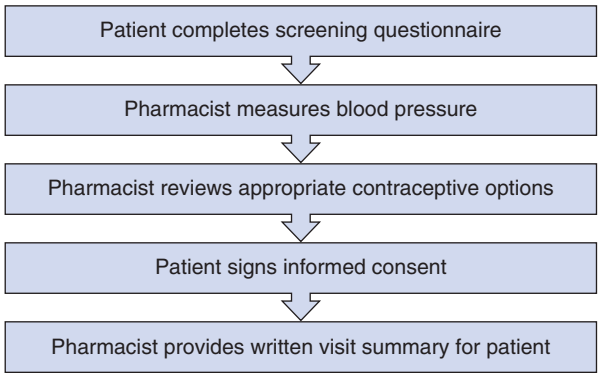


**Figure 2.** General algorithm of pharmacist's procedure for prescribing of contraceptives.

Information from Kooner, M, Joseph, H, Griffin, B. Hormonal contraception prescribing by pharmacists: 2019 update. J Am Pharm Assoc 2020;60:e34-9.

**Table 1.** Major Contraception Policy Elements

| | |
|---|---|
| Contraceptive methods | All current statewide protocols allow pills and patches. Colorado does not allow vaginal rings. Colorado, Hawaii, and Utah do not allow depot medroxyprogesterone acetate. |
| Age restrictions | Colorado, Tennessee, and Utah include age restrictions for patients (18 years and older), whereas other states have no age restrictions but require certain specific actions by pharmacists if services are provided for minors. |
| Duration of prescriptive authority | Most states have no restrictions. Colorado, Oregon, and Utah limit pharmacists' prescribing to 2 or 3 years without evidence of passing an annual exam. Some states require pharmacists to counsel patients about the need for routine gynecological screening. |
| Pharmacist training | California, Tennessee, and Utah do not require additional training of students graduating from accredited schools of pharmacy. More and more states are requiring their state board of pharmacy and/or department of health to approve any training programs. |
| Documentation and reporting | All current statewide protocols require pharmacists to notify the patient's primary care provider. Utah also requires reporting to the state's department of health. |
| Professional practice and service delivery | Colorado, Hawaii, Oregon, and Tennessee prohibit pharmacists and pharmacies from requiring appointments. Washington requires pharmacists to post a sign promoting services. |
| Fees | Some states address fees in their legislations; other states leave fees to rule making or the marketplace. For example, Tennessee originally proposed a $20 capped fee, but the amended bill specified that individual pharmacies or corporate employers shall set their prices. Washington, D.C., originally proposed a $25 fee, but in amendments specified the amount would be determined through regulation by the District of Columbia Department of Insurance, Securities and Banking and mandated that patients have access to co-pay-free birth control covered by insurers. |
| Model | California, Colorado, Hawaii, Maryland, Minnesota, New Mexico, Oregon, and Virginia allow via statewide protocol; Idaho, Michigan, Montana, Nebraska, South Dakota, Tennessee, Washington, and Wisconsin allow via CPA; and Utah allows via standing order. |
| Legislative scope of bill | Most states passed bills focused on hormonal contraception, but some states, such as Idaho, passed wider legislation to include other clinical services (e.g., nicotine replacement products, naloxone) |

Information from: Rafie S, Landau S. Opening new doors to birth control: state efforts to expand access to contraception in community pharmacies. Birth Control Pharmacist, 2020.

**Table 2.** Description of Available Models for Access to Contraceptive Medications

| Model | Description |
|---|---|
| Prescription[a] | Requires a prescription from a licensed prescriber, at which time the drug can be dispensed by a pharmacist or directly by the prescriber |
| Pharmacist prescribing[b] | Requires a prescription, which can be issued directly by a pharmacist with prescriptive authority; authority can apply to a single drug, a drug class, or a specific disease state |
| Behind the counter | Over-the-counter, with nonclinical restrictions such as age, quantity, location of sale, or documentation |
| Over-the-counter[a] | Available without a prescription at any location with no restrictions; also known as *nonprescription* |

[a]Only two classifications recognized by the FDA.

[b]Pharmacist prescribing includes authority from a collaborative practice agreement or collaborative drug therapy management arrangement—furnishing per protocol and dispensing per standing order.

Information from: Rafie S, Landau S. Opening new doors to birth control: state efforts to expand access to contraception in community pharmacies. Birth Control Pharmacist, 2020.

contraception directly from pharmacists (1) were significantly younger (18–24 years old: 82 [56.9%] vs. 115 [43.2%], p=0.03), (2) had attained lower levels of education (bachelor's degree: 38 [26.4%] vs. 100 [37.6%], p=0.002), and (3) were more likely to be uninsured (16 [11.1%] vs. 8 [3.0%] participants, p=0.001) (Rodriguez 2020). In California and Oregon, pharmacists' contraception prescribing was described across 391 locations within a supermarket-based pharmacy chain (Lu 2019). A total of 2117 visits were completed by 381 trained pharmacists, and 1970 HC prescriptions were issued. Documentation for 676 visits (32%) revealed that patients in various age-groups (range 13–55 years old) and geographic locations (22 states total) used the service. Most had health insurance (74%), had seen a primary care provider in the past year (89%), and were previous HC users (91%). The contraceptive methods prescribed were pills (n=1886, 95.7%), vaginal rings (n=51, 2.6%), patches (n=31, 1.6%), and injectables (n=2, 0.1%).

### Impact of Unintended Pregnancy

Unintended pregnancies are those that were not desired at the time of intercourse. They encompass both pregnancies that the women wanted in the future but not at that time (mistimed) and pregnancies the woman never wanted (unwanted). Although the rate of unintended pregnancy is decreasing in the United States, it remains high (Tepper 2016). In 2008, an estimated 51% of all pregnancies were unintended, of which 40% resulted in elective abortion and 27% resulted in births (Finer 2016). By 2011, the percentage of all unintended pregnancies had declined to 45%, although some groups still experienced disproportionately higher rates. Among teens aged 15–19 years, 75% of pregnancies were unintended. Unintended pregnancy rates were highest among women who were aged 18–24 years, had low incomes (<200% of federal poverty level), had not completed high school, were women of color, and were cohabiting but had never married (Finer 2016).

According to a 2019 sexual and reproductive health report, adolescent women aged 15–19 years have a much higher unmet need for modern contraception compared with all women of reproductive age who want to avoid pregnancy (43% vs. 24%) (Sully 2019). Although data on wealth disparities are widely available, data that speak to other important types of marginalization and discrimination are not. The groups about which information is limited—and whose needs are often overlooked—include adolescents younger than the age of 15 years, adolescents with disabilities, racial and ethnic minorities, indigenous populations, and LGBTQ+ adolescents.

Unintended pregnancy has been associated with a range of negative outcomes across several domains, including mother and infant health; socioeconomic, school, and career trajectories; mental health; and parents' relationship quality (Gipson 2008, Kavanaugh 2016, Sonfield 2013). Nationally, government expenditures on births, abortions, and miscarriages resulting from unintended pregnancies totaled $21 billion in 2010, which accounts for 51% of the total spending for all publicly funded pregnancies (Sonfield 2015). Pharmacists' prescriptions of HC were shown to prevent 51 unintended pregnancies in Oregon—at a savings to Medicaid of $1.6 million over 2 years (Rodriguez 2019)

More than 60% of women aged 15–49 years in the United States reported using contraception from 2017 to 2019 (Figure 3) (Daniels 2020). The most-common contraceptive methods used were female sterilization (18.1%), oral contraceptive pill (14%), long-acting reversible contraceptives (LARCs) (10.4%), and the male condom (8.4%). Current condom use was higher among both Hispanic women (10.5%) and non-Hispanic Black women (11%) compared with non-Hispanic white women (7%). The use of LARCs was similar among women aged 20–29 years (13.7%) and 30–39 years (12.7%) and lower among women aged 15–19 years (5.8%) and 40–49 years (6.6%). Current contraceptive use did not differ significantly across educational levels (69.1%–71.3%). Female sterilization declined, whereas the use of LARCs and the pill increased with higher education. About 35% of women aged 15–49 years were not currently using contraception. The reasons for not using contraception included seeking pregnancy, being pregnant or postpartum, or not being sexually active.

## CONTRACEPTIVE METHODS

Given the wide range of options available, the choice of contraceptive method is driven by patient preference, and a shared decision-making approach should be taken. However, health care providers can assist in educating patients on the several factors to take into consideration. The best method is one that is safe and effective, will be used consistently, is acceptable to the patient and the patient's partner, and does not cause bothersome side effects. Before the initiation of any HC, a patient should be evaluated for past and present medical history, including obstetric history and desire for future children, medication allergies, medication use—including vitamins, herbal supplements, and OTC products—an accurate sexual history (e.g., number of current sexual partners), and history of sexually transmitted disease (STD) or pelvic inflammatory disease. Factors to consider when assisting patients in choosing an appropriate method include efficacy, convenience, dosing frequency, reversibility, affordability, previous use, side effects or tolerability concerns from any past uses, and protection against STDs.

Hormonal contraception methods are commonly used for prevention of pregnancy. The primary non-contraceptive benefits of hormonal products are improvements in menstrual cycle irregularity, premenstrual syndrome, premenstrual dysphoric disorder, dysmenorrhea, menstrual migraine, menorrhagia (excessive bleeding), anemia, and pelvic pain in women with endometriosis (ACOG 2010). Other benefits are treatment of hirsutism and acne in women with polycystic

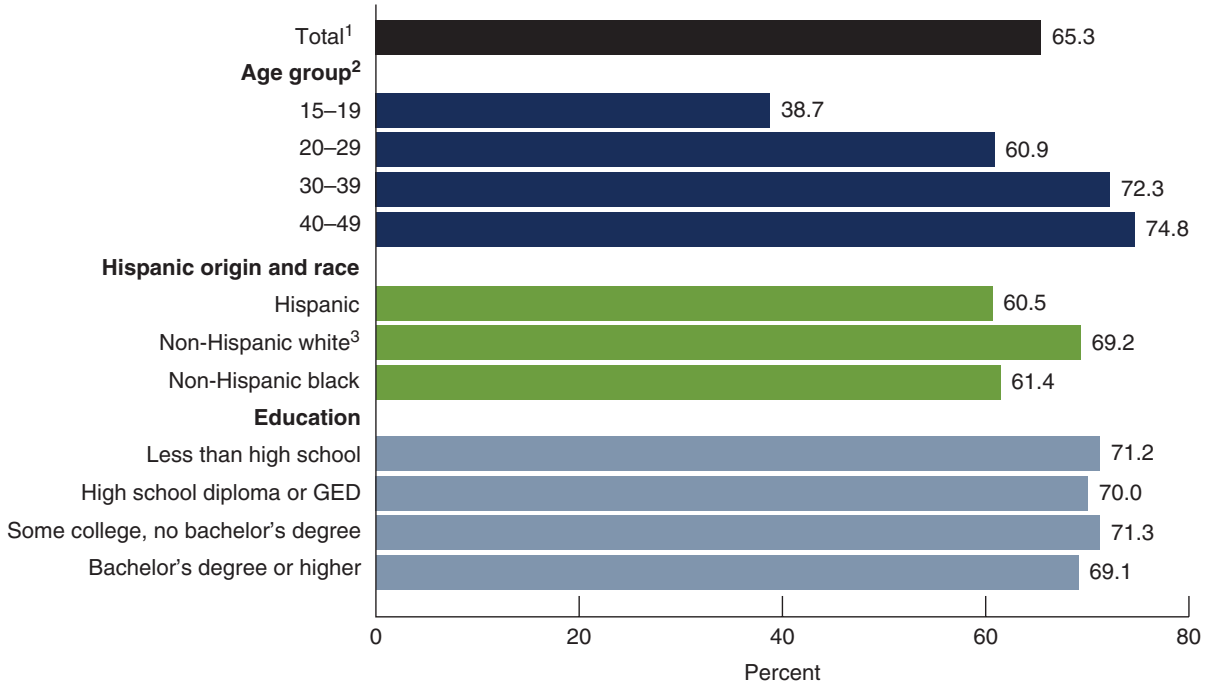


**Figure 3.** Percentage currently using any contraceptive method among all women 15–49 years and by age group, Hispanic origin and race, and education: United States, 2017–19.

Note: The population size referenced for women aged 15–49 years is 72.2 million. Analyses of education are limited to women aged 22–49 years at the time of interview. Less than high school means no high school diploma or no general equivalency diploma (GED).

[1]Includes persons of other and multiple race and origin groups, not shown separately.

[2]Significant linear trends across all four age-groups.

[3]Significantly different from non-Hispanic Black women.

