

PRN OPINION PAPER

Roles of the Pharmacist in the Use of Safe and Highly Effective Long-Acting Reversible Contraception: An Opinion of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy

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The U.S. population continues to experience an alarmingly high rate of unintended pregnancies that have an impact on individual families and society alike. Lack of effective contraception accounts for most unintended pregnancies, along with incorrect use of contraceptives. The most common reversible contraceptive method used in the United States is the oral contraceptive pill, which has significant failure and discontinuation rates. Use of long-acting reversible contraceptive (LARC) methods has been increasing in recent years after efforts to educate providers and patients. Women are more likely to use LARC methods when barriers such as access and cost are removed. An uptake in the use of LARC methods would allow for markedly reduced contraception failure rates and higher user satisfaction and thus higher continuation rates than those seen with current contraception use. Promoting the use of LARC methods is an important strategy in improving both individual and public health outcomes by reducing unintended pregnancies. The pharmacist's role in family planning is expanding and can contribute to these efforts. Although knowledge regarding LARC has not been studied among pharmacists, a knowledge deficit exists among health care professionals in general. Thus pharmacist education and training should include LARC methods along with other contraceptives. The American College of Clinical Pharmacy Women's Health Practice and Research Network advocates for the pharmacist's role in the use of safe and highly effective LARC methods. These roles include educating patients, informing providers, facilitating access by providing referrals, and modifying institutional procedures to encourage provision of LARC methods.

KEY WORDS long-acting reversible contraception, LARC, intrauterine contraception, intrauterine device, contraceptive implant, health care delivery, pharmacy practice, pregnancy prevention, contraception, pharmacy education.

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More than half (51%) of the 6.6 million pregnancies/year in the United States are unintended.¹ This rate is higher than most developed nations, and although the rate of unintended pregnancies globally has declined almost 20%, the rate in the United States has remained relatively stable for over a decade.² Among U.S. women using contraception, over a third (35%) use their method incorrectly, inconsistently, or with gaps of at least 1 month, resulting in nearly all (95%) of the unintended pregnancies experienced by contraception users.³ The impact of unintended pregnancies extends beyond the women and families involved and results in substantial societal costs. In the United States, 40% of unintended pregnancies result in abortion.¹ Live births from unintended pregnancies cost \$12.5 billion in 2008; of those, 65% were covered under public health insurance programs.⁴

The copper (Cu) T 380A intrauterine device (IUD) (ParaGard Teva Pharmaceuticals, Sellersville, PA), the two levonorgestrel (LNG)-releasing IUDs (Mirena and Skyla [low-dose]; Bayer HealthCare Pharmaceuticals, Wayne, NJ), and the etonogestrel-releasing implant (Nexplanon; Merck, Whitehouse Station, NJ) are the four long-acting reversible contraceptive (LARC) methods currently approved by the U.S. Food and Drug Administration (FDA) and marketed as nonpermanent or reversible methods of contraception. These methods provide 3–10 years of effective contraception after insertion by a trained health care professional, which currently does not include pharmacists.⁵ Table 1 summarizes these LARC methods.^{6, 7} The key advantage of all LARC methods is that effectiveness does not depend on user motivation and adherence.

The distinction between typical use and perfect use is critical when discussing contraceptive efficacy. 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 rather provide an idea of the actual experience of the individual using that method.⁶ With typical use, up to 10% of women using short-acting hormonal contraceptives (i.e., oral contraceptive pills, patch, ring, injectable) experience method failure and become pregnant in the first year.⁶ Patients who use LARC rarely (less than 1%) become pregnant in the first year of use, and therefore LARC methods are considered highly effective.⁶ This 6–10-fold difference in failure rates is not due to differences in the inherent efficacies of each method but rather is due to the ease or difficulty of using the various methods.⁶ In other words, the similarly low typical and perfect use failure rates of LARC methods reflect both efficacy and ease of use.

