Updates in Contraception

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Learning Objectives

1. Demonstrate an understanding of the scope and impact of unintended pregnancy.
2. Distinguish highly effective contraceptive methods.
3. Evaluate appropriate screening assessments for the various methods of contraception.
4. Apply the medical eligibility criteria for contraceptive use to individual patients.
5. Develop an emergency contraception plan for individual patients.
6. Compose effective communications to women regarding contraception.
7. Justify expanding access to contraception in pharmacies.

Introduction

Pharmacists are introduced to contraception in the pharmacy school curricula, and many commonly encounter these medications because they are used by female patients from adolescence to menopause. In the past few years, more products and agents have become available for women; by contrast, men continue to have limited options. This chapter discusses background statistics, recently approved contraceptive methods, changes in prescription status of emergency contraceptive (EC) pills, the pharmacist's expanding role in providing contraception, and national guidelines for contraceptive use and family planning services.

Epidemiology of Unintended Pregnancy

An estimated 51% of the 6.6 million pregnancies each year in the United States are unintended, a rate much higher than in other developed countries. Of these unintended pregnancies, 40% result in abortion (elective terminations only), and 27% result in births (Finer 2014). Some populations are disproportionately affected by this public health problem. Although teen birth rates have been falling, about 6% of teens ages 15 to 19 years will become pregnant each year, and 82% of these pregnancies will be unintended (Finer 2014; Kost 2010). Furthermore, women of color have more unintended pregnancies than do white women in the United States (Finer 2014).

An unintended pregnancy not only has immediate implications for the woman and her family, but also has far-reaching implications for society. Unintended childbearing has significant negative effects on maternal behaviors and infant health, such as delayed recognition of pregnancy, delayed prenatal care, preterm birth, low birth weight, and not breastfeeding (Kost 2015; Orr 2000).

Baseline Knowledge Statements

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

- Physiology of the menstrual cycle
- Pharmacology and mechanism of action of current contraceptive methods
- Basic medical eligibility criteria for contraceptive use

Additional Readings

The following free resources are available for readers wishing additional background information on this topic.

- Centers for Disease Control and Prevention. U.S. medical eligibility criteria for contraceptive use, 2010.
- Centers for Disease Control and Prevention. U.S. selected practice recommendations for contraceptive use, 2013.

Abbreviations in This Chapter

CHC	Combined hormonal contraceptive
COC	Combined oral contraceptive
EC	Emergency contraception
IUD	Intrauterine device
LARC	Long-acting reversible contraceptive
STD	Sexually transmitted disease

Annual state and public expenditures for births resulting from unintended pregnancies in the United States are estimated to total $12.5 billion (Sonfield 2013).

Among women of reproductive age (15–44 years), more than two-thirds (69.9%) are at risk of unintended pregnancy, and most of these women (89.0%) are currently using a method of contraception (Jones 2012). The contraceptive methods used most often are oral contraceptive pills and female sterilization, followed by condoms and all other contraceptive methods. Although the most common methods used today have largely remained the same compared with 1995, use of the other contraceptive methods has shifted. Figure 1-1 compares the methods selected by women using contraception in 1995 versus 2006–2010.

Definitions

Family planning is an umbrella term for a person's plans regarding whether and when to have children. Family planning includes strategies to prevent pregnancy when a pregnancy is not desired, as well as strategies to facilitate pregnancy when a pregnancy is desired, such as treatment for infertility. Unintended pregnancies are those that were not desired at the time of intercourse. It encompasses both pregnancies the woman wanted in the future but not at that time, known as mistimed pregnancies, and pregnancies the woman never wanted, known as unwanted pregnancies.

When discussing contraception, it is important to recognize when a pregnancy begins. *Pregnancy* is defined as the period from implantation to termination or extraction of the fetus according to the American College of Obstetricians and Gynecologists (ACOG), a definition accepted by the U.S. federal government. Thus, contraception is any means of preventing pregnancy. Emergency contraception is any method of contraception including both hormonal and nonhormonal options that can be used after intercourse to prevent pregnancy.

Barriers to Contraceptive Use

The high incidence of unintended pregnancies is a reflection of the challenges and barriers Americans face in preventing mistimed or unwanted pregnancy. Barriers encountered when accessing effective methods of contraception lead to inconsistent use and unintended pregnancies (Gold 2009). Research supports safe expansion of access to hormonal contraceptive products and services beyond the current prescription-only model (Gardner 2008; Grossman 2008; Monastersky Maderas 2007; Shotorbani 2006). This is discussed further in the section regarding expanding access to contraception in pharmacies.

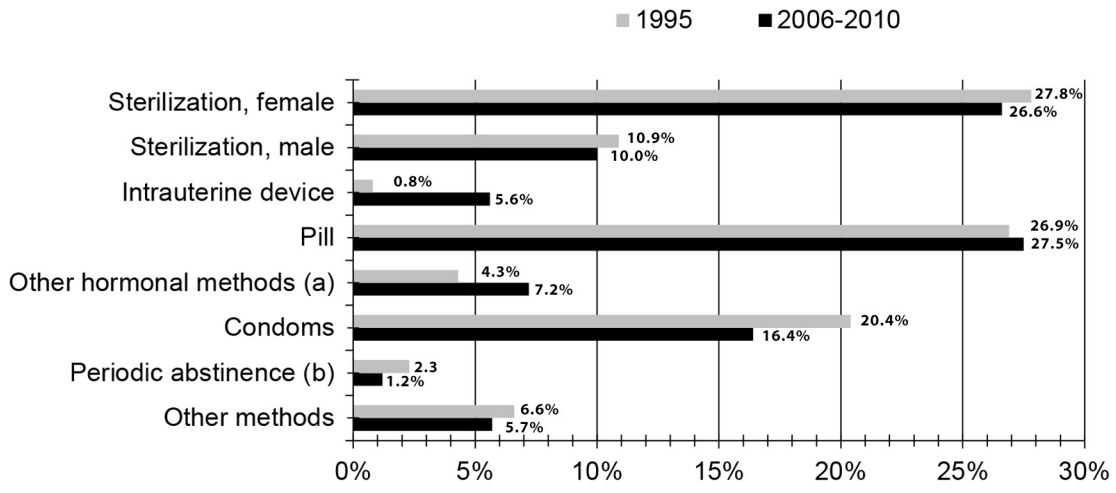

Figure 1-1. Distribution of methods among women using contraception, 1995 vs. 2006–2010.

[a]For 1995, includes implant and injectable. For 2006–2010, also includes patch and ring.
[b]Includes calendar method, natural family planning, cervical mucus test, and temperature rhythm.
Information from: Jones J, Mosher W, Daniels K. Current Contraceptive Use in the United States, 2006-2010, and Changes in Patterns of Use Since 1995. National Health Statistics Reports; No. 60. Hyattsville, MD: National Center for Health Statistics, 2012.

Barriers to Hormonal Contraception

Obtaining a prescription for contraception often presents the initial barrier to access. Hormonal contraceptives can be provided according to an assessment of a woman's medical history and blood pressure (Stewart 2001; Hannaford 1996). Reproductive health preventive screenings such as the Papanicolaou (Pap) tests, pelvic examinations, and breast examinations are not medically necessary for the provision of hormonal contraception (Stewart 2001). Despite these clinical guidelines, many providers continue to require pelvic examinations before prescribing hormonal contraceptives, creating a barrier to contraceptive access (Henderson 2010). Most obstetricians/gynecologists (79%) consider at least one pelvic examination component (bimanual examination > speculum examination > external genitalia visual inspection) to be of some importance for determining hormonal contraception eligibility (Yu 2014).

Once a woman obtains a prescription for hormonal contraception, more barriers must be overcome in obtaining supplies from the clinic or pharmacy. It has become a challenge to obtain 90-day supplies at community pharmacies because more insurers require use of their mail-order pharmacies for that benefit. Studies have shown that women who are provided more pill packs at their first visit (12 or 13 packs) have higher continuation rates and lower unintended pregnancy and abortion rates than those who received 1 or 3 packs (Steenland 2013; Foster 2011; White 2011). It is now recommended that up to a 1-year supply (e.g., thirteen 28-day pill packs) of oral contraceptives be prescribed or provided, depending on the patient's preferences and anticipated use (CDC 2013). Furthermore, most pharmacies do not have a private counseling area, which may deter some patients from accessing services, and some pharmacies do not stock EC or nonhormonal contraceptive methods (Rafie 2013a).

Barriers to EC

Emergency contraception has a storied history of barriers to access. Levonorgestrel-containing EC pills were initially approved as prescription-only, followed by several nonprescription status changes. In 2006, the product became available over the counter (OTC) to adult women and men 18 years or older with government-issued photo identification. This created a de facto behind-the-counter access model (Box 1-1). The age limit was decreased from 18 to 17 years of age in 2009 and removed altogether in 2013. However, these changes were not applied universally to all levonorgestrel-containing EC pill products. In 2013, when the age restrictions were removed from the branded 1-pill product (Plan B One-Step), they remained in place for the generic 2-pill products. At the time of writing, all products were available OTC without restriction (e.g., age, sex, identification) except for the generic 2-pill products. Age restrictions created barriers for younger women, whereas identification requirements created barriers for undocumented women. Both restrictions created a barrier by requiring the involvement of a pharmacy gatekeeper.