Information from: CDC National Center for Health Statistics, National Survey of Family Growth, 2017–2019.

ovary syndrome and decreasing the risk of endometrial, ovarian, and colorectal cancers. Among oral contraceptive pill users, 14% use the method solely for non-contraceptive indications, and 58% use the method at least in part for indications other than pregnancy prevention.

Effectiveness is assessed based on failure rate (the percentage of women who have unintended pregnancies within 1 year of using the method). Perfect-use efficacy rates are determined in clinical trials when the contraceptive method is used correctly and consistently. Typical-use efficacy rates are estimates of population-based effectiveness, which includes imperfect (inconsistent or incorrect) use. In clinical trials, the primary efficacy measure for contraceptives is the Pearl Index, which reflects the number of unintended pregnancies among all of the cumulative years of exposure. One of the limitations of the Pearl Index is the use of a pregnancy intent-to-treat population, which assumes that the rate of unintended pregnancies in women lost to follow-up is the same as in women who continued in the study. Also of concern is the use of variable durations of exposure, as the risk of unintended pregnancy decreases over time. Thus, allowing women to contribute more years of risk would drive the Pearl Index down. Although the Pearl Index is used in product labeling, typical-use efficacy rates are used in clinical practice and should be communicated to women (Mansour 2010, Trussell 2011).

Contraceptive methods can be divided into three categories with respect to typical-use effectiveness. Highly effective methods result in unintended pregnancies in less than 1% of users and include permanent sterilization and LARCs, such as the subdermal implant and intrauterine device (IUD). Moderately effective methods result in unintended pregnancies in 4%-7% of users, and include the depotmedroxyprogesterone (DMPA) injection and combined hormonal contraceptives (CHCs). Less-effective methods are those that have a more than 13% failure rate; they include other barrier methods, withdrawal, fertility-awareness-based methods, and spermicides. A chart depicting those categories with a graphic display of each method and its typical-use failure rate is a useful tool for patient and provider understanding (Figure 4). Overall, contraceptive methods designed for use at or near the time of sex (e.g., condom, diaphragm) may be less effective than other birth control methods (e.g., IUD, contraception pill). If use is inconsistent or if a method fails, EC can reduce

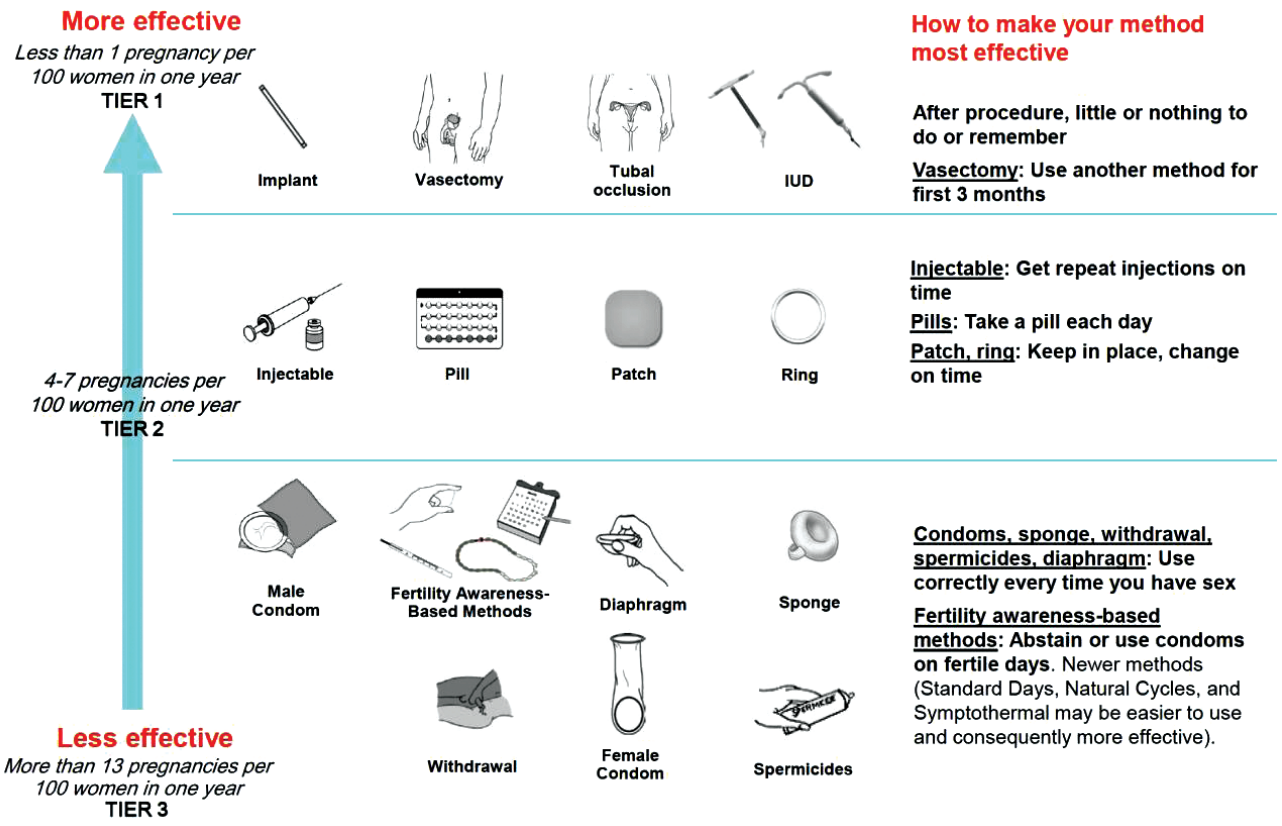


**Figure 4.** Comparison of typical effectiveness of contraceptive methods.

Information from: World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP). Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD; Geneva, Switzerland: CCP and WHO; 2011; and Trussell J, Aiken ARA, Micks E, et al. Efficacy, safety, and personal considerations. In: Hatcher RA, Nelson AL, Trussell J, et al, eds. Contraceptive Technology, ed 21. New York, NY: Ayer Company Publishers, Inc., 2018.

the risk of pregnancy for up to 5 days after sexual intercourse (see section on emergency contraception).

## Review of Available Products

### *Fertility-Awareness-Based Methods*

Fertility-awareness-based methods involve the monitoring of various signs and symptoms of fertility during the menstrual cycle to identify the fertile window or during the days of the cycle when unprotected vaginal intercourse is most likely to result in pregnancy. The average menstrual cycle lasts 28 days, but normal cycles can vary from 21 to 35 days, with about 9 fertile days each month. The amount of time before ovulation occurs may vary from 13 to 20 days and can be different from month to month in the same patient. After ovulation, every patient (unless a health problem exists that affects the menstrual cycle or the patient becomes pregnant) will have a period within 14 to 16 days. Examples of fertility-awareness-based methods are withdrawal (coitus interruptus), calendar method or rhythm method, symptothermal method, 2-day method, basal body temperature method, and standard days method. Typical use shows failure rates up to 23% (see Figure 4) (Trussell 2018). These methods may be advantageous in the context of personal, cultural, or religious beliefs that prohibit the use of other contraceptive methods, and they may be best used in sexual partnerships that support abstaining from sexual intercourse, withdrawal, or the use of barrier methods during the fertile window. Disadvantages include lack of protection against STDs, lack of diligent monitoring of fertility signs (e.g., cervical secretions, temperature), and lack of tracking of fertile days.

### *Barrier Methods*

Nonhormonal reversible contraceptive methods that are used at the time of intercourse to prevent pregnancy include the diaphragm, cervical cap, sponge, male or female condom, and spermicides. These barrier methods prevent functioning

sperm from entering the female reproductive tract. The diaphragm, cervical cap, and contraceptive sponge function largely by maintaining a reservoir of contraceptive gel against the cervix. Spermicidal foams, gels, creams, films, and suppositories provide contraception by immobilizing sperm and thus creating a chemical barrier against the normal ascent of sperm into the upper genital tract. For the primary indication of pregnancy prevention, these contraceptives are considered second tier (diaphragm) or third tier (cervical cap, contraceptive sponge, and spermicide) in efficacy below LARCs and other hormonal contraceptive methods (see Figure 4). The newest product is Phexxi, a vaginal gel approved in 2020 (see New Products). Typical-use failure rates for the barrier methods range from 13% to 23% (Trussell 2018).

Advantages for barrier methods include immediate onset, reversibility, and good safety profile, if used correctly. Barrier methods have no effect on endogenous hormones, and they have minimal adverse effects; therefore, they are safe to use in patients with many medical conditions. They are also relatively inexpensive, and several are available OTC. Disadvantages include substantially higher failure rates than hormonal methods, IUDs, and implants. The diaphragm, cervical cap, contraceptive sponge, and nonoxynol-9-containing spermicides do not protect against STDs, and they require motivation and the right technique to use them correctly at each act of sexual intercourse. The necessary concomitant spermicide must be inserted before intercourse is initiated, which may be inconvenient or may reduce spontaneity. With regard to several of these methods, it is hard to keep their use private from a partner. As a result, discontinuation rates are higher among users of the cervical cap or diaphragm (52%), sponge (48%), and spermicide (39%) compared with users who use IUDs (36%) and hormonal pills (29%) (Moreau 2007).

### *Short-Acting Reversible Contraceptive Methods*

Short-acting reversible contraceptive methods include both CHCs and progestin-only contraceptives.

#### Combined Hormonal Contraceptives

The formulations of combined oral contraceptives (COCs) available in the United States are the tablet, transdermal patch, and vaginal ring. A CHC's estrogen and progestin prevent pregnancy by feedback inhibition of hormones in the pituitary gland (Mitchell 2019). Estrogen also increases sex-hormone-binding globulin, a hormone in the body that binds free androgens. That action is considered one of the reasons most CHCs help improve acne and hirsutism. Estrogen also prevents breakthrough bleeding in the early cycle because of its effects on the endometrium. The effectiveness of CHCs is more than 90%, with a typical use-failure rate of about 7% (see Figure 4) (Trussell 2018). The contraceptive patch is less effective compared with the oral formulation (3% vs. 0.6% failure rates) in women who weigh more than 90 kg (Mitchell 2019).

Different formulations of CHCs contain varying amounts of estrogen and progestin, resulting in varying side effects. Typical doses of estrogen range from 20 to 50 mcg of ethinyl estradiol (EE). Lower doses of estrogen (≤35 mcg) are used in most regimens to reduce side effects. Four generations of progestins are found in available CHCs: first generation (e.g., norethindrone acetate, ethynodiol diacetate), second generation (e.g., norgestrel, levonorgestrel), third generation (e.g., desogestrel, norgestimate), and fourth generation (e.g., drospirenone, segesterone acetate) (Mitchell 2019). In addition, to reduce side effects, products are available that provide an extended cycle (84 active pills and 7 placebo pills), a continuous cycle (0 placebo pills), shorter placebo regimens (4 placebo pills), and low-dose estrogen (10 mcg EE) during placebo pills.

Initially, all COCs were monophasic, but they are now also available in triphasic and quadriphasic regimens to reduce adverse effects. Common side effects (Box 1) attributed to CHCs are breast tenderness, headache, migraine, nausea, nervousness, vomiting, dizziness, weight gain, acne, tiredness, loss of libido, and increase in blood pressure (Mitchell 2019). Lower doses of estrogen and newer progestins are now included to reduce those side effects. Particularly, desogestrel, norgestimate, and low-dose drospirenone were designed to cause fewer androgenic side effects such as acne, hirsutism, androgenic weight gain, and negative effects on the lipid profile. The most-serious adverse effects of CHCs are VTE, heart attack, and stroke. The use of CHCs is contraindicated in patients with histories of migraines with aura—given the

**Box 1. Adverse Effects of Contraceptive Agents Based on Hormone Content**

Too much estrogen
- Bloating
- Breast tenderness
- Mood changes
- Headache
- Nausea
- Heavy menses
- Fibroid growth
- Melasma
- Vision changes
- Cyclic weight gain

Not enough estrogen
- Breakthrough bleeding early in cycle
- Light menses
- Vaginal dryness
- Spotting
- No withdrawal bleeding

Not enough progestin
- Acne[a]
- Hirsutism
- Decreased libido
- Depression
- Increased appetite
- Increased libido[a]
- Noncyclical weight gain
- Less energy
- Cholestatic jaundice[a]
- Yeast infections
- Hair loss[a]
- Swelling in arms or legs[a]

Too much progestin
- Breakthrough bleeding late in cycle
- No withdrawal bleeding
- Heavy menses

[a]Indicates androgen excess.

Information from: Mitchell J, Mager N, Downing D. Hormonal and emergency contraception. In: O'Connell M, Smith JA. Eds. Women's Health Across the Lifespan, 2nd ed. McGraw-Hill, 2019.

increase in risk of stroke. When counseling patients on the potential risks of CHCs, the prescriber can offer a helpful acronym: ACHES (see section on pharmacist's role).