LARC methods also have higher continuation rates compared with the short-acting hormonal contraceptives at 1 year (78–84% vs 56–68%) and 2 years (77% vs 41%).^{6, 8} These continuation rates reflect user satisfaction. User satisfaction rates after 1 year of use are much higher for LARC (84%) than for short-acting methods (53%).⁹ Among U.S. women using contraception, IUD use has increased from less than 1% in 1995 to 5.6% in 2010.¹⁰ In spite of this, the contraceptive pill remains the most frequently used reversible contraceptive method.¹⁰

The American College of Clinical Pharmacy (ACCP) Women's Health Practice and Research Network (PRN) advocates for an expanded role of pharmacists in the use of safe and highly effective LARC methods. This article reflects the opinions of the Women's Health PRN regarding this expanded role in advocating for and facilitating the use of LARC methods. These roles include educating patients, informing providers, facilitating access by providing referrals, and modifying institutional procedures to encourage provision of LARC methods.

This article represents the opinion of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy (ACCP). It does not necessarily represent an official ACCP commentary, guideline, or statement of policy or position.

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Table 1. Long-Acting Reversible Contraceptive Methods^{6, 7}

Method	Duration, yrs	Adverse effects		Proportion of women experiencing an unintended pregnancy within the first year of typical use	Proportion of women continuing use at 1 year	Average wholesale price for device ^a
		Common	Rare			
Etonogestrel implant	3	Irregular bleeding; implant site reactions	Failed insertion; complicated removal; nerve or blood vessel injury in arm	0.05%	84%	\$791.30
Low-dose levonorgestrel-releasing IUD	3	Lighter bleeding or amenorrhea	Perforation; expulsion; ovarian cysts	Data not available		\$780.38
Levonorgestrel-releasing IUD	5	Lighter bleeding or amenorrhea	Perforation; expulsion; ovarian cysts	0.2%	80%	\$927.18
Copper IUD	10	Heavier, longer bleeding; spotting	Perforation; expulsion	0.8%	78%	\$717.60

IUD = intrauterine device.

^aDoes not include additional costs of office visit or insertion procedure.

Eligibility for LARC Use

In 2010, the U.S. Centers for Disease Control and Prevention adapted the World Health Organization’s Medical Eligibility Criteria (MEC) for Contraceptive Use to include a list of conditions specific to the United States. Development of this tool allows for guidance regarding the safety and effectiveness of the various contraceptive methods for women with conditions that may affect their eligibility to use contraception. LARC meth-

ods do not contain estrogen and thus have considerably fewer contraindications than the more popular short-acting combined hormonal contraceptive methods. A minority of women are not candidates for an IUD and/or implant use due to the conditions listed in Table 2.¹¹ LARC should be discussed and recommended for most patients. Ultimately, user preference dictates which method is selected. LARC methods are the safest and most effective methods of reversible contraception for the general patient population.^{5, 11}

Table 2. Conditions with Unacceptable Health Risk or Risks That Outweigh the Advantages If a Long-Acting Reversible Contraceptive Method Is Used^{a,11}

Unacceptable health risk	Risks usually outweigh advantages
Pregnancy ^b	Migraine with aura ^c (continuation only)
Current breast cancer ^c	History of breast cancer ^c
Cervical cancer ^b	Ischemic heart disease ^c
Endometrial cancer ^b	Stroke (continuation of implant only)
Current pelvic inflammatory disease ^b	Very high individual likelihood of exposure to gonorrhea or chlamydia infection ^b (initiation only)
Current purulent cervicitis or chlamydia or gonorrhea infection ^b	AIDS ^b (initiation only)
Immediately postseptic abortion ^b	Systemic lupus erythematosus with positive or unknown antiphospholipid antibodies (LNG-IUD only)
Postpartum puerperal sepsis ^b	Systemic lupus erythematosus with severe thrombocytopenia (Cu-IUD only)
Pelvic tuberculosis ^b (initiation only)	Severe, decompensated cirrhosis ^c
Unexplained vaginal bleeding, before evaluation ^b (initiation only)	Benign hepatocellular adenoma ^c
Distorted uterine cavity ^b	Malignant hepatoma ^c
Gestational trophoblastic disease with elevated β-human chorionic gonadotropin levels or malignant disease ^b	Complicated solid organ transplantation ^a (initiation only)
	Pelvic tuberculosis ^b (continuation only)
	Unexplained vaginal bleeding, before evaluation (implant only)
	Gestational trophoblastic disease with decreasing or undetectable β-human chorionic gonadotropin levels ^b

AIDS = acquired immunodeficiency syndrome; Cu-IUD = copper intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device.