Box 1-1. Definitions of Various Models of Access to Contraceptives

A given contraceptive method may be available by one or several of the following models of access:

- Prescription-only: Approved as a prescription drug by the FDA
- Pharmacy access: Approved as a prescription drug by the FDA and available directly from a pharmacist without a prior prescription, either under a statewide authority or under a collaborative practice agreement with a prescriber; the pharmacist initiates the prescription and can dispense the medication
- Behind-the-counter: Approved as a nonprescription drug by the FDA but has additional restrictions requiring oversight by the pharmacy, such as identification requirements or sex or age restrictions; this is a de facto category and not recognized by the FDA
- Over-the-counter: Approved as a nonprescription drug by the FDA

The string of regulatory changes regarding access to EC has significantly affected consumer access to this contraceptive method. Secret shopper studies have documented the pervasive confusion and resulting misinformation and refusals by pharmacy staff (Bell 2014; Wilkinson 2014; Samson 2013; Nelson 2009). The most common types of misinformation provided to patients were the time window in which EC is effective and the age restrictions. Men trying to purchase this product experience refusals about 20% of the time (Bell 2014). As noted earlier, the product is not consistently stocked in all pharmacies. Many pharmacies offer to order the product if not in stock, but that would not meet the needs of the patient, given the importance of timely administration. Finally, the cost of a single dose of EC ranges from $40 to $50 in retail pharmacies (ASEC 2013).

There are two particular situations – after sexual assault and on incarceration – when women are particularly vulnerable to unintended pregnancies and should be offered EC. A retrospective evaluation of more than 179,000 visits to emergency departments by survivors of sexual assault or rape found that only 8.9% of females 12 years or older were provided EC, despite guideline recommendations (Straight 2007). A more recent survey of emergency medicine residents found that 71.2% always offered EC after sexual assault (Chen 2014). Together with prophylaxis for infections, the Centers for Disease Control and Prevention (CDC) recommends EC when the assault could result in pregnancy (CDC 2010a).

Women may engage in risky behaviors before arrest, including unprotected intercourse; they are also therefore potential candidates for EC. One cross-sectional survey

study found that 29% of women arrested in the previous 24 hours were eligible for EC, though only 48% were willing to take EC if offered (Sufrin 2009). The primary predictor of willingness to take EC was not having a misperception about its safety, efficacy, or mechanism of action (Sufrin 2009). Despite an ACOG recommendation that EC be available to incarcerated women, only 4% of correctional health providers have EC available at their facilities (Sufrin 2010; ACOG 2005).

Women are often unaware of the many contraceptive methods available. Emergency contraception, in particular, is not used as often as it is indicated. Only one in nine women of reproductive age (15–44 years old) surveyed between 2006 and 2010 reported having ever used EC (Daniels 2013). Of those, 59% had used EC once, 24% twice, and 17% three times or more. Among women who reported using EC, almost equal proportions had used EC because of fear of method failure (45%) and unprotected intercourse (49%). Although many consumers may be aware of EC, knowledge gaps remain about how to access it, the time interval in which it can be used, and its mechanism of action.

Barriers Created by Misconceptions

Patients and clinicians have misconceptions about many contraceptive methods, such as the mechanism of action of EC pills, effectiveness of condoms, adverse effects of contraceptive pills, and complications of intrauterine devices (IUDs). Intrauterine devices in particular have a long history of myths and misconceptions that remain today despite the new and improved devices available. One common myth is that IUDs increase the risk of sexually transmitted diseases (STDs) and pelvic inflammatory disease that may result in infertility. Furthermore, many believe that IUDs can only be used by parous women and that IUDs have high complication rates, such as uterine perforations. Though a potential complication of IUD insertion, uterine perforation occurs in less than 1 in 1000 insertions. These misconceptions are held not only by patients but by providers as well and result in a lack of patient counseling and limited provision of IUDs. In recent years, educational efforts have been aimed at consumers and providers alike to address this barrier. The ACOG has long recommended IUDs as a first-line contraceptive method for adolescent and nulliparous women, and the American Academy of Pediatrics is now doing the same (AAP 2014; ACOG 2012a).

Misconceptions about contraceptive adverse effects are pervasive. One-third of pill users discontinued therapy within 12 months, and adverse effects are the principal reason for discontinuation (Raine 2011; Trussell 2011). Clinical trials for oral contraceptives have consistently lacked a control group; thus, it cannot be inferred that the vague adverse effects reported in these studies, such as weight gain and mood changes, are in fact a result of therapy. Experts in the field have proposed that the long list of adverse effects included in the contraceptive pill labels may be leading to a "nocebo" effect, wherein women experience illness as a result of expectations of that outcome (Grimes 2011). The common nonspecific adverse effects are reported at equivalent frequencies when women are taking inert pills or combined hormonal contraceptive (CHC) pills. Regardless of whether these adverse effects are actually reflective of background prevalence of these complaints or a nocebo effect, it may be harmful to counsel women to expect them.

More than one-third (35%) of U.S. women using contraception use their method incorrectly, inconsistently, or with gaps of at least 1 month, resulting in almost all (95%) of the unintended pregnancies experienced by contraception users (Gold 2009). Optimistic counseling, when the woman is told she will feel well and do well on her selected contraceptive method, has been suggested as a strategy to improve correct, consistent, and continued use, providing the user with an effective method of contraception. Women should still be counseled about the warning signs for serious adverse effects that warrant immediate attention (e.g., abdominal pain, severe chest pain, severe headache, vision loss or blurring, or severe leg pain).

Barriers Created by Cost

Another major barrier to contraception use is cost. Long-acting reversible contraceptive (LARC) methods are associated with higher initial costs; however, LARC methods are more economical after 1 year because of lower failure and pregnancy rates (Crespi 2013). Women are more likely to select a LARC method over other contraceptive methods when cost considerations are removed (Kavanaugh 2011; Madden 2011). The Contraceptive CHOICE Project, a large prospective cohort study of 1404 adolescent girls 15–19 years of age in the St. Louis region who were followed for 2–3 years, found that when offered no-cost contraception, 72% chose a LARC method and had much lower unintended pregnancy rates (Secura 2014).

With the Patient Protection and Affordable Care Act (ACA) implementation in 2012, more Americans are expected to have insurance. One of the key benefits under the ACA is the coverage of women's preventive health care, such as the well woman visit, contraception, STD/HIV screening, cervical cancer screenings, prenatal care, mammograms, and other services, by health plans with no patient cost sharing (copayment, coinsurance, or deductible). The Institute of Medicine and the Health Resources and Services Administration developed the guidelines outlining the services that will be covered throughout a woman's life span. This benefit was implemented in 2013; however, grandfathered plans and those provided by religious organizations are excluded. In 2014, the Supreme Court ruled that closely held corporations could exercise religious objections to coverage of contraceptives for their employees. The government is accommodating

this religious belief but has another mechanism to ensure the affected women are still afforded the same coverage. States have taken action on this issue as well; 20 states allow certain employers and insurers to refuse to comply with the mandate, and 8 states do not permit refusals by any employers or insurers.

The benefit ensures women's access to the full range of U.S. Food and Drug Administration (FDA)-approved contraceptive methods, as well as patient education and counseling, as prescribed by a health care provider. Plans are permitted to use reasonable cost-mitigation strategies, such as covering the generic product but not the brand product. However, if the brand product is medically necessary or the generic version is not available, the plan must cover the brand product without patient cost sharing. The full spectrum of contraceptive options will be available to women, including IUDs, CHCs, diaphragms, and EC. Over-the-counter products and medications are not covered by this benefit unless they are FDA approved and prescribed by a health care provider. This benefit does not apply to men or to grandfathered insurance plans.

Choice of Method

Unlike other medication therapies, contraception is largely the patient's choice. The provider's role is to determine which methods are safe and effective for use by the patient and educate the patient on her options. Ultimately, the patient will select her method(s) of contraception. This may be a shift in practice for pharmacists compared with other drugs that may be recommended largely on the basis of efficacy and safety profile comparisons.

Effectiveness

The most widely accepted expression of the effectiveness of contraceptive methods is failure rate (the percentage of women who have an unintended pregnancy in 1 year of using the method). Whereas the product prescribing information states the efficacy or failure rate resulting from perfect use, health care professionals should communicate the results from typical use to inform patients. The distinction between typical use and perfect use cannot be overlooked. Perfect use efficacy rates are determined in clinical trials when contraceptive methods are used correctly and consistently. In contrast, typical use is the estimate of population-based effectiveness, which includes imperfect (inconsistent or incorrect) use. Thus, typical use efficacy rates do not imply the inherent efficacy of a contraceptive method but provide an idea of the actual experience of the individual using that method (Trussell 2011).

With typical use, 6% of women using short-acting hormonal contraceptives (e.g., injectable contraceptives) and 9% using CHCs (e.g., oral pills, transdermal patch, vaginal ring) will have method failure and become pregnant in the first year (Trussell 2011). However, less than 1% of women using LARC methods (i.e., implants, IUDs) become pregnant in the first year of use; therefore, LARC methods are considered highly effective. This 6- to 10-fold difference in failure rates occurs not because of differences in the inherent efficacies of each method but because of the ease or difficulty of using the various methods. That is, the similarly low typical and perfect use failure rates of the LARC methods reflect both efficacy and ease of use (Trussell 2011).

Efficacy of EC is a reflection of the percentage of pregnancies that would have occurred without the intervention but that were averted using the intervention. This can be difficult to calculate when the background rate of pregnancies is estimated.