Other formulations of CHCs are available such as vaginal rings and transdermal patches. Two contraceptive vaginal rings are available: the disposable NuvaRing/EluRyng (EE 150 mcg/day and etonogestrel 120 mcg/day) and the reusable Annovera (EE 13 mcg/day and segesterone acetate 150 mcg/day) (see section on new products). The rings are flexible, transparent, and colorless. Women insert a ring vaginally and leave it in place for 3 weeks. Also on the market are two contraceptive patches; each one gets applied to the skin every 7 days for 3 weeks. Xulane delivers EE 35 mcg/day and norelgestromin 150 mcg/day, and Twirla delivers EE 30 mcg/day and levonorgestrel 120 mcg/day (see New Products). It has been suggested that the Xulane transdermal patch is associated with an increased risk of VTE because of higher estrogen exposure compared with COCs. Xulane's labeling includes a warning about the higher VTE risk and says that women worried about blood clots should discuss with their provider other, alternative methods. As part of Twirla's approval, the FDA is requiring a long-term, prospective, observational, postmarketing study comparing the risks of VTE and arterial thromboembolism in new users of Twirla with the risks in new users of other CHCs (see VTE section under chronic conditions).

The advantages of CHCs are that they are highly effective, are completely reversible, and provide non-contraceptive benefits such as improvement in menorrhagia and acne (Table 3). Disadvantages include the side-effect profile (see Box 1) and the necessity of remembering medication. The need to understand the correct and consistent use of formulations may pose a barrier in those with low health literacy. Some formulations, such as the patch and the vaginal ring, may cause local skin or vaginal irritation.

### Progestin-Only Contraceptive Pills

For women with contraindications to estrogen or for those seeking alternative forms of HC, many forms of progestin-only contraceptives are available. Progestin-only pills (POPs) are ideal for patients who have contraindications to CHCs or who prefer not to use CHCs. POPs are currently available in the United States as norethindrone 0.35 mg or drospirenone 4 mg (Slynd 2019) (see New Products). There is a desogestrel

**Table 3.** Summary of Available HC Options

| Method | Effectiveness (%) | Relative advantages | Relative disadvantages |
|---|---|---|---|
| COC | >90 | Highly effective with correct and consistent use; lessens irregular bleeding compared with progestin-only pill; non-contraceptive benefits | Estrogen-related side effects; COCs containing drosperinone may increase risk of hyperkalemia; requires daily intake; limited use in patients at risk of VTE and history of migraine with aura |
| Transdermal patch | >90 | Highly effective with correct and consistent use; increased adherence | Same as COCs; possibly reduced efficacy in patients >90 kg; skin irritation; not recommended if BMI >30 |
| Vaginal ring | >90 | Highly effective with correct and consistent use; discreet; requires removal only one time per month; reusable ring available | Same as COCs; vaginal irritation |
| POP | >90 | Highly effective with correct and consistent use; safe if contraindication to estrogen or if preference to avoid estrogen. | Irregular menstrual bleeding; mild headaches; acne; strict adherence (norethindrone); increased risk of hyperkalemia with drosperinone |
| DMPA | >90 | Same as POP; protection for 12 weeks | Irregular or prolonged menstrual bleeding; decreased BMD with use >2 years; injectable; reinjection within 2 weeks of schedule |
| Subdermal implant | >99 | Same as POP; long duration of action (3 years) | Lighter or infrequent menstrual bleeding; requires minor procedure for insertion and removal |
| LNG-IUDs | >99 | Same as POP; long acting (3–6 years) | Discomfort with placement; should not be used if current STD, PID, or unexplained vaginal bleeding; requires minor procedure for insertion and removal |

BMD = bone mineral density; COC = combined oral contraception; DMPA = depot medroxyprogesterone acetate; HC = hormonal contraception; LNG-IUDs = levonorgestrel intrauterine devices; PID = pelvic inflammatory disease; POP = progestin-only pill; STD = sexually transmitted disease.

POP formulation available in other countries, but not available in the United States. Norethindrone POPs are taken daily as a 28-day regimen with no placebo pills. Similar to CHCs, efficacy is more than 90%, with a typical-use failure rate of about 7% (Trussell 2018). The advantages of POPs include avoidance of estrogen-related side effects and limited impact on breast milk production, so they may be more acceptable for use while breastfeeding compared with CHCs. But even though it is associated with fewer health risks than CHCs are, progestin-based contraception should not be used in women who may be pregnant, who have a known or suspected carcinoma of the breast, who have undiagnosed abnormal vaginal bleeding, or who have acute liver disease, including malignant or benign liver tumors (Mitchell 2019). The disadvantages of norethindrone POPs are a shorter missed-dose window (3 hours) compared with Slynd and COCs, potential loss of efficacy in those who weigh more than 70 kg, and risk of ectopic pregnancy.

### *Long-Acting Reversible Contraceptive Methods*

Dosage forms are injectables, subdermal implants, and IUDs. Depot medroxyprogesterone acetate is a long-acting progestin injectable administered as 150 mg intramuscularly or 104 mg subcutaneously every 11–13 weeks. Clinical trials have demonstrated similar efficacy with both DMPA formulations (Toh 2004). A DMPA formulation must be initially administered within 7 days of the beginning of menstruation so as to reliably prevent ovulation. However, DMPA may be administered at any time during a woman's cycle. If it is beyond the initial 7 days of the start of her cycle, a backup method should be used for the first week. There is a 2-week grace period for pregnancy prevention should a dose be delayed (up to 15 weeks from prior injection). The progestin-only implant (Nexplanon) contains 68 mg of etonogestrel, the active metabolite of desogestrel. Nexplanon is FDA approved to prevent pregnancy for up to 3 years. Four levonorgestrel-releasing IUDs (LNG-IUDs) are available that differ by levonorgestrel level, and a single nonhormonal copper IUD is available. The LNG-IUD is a small, T-shaped device placed inside the uterus by a trained provider and is indicated for prevention of pregnancy for 3–6 years. The copper IUD is approved for up to 10 years of use (see Overview of Emergency Contraception section). The implant and IUDs are highly effective more than 99% of the time, with a typical-use failure rate of 0.1% – 0.4% (see Figure 4) (Trussell 2018).

The advantages of LARCs are that they are highly effective, avoid estrogen side effects, are not affected by body weight (implant is not well studied in obese women), and improve adherence (implant and IUDs). Depot medroxyprogesterone acetate has non-contraceptive benefits and can be used in the treatment of menorrhagia, dysmenorrhea, endometriosis-associated pain, ovulatory pain, and vasomotor symptoms of menopause. With hormonal IUDs, menstrual bleeding is significantly reduced overall, which may be beneficial in a patient with iron deficiency anemia. Disadvantages include the need for provider administration and irregular bleeding. Specific to DMPA, there may be a potential delay in return to fertility (up to 14 weeks), and prolonged use can result in hypoestrogenism, which is associated with bone loss. The DMPA package insert includes a statement that warns women of significant loss of bone mineral density (BMD) with increasing duration of use, which may not be completely reversible (Kaunitz 2008). An association with DMPA and weight gain has not been shown conclusively in studies (Mitchell 2019). Intrauterine devices may increase the risks of (1) pelvic inflammatory disease in the presence of an STD at time of insertion and (2) ectopic pregnancy if pregnancy were to occur. For those reasons it is imperative to counsel women on major warning signs and when to seek immediate medical care (see section on patient counseling).

Both short-acting and long-acting hormonal contraceptives are highly effective at preventing pregnancy, but they do not protect against STDs, including HIV. Women should be educated and advised to combine all forms of HC with a condom in order to reduce the risk of STDs.

## New Products

### *Phexxi*

Phexxi (lactic acid, citric acid, and potassium bitartrate) vaginal gel was approved in 2020. It is supplied in a prefilled single-dose (5-g) vaginal applicator and comes in a box of 12 applicators. The mechanism of action is a pH-lowering effect and reduction in sperm motility. Typical effectiveness is expected to be 86%, and one applicator must be used no more than 1 hour before each episode of vaginal intercourse. Phexxi should not be used following vaginal intercourse. Advantages include safe use with most other contraceptives (avoid with vaginal rings), hormone-free product, and increased efficacy compared with many of the barrier methods. Side effects reported more commonly in clinical trials were vaginal burning and pruritus. A disadvantage to Phexxi is the need to apply no more than 1 hour before each act of vaginal intercourse.

### *Annovera*

Annovera (EE 13 mcg/day and segesterone acetate 150 mcg/day) is a new vaginal ring. The vaginal ring must remain placed for 3 weeks followed by 1 week, during which it is removed, washed, and stored for reuse every month. The same vaginal ring is used for 13 cycles (1 year). This regimen is different from that of the EluRyng/NuvaRing, which requires use of a new ring every month. Effectiveness is comparable to other CHCs (see Figure 4). Annovera contains a new, nonoral progestin. It is of note that women with BMIs of more than 29 were excluded from trials and that Annovera is twice as thick as NuvaRing (8.4 mm compared with 4 mm). Like for other CHCs, a boxed warning states that women older than the age of 35 years who smoke should not use Annovera.

### *Twirla*

Twirla (EE 30 mcg/levonorgestrel 120 mcg) is a new contraceptive patch. Like Xulane (EE 35 mcg/day and norelgestromin 150 mcg/day), it is supplied as three patches for 3 weeks of use and 1 week of no patch—for placebo. Efficacy is similar to Xulane's (see Figure 4). Advantages are also similar, but Twirla does contain a lower dose of EE compared with Xulane, and it likely carries a lower risk of VTE. Twirla contains a boxed warning to avoid use in women older than 35 years of age who smoke and women with BMIs of 30 or more. Compared with Xulane, Twirla has a larger shape/size (28 $cm^2$ vs. 14 $cm^2$), which may make it more difficult to wear discretely.

### *Slynd*

Slynd (drosperinone 4 mg) is a POP that offers certain significant advantages over the norethindrone-containing POP. It is supplied in a 28-day pack with four placebo pills compared with no placebo pills in the norethindrone pack. Effectiveness is similar to other oral contraceptives described earlier (see Figure 4). The time window for a missed dose is 24 hours compared with 3 hours for the norethindrone-containing product. Slynd is safe to use in women with histories of cardiovascular disease. Postpartum risk of thromboembolism and patient risk factors should be considered before prescribing Slynd. Disadvantages are similar to those discussed previously under progestin-only pills. Drospirenone is contraindicated in women with positive or unknown antiphospholipid antibodies, with current breast cancer or histories of breast cancer, with hepatocellular adenoma, with malignant hepatoma, or with severe hepatitis. Drospirenone has antimineralocorticoid activity, including the potential for hyperkalemia in high-risk women—comparable to a 25-mg dose of spironolactone—and is therefore contraindicated in women with conditions that predispose to hyperkalemia (e.g., renal impairment, hepatic impairment, and adrenal insufficiency). Women receiving daily, long-term treatment for chronic conditions or diseases by means of medications that may increase serum potassium concentration should have their serum potassium concentration checked before starting treatment and during the first treatment cycle.

## SCREENING AND ASSESSMENT

### 2016 and 2020 U.S. MEC Updates

In 2010, the CDC first published U.S. MEC, which incorporated WHO's global guidance for providing recommendations on the safe uses of contraceptive methods (CDC 2016a). Eligibility criteria are based on patients' various medical conditions and other characteristics and provide four distinct categories that highlight any potential risks with specific-method use (Box 2).

The MEC was updated in 2016, with the following noteworthy changes.

- Addition of recommendations for women with cystic fibrosis, women with multiple sclerosis, and women receiving certain psychotropic drugs or St. John's wort (Table 4)
- Revisions to the recommendations for postpartum women, women who are breastfeeding, and women with known dyslipidemias, migraine headaches, superficial venous disease, gestational trophoblastic disease, and STDs (see Table 4)
- Revisions to the recommendations for women with human HIV and women who are receiving antiretroviral therapy (Table 5)
- Revisions to the recommendations for EC, including the addition of ulipristal acetate (UPA) (Table 6)

**Box 2. Categories for Classifying Medical Eligibility for Hormonal Contraceptives and IUDs**

Category 1. A condition for which there is no restriction on the use of the contraceptive method

Category 2. A condition for which the advantages of using the method generally outweigh the theoretical or proven risks

Category 3. A condition for which the theoretical or proven risks usually outweigh the advantages of using the method

Category 4. A condition that represents an unacceptable health risk if the contraceptive method is used

IUD = intrauterine device.

Information from: CDC. U.S. medical eligibility criteria for contraceptive use, 2010. MMWR 2010;59(RR04):1-81.

Based on the 2019 WHO recommendations, the CDC published updated guidelines in April 2020 regarding contraceptive use in women at high risk of HIV infection (see Table 5). Two main changes were adopted.