^aAccording to category 3 or 4 in the U.S. Centers for Disease Control and Prevention Medical Eligibility Criteria for Contraceptive Use.¹¹

^bIUD methods only.

^cProgestin methods only.

Special Patient Populations

Postabortion Patients

Approximately half of U.S. women obtaining an abortion have had at least one other abortion in the past, underscoring the need for effective contraception in this population.¹² LARC use has a profound impact on repeat pregnancies and abortions, resulting in about half as many repeat pregnancies and repeat abortions.^{13–15} Immediate insertion of an LNG-IUD, Cu-IUD, or implant after an abortion has the advantage of ensuring that the patient is not pregnant, eliminating the need for an additional visit for insertion and minimizing time without an effective contraceptive method.¹⁶ IUD insertion immediately after spontaneous or induced abortion is safe and effective.¹⁶ If not inserted immediately after abortion, many women do not return for an insertion visit.¹⁷

Postpartum Patients

Postpartum contraception is essential to prevent unintended pregnancy and short birth intervals because these are two factors associated with adverse maternal and infant outcomes.^{18–20} Women can ovulate as early as 25 days after delivery if not breastfeeding. Early postpartum insertion of LARC is highly favorable and not associated with an increase in complications.^{5, 11, 21} Insertion as early as within 10 minutes and up to more than 4 weeks after delivery of the placenta is safe for LNG- and Cu-IUD (category 1 or 2 in the U.S. MEC) in both breastfeeding and non-breastfeeding women.²² However, the presence of puerperal sepsis is an unacceptable health risk (category 4) for IUD use.²² Insertion of an implant is safe in breastfeeding and nonbreastfeeding postpartum women without other risk factors for venous thromboembolism (category 1 or 2).²² During this postpartum period, women are accessing the health care system more frequently, allowing for more convenient insertion at a time when they desire safe and effective options to avoid or delay another pregnancy.^{20, 23}

Adolescents

LARC is of particular importance to adolescents. The vast majority (82%) of pregnancies among adolescents 15–19 years of age are unintended, creating barriers to education and work opportunities, and resulting in decreased future

earning potential.^{1, 24} Although LARC use is increasing, adolescent use remains relatively low. LARC use increased from 0.3% of women 15–19 years of age in 2002 to 4.5% in 2009.²⁵

Barriers to use of LARC in adolescents result from misinformation and lack of knowledge on the part of both patients and providers, higher upfront costs, and problems with access.^{26–28} Specific (but unfounded) concerns in this population include the fear that IUD use may lead to infertility, elevate the risk of pelvic inflammatory disease (PID), or result in increased expulsion rates.^{5, 29, 30} In fact, tubal infertility has been associated with previous chlamydia infection and not IUD use.³¹ Although the risk of PID increases within 20 days after IUD insertion, this is most likely due to the presence of an existing infection and not related to the IUD itself.³² Because sexually active adolescents are at higher risk of sexually transmitted infections than older women, they should all be screened for chlamydia regardless of the type of contraception they are seeking. Younger age is associated with a slightly increased risk of expulsion, but adolescents are not more likely to discontinue using their IUD compared with older women, and the risk of expulsion should not rule out this method.^{30, 33} Another concern is related to adverse effects on the bone mass acquired during adolescence; however, current LARC methods have not been shown to affect bone mineral density.³⁴ Overall, LARC methods are safe, effective, and should be considered a first-line option for adolescents.^{5, 35}

Patients with Chronic Medical Conditions

The prevalence of chronic disease is increasing among women of reproductive age, resulting in increased pregnancy-associated morbidity and mortality.³⁶ Although pregnancy is not necessarily contraindicated in all patients with chronic disease, LARC methods offer these women a safe and highly effective option to prevent pregnancy. Patients with medical conditions that render pregnancy unsafe for a period of time may also benefit greatly from LARC use. For example, bariatric surgery and solid organ transplant recipients should avoid pregnancy for 12–24 months after their surgeries.^{37–40}

Roles of the Pharmacist

Pharmacists in any practice setting can screen patients for contraceptive needs and identify

patients who may benefit from optimization of their contraceptive method.