The primary efficacy measure in contraceptive trials is the Pearl Index, which can be a very misleading measure of contraceptive failure. It reflects the number of unintended pregnancies among all the cumulative years of exposure to unintended pregnancy. One of the pitfalls of this measure is the use of a pregnancy intent-to-treat population, which assumes that the rate of unintended pregnancy in women lost to follow-up is the same as in women who continued in the study. Furthermore, use of variable durations of exposure is flawed because the risk of unintended pregnancy decreases over time. Thus, allowing women to contribute more years of risk would drive the Pearl Index down. Finally, only the pregnancies reported by the women themselves have traditionally been included in this computation. If pregnancy tests were administered routinely during the study period, more pregnancies (e.g., those resulting in early fetal loss) would likely be detected. Failure rates from clinical trials that do not use routine pregnancy testing cannot be compared with those that do. The Pearl Index is not used in clinical practice; however, it continues to be used in product labeling. When interpreting the Pearl Index reported in product labeling, a lower number reflects higher efficacy, and values usually range from 1 to 3.

Nomenclature

Contraceptive methods can be divided into three categories with respect to effectiveness. Highly effective methods are those that result in unintended pregnancies in less than 1% of users and include permanent sterilization and LARC or highly effective reversible contraceptives, such as the subdermal implant and IUDs. Moderately effective methods result in unintended pregnancies in 6%–12% of users and include the depot medroxyprogesterone acetate injection, CHCs, and the diaphragm. Less effective methods include the other barrier methods, withdrawal, fertility awareness–based methods, and spermicides. A chart depicting these categories with a graphic display of each method and its typical use failure rate is a useful tool for patient and provider understanding (Figure 1-2).

Noncontraceptive Benefits

Many women use contraception solely for preventing pregnancy, and others use contraception for both preventing pregnancy and for noncontraceptive effects. The primary

noncontraceptive benefit of hormonal contraceptives is improvement in menstrual cycle–related problems such as menstrual irregularity, premenstrual syndrome, premenstrual dysphoric disorder, dysmenorrheal (pain), migraine, menorrhagia (excessive bleeding), anemia, and pelvic pain in women with endometriosis. Other benefits include treatment of hirsutism and acne in women with polycystic ovary syndrome, as well as decreasing the risk of endometrial, ovarian, and colorectal cancers (ACOG 2010). Among oral contraceptive pill users, 14% use the method solely for noncontraceptive indications, and 58% use the method, at least in part, for indications other than contraception. Of importance, not all contraceptive users are sexually active; in one survey, 9% of sexually experienced pill users were not currently sexually active (no sex in the past 3 months) (Jones 2011).

Screening and Eligibility

For years, U.S. providers have relied on the World Health Organization (WHO) Medical Eligibility Criteria for Contraceptives. However, this guidance document was intended to be adapted by each country. In 2010, the CDC adapted the WHO guidance to create the U.S. Medical Eligibility Criteria for Contraceptive Use (MEC). In addition to the medical conditions and patient characteristics listed in the original WHO guidance, the CDC guidance includes other conditions relevant to the U.S. patient population, including solid organ transplantation, bariatric surgery, peripartum cardiomyopathy, endometrial hyperplasia, and inflammatory bowel disease.

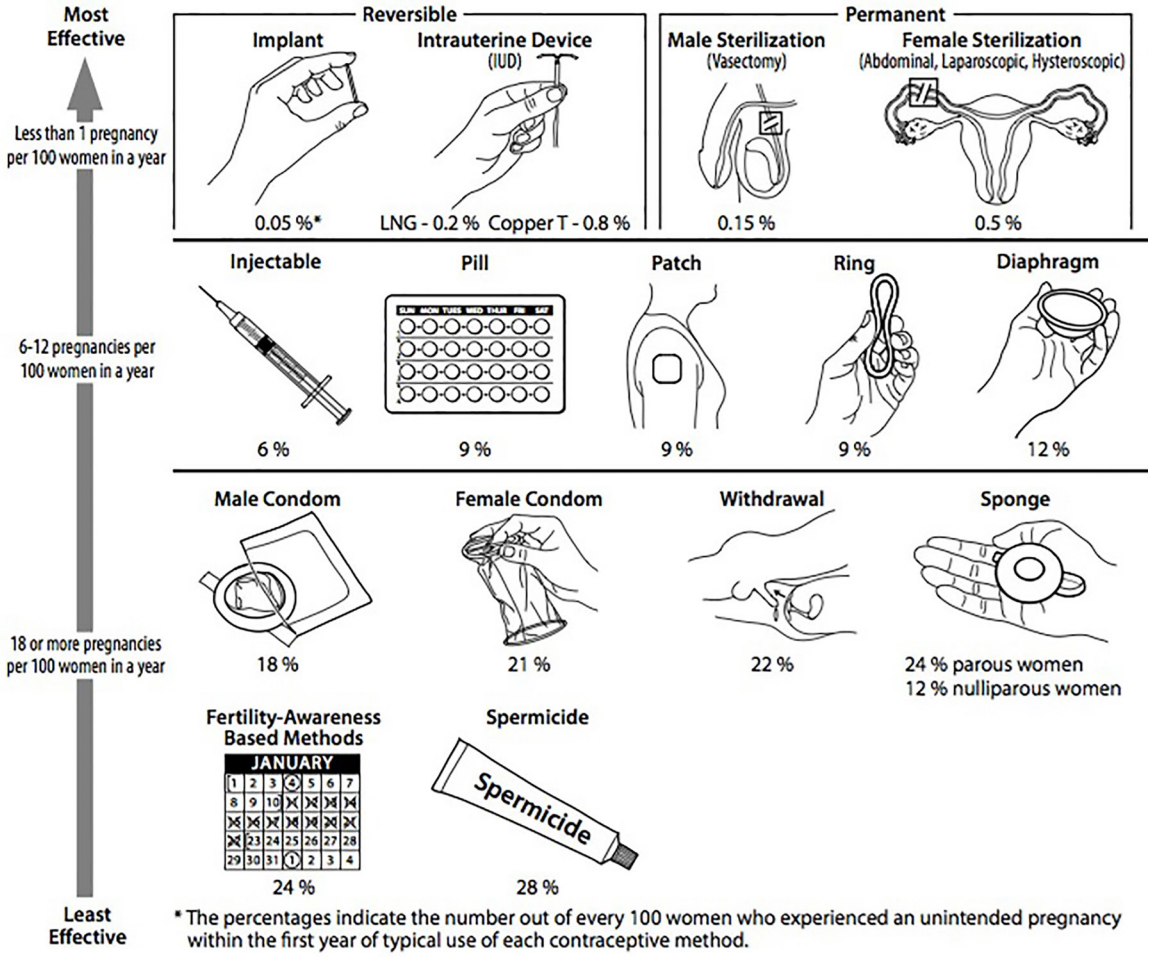

Figure 1-2. Tiered effectiveness of family planning methods.

Reprinted from: Centers for Disease Control and Prevention. U.S. selected practice recommendations for contraceptive use, 2013. MMWR 2013;62(RR-5):1-59.

CDC Medical Eligibility Criteria for Contraceptive Use

The CDC MEC provides guidance on which contraceptive methods are safe for individual patients. For each patient characteristic or medical condition, eligibility criteria are listed for the various contraceptive methods according to four classifications (Box 1-2). Although patients are eligible to use all the methods regardless of age and weight, many characteristics and conditions should be carefully considered when determining eligibility for initiating or continuing a given contraceptive method. Two updates have been issued regarding eligibility for contraceptive use in the postpartum period and among women at high risk of or with HIV infection (CDC 2012, 2011).

Box 1-2. Categories for Classifying Medical Eligibility for Hormonal Contraceptives and IUDs

Category 1. A condition for which there is no restriction for 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.
Reprinted from: Centers for Disease Control and Prevention. U.S. medical eligibility criteria for contraceptive use, 2010. MMWR 2010;59(RR-4):1-81.

Table 1-1. Eligibility for the Use of Contraceptive Methods During the Postpartum Period[a]

Condition	COC/P/R	POP	DMPA	Implants	LNG-IUD	Cu-IUD
Postpartum (non-breastfeeding women)						
< 21 days	4	1	1	1		
21 to 42 days with other risk factors for VTE[b]	3[c]	1	1	1		
21 to 42 days without other risk factors for VTE	2	1	1	1		
Postpartum (breastfeeding women)						
< 21 days	4	2	2	2		
21 to < 30 days with other risk factors for VTE	3[c]	2	2	2		
21 to < 30 days without other risk factors for VTE	3	2	2	2		
30 to 42 days with other risk factors for VTE	3[c]	1	1	1		
30 to 42 days without other risk factors for VTE	2	1	1	1		
Postpartum (in breastfeeding or non-breastfeeding women, including post-cesarean section)						
< 10 minutes after delivery of the placenta					2	1
10 minutes after delivery of the placenta to < 4 weeks					2	2
≥ 4 weeks					1	1
Puerperal Sepsis					4	4

[a]For definitions of categories 1–4, see Box 1-2.
[b]Risk factors for VTE include age ≥ 35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, BMI ≥ 30 kg/m^2, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking.
[c]For women with other risk factors for VTE, these risk factors might increase the classification to a "4"; for example, smoking, deep venous thrombosis/pulmonary embolism, known thrombogenic mutations, and peripartum cardiomyopathy.

COC = combined oral contraceptive, patch, ring; Cu-IUD = copper intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; P = combined hormonal contraceptive patch; POP = progestin-only pill; R = combined hormonal contraceptive ring; VTE = venous thromboembolism.
Reprinted from: Centers for Disease Control and Prevention. Update to CDC's U.S. medical eligibility criteria for contraceptive use, 2010: revised recommendations for the use of contraceptive methods during the postpartum period. MMWR 2011;60(RR-26):878-83.