- Restrictions were removed for MEC Category 1 use of all contraception methods, now including IUDs and DMPA injection. Previously, high risk of HIV was a condition for which copper-containing and progesterone-releasing IUD and DMPA use was in MEC Category 2 (benefits generally outweigh the risks of the condition).
- The CDC has clarified that its recommendations for contraception in women taking nucleoside reverse transcriptase inhibitors (NRTIs) apply to all NRTI indications: prevention or treatment of HIV infection. Most contraceptive methods are MEC Category 1—except the initiation of IUDs in women whose HIV viral loads are not controlled or who are not receiving antiretroviral therapy because of the risk of PID with IUD insertion (MEC Category 2).

### Selected Practice Recommendations Updates

In 2013, the CDC incorporated WHO's guidance and published the first U.S. Selected Practice Recommendations for Contraceptive Use (SPR). The SPR serves as a companion to the MEC and provides evidence-based guidance on how to

**Table 4.** 2016 Summary of Changes to MEC

| Condition | Cu-IUD | LNG-IUD | Implant | DMPA | POP | CHCs |
|---|---|---|---|---|---|---|
| **Cystic Fibrosis**<br>*Note:* Classifications must be adjusted if patient also has diabetes, liver disease, gallbladder disease, or VTE or is taking antibiotics | 1 | 1 | 1 | 2 | 1 | 1 |
| **Multiple Sclerosis** | 1 | 1 | 1 | 2 | 1 | 3 |
| a. With prolonged immobility | | | | | | |
| b. Without prolonged immobility | 1 | 1 | 1 | 2 | 1 | 1 |
| **Psychotropic medications** | 1 | 1 | 1 | 1 | 1 | 1 |
| SSRIs | | | | | | |
| St. John's wort | 1 | 1 | 2 | 1 | 2 | 2 |
| **Postpartum women** | | | | | | |
| With other risk factors for VTE | - | - | 1 | 1 | 1 | 3/4 |
| • Age ≥35 years<br>• Previous VTE<br>• Thrombophilia<br>• Immobility<br>• Blood transfusion at delivery<br>• Peripartum cardiomyopathy<br>• BMI ≥30 kg/m$^2$<br>• Postpartum hemorrhage<br>• Post-Cesarean delivery<br>• Preeclampsia<br>• Smoking | | | | | | *Note:* Classification for CHC is 4 with presence of other VTE risk factors |
| **Postpartum breastfeeding** | | | | | | |
| a. <21 days postpartum | - | - | 2 | 2 | 2 | 4 |
| b. 21 to <30 days postpartum regardless of VTE risk factors | - | - | 2 | 2 | 2 | 3 |
| c. 30-42 days postpartum | | | | | | |
| i. with other VTE risk factors | - | - | 1 | 1 | 1 | 3 |
| ii. without VTE risk factors | - | - | 1 | 1 | 1 | 2 |
| d. >42 days postpartum | - | - | 1 | 1 | 1 | 2 |
| **Postpartum non-breastfeeding women** | | | | | | |
| a. <21 days postpartum | - | - | 1 | 1 | 1 | 4 |
| b. 21-42 days postpartum | | | | | | |
| i. with other VTE risk factors | - | - | 1 | 1 | 1 | 3 |
| ii. without VTE risk factors | - | - | 1 | 1 | 1 | 2 |
| c. >42 days postpartum | - | - | 1 | 1 | 1 | 1 |
| **Women with several risk factors for CVD** (e.g., older age, smoking, DM, HTN, DL) | 1 | 2 | 2 | 3 | 2 | 3/4<br>*Note:* Classification for CHC is 4 with presence of other VTE risk factors |
| **SVT** (acute or history) | 1 | 1 | 1 | 1 | 1 | 3<br>*Note:* Consider CHC if SVT is associated with peripheral intravenous catheter, because risk of thrombosis is lower |

(*continued*)

**Table 4.** 2016 Summary of Changes to MEC (*continued*)

| Condition | Cu-IUD | LNG-IUD | Implant | DMPA | POP | CHCs |
|---|---|---|---|---|---|---|
| **Headache** | | | | | | |
| a. Nonmigraine mild or severe | 1 | 1 | 1 | 1 | 1 | 1 |
| b. Migraine | | | | | | |
| i. Without aura | 1 | 1 | 1 | 1 | 1 | 2 |
| ii. With aura | 1 | 1 | 1 | 1 | 1 | 4 |
| **Gestational trophoblastic disease** (under close medical supervision) | 1 | 1 | 1 | 1 | 1 | 1 |
| a. Suspected | 2 | 2 | 1 | 1 | 1 | 1 |
| i. Uterine size first trimester | 1 | 1 | 1 | 1 | 1 | 1 |
| ii. Uterine size second trimester | 2/1 | 2/1 | 1 | 1 | 1 | 1 |
| b. Confirmed | 2/1 | 2/1 | 1 | 1 | 1 | 1 |
| i. Undetectable or nonpregnant β-hCG | 4/2 | 4/2 | 1 | 1 | 1 | 1 |
| ii. Decreasing β-hCG levels | | | | | | |
| iii. Persistently elevated β-hCG levels or malignant disease with no evidence or suspicion of intrauterine disease | | | | | | |
| iv. Persistently elevated β-hCG levels or malignant disease with evidence or suspicion of intrauterine disease | | | | | | |
| **Sexually transmitted diseases with other factors** (gonorrhea and chlamydia) | 2 | 2 | 1 | 1 | 1 | 1 |

β-hCG = beta human chorionic gonadotropin; CHCs = combined hormonal contraceptives; Cu-IUD = copper intrauterine device; DL= dyslipidemia; DM = diabetes mellitus; DMPA = depot medroxyprogesterone acetate; HTN = hypertension; LNG-IUD = levonorgestrel intrauterine device; MEC = Medical Eligibility Criteria for Contraceptive Use; POP = progestin-only pill; SSRIs = selective serotonin reuptake inhibitors; SVT = superficial venous thrombosis.

use contraceptive methods safely and effectively once they are deemed to be medically appropriate. It also provides guidance on how to reasonably determine whether a woman is not pregnant (Box 3). An update to the SPR occurred in 2016 and included guidance as follows with regard to starting regular contraception after ulipristal acetate (UPA) EC pills.

- Advise the woman to start or resume HC no sooner than 5 days after use of UPA, and provide or prescribe the regular contraceptive method as needed. For methods requiring a visit to a health care provider, such as DMPA, implants, and IUDs, starting the method at the time of UPA use may be considered; the risk that the regular contraceptive method might decrease the effectiveness of UPA must be weighed against the risk of not starting a regular hormonal contraceptive method.
- The woman must abstain from sexual intercourse or must use barrier contraception for the next 7 days after starting or resuming regular contraception or until her next menses, whichever comes first.
- Any nonhormonal contraceptive method can be started immediately after the use of UPA.
- Advise the woman to have a pregnancy test if she does not have a withdrawal bleed within 3 weeks.

The 2016 SPR also included recommendations about medications that ease IUD insertion.

- Misoprostol is not recommended for routine use before IUD insertion. Misoprostol might be helpful in certain other circumstances (e.g., in women with recent failed insertions).
- Paracervical block with lidocaine might reduce patient pain during IUD insertion.

## Applying MEC and Resources

The MEC and SPR for contraceptive use are intended to help health care providers address issues related to the use of contraceptives, such as how to help a woman (1) initiate a method, (2) learn which examinations and tests are needed before starting, (3) find out what kinds of regular follow-up are needed, and (4) address problems that often arise during use, including missed pills and side effects such as unscheduled bleeding. The Reproductive Health Access Project (RHAP) is a national nonprofit organization that works directly with

**Table 5.** Summary of Changes in Women with HIV Infection

| Condition | Cu-IUD[a] | LNG-IUD[a] | Implant | DMPA | POP | CHCs |
|---|---|---|---|---|---|---|
| **HIV infection** | | | | | | |
| For women with HIV infection who are not clinically well or not receiving ART therapy, this condition is associated with increased risk of adverse health events as a result of pregnancy | — | — | 1 | 1 | 1 | 1 |
| a. Clinically well receiving ART | 1/1[a] | 1/1 | — | — | — | — |
| b. Not clinically well or not receiving ART | 2/1 | 2/1 | — | — | — | — |
| **Cystic fibrosis** | 1 | 1 | 1 | 2 | 1 | 1 |
| This condition is associated with increased risk of adverse health events as a result of pregnancy (see Box 2) | | | | | | |
| **Antiretroviral Therapy** | | | | | | |
| a. Nucleoside reverse transcriptase inhibitors | | | | | | |
| i. Abacavir (ABC) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| ii. Tenofovir (TDF) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| iii. Zidovudine (AZT) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| iv. Lamivudine (3TC) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| v. Didanosine (DDI) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| vi. Emtricitabine (FTC) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| vii. Stavudine (D4T) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| b. Nonnucleoside reverse transcriptase inhibitors | | | | | | |
| i. Efavirenz (EFV) | 1/2<br>1 | 1/2<br>1 | 2 | 1 | 2 | 2 |
| ii. Etravirine (ETR) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| iii. Nevirapine (NVP) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| iv. Rilpivirine (RPV) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| c. Ritonavir-boosted protease inhibitors | | | | | | |
| i. Ritonavir-boosted atazanavir (ATV/r)<br>ii. Ritonavir-boosted darunavir (DRV/r)<br>iii. Ritonavir-boosted fosamprenavir (FPV/r)<br>iv. Ritonavir-boosted saquinavir (SQV/r)<br>v. Ritonavir-boosted tipranavir (TPV/r) | 1/2<br>1 | 1/2<br>1 | 2 | 1 | 2 | 2 |
| vi. Ritonavir-boosted lopinavir (LPV/r) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| d. Protease inhibitors without ritonavir | | | | | | |
| i. Atazanavir (ATV) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 2 |

(*continued*)

**Table 5.** Summary of Changes in Women with HIV Infection (*continued*)

| Condition | Cu-IUD[a] | LNG-IUD[a] | Implant | DMPA | POP | CHCs |
|---|---|---|---|---|---|---|
| ii. Fosamprenavir (FPV) | 1/2<br>1 | 1/2<br>1 | 2 | 2 | 2 | 3 |
| iv. Nelfinavir (NFV) | 1/2<br>1 | 1/2<br>1 | 2 | 1 | 2 | 2 |
| i. Maraviroc (MVC) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| e. CCR5 co-receptor antagonists | | | | | | |
| i. Maraviroc (MVC) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| f. HIV integrase strand transfer inhibitors | | | | | | |
| i. Raltegravir (RAL) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| ii. Dolutegravir (DTG) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| iii. Elvitegravir (EVG) | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |
| g. Fusion inhibitors | | | | | | |
| i. Enfuvirtide | 1/2<br>1 | 1/2<br>1 | 1 | 1 | 1 | 1 |

[a]For Cu-IUD and LNG-IUD, classification for initiation and continuation varies and is denoted as initiation category (I) or continuation category (C).

CHC = combined hormonal contraceptive; Cu-IUD = copper intrauterine device; DMPA = depot medroxyprogesterone acetate; LNG-IUD = levonorgestrel intrauterine device; POP = progestin-only pill.

Information from: CDC. Contraceptive Guidance for Health Care Professionals. U.S. Medical Eligibility Criteria for Contraceptive Use. 2020, use, 2016. *Recommendations and Reports* 2016;65;1-66.

primary care providers to help them integrate abortion, contraception, and miscarriage care into their practices. The RHAP organization offers contraception resources, including administrative tools, clinical tools, teaching tools, and patient information sheets as well as mobile applications (Contraception by CDC and Contraception Point-of-Care by RHAP) for quick access to tools used in contraceptive decision making. The CDC MEC/SPR app is an easy-to-use reference by means of its streamlined interface that combines information from CDC family-planning guidance documents. It is available for iOS and Android operating systems. In addition, the SPR eBooks are free for downloading to Apple and Android mobile devices, but an eReader app is required to display the eBooks on a phone or tablet.