Postpartum

The postpartum period is an important time to evaluate the safe use of contraception. Ovulation can occur as early as 25 days after delivery among non-breastfeeding women. Thus, contraceptive use is critical to achieve desired birth intervals. When determining eligibility for contraceptive methods, the objective to prevent an unintended pregnancy must be balanced with the woman's risk of venous thromboembolism and breast milk production for the infant. Breastfeeding is commonly assumed to serve as an effective method of birth control in the postpartum period. However, breastfeeding must constitute 85%–100% of the infant's feeds in order to rely on breastfeeding to suppress ovulation. Table 1-1 summarizes eligible contraceptive methods in the postpartum period. There are some restrictions in the first 42 days postpartum, but none thereafter. Intrauterine devices can be inserted postpartum, even immediately, in the absence of puerperal sepsis, which may present with symptoms such as fever, chills, malaise, lower abdominal pain, subinvolution of the uterus, or purulent and foul-smelling discharge.

Drug-Drug Interactions

The CDC MEC also provides guidance regarding eligibility for the use of contraceptive methods with concomitant drug therapy. Because women are using contraception for most of their reproductive years, there is a high likelihood of concurrent medication intake. The unexpected onset of breakthrough bleeding or spotting may be the first indication of a drug-drug interaction, but this does not necessarily reflect a reduction in contraceptive effectiveness (Dickey 2014). The sex steroids estrogen and progestin found in combined oral contraceptive (COC) methods may affect the pharmacokinetics of the concomitant drug and vice versa. Little evidence has been added to our body of knowledge on drug-drug interactions with hormonal contraceptives in the past few years. However, the CDC MEC provides clear guidance based on a comprehensive review of the evidence to date. Table 1-2 summarizes the MEC categories for concomitant drug therapy and contraceptive use. In general, studies evaluating potential interactions are lacking. The most recent drug-drug interaction studied is that between COCs and lamotrigine. The CDC also reviewed and summarized the effects of hormonal contraceptives and concomitant antiretrovirals on one another (CDC 2010b).

CDC Select Practice Recommendations for Contraceptive Use

Whereas the CDC MEC guides clinicians in determining who can use contraceptive methods safely, the CDC Select Practice Recommendations (SPR) guide clinicians on how to initiate and manage use of specific contraceptives (CDC 2013). The CDC adapted the WHO's SPR for contraceptive use in 2013; the result is evidence-based guidance on common but sometimes complicated issues for each contraceptive method such as clinical information needed to initiate therapy, recommended follow-up, and managing nonadherence and adverse effects.

Screening and Assessments

Pharmacists may find the following recommendations the most useful: screening tests for determining eligibility, initiation, and backup contraception; monitoring; and switching between methods. Before any contraceptive method can be initiated, providers should be reasonably certain that a woman is not pregnant using the criteria listed in Box 1-3. For contraceptive methods that can be safely provided by pharmacists and at pharmacies (i.e., pills, patch, ring, injection), the only recommended screening test is blood pressure for CHC methods. Table 1-3 summarizes when to start the various contraceptive methods with respect to the menstrual cycle and the time interval for using backup contraception.

Missed Dose Instructions

The SPR also includes algorithms for late or missed CHC doses that greatly simplify the instructions. Figure 1-3 describes the instructions for late or missed pills. The instructions for the other CHCs are similar except they require a new patch or ring to be applied or inserted as soon as possible after a missed dose (e.g., delayed insertion or application, detachment).

Expanding Access and the Pharmacist's Role

Definitions of Access Models

Except for barrier methods and EC, all contraceptive methods remain prescription-only. The various models of access for contraceptives are explained in Box 1-1. Pharmacy access is a model that allows the pharmacist to screen patients, initiate a prescription for medications outlined in the agreement, and furnish the medications directly to the patient. Pharmacy access to hormonal contraception presents an opportunity for safely increasing access for all women, particularly women with lower socioeconomic status who are at greatest risk of unintended pregnancies (Finer 2014). Pharmacy access to contraception has the potential to prevent 500,000 unintended pregnancies and save almost $250 billion in public funds each year (Landau 2006).

Evidence for Expanding Access

For such a change to occur, support from women, pharmacists, and prescribing providers is needed. A national consumer survey of more than 800 women found that 68%

Table 1-2. Eligibility for the Use of Contraceptive Methods with Concomitant Drug Therapy[a]

Drug	COC/P/R	POP	DMPA	Implant	LNG-IUD	Cu-IUD
Antiretroviral therapy						
Nucleoside reverse transcriptase inhibitors (NRTIs)	1[b]	1	1	1	I - 2/3[c] C - 2	I - 2/3[c] C - 2
Non-nucleoside reverse transcriptase inhibitors (NNRTIs)	2[b]	2[b]	1	2[b]	I - 2/3[c] C - 2	I - 2/3[c] C - 2
Ritonavir-boosted protease inhibitors	3[b]	3[b]	1	2[b]	I - 2/3[c] C - 2	I - 2/3[c] C - 2
Anticonvulsant therapy						
Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3[b]	3[b]	1	2[b]	1	1
Lamotrigine	3[b]	1	1	1	1	1
Antimicrobial therapy						
Broad-spectrum antibiotics	1	1	1	1	1	1
Antifungals	1	1	1	1	1	1
Antiparasitics	1	1	1	1	1	1
Rifampicin or rifabutin	3[b]	3[b]	1	2[b]	1	1

[a]For definitions of categories 1–4, see Box 1-2.
[b]See the complete guidance for clarification.
[c]Initiating an intrauterine device is a category 3 for patients with AIDS and category 2 for patients with high risk of HIV, HIV infection, or clinically well on antiretroviral therapy.
C = continuation of contraceptive method; COC = combined oral contraceptive, patch, ring; Cu-IUD = copper intrauterine device; I = initiation of contraceptive method; LNG-IUD = levonorgestrel-releasing intrauterine device; P = combined hormonal contraceptive patch; POP = progestin-only pill; R = combined hormonal contraceptive ring.

Reprinted from: Centers for Disease Control and Prevention. U.S. medical eligibility criteria for contraceptive use, 2010. MMWR 2010;59(RR-4):1-81.

would use pharmacy access to hormonal contraception if it were available, and 41% would start using contraception (Landau 2006). Women who were uninsured or low income showed greater interest in this access model.

Studies have shown that women can accurately screen themselves for contraindications to hormonal contraception by using a self-administered medical history questionnaire; results show greater than 90% agreement with their provider's assessment (Grossman 2008; Shotorbani 2006). Pharmacists can also efficiently screen women for safe use of hormonal contraceptives and prescribe an appropriate method under protocol in a community pharmacy setting (Gardner 2008). Pilot studies of pharmacy access to various forms of hormonal contraception (i.e., pill, patch, ring, injectable) had encouraging outcomes, including method continuation and satisfaction (Gardner 2008; Monastersky Maderas 2007). Convenience was ranked as the primary reason women elected to obtain their contraceptive method directly from a pharmacist in a Washington State pilot

Box 1-3. How to Be Reasonably Certain That a Woman Is Not Pregnant

A health care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

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

Reprinted from: Centers for Disease Control and Prevention. U.S. selected practice recommendations for contraceptive use, 2013. MMWR 2013;62(RR-5):1-59.

Table 1-3. 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
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection
Levonorgestrel-releasing 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
Combined hormonal contraceptive	Anytime	If > 5 days after menses started, use backup method or abstain for 7 days	Blood pressure measurement
Progestin-only pill	Anytime	If > 5 days after menses started, use backup method or abstain for 2 days	None

[a]If the provider is reasonably certain the woman is not pregnant (see Box 1-3).

IUD = intrauterine device.

Reprinted from: Centers for Disease Control and Prevention. U.S. selected practice recommendations for contraceptive use, 2013. MMWR 2013;62(RR-5):1-59.

study (Gardner 2008). Many studies of women, including adolescents, showed that self-injection of subcutaneous depot medroxyprogesterone may be a convenient alternative to clinic visits (Williams 2013; Cameron 2012; Prabhakaran 2012; Lakha 2005).

Support for Expanding Access

A survey of almost 3000 U.S. pharmacists found that 85% were interested in providing direct pharmacy access to hormonal contraceptives (Landau 2009). Pharmacists are well trained to obtain and assess both blood pressure and medical history, with most (95%) feeling competent in these skills (Landau 2009). In addition, almost all California pharmacy students (96%) were interested in providing hormonal contraception under a pharmacy access model (Rafie 2011). One pharmacist-perceived barrier was resistance from physicians (Landau 2009).

Interviews with California physicians and advanced practice clinicians revealed that most believed the current prescription-only model was too restrictive, and more than one-third were in favor of pharmacist-provided hormonal contraception (Rafie 2012). In a national survey, most providers (i.e., 88% of physicians and 84% of midlevels) were supportive or neutral toward expanding access for the pill, patch, and ring contraceptives to include pharmacy access. Despite overall support for pharmacy access, however, more than 70% of respondents were concerned that expanded access would result in decreased reproductive health preventive screening. Slightly fewer providers supported or were neutral toward behind-the-counter access (65% for pill/patch/ring, 55% injectable) and OTC access (47% for pill/patch/ring, 36% injectable) than for pharmacy access. Provider concerns about lower rates of reproductive health preventive screenings and pharmacist training issues would need to be appropriately addressed, together with any policy changes.

In recent years, many professional associations have stated their support for expanding access to oral contraceptives. Within the pharmacy profession, the American College of Clinical Pharmacy Women's Health Practice and Research Network issued opinion statements supporting OTC access to oral contraceptives and OTC access to EC pills without restriction (Rafie 2013b; McIntosh 2011). Physician organizations such as ACOG and the American Academy of Family Physicians also have statements of support for OTC access to oral contraceptives (AAFP 2014; ACOG 2012b).

Quality Patient Care Updates

Permanent, Long-Acting, and Short-Acting Contraception

Permanent Contraception

For women seeking to end their fertility, a permanent method is available in addition to surgical options (e.g., tubal ligation) and bilateral tubal occlusion after hysteroscopic placement of inserts (Essure). A second transcervical, hysteroscopic sterilization system (Adiana) was approved by the FDA in 2009. The procedure consists of hysteroscopically passing

a catheter inside the fallopian tube, where the catheter emits radiofrequency energy to create a lesion. An implantable silicone matrix is delivered to each prepared tube, and tissue grows around the matrices to block the tubes, according to the product labeling. Like the Essure method, Adiana requires hysterosalpingography at 3 months to confirm blockage. A reliable form of contraception other than an IUD must be used until bilateral tubal occlusion can be confirmed. Women are at risk of ectopic pregnancy after this procedure. Mild and transient adverse effects include cramping (26%), vaginal spotting (12%), postprocedure bleeding (10%), pelvic pain (9%), back pain (8%), and nausea (5%), according to the package insert. These hysteroscopic procedures provide women with noninvasive methods of permanent birth control or sterilization. However, the potential loss to follow-up to confirm occlusion and the resulting unintended pregnancies must be considered when discussing this option (Palmer 2009).

Long-Acting Reversible Contraception

Intrauterine Contraception

A new low-dose levonorgestrel-releasing device (Skyla) was approved by the FDA in 2013. The device contains 13.5 mg of levonorgestrel and releases a decreasing amount of levonorgestrel daily for 3 years. The advantages of this device over the original levonorgestrel-releasing device (Mirena) are its smaller size (28 mm × 30 mm) and approved use in nulliparous women and adolescents. The disadvantages are its shorter duration of in-placement use (3 years vs. 5 years) and lower incidence of amenorrhea (12% vs. 24%), which is a desired effect for many IUD users, according to product labeling.

Another levonorgestrel-releasing device (Liletta) was approved by the FDA in early 2015 and is now available. The device contains 52 mg of levonorgestrel and releases a decreasing amount of levonorgestrel daily for 3 years. The device is indicated for use to prevent pregnancy regardless of parity, despite being the same size (32 mm × 32 mm)

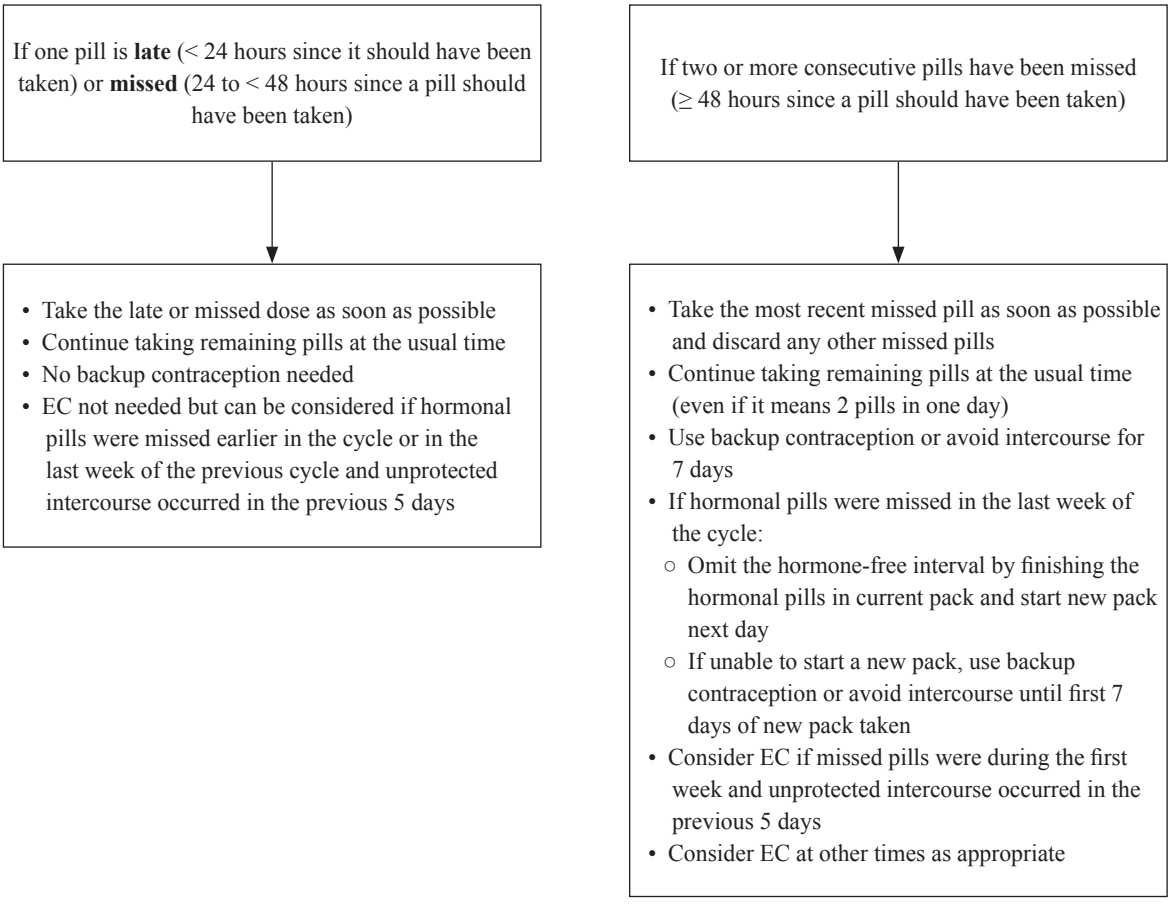

Figure 1-3. Algorithm for late and missed doses of combined hormonal contraceptive pills.

Reprinted from: Centers for Disease Control and Prevention. U.S. selected practice recommendations for contraceptive use, 2013. MMWR 2013;62(RR-5):1-59.

as the original levonorgestrel-releasing device (Mirena), which provides a marketing advantage. Another advantage is the 19% incidence of amenorrhea within 1 year; by the third year of treatment, more than one-third of women in the clinical trial were amenorrheic. The trial is ongoing to evaluate the use of this device for up to 4, 5, and 7 years.

The disadvantage of all devices is that a clinician is required to both initiate and discontinue use.

Implantable Contraception

A single contraceptive implant remains on the market. However, the original product (Implanon), which was modified in 2011, now bears a new brand name (Nexplanon). There are two key differences between the original product and the modified product. First, the modified device is now radiopaque, allowing location verification by visualizing with ultrasonography, radiography, computed tomography, or magnetic resonance imaging. Second, the original applicator rarely led to deep insertions, resulting in contraceptive failure and/or difficult removal requiring a surgical procedure, whereas the current applicator is preloaded and has been modified to facilitate more accurate insertions. The device itself is still a single rod containing 68 mg of etonogestrel that releases a decreasing amount of etonogestrel daily for 3 years. Thus, no changes in efficacy or safety are anticipated other than reducing contraceptive failures caused by insertion errors. The advantage of this device is that it is highly effective. The disadvantage of all devices is that a clinician is required to both initiate and discontinue use.

Oral Contraception

Quadriphasic Oral Contraceptive Pill

In 2010, the FDA approved the first quadriphasic, combination estrogen/progestin oral contraceptive product (Natazia) for prevention of pregnancy (Rafie 2013c). In 2012, the product received approval for the treatment of heavy menstrual bleeding. The estrogen component is estradiol valerate, and the progestin component is dienogest. Estradiol valerate is a novel estrogen with structural similarity to 17β-estradiol and a shorter half-life than ethinyl estradiol, according to the package insert. Therefore, it theoretically may have less adverse effects on lipid and glucose metabolism and a decreased risk of thromboembolic or cardiovascular complications, although evidence to support this is currently lacking. The effects of a 2-mg/day dose of estradiol valerate on the hypothalamic-pituitary-ovarian axis and on endometrium and ovarian function are expected to be similar to that of ethinyl estradiol 20 mcg/day (Kiley 2011). Dienogest is a unique progestin because of its structure and pharmacologic properties. It is a C-19 nortestosterone derivative, like norethindrone, but has properties similar to progesterone derivatives such as levonorgestrel and desogestrel (Ruan 2012). In this quadriphasic dosing regimen, dienogest is increased during week 2 of the cycle, whereas estradiol valerate is decreased on day 2 and again on day 24 (Figure 1-4).

Efficacy is similar to other COCs, with Pearl Indices of 1.64 for U.S. trials and 1.04 for trials in Europe, according to the product labeling. At this time, no distinct safety advantages or disadvantages can be considered when comparing estradiol valerate/dienogest with other COCs containing ethinyl estradiol 35 mcg or less. According to the product labeling, more than 10% of women from the clinical trials discontinued use because of adverse reactions such as menstrual disorder and abnormalities, mood alterations, acne, headache/migraine, and weight increase. Although a backup method of contraception is needed for the first 7 days when initiating other CHCs, women should be advised to use a backup method of contraception for the first 9 days when initiating estradiol valerate/dienogest. The product labeling has specific missed pill instructions for this COC formulation. However, the generic missed pill instructions from Figure 1-3 can be used for simplicity, except that the duration of backup is 9 days rather than 7 days.