### *Chronic Medical Conditions*

#### Obesity

The level of effectiveness of EC in women weighing more than 70 kg or with BMIs indicating overweight or obesity have been of concern (Erkkola 2005). A systematic review completed in 2015 that examined LNG and UPA EC options found weak evidence that an increased BMI of more than 30 kg/m$^2$ or a weight greater than 75 kg resulted in increased LNG EC failure rates (Kapp 2015). The review also found evidence of a two-fold increase in the risk of pregnancy in patients using UPA who had BMIs of more than 30 kg/m$^2$. However, the same systematic review also found no association between the rate of pregnancy after LNG EC use and a patient's weight or BMI. And even though clinical trials were not designed to study the impact of weight or body size and have not found robust evidence to indicate whether weight or BMI issues could change the effectiveness of EC, two pharmacokinetic studies involving LNG found that serum concentrations of LNG EC in an obese patient were about 50% of those in a patient with normal BMI. Furthermore, obese patients given a double dose of LNG EC achieved approximately the same serum concentrations as patients with normal BMIs. An American Society for Emergency Contraception data analysis also indicates that

**Table 6.** Summary of Changes for Emergency Contraception

| Condition | Cu-IUD | UPA | LNG | COC |
|---|---|---|---|---|
| **Pregnancy** | 4 | NA | NA | NA |
| **Breastfeeding** | 1 | 1 | 1 | 1 |
| **Past ectopic pregnancy** | 1 | 1 | 1 | 1 |
| **History of bariatric surgery**<br>This condition is associated with increased risk of adverse health events as a result of pregnancy (see Box 2) | | | | |
| a. Restrictive procedures: Decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy) | 1 | 1 | 1 | 1 |
| b. Malabsorptive procedures: Decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion) | 1 | 1 | 1 | 1 |
| **History of severe cardiovascular disease** (ischemic heart disease, cerebrovascular attack, or other thromboembolic conditions)<br>This condition is associated with increased risk of adverse health events as a result of pregnancy (see Box 2) | 1 | 2 | 2 | 2 |
| **Rheumatoid arthritis** | | | | |
| a. Receiving immunosuppressive therapy | 2 | 1 | 1 | 1 |
| b. Not receiving immunosuppressive therapy | 1 | 1 | 1 | 1 |
| Migraine | 1 | 1 | 1 | 2 |
| **Inflammatory bowel disease** (ulcerative colitis or Crohn's disease) | 1 | 1 | 1 | 1 |
| Severe liver disease (including jaundice)<br>This condition is associated with increased risk of adverse health events as a result of pregnancy (see Box 2) | 1 | 2 | 2 | 2 |
| **Solid-organ transplantation**<br>This condition is associated with increased risk of adverse health events as a result of pregnancy (see Box 2) | | | | |
| a. Complicated: Graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy | 3 | 1 | 1 | 1 |
| b. Uncomplicated | 2 | 1 | 1 | 1 |
| **Repeated EC use** | 1 | 1 | 1 | 1 |
| **Sexual assault** | 2 | 1 | 1 | 1 |
| **Obesity (BMI ≥30 kg/m$^2$)** | 1 | 2 | 2 | 2 |
| **CYP3A4 inducers (e.g., bosentan, carbamazepine, efavirenz, felbamate, griseofulvin, lumacaftor, oxcarbazepine, phenytoin, rifampin, St. John's wort, and topiramate)** | 1 | 2 | 2 | 2 |

COC = combined oral contraceptive; Cu-IUD = copper intrauterine device; EC = emergency contraception; LNG = levonorgestrel; UPA = ulipristal acetate.

Information from: CDC. Contraceptive Guidance for Health Care Professionals. U.S. Medical Eligibility Criteria for Contraceptive Use. 2020,

### Box 3. How to Be Reasonably Certain That a Woman Is Not Pregnant

A woman is likely not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria.

- She is at 7 or more days after the start of normal menses.
- She has not had sexual intercourse since the start of latest normal menses.
- She has been correctly and consistently using a reliable method of contraception.
- She is at 7 or more days after a spontaneous or induced abortion.
- She is within 4 weeks postpartum.
- She is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and less than 6 months postpartum

reduced efficacy should be suspected at a weight greater than 154 lb for LNG EC and 194 lb for UPA EC (ASEC 2016).

Some reports say contraceptive patch efficacy may be reduced in women weighing more than 90 kg (Mitchell 2019). A Cochrane review concluded there was not sufficient evidence that any form of HC lacks efficacy in overweight or obese women. Furthermore, the MEC rates most HC as Category 1, with no restrictions regarding their use in women with obesity. Hormonal IUDs are not affected by weight, which therefore circumvents whether maintaining serum concentrations should be of theoretical concern. A study of 128 women using a low-dose COC reported no weight gain among 52% of the women (defined as a gain of more than 2 pounds from starting weight); 33% had a weight gain or loss of 5 pounds or less. Excess estrogen can lead to water retention and a bloated feeling, resulting in cyclic weight gain. If a woman feels that potential weight gain with HC is of concern, a low-dose estrogen product may be the best choice. Too much progestin can lead to increased appetite and noncyclic weight gain, which also applies to progestin-only contraceptives. Drospirenone has an antimineralocorticoid property that counteracts the effect of estrogen, resulting in less water retention and less weight gain. In addition, because drospirenone has antiandrogenic properties, increases in appetite may not be as apparent.

### Tobacco Use

Smoking is a risk factor for both VTE and atherosclerotic cardiovascular disease, which in turn increases risks of VTE or thrombosis associated with the use of CHC. Combined hormonal contraceptives can be used in a woman who smokes and is younger than 35 years of age (Category 2). However, for a woman aged 35 years or older who smokes fewer than 15 cigarettes per day, the use of CHCs is not recommended unless other methods are not available or acceptable (Category 3). A woman aged 35 years or older who smokes 15 or more cigarettes per day should not use CHCs because of the unacceptable health risks of myocardial infarction and stroke (Category 4).

### Venous Thromboembolism

Two of the most serious adverse effects of CHCs are development of a VTE and changes in corneal function. The primary risk is felt to be related to the estrogen component of CHCs. However, some controversy exists as to whether third-generation progestins promote a higher risk of thromboembolic events compared with second-generation progestins. One study reported a twofold increase in nonfatal VTE among women using the third-generation progestins desogestrel or gestodene (used in Europe) compared with the second-generation levonorgestrel. A subsequent study suggested that desogestrel-containing CHCs significantly increased the risk of nonfatal VTE compared with levonorgestrel and norgestimate. Both studies have been criticized for confounding variables, such as selection bias, duration of use, detection bias, smoking status, age, and weight. To avoid such controversy with the progestin drospirenone, Dinger et al. investigated whether there was a higher risk of adverse cardiovascular or other events compared with other progestin components. The trial followed more than 58,000 women, and the authors concluded that the risk of cardiovascular, thromboembolic, and other events was similar between the two groups. However, many other studies show a possible increased risk of VTE with drospirenone use compared with the use of other progestins. The FDA published a safety communication in 2012 regarding drospirenone use and increased the risk of thrombosis.

It is important to note that VTE risk increases with CHC use, but all women should be counseled on the relative risk of VTE with CHCs versus the possibly higher risk of VTE in pregnancy. Combined hormonal contraceptives are not recommended for women older than 35 years who smoke; women with high risk of blood clots, including those with histories of VTE; women who are taking anticoagulants; women who have migraines; and women who are taking seizure medications. A controlled, prospective, observational cohort study comparing the risks of fatal and nonfatal VTE and arterial thromboembolism in new users of Twirla compared with new users of oral CHCs (primary comparator) and new users of Xulane (secondary comparator) in U.S. women of reproductive age using CHCs primarily for contraceptive reasons is currently being conducted, with consideration of possible confounders such as age, BMI, and smoking.

### Hypertension

Estrogen has been known to increase blood pressure because of its high biological potency compared with estradiol, which

is a thousand times more potent. Estrogen exacerbates the production of hepatic angiotensinogen, which in turn causes the renin-angiotensin-aldosterone system to increase blood pressure (Oelkers 1996). In addition, the risks of myocardial infarction or stroke increase in women older than age 40 with histories of hypertension. A small, nonrandomized study showed an increase in systolic blood pressure by 8 mm Hg and diastolic blood pressure by 6 mm Hg in women using a low-dose oral contraceptive compared with women using a copper IUD (Cu-IUD). Another small study observed a similar, 8.33-mm Hg increase in systolic blood pressure in mildly hypertensive women using a low-dose COC compared with those who were not. The MEC rates CHCs as a Category 3 for use when the risks may outweigh the benefits for those with blood pressures ranging from systolic 140–159 mm Hg or diastolic 90–99 mm Hg and as a Category 4 for those with blood pressures equal to or higher than 160 mm Hg systolic or 100 mm Hg diastolic. Patients with uncontrolled hypertension should not use CHCs but may use progestin-only contraceptives, which are rated as Category 2—with the exception of DMPA, which is Category 3. Per the MEC, no contraindications are listed for EC use in women with hypertension.

### Headache

In general, headaches are classified depending on accurate diagnoses of severe headaches that are migraines and those that are not. Those that are not migraines are considered Category 1, with no restrictions for most methods. For those that are migraines, classification is further dependent on a diagnosis of ever experiencing aura. Among women with migraine, oral contraceptive use is associated with an approximately threefold increased risk of ischemic stroke compared with nonuse, although most studies did not specify migraine type or oral contraceptive formulation. The only study to examine migraine type found that the risk of ischemic stroke among women with migraine with aura increased to similar levels among both oral contraceptive users and nonusers, compared with women without migraine. The risk of ischemic stroke also increases among women with migraine with aura (CDC 2016a). According to the MEC recommendations, CHC is classified as Category 2 in those with migraines without aura, including menstrual migraines. However, in those with migraines with aura, CHC is classified as Category 4, and a progestin-only or nonhormonal method should be considered.

### Cancer

The overall lifetime risk of breast cancer in women is 12.4% (Mitchell 2019). There has been much controversy over whether HCs are associated with an increased risk of breast cancer. In 2018, a large study of Danish women found that the risk of breast cancer increased with the use of HC, including progestin-only IUDs. However, the absolute increased risk was very small: one extra case of breast cancer for every 7690 women using HC for 1 year. In women with current breast cancer, use of HC is classified as Category 4 because breast cancer is a hormonally sensitive tumor, and theoretically, HC may cause tumor growth.

The lifetime risk of ovarian cancer is reported as 1 in 78 women. Combined hormonal contraceptives have been shown to decrease the risk of ovarian cancer, with a lower risk with longer CHC use. The incidence of ovarian cancer has been shown to decrease by 41% after 4 years of use, 54% after 8 years, and 61% after 12 years.

Similarly to ovarian cancer, CHCs show a benefit in decreasing the risk of endometrial cancer. Combined oral contraceptive use reduced endometrial cancer by about 50% and remained protective 15–20 years after discontinuation. Women with cancer should be referred to a specialist for contraceptive needs so as to avoid the risk of drug-drug interactions or drug-disease interactions.

### *Special Populations*

Additional considerations exist for the use of barrier methods in women at high risk of HIV (Tepper 2020). Correct and consistent use of condoms can reduce the risk of pregnancy and STDs, including HIV. No drug interactions between antiretroviral therapy and barrier methods are known. High risk of HIV is a MEC Category 4 for spermicides and diaphragms (with spermicide). Repeated use and high-dose use of nonoxynol-9 is associated with increased risk of genital lesions, which might increase the risk of HIV infection. Women at high risk of HIV are eligible to use all HC methods and IUDs. Recommended HIV-infection-prevention measures—including preexposure and postexposure prophylaxis, limiting the number of sexual partners, and correct and consistent use of condoms—should be strongly encouraged and integrated into family planning services for all women at high risk of HIV.

In the LGBTQ+ community, there exist both (1) fear of discrimination on the part of providers based on the community's various sexual orientations and (2) general lack of provider knowledge, which leads to unmet reproductive health care needs (Mitchell 2019). To provide culturally competent care, providers should use gender-neutral language, should make patients—especially teens—aware of their right to obtain confidential care, should give assurance of confidentiality at each visit, and should avoid making assumptions regarding sexuality. In particular, transgender men (those assigned female sex at birth but who identify as male) who use testosterone therapy often have knowledge gaps and misconceptions regarding their risk of pregnancy. Patients using testosterone or gonadotropin-releasing-hormone analogues are generally still able to become pregnant (Light 2014). However, because of the teratogenicity of testosterone, it is imperative that effective contraception be used during therapy. For such patients, LNG-IUD, DMPA, progestin-only implants, and POPs are appropriate HC options. Generally, progestin does

not interfere with testosterone therapy, but it does provide adequate contraception. It may also suppress or decrease menstruation, which may be an added benefit. Estrogen may interact with testosterone and should be avoided in patients using testosterone therapy.

## PHARMACIST'S ROLE

The pharmacist's role is to determine which contraceptive methods are safe and effective and to educate patients on correct and consistent use of contraceptives. In states in which legislation allows, pharmacists are authorized to prescribe, issue, and dispense contraception to patients. In states in which legislation does not allow pharmacists' prescribing of HC methods, pharmacists remain an access point for patients pursuing nonhormonal contraceptive methods available OTC without a prescription. Irrespective of legislation, pharmacist–patient counseling should take place during the dispensing of contraception. According to Figure 4, such education should cover effectiveness, typical-use failure rates, and risks associated with those methods. To increase awareness of serious potential adverse effects that warrant immediate attention by a health care provider, pharmacists should counsel by using the mnemonic *ACHES* for CHCs and *PAINS* for IUDs (Box 4). Patients should be educated on correct use of all methods, including appropriate initiation (Table 7) and how to handle late or missed doses of hormonal contraceptives (Figure 5). Last, pharmacists should assess patients and educate them on potential drug-drug interactions. Combined hormonal contraceptives and progestin-only contraceptives are hepatically metabolized and may be affected by other drugs that undergo hepatic metabolism. Plus, CHCs may affect the metabolism of other drugs because estrogens are substrates of CYP 3A4 isoenzymes (Box 5).