Lowest Estrogen Oral Contraceptive Pill

In 2010, the FDA approved the first ethinyl estradiol 10-mcg oral contraceptive pill (Lo Loestrin Fe) for

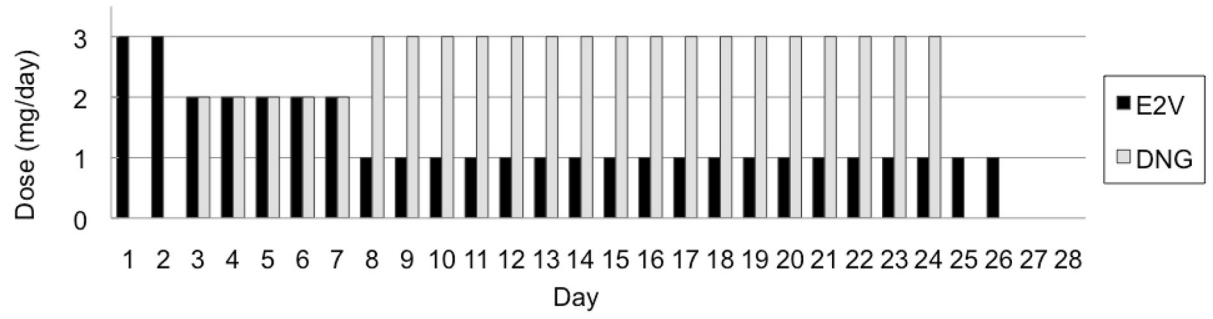

Figure 1-4. Daily doses of estradiol valerate (E2V) and dienogest (DNG) in the quadriphasic regimen.

prevention of pregnancy. This is now the lowest estrogen-containing COC pill available. Each pill pack contains 24 tablets with ethinyl estradiol 10 mcg and norethindrone 1 mg, followed by 2 tablets with ethinyl estradiol 10 mcg and 2 placebo tablets with ferrous fumarate 75 mg. The ferrous fumarate tablets serve no therapeutic purpose. A clinical trial following more than 1200 women for 1 year found that the pregnancy rate (Pearl Index) in women 18–35 years of age was 2.92 pregnancies per 100 woman-years of use (95% CI, 1.94–4.21), according to the product labeling. This Pearl Index is higher than that of any other COC approved by the FDA to date, reflecting a slightly higher failure rate. Women with a body mass index (BMI) of 35 kg/m^2 or greater were excluded from the study. Because of a lack of sufficient evidence, a Cochrane review found no association between BMI and the effectiveness of hormonal contraceptives (Lopez 2013).

The reduced dose of ethinyl estradiol leads to 40% less ethinyl estradiol exposure over a 28-day treatment cycle compared with an ethinyl estradiol 20-mcg formulation; thus, estrogen-related adverse effects are expected to be lower. However, this was not shown in the clinical trial, and adverse effects were similar to those of other COCs. According to the product labeling, more than 10% of study participants discontinued use because of an adverse reaction such as menstrual irregularities, headache/migraine, mood disorder, and weight fluctuation. Patients should be counseled about the possibility of lighter and shorter periods, even amenorrhea. This product has a niche, given that some women may be seeking the lowest possible estrogen dose and thus may be willing to accept the lower efficacy rate to achieve that.

Some updates have been added to the prescribing information for CHCs in the past few years. Between 2011 and 2013, a boxed warning was added to the labeling for all CHCs, including pills, the patch, and the ring, regarding risk of smoking and serious cardiovascular events. The CHC boxed warning text was added to the existing boxed warning for the transdermal patch regarding higher venous thromboembolism risk because of increased area under the curve compared with oral contraceptives. The warnings and precautions for drospirenone-containing oral contraceptives were expanded to include the higher risk of venous thromboembolism compared with COCs containing levonorgestrel and other progestins.

Emergency Contraceptives

There are several updates regarding ECs. The Yuzpe regimen, consisting of larger doses of oral contraceptive pills, has largely fallen out of use with the availability of dedicated levonorgestrel-containing pills. This Yuzpe regimen was less effective (failure rates of 2.0%–3.5%), was more onerous (e.g., pill burden, multiple doses), and resulted in more adverse effects (e.g., nausea, vomiting) than levonorgestrel. The single 1.5-mg dose of levonorgestrel is preferred to two 0.75-mg doses 12 or 24 hours apart, primarily for ease of adherence.

Changes in Nonprescription Status

As described earlier in the Barriers to EC section, the levonorgestrel 1.5-mg product (Plan B One-Step) was approved as a nonprescription drug, and all age and identification requirements were removed in 2013. Then in 2014, several generic single 1.5-mg dose products were approved, which became available on OTC shelves.

Ulipristal Acetate

Ulipristal acetate (Ella) became available by prescription only in 2010. A selective progesterone receptor modulator, the agent has both agonistic and antagonistic properties. Its mechanism of action is primarily to delay ovulation, although there may be effects on the endometrium that decrease the likelihood of implantation (Shrader 2011). Ulipristal acetate is taken as a single 30-mg dose by mouth as soon as possible after unprotected intercourse. Although it can be taken up to 120 hours after unprotected intercourse, efficacy decreases with time. Ulipristal acetate is most effective if taken before luteinizing hormone (LH) begins to rise and less effective after it has peaked (Shrader 2011). Ulipristal acetate is the most effective EC pill, with failure rates of 0.9%–2.1% in clinical trials, compared with levonorgestrel failure rates of 0.6%–3.1% (Cleland 2014). The difference in efficacy is thought to be a result of the added benefit of ulipristal acetate after the LH surge; ulipristal disrupts ovulation at this point, whereas levonorgestrel is ineffective.

In addition to the differences in effectiveness, there are other key distinctions between ulipristal acetate and levonorgestrel. Although a woman can initiate or restart her contraceptive method on the same day as ulipristal acetate, any hormonal method requires use of a backup barrier method of contraception or abstinence for 14 days, according to the package insert. Ulipristal acetate can be used only once per menstrual cycle. According to the package insert, ulipristal acetate interacts with cytochrome P450 3A4 enzyme inducers, resulting in the potentially reduced effectiveness of ulipristal acetate.

Impact of Body Weight on Efficacy

Although no studies have evaluated the relationship between patient body weight and EC pill effectiveness, meta-analyses of pooled data suggest reduced effectiveness in women with higher body weight (Kapp 2015; Glasier 2011). The first meta-analysis evaluated failure rates for both levonorgestrel and ulipristal acetate, which increased from 1.3% and 1.1% to 5.8% and 2.6%, respectively, in women with a BMI of 30 kg/m^2 or greater (Glasier 2011). The authors of this meta-analysis modeled the available data and concluded that levonorgestrel may be ineffective for women with a BMI of 26 kg/m^2 or greater and ulipristal may be ineffective for women with a BMI of 35 kg/m^2 or greater.

The second meta-analysis evaluated failure rates for levonorgestrel only and found decreases in effectiveness

similar to those in the first meta-analysis (Kapp 2015). The authors of this meta-analysis found a significant drop in efficacy with increasing body weight, with pregnancy rates of 1.4% or less in women weighing up to 75 kg and rates of 5.7% or greater in women weighing more than 75 kg. Increasing BMI was also associated with decreasing efficacy, though BMI did not provide additional predictive value, so body weight is sufficient in clinical decision-making. Thus, women weighing more than 75 kg (165 lb) should be offered ulipristal or copper IUD, if desired, and timely access is feasible.

Tiered Approach to EC

Factors to consider when selecting a method of EC include time since unprotected intercourse, eligibility for each method, access to each method (e.g., prescription-only vs. OTC, cost, visit required), patient weight, acceptability of a copper IUD for long-term contraception, and desire to prevent pregnancy. A copper IUD is the most effective method (less than a 0.1% pregnancy rate after insertion) and its effectiveness is not affected by weight; however, a copper IUD necessitates a visit with a trained provider for insertion. With the high cost of the IUD, it should be used as the woman's contraceptive method beyond its use as EC to ensure cost-effectiveness. Although studies are ongoing, there currently is no evidence to support the use of the levonorgestrel IUD for EC, and it should thus not be used for this indication. Ulipristal remains prescription-only, whereas consumers can obtain levonorgestrel EC by prescription or OTC. Figure 1-5 presents an algorithm for selecting an effective method of EC.

It is recommended that all women using short-acting reversible contraceptives such as barrier methods, pills, patch, ring, or injectable be provided with EC in advance of need (CDC 2013). A Cochrane review found no increases in risk-taking behaviors (i.e., STD and frequency of unprotected intercourse) with advance provision of EC (Lopez 2013).

Lifestyle and Barrier Contraceptives

Female Condom

Historically, female condoms have not been popular methods of birth control. Female condoms make up less than 1% of the worldwide condom use (UN 2011). Many women find them uncomfortable. Products are being developed to better fit the female anatomy and result in a more pleasurable experience for both partners. The only female condom currently available in the United States is a second-generation product (FC2). However, three other female condoms are currently being studied, and a recent study showed that all three were noninferior to FC2 (Beksinka 2013).

The FC2 product is a nitrile (synthetic latex) condom approved by the FDA in 2009. The nitrile material is less expensive than the polyurethane used in the original female condom, allowing lower cost to consumers ($1–$2 per condom). The condom is a 6.5-inch pouch with a flexible ring at each end; the ring at the closed end serves to hold the condom in place. It may be difficult to insert initially, but women should be advised that it becomes easier with practice. The product comes with a silicone-based lubricant without spermicide, and either oil- or water-based lubricants can be used. It is highly recommended that a spermicide be added when using this method to increase contraceptive effectiveness. Unlike the male condom, the female condom can be inserted in advance of sexual intercourse, and it transmits heat. Other benefits of this method of contraception include protection against transmission of sexually transmitted infections and the woman controls its use, which may be important if the partner refuses to use a male condom.

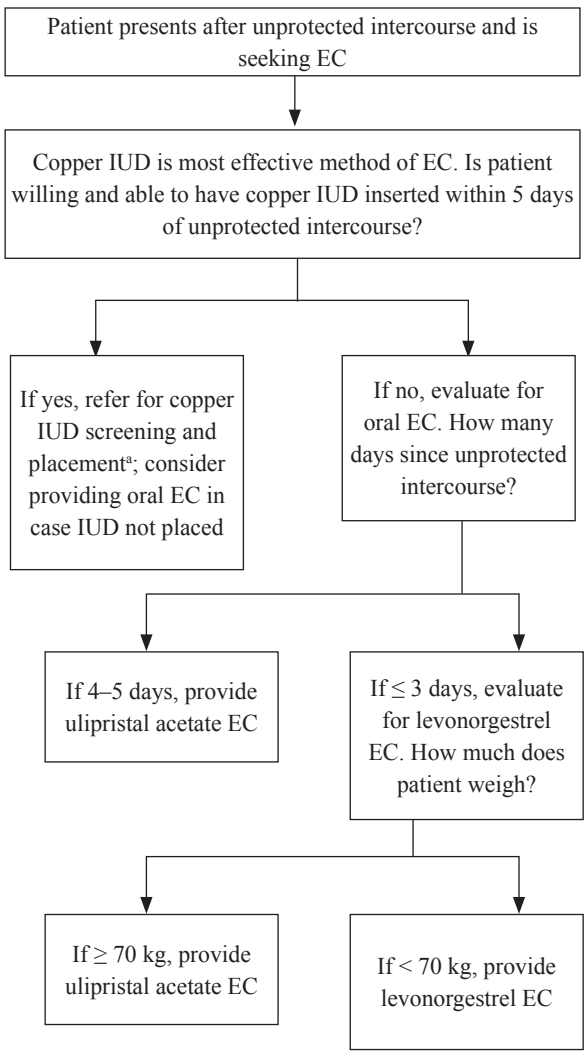

Figure 1-5. Emergency contraception (EC) algorithm for pharmacies.

[a]Screening required to be reasonably certain patient is not pregnant (see Box 1-3 for criteria).

Diaphragm

Diaphragms were widely used when they were one of the only available contraceptive methods. With the introduction of a wider range of contraceptive options, diaphragms have fallen out of favor, though about 5% of contraceptive users still prefer this barrier method. It is highly recommended to add a spermicide when using a diaphragm to increase contraceptive effectiveness.

A new diaphragm, Caya, has been approved for use in the United States and should be available in 2015. This is a single-size, silicone diaphragm that does not require fitting by a health care professional; it has been available in the European Union since 2013. The primary benefit of this birth control method, as cited by the women who use it, is that it is nonhormonal and easy to use, and no fitting is needed. No prescription is required in the European Union except in France and Italy; however, about 30% of users elected to visit their provider to confirm proper fit (Kessel 2014). Caya will require a prescription in the United States.

Patient Education

Patient education should include the full spectrum of contraceptive options, even if some methods are not available from that particular provider or provider site. Information regarding methods of contraception should be presented using a tiered approach, where the most effective methods are presented before the less effective methods. Using tools such as Figure 1-2, and working one's way from the top to bottom, can assist providers in discussing the full range of methods using the tiered approach.

In addition to discussing typical use failure rates with patients and educating them on all contraceptive methods, providers must take great care to communicate the risks associated with those methods. Patients may hear about the serious complications of contraception from popular media or word-of-mouth from friends. As a result, patient perceptions of many methods are fraught with inaccuracies, and providers have an opportunity to rectify patient understanding and knowledge.

Serious adverse events occur at an extremely low frequency among hormonal contraception users. For this reason, adequate evidence is lacking regarding the contribution of risk factors such as smoking, BMI, or family history as they relate to the incidence of venous thromboembolism among hormonal contraceptive users. For example, the baseline risk of stroke in women of reproductive age is very low. Although CHCs increase this risk, there are many ways to express the magnitude of that increase. The absolute risk is expressed as the incidence of the serious adverse event among the denominator, which in this case is either CHC users or CHC nonusers. Then the absolute risk among users can be compared with that of nonusers. However, the relative risk of a serious adverse event would be obtained by dividing the frequency of the outcome in users by the frequency in nonusers. The result would then be expressed as users being that many times as likely to have that serious adverse event compared with nonusers. Relative risk is commonly used when communicating risk, but it is less appropriate for rare events because the denominator is lost in the expression. Patients would benefit most from providers communicating risk using absolute risk using standard denominators, such as 6 in 100, 1000, or 10,000, rather than 1 in 17, 167, or 1667.

Take as an example a hypothetical serious adverse event that occurs in the general population of women not using oral contraceptive pills at a rate of 1 in 333 women. The absolute risk of this event increases to 1 in 167 (or 2 in 333) women who are using oral contraceptive pills. The relative risk of this event is 2 for women using oral contraceptive pills. This can be communicated to the patient as either an absolute risk or a relative risk. Telling the patient she is twice as likely to have this hypothetical event (the relative risk) is not as informative as telling her the event occurs in 3 of 1000 women not taking the pill and 6 of 1000 women taking the pill (the absolute risks).

When discussing the potential serious adverse events associated with contraceptives, providers can compare the absolute risks with those of the absolute risks related

Box 1-4. Recommended Screenings When Providing Contraceptive Services

Screenings for Women

History
- Reproductive life plan
- Medical history
- Current pregnancy status
- Sexual health assessment
- Tobacco use (combined hormonal methods in women ≥ 35 years)

Physical examination
- Height, weight, and BMI (not for eligibility but for monitoring hormonal methods)
- Blood pressure (combined hormonal methods)
- Pelvic examination (initiating diaphragm or IUD)

Laboratory testing
- Pregnancy test (if clinically indicated)
- Chlamydia and gonorrhea

Screenings for Men

History
- Reproductive life plan
- Medical history
- Sexual health assessment

BMI = body mass index; IUD = intrauterine device.
Information from: Gavin L, Moskosky S, Carter M, et al. Providing quality family planning services: recommendations of CDC and U.S. Office of Population Affairs. MMWR 2014;63(RR-4):1-54.

to everyday activities such as death from a motor vehicle crash or the absolute risks of the same adverse event during pregnancy or in the postpartum period. Although the provider's aim is to ensure that contraceptives are used safely, the risks of not using contraception and the resulting consequences must also be considered. It is unlikely that CHCs would present more risk to a patient than the alternative pregnancy she might have.

Another strategy that providers can use to ensure patient understanding of the magnitude of risk is a graphic representation of the absolute risk. The Paling Palette, for example, can be used to compare the absolute risks of different events or under different circumstances (e.g., with CHC vs. pregnancy) using a standard denominator. The palette is useful for showing absolute risks greater than 1 in 1000. For a standard denominator of 1000, a palette could have 20 blocks of 50 circles, stick figures, or other shapes. The provider could then mark off the absolute risk of one rare event (or use different colors for several events), clearly indicating both the chances of developing and not developing that event to the patient.

Practice Management

Developing a New Contraception Service

A business/practice plan should include the following:

- Relationship with other health professionals (e.g., physicians, advanced practice nurses, physician assistants) or offices/clinics to refer patients for services the pharmacist cannot provide (e.g., contraceptive device placement, diaphragm fitting, primary care services, pregnancy options, sexually transmitted diseases screening and treatment)
- Resources that would be needed (e.g., blood pressure monitor, scale, demonstration products)
- Criteria to evaluate the success of a service/clinic (see Quality Measures below)
- Need for practice protocol, either statewide board protocol or collaborative practice agreement

Quality Measures Appropriate for Pharmacist Contraceptive Services

Health outcomes	• Unintended pregnancy • Teen pregnancy • Contraceptive method continuation
Safety	• Providers who are following the most current CDC recommendations on safe use of contraceptives
Effectiveness	• Contraceptive methods available, including emergency contraception
Patient centered	Patient feedback/satisfaction: • Provider communicates well and is helpful • Provider spent enough time with patient • Provider is respectful and nonjudgmental • Services are confidential • Receives contraceptive method (or referral) that is acceptable
Efficient	• Electronic records
Timely	• Average time to next appointment • Walk-in services
Accessible	• Expanded hours • Referral links
Equitable	• Language assistance
Value	• Average cost per patient

Information from: Gavin L, Moskosky S, Carter M, et al. Providing quality family planning services: recommendations of CDC and U.S. Office of Population Affairs. MMWR 2014;63(RR-4):1-54.

Quality Improvement

Healthy People 2020 Goals

The U.S. Department of Health and Human Services Healthy People initiative is now in its third decade. One of the Healthy People 2020 goals is to improve pregnancy planning and spacing and prevent unintended pregnancy. There are 15 specific objectives to achieve this goal. Objectives have numerical targets. For example, the first objective is to increase the proportion of pregnancies that are intended from a baseline of 51% to a target of 56%, which would be a 10% improvement. Other objectives address birth spacing, teen pregnancies, and age at first intercourse, as well as formal instruction and talking to a parent or guardian about abstinence, birth control methods, STDs, and HIV/AIDS prevention. Clearly, family planning is a national public health priority.