### Mobile Apps

Over the years, many medical applications (apps) have replaced awareness-based methods that women rely on to identify when ovulation would occur so they can avoid unprotected intercourse during that time frame if trying to prevent pregnancy or can engage in intercourse if trying to conceive. Most apps were promoted as pregnancy-planning tools but never reviewed and approved by the FDA. In 2018, the FDA permitted marketing of the first mobile medical app that can be used as a method of contraception to prevent pregnancy (Natural Cycles). Other apps that are not FDA approved yet are compared in Table 8.

Oral Contraceptive Pill Reference is a useful tool for providers who have a basic understanding of contraceptive options and the physiology of fertility and conception. It contains a database of more than 100 different brand names and generic birth control pills available in the United States.

### Box 4. CHC and IUD Warning Signs

**CHC**

**A** = abdominal pain
**C** = chest pain (shortness of breath, coughing)
**H** = headache (severe headache, dizziness)
**E** = eye problems (seeing double, blurry vision)
**S** = severe leg pain (calf or thigh)

**IUD**

**P** = period is late
**A** = abdominal pain or pain with intercourse
**I** = infection or abnormal or odorous vaginal discharge
**N** = not feeling well, fever, chills
**S** = string (missing, shorter, longer)

CHC = combined hormonal contraceptive; IUD = intrauterine device.

Contraception Point-of-Care is a quick-reference app for students, residents, and faculty in primary care; it is available for both iOS and Android platforms. This app covers a wide variety of topics—from contraception eligibility to switching of methods, and it is well referenced with hyperlinks to PubMed or other appropriate sites. Some of the challenges with this app are clear visibility of charts on smaller devices and difficulty browsing through the myriad topics included.

### Online Resources

Many companies have established web-based services and smartphone apps to offer birth control prescriptions after the completion of an online questionnaire and, sometimes, a follow-up call with a health care provider. The prescription can be picked up at a local pharmacy or delivered by mail. For some patients, this is a more feasible alternative to providers' offices or local family-planning clinics. Many women get contraceptives through their providers, but the issue of access to birth control has become more pressing as more and more family-planning clinics close across the United States. Advocates argue that these online companies fill a gap, making at least some birth control methods more accessible—especially to women who live in so-called contraception deserts that lack reproductive health clinics. The American College of Obstetricians and Gynecologists recommends that all hormonal contraceptives—including rings, shots, and patches—be available without prescription. Table 9 lists prominent web-based services and details about easier access to contraception. Box 6 lists screening questionnaires that users are typically asked to complete for assessment and evaluation.

**Table 7.** When to Start Using Specific Contraceptive Methods

| Contraceptive method | When to start[a] | Additional contraception (i.e., backup) needed | Examinations or tests needed before initiation[b] |
|---|---|---|---|
| Cu-IUD | Anytime | Not needed | Bimanual examination and cervical inspection |
| LNG-IUD | Anytime | If >7 days after menses started, use backup method or abstain for 7 days | Bimanual examination and cervical inspection |
| Implant | Anytime | If >5 days after menses started, use backup method or abstain for 7 days | None |
| Injectable | Anytime | If >7 days after menses started, use backup method or abstain for 7 days | None |
| CHC | Anytime | If >5 days after menses started, use backup method or abstain for 7 days | Blood pressure measurement |
| POP | Anytime | If >5 days after menses started, use backup method or abstain for 7 days | None |

[a]If the provider is reasonably certain that the woman is not pregnant.

[b]Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (MEC Category 1) or generally can be used (MEC Category 2) in obese women. However, measuring weight and calculating BMI (weight [kg]/height [m]$^2$) at baseline might be helpful for monitoring any changes and counseling women for whom weight change is of concern when it is perceived to be associated with their contraceptive method.

CHC = combined hormonal contraceptive; Cu-IUD = copper intrauterine device; LNG-IUD = levonorgestrel intrauterine device; POP = progestin-only pill.

Reprinted from: CDC. U.S. Selected practice recommendations for contraceptive use, 2016. MMWR 2020.

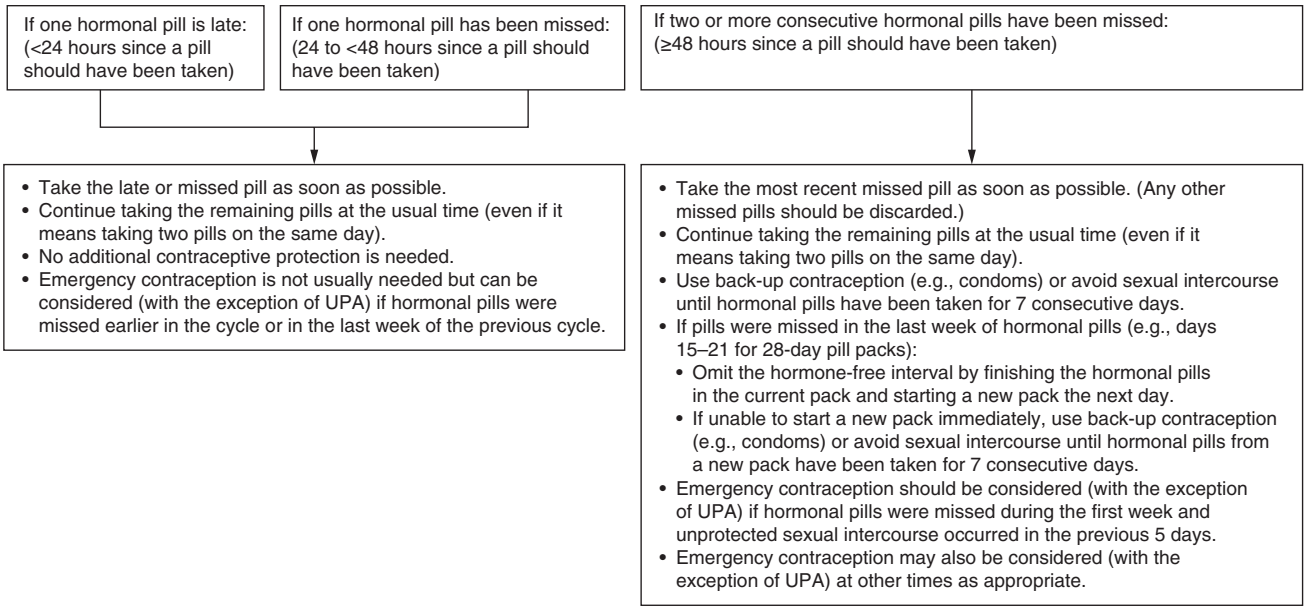


**Figure 5.** Recommended actions after late or missed COCs.

COC = combined oral contraceptive; UPA = ulipristal acetate.

Reprinted from: Curtis KM, Jatlaoui TC, Tepper NK, et al. U.S. selected practice recommendations for contraceptive use, 2016. Recommendations and Reports 2016;65;1-66.

### Box 5. Selected Drug-Drug Interactions with CHCs

Drugs that increase effect of CHCs
- Atazanavir
- Atorvastatin
- Indinavir

Drugs or herbals that decrease the effect of CHCs
- Amprenavir
- Barbiturates
- Carbamazepine
- Felbamate
- Griseofulvin
- Lopinavir
- Modafinil
- Nelfinavir
- Nevirapine
- Oxcarbazepine
- Phenopharbital
- Phenytoin
- Primidone
- Rifamycins
- Ritonavir
- Saquinavir
- St. John's wort
- Tipranavir

Drugs that *may* decrease the effect of CHCs
- Amoxicillin
- Ampicillin
- Ciprofloxacin
- Clarithromycin
- Doxycycline
- Erythromycin
- Fluconazole
- Metronidazole
- Minocycline
- Ofloxacin
- Tetracycline
- Topiramate

Metabolism or clearance altered by CHCs
- Acetaminophen
- Aspirin
- Benzodiazepines
- Beta-blockers
- Caffeine
- Corticosteroids
- Cyclosporine
- Lamotrigine
- Theophylline
- Tricyclic antidepressants

CHC = combined hormonal contraceptive.

## OVERVIEW OF EMERGENCY CONTRACEPTION

With the availability of several types of EC methods in the United States, pharmacists play a key role in providing patient education, in making product recommendations, and in ensuring access for patients of all ages. Figure 6 describes the history of EC.

A common misconception about EC is that it can cause an abortion (Gemzell-Danielsson 2013). Products for EC reduce the risk of pregnancy after intercourse by disrupting the timing of ovulation or preventing fertilization of an ovulated egg. If fertilization and implantation have occurred, EC will not induce an abortion. Two -approved oral EC products are available: levonorgestrel 1.5 mg single dose and UPA 30 mg onetime dose. The Cu-IUD is available for off-label EC use and is the most effective method. If a patient accepts an IUD recommendation and has no contraindications, the patient should be referred to an appropriate provider for insertion within 120 hours of unprotected vaginal intercourse. Several factors should be considered when recommending oral EC products, including time elapsed since unprotected vaginal intercourse, patient preference, and patient body weight (Figure 7). To reduce some of the barriers to EC access, providers should consider advance provision of EC prescriptions for women seeking other forms of HC.

**Table 8.** Comparison of Medical Applications to Prevent Pregnancy

| App | Features | Platform and cost |
|---|---|---|
| Natural Cycles | • FDA approved in 2018<br>• Promotes use of fertility-awareness methods for contraception<br>• Contains an algorithm that calculates the fertile days each month based on daily body temperature readings taken upon awakening<br>• Displays use protection on fertile days<br>• Recommendation is to abstain from sex or use protection | Android and iOS<br>Free |
| Bedsider Reminders | • Reminder to take contraception via text or e-mail<br>• Custom settings based on method of birth control<br>• Online locator to find emergency contraception or nearest family-planning clinics planning clinics | Android and iOS<br>Free |
| Kindara | • Fertility-tracking app to predict fertile days with a higher level of accuracy<br>• Tracking of basal body temperature, cervical mucus, cervix position, and symptoms of premenstrual syndrome | Google Play and iOS<br>Free |
| myPill | • Specifically for women taking oral contraceptives<br>• Visually looks like a 28-day pill pack; as each day passes, a pill in the pack disappears<br>• Allows configuration of active days and placebo days to correspond to specific oral contraceptive<br>• Other features include selection of form of oral contraception, tracking of symptoms, prediction function to help schedule holidays and travel in any time zone, customizable reminder message, snooze | Android and iOS<br>Free |
| myPatch | • Specifically for women using the contraceptive patch<br>• Makes it easy to change the start date of the patch and will remind to attach, switch, or remove<br>• An overview display allows review of past and current patch use for up to 6 months | iOS only<br>n/a |

**Table 9.** Web-Based Services for Access to Contraception

| Online pharmacy | Products and services |
|---|---|
| Nurx | • Pill, patch, ring, shot<br>• Requires a $15 fee for online medical consultation and unlimited access to providers for a year for follow-up questions and advice<br>• Pills cost as little as $0 with insurance or $15 per month without insurance<br>• Free shipping available |
| SimpleHealth | • Pill, patch, ring<br>• Onetime consultation fee of $20<br>• Birth control is $0 with most insurance and starts at $15 per month without insurance<br>• Free shipping available |
| HeyDoctor | • Pill, patch, ring, emergency contraception<br>• $25 fee for emergency contraception, $15-per-month fee for birth control<br>• Prescription is sent to pharmacy of choice |
| The Pill Club | • Pill, ring<br>• With insurance, $0 for consult and prescription, Plan B, and female condoms<br>• Without insurance, $9 per pack with one-year supply, $15 online consulting, and prescription<br>• Free, discreet delivery with additional goodies (sweet treats) |
| Lemonaid | • Pill<br>• Online questionnaire<br>• Some states require phone consultations<br>• Cost of $15 per pack per month<br>• Free delivery of a 3-month supply |
| Planned Parenthood | • Pill, patch, ring, shot, intrauterine device<br>• Consultation with provider<br>• Cost based on product selection |
| Pandia Health | • Pill<br>• Online questionnaire<br>• Cost of $15 per pack<br>• $20 fee for annual doctor review<br>• Free delivery |

**Box 6. Screening Questionnaires for Obtaining Birth Control Prescriptions from Online Resources**

1. State of residence
2. Consent to telehealth
3. Current gender
4. Birth gender
5. Date of birth
6. Height and weight
7. Smoking status
8. Previous history of contraceptive use
9. Preference for method of contraception
10. Pregnancy status
11. Breastfeeding status
12. Confirmation of at least 6 weeks postpartum
13. Diagnosis of hypertension
14. Most recent blood pressure reading
15. Medical history
16. Venous thromboembolism risk factors and history
17. Preference for frequency of periods
18. Current medication or herbal supplement use
19. Drug allergies
20. History of intolerance to contraceptives

### Copper IUD

#### *Efficacy and Safety*

The Cu-IUD creates a toxic environment for sperm via release of copper ions, thereby preventing fertilization of an egg (Gemzell-Danielsson 2013). If inserted within 120 hours of unprotected vaginal intercourse, the Cu-IUD is 99.9% effective in preventing pregnancy. Common adverse reactions that occur more frequently post-IUD insertion compared with other EC methods are pain, expulsion, spotting, heavier menstrual bleeding, and longer menstrual cycles. The Cu-IUD should not be inserted during active pelvic inflammatory infection or disease.