Quality Family Planning Services

Whereas the Healthy People goals are population based, the CDC developed guidance for providing quality family planning services in collaboration with the Office of Population Affairs in 2014 (Gavin 2014). These recommendations are to be used by individual providers as well as service sites. Several key recommendations pertain to which services (family planning, related preventive health services, and other primary preventive health services) to provide clients in the context of either a family planning or other visit, how to provide family planning and contraceptive services, how to address the special needs of adolescents, and how to implement a quality improvement program. As the U.S. health care system evolves with expanded insurance coverage, primary care providers and others will be expected to integrate family planning services into their range of services, even when the patient's primary reason for the visit is not family planning. Quality planning services are defined as those that unite safety, effectiveness, a client-centered approach, timeliness, efficiency, accessibility, equity, and value. Box 1-4 lists the

services that should be provided with contraceptive services. However, the delivery of related preventive services should not become a barrier to a client's ability to receive contraceptive services. For pharmacists and pharmacies delivering services, strong referral links will be critical.

When counseling adolescents, abstinence should be promoted as an effective way to prevent pregnancy and STDs. If adolescents indicate that they are or will be sexually active, the provider should provide contraceptive counseling on methods to prevent pregnancy and condoms to prevent STDs. To confirm patient understanding of the most important information relayed, the teach-back method (where patients repeat back what they learned) may be used. Elements of contraceptive counseling should include method effectiveness, correct method use, STD protection, warning signs for serious adverse events and what to do, and when to return for follow-up.

Finally, performance improvement is encouraged as a means to develop and improve metrics reflecting both process and outcomes. Periodic evaluation of metrics (e.g., quarterly) would be judicious in identifying gaps and making improvements.

Conclusion

Many updates in products, clinical guidelines, and service delivery considerations have been made in the past few years. Pharmacists with up-to-date knowledge on the issues surrounding safe and effective contraceptive use and provision of services can help contribute to efforts addressing this health issue, which deserves greater recognition and attention.

Practice Points

In determining the optimal contraceptive method, practitioners and patients should discuss and consider the following:

- Family planning goals and desired duration of pregnancy prevention
- Medical history and blood pressure to determine eligibility for methods
- Perfect and typical use effectiveness of methods
- Noncontraceptive 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

Questions 1–6 pertain to the following case.
S.G., a 22-year-old female college student, presents to the pharmacy seeking a prescription for oral contraceptive pills. Her medical history reveals irregular menses but no chronic conditions that would render contraceptive use unsafe. You counsel her on contraceptive methods, and she is interested in a combined hormonal contraceptive pill but is concerned about long-term exposure to estrogen. After discussing different options, S.G. decides to try the pill with the lowest estrogen content.

1. Which one of the following screening tests is best to administer to S.G. at this time?

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

2. In discussing this contraceptive method's effectiveness with S.G., which measure is the most accurate to use?

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

3. In counseling S.G. on the problems that may be improved with the noncontraceptive benefits of her new medication, which one of the following is most important to include?

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

4. S.G. is counseled on the serious adverse effects of her new medication. Which one of the following is the best measure of risk to communicate to her?

   A. Relative risk.
   B. Absolute risk.
   C. Odds ratio.
   D. Hazard ratio.

5. Which one of the following best represents the number of pill packs you should dispense to S.G., if possible?

   A. 1.
   B. 3.
   C. 4.
   D. 13.

6. One month later, S.G. returns to the pharmacy with complaints of continued menstrual irregularities. You determine she has not been taking her new medication consistently. Which is the best counseling to provide S.G.?

   A. Warn her that this contraceptive method may fail.
   B. Instruct her on correct and consistent use.
   C. Encourage her to consider other contraceptive methods.
   D. Discuss other contraceptive pill formulations.

Questions 7–10 pertain to the following case.
T.M., a 40-year-old mother of one, presents to the women's health clinic for prenatal care during her second pregnancy. This second pregnancy was unintended, and the baby was conceived while T.M. was using the withdrawal method with her partner. You take this opportunity to counsel her on her contraceptive options after this pregnancy.

7. Using the tiered approach, which one of the following contraceptive methods would be best to present first to T.M.?

   A. Diaphragm.
   B. Oral contraceptive pills.
   C. Intrauterine device (IUD).
   D. Injectable progestin.

8. Because she has a neighbor who is happy with an IUD, T.M. asks you about this method of contraception. She expresses her desires to end her fertility after this pregnancy. You counsel her on the long-acting reversible and permanent forms of contraception available to her. She would like the device that prevents pregnancy for the longest duration possible. Which one of the following would best help T.M. achieve and sustain this goal?

   A. Levonorgestrel-releasing device 52 mg (Mirena).
   B. Etonogestrel implant 52 mg (Liletta).
   C. Copper intrauterine device (ParaGard).
   D. Levonorgestrel-releasing device 13 mg (Skyla).

9. Which one of the following complications would be most appropriate to counsel T.M. about regarding the use of an IUD?

   A. Sexually transmitted diseases.
   B. Pelvic inflammatory disease.
   C. Infertility.
   D. Uterine perforation.

10. T.M. decides she would like to have an IUD inserted after she delivers in the hospital. Which one of the following, if experienced by T.M., would be most likely to preclude her providers from inserting the IUD after delivery?

    A. Fever after delivery.
    B. Postpartum hemorrhage.
    C. Epidural use during delivery.
    D. Cesarean section.

Questions 11–13 pertain to the following case.
R.R. is a 29-year-old woman (weight 60 kg) who received a kidney transplant. She presents to the transplant clinic for a routine follow-up. Because this is your first time seeing her, you do a medical history. She tells you that she has always used either oral contraceptive pills or condoms to prevent pregnancy, but she has not been using anything since her transplant 6 weeks ago. You find out that R.R. last had sexual intercourse 2 days ago.

11. Which one of the following would be the most effective form of emergency contraception to recommend for R.R.?

    A. Yuzpe regimen.
    B. Copper IUD.
    C. Ulipristal acetate.
    D. Levonorgestrel.

12. Which one of the following would be the most appropriate form of contraception to discuss with and recommend for R.R. once your are reasonably certain she is not pregnant?

    A. Combined oral contraceptives.
    B. Condoms.
    C. Depot medroxyprogesterone acetate.
    D. Levonorgestrel-releasing IUD.

Questions 13–16 pertain to the following case.
R.P. calls the pharmacy with concerns that she is having nausea and wants to know if she might be pregnant or having some other bad reaction to her contraceptive, product X. She wants to know the chances that her method has failed or whether she is having a serious adverse effect. When asked about adherence, she says she usually takes her birth control on time but that she stopped 3 days ago because she was worried that the hormones were leading to her nausea. After determining which method R.P. is using, you review the product labeling.

13. The package insert for product X states that the failure rate is 0.3% with perfect use and 0.9% with typical use. Which one of the following best describes the category of R.P.'s contraceptive method?

    A. Highly effective.
    B. Combined hormonal.
    C. Progestin-only.
    D. Moderately effective.

14. R.P. is still concerned about a serious adverse effect, problem Y. The package insert states that 572 women among the total 11,593 women in the clinical trial discontinued from the trial because of problem Y. You know that the incidence of problem Y in the general population is about 2%. Which one of the following represents the best way to communicate this information to R.P.?

    A. You are twice as likely to experience problem Y while using product X.
    B. Your risk of problem Y increases by 250% while using product X.
    C. Five of 100 women using product X will experience problem Y.
    D. 572 of 11,593 women using product X will experience problem Y.

15. R.P. tells you she has lost confidence in her birth control method and wants something she can rely on to prevent pregnancy without using hormones. Which method would be best to discuss with R.P.?

    A. Female condom.
    B. Withdrawal.
    C. Diaphragm.
    D. Copper IUD.

16. R.P. wants to know how long she would need to abstain or use a backup method of contraception with each of the above mentioned contraceptive methods. All are used immediately before intercourse except for the copper IUD, which needs to be inserted in advance. Which one of the following best describes the number of days that R.P. would need to use a backup method of contraception for the copper IUD?

    A. 0.
    B. 1.
    C. 2.
    D. 7.

Questions 17–19 pertain to the following case.
A.W. presents to your new pharmacist hormonal contraception service, inquiring about birth control. Her entire family shares the same primary care physician, and A.W. wants to keep her birth control information confidential. She completes the medical history questionnaire but does not want to have her blood pressure measured. A.W. states that her regular physician checked her blood pressure during her last visit, but she does not recall the results.

17. Which one of the following contraceptive methods would be most appropriate to offer A.W.?

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

18. Which physical assessment would be best for monitoring A.W. at this time?

    A. Body fat measurement.
    B. Weight measurement.
    C. Breast examination.
    D. Pelvic examination.

19. Before A.W.'s new contraceptive is initiated, which one of the following would best ascertain that she is not pregnant?

    A. Completing a urine pregnancy test.
    B. Starting her period 4 days ago.
    C. Delivering a baby 6 months ago.
    D. Having no signs or symptoms of pregnancy.

20. A young, nulliparous woman is interested in initiating contraception. Other than preventing pregnancy indefinitely, she would like her method to help with her heavy menstrual bleeding. Which one of the following IUDs would be best to recommend for this patient?

    A. Copper IUD (ParaGard).
    B. Levonorgestrel-releasing device 52 mg (Liletta).
    C. Levonorgestrel-releasing device 52 mg (Mirena).
    D. Levonorgestrel-releasing device 13 mg (Skyla).