#### *Advantages and Disadvantages*

One advantage of the copper IUD as EC is the potential for use beyond the 120-hour window. If the ovulation day can be accurately predicted, insertion of a copper IUD within 5 days after ovulation can still provide effective pregnancy prevention. In addition, insertion may occur up to 12 days after unprotected vaginal intercourse as long as pregnancy is ruled out (Curtis 2016a, Practice Bulletin 2015a). Compared with oral

## Patient Care Scenario

**B.L., a 34-year-old woman, presents to your pharmacy for advice about contraception. She says she would be willing to take oral contraception, but her schedule is hectic. She has a past medical history of anemia. Family history includes mom who had breast cancer at the age of 65 years. B.L. typically experiences bloating and pain for 3 days before menses and reports having a heavy menstrual cycle that lasts 7–9 days. After a review of U.S. MEC and a discussion of it with B.L., her preference is to start hormonal contraception. However, she is worried about efficacy, side effects, and breast cancer given her family history.**

- **Per CDC U.S. MEC, what is the recommendation for use of COCs in B.L.?**
- **What information is best to use for educating B.L. on how oral contraception works and its effectiveness in preventing pregnancy?**
- **What examinations and tests are needed before initiation of oral contraceptives for B.L.?**
- **What side effects are pertinent to B.L.?**
- **What non-contraceptive benefit(s) of an oral contraceptive would most apply to B.L.?**
- **What are appropriate options based on B.L.'s symptoms and contraceptive needs?**

### ANSWER

**Per CDC U.S. MEC, what is the recommendation for use of COCs in B.L.?**

**Per CDC U.S. MEC, COCs would be considered Category 1, which means there is no restriction for the use of the contraceptive method.**

**What information is best for educating B.L. on how oral contraception works and its effectiveness in preventing pregnancy?**

**Oral contraceptives are composed of varying doses of estrogen and progestin, which prevent pregnancy by inhibiting ovulation, thickening cervical mucus, and altering the endometrial lining. Effectiveness is more than 90%, with a typical-use failure rate of about 7%, which is categorized as moderately effective.**

**What examinations and tests are needed before initiation of oral contraceptives?**

**Blood pressure measurement or report is essential and mandatory in all circumstances for safe and effective use of oral CHC. However, this is not mandatory for POPs.**

**What side effects are pertinent to B.L.?**

**Common side effects of oral contraceptive pills include nausea, headaches, breast tenderness, and breakthrough bleeding. Rarer but serious side effects include VTE, stroke, and myocardial infarction. The risks are increased in women with migraines with aura, uncontrolled hypertension, and diabetes with complications, as well as in women older than 35 years who smoke. Progestin-only contraceptives may be safer options for women with hypertension. There is no association with increased risk of breast cancer in nonmutation carriers.**

**What non-contraceptive benefit(s) of an oral contraceptive would most apply to B.L.?**

**Oral contraceptive use may minimize B.L.'s dysmenorrhea and menorrhagia, thereby offering her improved cycle control and regularity and reduction of the risk of iron deficiency anemia.**

**What are appropriate options based on her symptoms and contraceptive needs?**

**Extended-cycle oral contraceptive pills may reduce unwanted menstrual symptoms by preventing endogenous estradiol production with shorter hormone-free intervals. Discussing a patient's preferences for menstrual frequency and the patient's tolerance for scheduled and unscheduled bleeding will be important in deciding whether a traditional or an extended-cycle oral contraceptive would best fit her needs.**

**Transdermal patch and vaginal ring formulations are available options if she has difficulty with adherence because of her hectic schedule. Annovera, for example, is a vaginal ring that remains in place for 3 weeks. The transdermal patch may be less effective in obese women of 90 kg or more.**


1. CDC. U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. MMWR 2016;65(RR-3)
2. CDC. U.S. Selected practice recommendations for contraceptive use, 2016. MMWR 2016;65(RR-4)


EC methods, the copper IUD's efficacy is not influenced by patient body weight or BMI (Practice Bulletin 2015b). The copper IUD is also a nonhormonal contraceptive method that is FDA approved for up to 10–12 years (Curtis 2016a). The main disadvantage in use of the copper IUD as EC is the need for an in-clinic visit for vaginal insertion, which may pose barriers related to access, affordability, and patient comfort level.

## Ulipristal Acetate

### *Efficacy and Safety*

Ulipristal acetate, a selective progestin receptor modulator, binds to progesterone receptors and delays or inhibits ovulation by delaying follicular rupture and possibly affecting luteinizing-hormone levels (Gemzell-Danielsson 2013, Koyama 2013). For maximum effectiveness, it should be administered within 120 hours after unprotected vaginal intercourse in a onetime dose of 30 mg. Concurrent use of any other progestin-containing hormonal contraceptives results in competitive

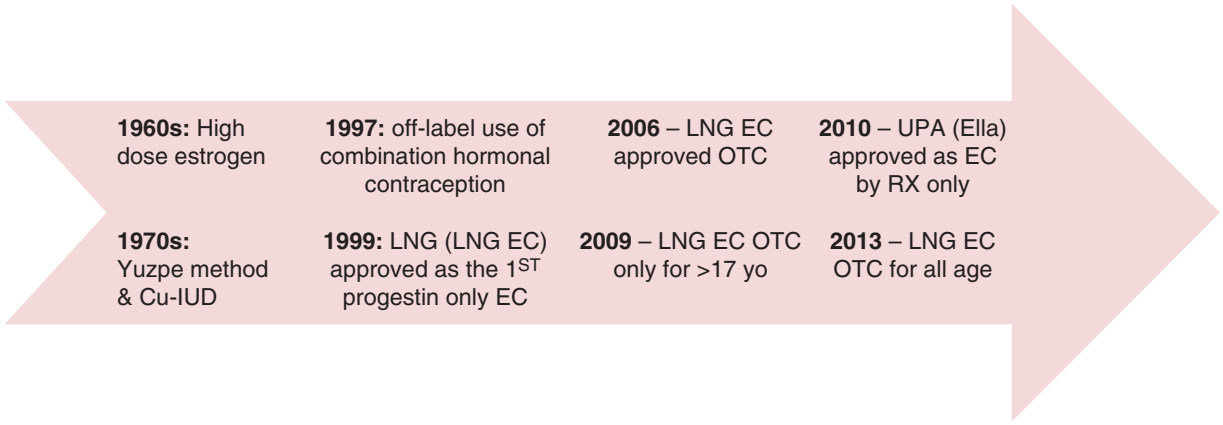


**Figure 6.** History of emergency contraception.

Information from: Verywell Health. The History of Emergency Contraception [homepage on the Internet]. [homepage on the Internet].

drug binding and reduced exposure and effectiveness of both agents, including a decrease in UPA efficacy. If a patient must

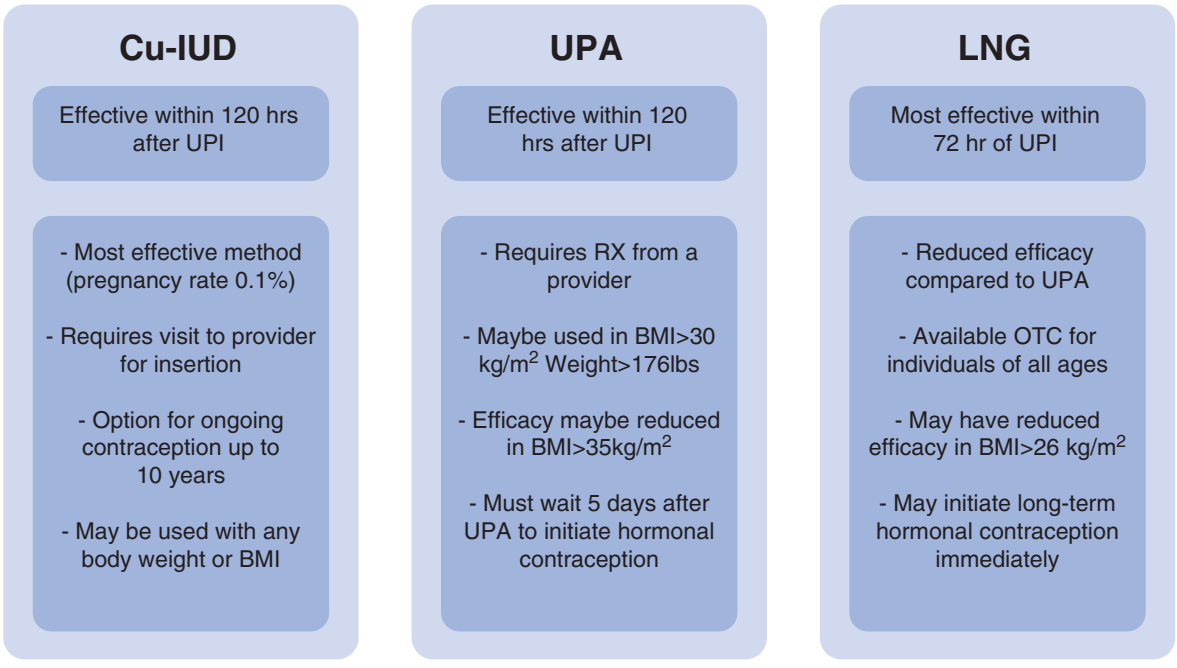


**Figure 7.** Factors to consider for selection of an EC method.

Cu-IUD = copper intrauterine device; EC = emergency contraception; LNG = levonorgestrel; UPA = ulipristal acetate.

Information from: Curtis KM, Jatlaoui TC, Tepper NK, et al. U.S. selected practice recommendations for contraceptive use, 2016. MMWR Recomm Rep 2016;65:1-66. Trussell J, Raymond E, Cleland K. 2017. Emergency contraception: a last chance to prevent unintended pregnancy. Cleland K, Zhu H, Goldstuck N, et al. The efficacy of intrauterine devices for emergency contraception: a systematic review of 35 years of experience. Hum Reprod 2012;27:1994. Glasier AF, Cameron ST, Fine PM, et al. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. Lancet 2010;375:555. Shen J, Che Y, Showell E, et al. Interventions for emergency contraception. Cochrane Database Syst Rev 2019. Turok DK, Godfrey EM, Wojdyla D, et al. Copper T380 intrauterine device for emergency contraception: highly effective at any time in the menstrual cycle. Hum Reprod 2013;28:2672.

start a progestin-containing hormonal contraceptive immediately after UPA use, a barrier method should be used for 14 days following the UPA dose—or until menses occurs, whichever occurs first (Curtis 2016a). A pregnancy test should be obtained if a period does not occur within 3–4 weeks of unprotected vaginal intercourse. Ulipristal acetate may cause changes to menstrual cycle length, with menses occurring earlier or later than expected.

Common adverse reactions to UPA include headaches (20%), abdominal pain (10%), nausea (13%), and dysmenorrhea (9%) (Creinin 2006, Fine 2010, Moreau 2012). Ulipristal acetate may be taken with or without food. It has been shown to pass into breast milk, so the risks versus the benefits should be discussed before use in a lactating woman. It is predominantly metabolized by CYP3A4, and therefore, strong inducers may decrease plasma concentrations and efficacy, whereas inhibitors may increase serum concentrations.

### *Advantages and Disadvantages*

Both UPA and LNG have similar efficacy in preventing pregnancy, but UPA is more consistently effective for 120 hours (Fine 2010). Plus, UPA was noninferior to LNG when used within 72 hours of unprotected vaginal intercourse, and there was a nonsignificant difference in pregnancy rates between the two groups (UPA 0.9% [95% CI, 0.2%–1.6%] vs. LNG 1.7% [95% CI, 0.8%–2.6%]) (Creinin 2006). However, when used from 72 to 120 hours after unprotected vaginal intercourse, UPA has demonstrated superior efficacy in preventing pregnancies in comparison to LNG (Glasier 2010).

Despite its effectiveness, UPA is rarely used as an EC method because of lack of clinician knowledge regarding availability, barriers to accessing a prescription-only product, and cost. Significantly fewer health care providers have heard about UPA compared with LNG. And fewer reproductive-health-care providers recommend UPA despite having knowledge about its availability (Batur 2016). A survey of 10 U.S. cities reported that only 10% of pharmacies stock UPA, though 72% had the ability to order it with a mean wait time of 24 hours (Shigesato 2018).

## Levonorgestrel

### *Efficacy and Safety*

Levonorgestrel inhibits follicular development and delays ovulation to prevent pregnancy if administered before the luteinizing-hormone surge (Hapangama 2001, Marions 2002). It is not effective if administered once the luteinizing-hormone surge has occurred. Levonorgestrel is an FDA-approved EC method as a single oral 1.5-mg dose to be taken as soon as possible after unprotected vaginal intercourse. Although approved for use within 72 hours of unprotected vaginal intercourse, there may be some efficacy for up to 5 days (120 hours) (Gemzell-Danielsson 2013, Glasier 2011, Piaggio 2010). In the United States, single-dose LNG is available over the counter without age restrictions (available under several commercial names, including Plan B One-Step) (Practice Bulletin 2020). See earlier section covering advantages and disadvantages of ulipristal acetate for comparative pregnancy prevention efficacy information. Women with several incidences of unprotected vaginal intercourse later in a cycle have a 7.3% risk of pregnancy despite LNG dose administration (Glasier 2011). Common side effects associated with LNG use include menstrual changes, nausea, lower-abdominal pain, fatigue, headache, dizziness, breast pain, and vomiting.

The available LNG IUD products for contraception and heavy menstrual bleeding are currently being assessed for potential roles as EC methods (LIFE trial). Currently, a patient can start LNG EC and an LNG IUD simultaneously. That combination was almost 100% effective at preventing pregnancy among 110 women (1 pregnancy occurred in a woman with several instances of unprotected vaginal intercourse). The continuation rate for LNG IUD is 70% compared with 60% among Cu-IUD users (RAPID, QuickSTART trials).

### *Advantages and Disadvantages*

Levonorgestrel is available OTC without a prescription, which makes it easier to access. However, its OTC status could result in lack of prescription coverage, and the out-of-pocket cost could be variable: from $10 to more than $40. Internet-based providers make it available at lower cost, but credibility and quick access should be considered, whereas as an OTC product, many pharmacies stock LNG EC behind the counter, which may limit access based on pharmacy operating hours. Reported barriers to LNG EC use include pharmacies' not stocking the medication, keeping this OTC medication in a locked location or behind the counter, employees who provide incorrect information about restrictions, and high cost (FDA 2016).

Levonorgestrel has decreased efficacy when used 72–120 hours post unprotected intercourse and if used after ovulation has occurred. Ulipristal acetate was found to lose its efficacy in women with BMIs of more than 35 kg/m$^2$, whereas LNG was found to lose efficacy in women with BMIs of more than 26 kg/m$^2$. Data showing LNG's reduced efficacy in obese women are conflicting, and further research is needed (FDA 2016). More-recent studies have demonstrated that a double dose of LNG in obese women may result in improved efficacy and similar blood concentrations, but again, more research is needed before recommending this dosing approach (Edelman 2016, Praditpan 2017). Absorption and efficacy of LNG are reduced in patients who have had malabsorptive bariatric procedures, and therefore, a Cu-IUD would be the most appropriate EC method.

Levonorgestrel may have decreased efficacy when used concurrently with CYP450 3A inducers—specifically, efavirenz, rifampin, carbamazepine, and phenytoin. Studies evaluating the use of double doses of LNG to combat the issue of reduced efficacy caused by drug-drug interactions have been performed, but further research is needed to inform clinical care in that situation (Medicines and Healthcare products Regulatory Agency 2016).

## CONCLUSION

Pharmacists' prescribing of hormonal contraception increases access and has the potential to decrease rates of unintended pregnancy while increasing awareness of the contraception options available to all women of childbearing age. A variety of HC options are available. Selection of an appropriate contraceptive method is essential for successful outcomes. Health care providers should consider such factors as accessibility, adherence, ease of use, cost, return to fertility, past medical history, potential drug-drug interactions, and side-effect profile in order to meet the needs of an individual. Proper education and counseling with regard to initiation and contraceptive mishaps are key to achieving optimal outcomes. The risk of unintended pregnancy is often underestimated, and health care providers, advocacy groups, and government agencies should inform patients on the correct and consistent use of contraception and how to appropriately use EC.

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### Practice Points

**Expansion of the pharmacist's scope of practice so that it includes prescribing of birth control increases access and contributes to consistent use of contraceptive methods. Pharmacists should take full advantage of this opportunity to expand their clinical role.**

**In determining the optimal contraceptive method, providers should discuss and consider the following with all patients:**

- **Family-planning goals and desired duration of pregnancy prevention**
- **Medical history and required exam(s) to determine eligibility criteria for methods**
- **Medication review to screen for potential drug-drug interactions**
- **Effectiveness and safety of methods**
- **Non-contraceptive benefits**
- **Ability to use method correctly and consistently**
- **Need for advance provision of emergency contraception**
- **Need to abstain or use backup method**


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# Self-Assessment Questions

1. You will be relocating to a state that allows pharmacists to prescribe hormonal contraception. The position you were hired for is in a women's health clinic and you are expected to develop a contraception service. Which one of the following would be the best to include in development of this service?

   A. Discuss clinical operations with the clinic manager (i.e., who will take patient vital signs upon arrival).
   B. Purchase a blood pressure monitor and scale for your own use.
   C. Find and print resources for patient education.
   D. Research best practices and quality measures to evaluate the success and track outcomes of your service.

2. A 38-year-old woman (weight 75 kg, height 5' 8") presents to your office for assistance with choosing a contraceptive method. Her medical history includes type 2 diabetes (2 years) and hypertension (2 years). Both diabetes and hypertension are well managed. The patient currently takes lisinopril 5 mg PO daily and metformin 500 mg PO bid. She is currently using an extended-cycle oral contraceptive pill but has difficulty with adherence. The patient previously tried an implant, patch, and injectable. She tolerated the implant and the patch but did not tolerate the injectable. She is currently sexually active and in a monogamous relationship. She would like to try a newer product, preferably one she has not previously used. Which one of the following is best to recommend for this patient?

   A. Twirla
   B. Annovera
   C. Slynd
   D. Phexxi

**Questions 3 and 4 pertain to the following case.**

D.G., a 31-year-old woman with a medical history significant of only epilepsy, presents to your pharmacy to discuss depot medroxyprogesterone acetate (DMPA). Social history is negative for smoking, alcohol, and illicit drug use. She has been using this injectable contraceptive for 2 years. She likes not having to take a daily pill and is pleased that her menstrual cycles have lightened substantially. However, D.G. has read some reports about the effects of DMPA on "bone strength". She wonders if there are other harmful effects of DMPA and if it is still safe for her to use.

3. Which one of the following is the best counseling point to give D.G. regarding the use of DMPA?

   A. Data has shown an increased risk of stroke, MI, and VTE.
   B. It is not safe to use in a woman with family history of breast cancer.
   C. May contribute to BMD loss which is reversible with discontinuation.
   D. Associated with a longer return to fertility than other contraceptive methods.

4. D.G. decides to switch to a COC. Which one of the following is the best counseling point to give D.G. regarding the use of COCs?

   A. There is an FDA warning regarding risk of smoking and serious cardiovascular events.
   B. There is a potential for a drug-drug interaction with antiepileptic medications.
   C. If a dose is late and taken the next day, an additional contraceptive method is needed.
   D. You can initiate immediately without waiting for examinations or tests.

**Questions 5–7 pertain to the following case.**

A.R. is a 22-year-old female student who presents to the pharmacy seeking a prescription for oral contraception. Her medical history reveals no chronic conditions other than a history of acne. You counsel A.R. on contraceptive methods, and she is interested in a CHC, but is concerned about long-term exposure to estrogen. After discussing different options, she decides to try an oral method with the lowest estrogen content.

5. Which one of the following screening tests is best to obtain before initiating contraception for A.R.?

   A. Pelvic examination
   B. Breast examination
   C. Blood pressure
   D. Chlamydia and gonorrhea screening

6. In discussing this contraceptive method's effectiveness with A.R., which one of the following is the best measure to use?

   A. Pearl Index
   B. Proportion of pregnancies averted
   C. Perfect use failure rate
   D. Typical use failure rate

7. In counseling A.R. on the non-contraceptive benefits of her method, which one of the following is most important to include?

   A. Menstrual cycle–related problems
   B. Premenstrual syndrome
   C. Migraine
   D. Acne

**Questions 8 and 9 pertain to the following case.**

E.S., a 35-year-old woman, presents to your outpatient clinic for prenatal care during her second pregnancy. This pregnancy was unintended, and the baby was conceived while she was using the withdrawal method with her husband of 8 years. You take this opportunity to counsel E.S. on her contraceptive options after this pregnancy.

8. Using the tiered approach, which one of the following contraceptive methods is best to discuss first with E.S.?

   A. Diaphragm
   B. CHC
   C. IUD
   D. DMPA

9. E.S. expresses interest in a postpartum IUD. You inquire about her family planning after this pregnancy, and she expresses a desire to end her fertility after this pregnancy. After counseling her on the LARCs and permanent forms of contraception available, she decides she would like a method to prevent pregnancy for the longest duration possible. Which one of the following is best to recommend to help E.S. achieve and sustain this goal?

   A. Levonorgestrel-releasing device (Mirena)
   B. Levonorgestrel-releasing device (Liletta)
   C. Copper intrauterine device (ParaGard)
   D. Levonorgestrel-releasing device (Skyla)

10. A 19-year-old woman presents to the pharmacy for consultation to initiate a new contraceptive method. She is interested in a method that will be highly effective and does not require a medical visit or daily administration. Which one of the following contraceptive methods is best to recommend for this patient?

    A. Segesterone/ethynyl estradiol (Annovera)
    B. Levonorgestrel/ethinyl estradiol extended cycle (Seasonique)
    C. Levonorgestrel-releasing intrauterine device (Mirena)
    D. Depot medroxyprogesterone acetate (DMPA)

11. A 36-year-old woman (weight 92 kg, height 5' 6") comes to clinic. The patient takes amlodipine 5 mg orally daily for hypertension and St. John's Wort supplement for "mood." The patient smokes one-half PPD and her blood pressure today is 150/90 mm Hg. She is very concerned about gaining weight. She is interested in a pharmacist-prescribed contraceptive and has no preference on type of product. Your state allows pharmacist contraceptive prescribing. According to the CDC MEC, which one of the following is best to recommend for this patient?

    A. Drosperinone 4 mg tablet
    B. Depot medroxyprogesterone acetate
    C. Levonorgestrel/ethinyl estradiol extended cycle tablet
    D. Levonorgestrel/ethinyl estradiol patch

**Questions 12 and 13 pertain to the following case.**

S.F. is 21-year-old female college student presenting to your new pharmacist hormonal contraception service. She is inquiring about birth control; however, S.F. is also concerned about her family finding out about her decision to use contraception. Her blood pressure today is 140/82 mm Hg.

12. Which one of the following contraceptive methods is best to recommend for S.F.?

    A. Depot medroxyprogesterone acetate
    B. Combined oral contraceptive
    C. Transdermal contraceptive patch
    D. Contraceptive vaginal ring

13. Before she initiates a new contraceptive, which one of the following would best establish that S.F. is not pregnant?

    A. Completing a urine pregnancy test
    B. Started menstrual cycle 6 days ago
    C. Youngest child is 7 months old
    D. No signs or symptoms of pregnancy

14. Your state has granted prescriptive authority to pharmacists for contraceptives, including EC. A 24-year-old woman (BMI 31.5 kg/m$^2$) presents to your clinic after having unprotected vaginal intercourse 3 days ago. The patient prefers an oral EC method. Which one of the following is best to recommend for this patient?

    A. Refer the patient to a physician.
    B. Dispense levonorgestrel 1.5 mg.
    C. Prescribe and dispense ulipristal acetate 30 mg.
    D. Refer patient to online pharmacy to obtain ulipristal acetate 30 mg.

15. A woman presents to your community pharmacy seeking two-dose levonorgestrel emergency contraception (EC) after unprotected vaginal intercourse 48 hours ago. She states that she has had success with this specific EC method in the past. The patient currently has no health insurance and is unable to consult a health care provider to consider any other EC options. Which one of the following is best to recommend for this patient?

    A. Levonorgestrel one dose
    B. Levonorgestrel two doses
    C. Ulipristal acetate
    D. Copper intrauterine device (Cu-IUD)