Prescribing Authorities

Pharmacists are becoming increasingly important providers of family planning services. For years, pharmacists have been providing emergency contraception directly to patients. Pharmacists' presence in the community is critical given that emergency contraception is now available over the counter, and patients are now more likely to seek medical advice from pharmacists.

Evaluations of pharmacy access to emergency contraception, combined hormonal contraception, and depot medroxyprogesterone have demonstrated safety and patient satisfaction.⁴¹⁻⁴⁶ Women have indicated interest in obtaining their hormonal contraception directly from the pharmacist.⁴⁷ Pharmacists and pharmacy students alike have indicated strong interest in providing hormonal contraception directly to patients, a model supported by physicians and advanced-practice clinicians.⁴⁸⁻⁵⁰ California passed legislation in October 2013 expanding the pharmacist scope of practice to include furnishing self-administered hormonal contraceptives according to a standardized protocol that has yet to be developed and implemented.⁵¹

Reproductive health professionals have anecdotally voiced concerns that patients accessing emergency contraception or self-administered hormonal contraceptives directly at the pharmacy may represent missed opportunities for more effective LARC methods. On the contrary, pharmacists can integrate LARC education and referrals into these expanding practices. Evaluating and documenting the impact of pharmacist contraceptive services, particularly LARC education and referrals, may support optimization, reimbursement, and expanded adoption of these pharmacist-prescribing authorities.

Community Pharmacy Practices

Community pharmacists are easily accessible members of the health care team and the most prevalent providers in rural areas.⁵² Community pharmacists are well positioned to educate patients regarding various contraceptive options including highly effective LARC methods. For example, a patient who presents to the pharmacy requesting oral emergency contraception may be referred for a Cu-IUD, the most effective

emergency contraceptive method, which may be especially important for overweight or obese women.⁵³ However, the pharmacist needs to be aware of which providers are able to place Cu-IUDs and effectively educate the patient about the benefits and risks of Cu-IUDs to decrease misinformation and fears regarding use. This model has been implemented in England, and uptake of the Cu-IUD nearly tripled for women seeking emergency contraception in pharmacies after an educational intervention with community pharmacists.⁵⁴ As part of this effort in England, accredited pharmacists completed an online module and a 2-hour live course that emphasized using the Cu-IUD as first-line therapy due to high efficacy compared with hormonal emergency contraceptives. Once patients were identified for Cu-IUD emergency contraceptive use, a referral form that included the patient's name, address, phone number, and pertinent clinical information was either faxed directly or taken by the patient to her sexual health clinic of choice for immediate assessment and placement. The National Health Service funded the various methods of emergency contraception, which is the primary mechanism throughout the United Kingdom. Because emergency contraception is not universally available in the United States at no cost to patients who need it at this time, the generalizability is somewhat limited; however, qualifying patients could be referred to centers that offer low- or no-cost family planning services and contraceptive methods.

Pharmacists also play an important role in chronic disease management, representing another important opportunity to provide LARC counseling and referrals. For instance, a pharmacist in a community setting may recommend LARC for a patient seen for diabetes mellitus management who is not satisfied with her current contraceptive method and, further, make a referral to a provider for LARC. One important consideration for community pharmacies is making available a private area for discussing confidential or sensitive matters. Currently, most community pharmacies have a public or semiprivate patient counseling area.⁵⁵

Collaboration and support from other health care providers is essential for clinical pharmacy services to be successful.⁵⁶ Local health departments and family planning clinics are ideal partners.⁵⁶ Collaborative practice agreements with individual practitioners or those in specialty clinics may facilitate patient access as well.

Health-System Pharmacy Practices

Health-system pharmacists are medication experts who have a vital role in intervening with both patients and prescribers to provide education, referrals, and recommendations. In collaboration with other members of the health care team, hospital pharmacists can help create systems for postpartum LARC insertion prior to hospital discharge because LARC is safe to use while breastfeeding. Pharmacists can also ensure that patients with conditions in which pregnancy is contraindicated are provided with adequate education regarding LARC options. Pharmacists can help create systems to ensure that women presenting to the emergency department after sexual assault are offered referrals for Cu-IUDs for emergency contraception as part of their standard care. These are a few examples of initiatives to facilitate the use of LARC.

As previously discussed, some patients have chronic medical conditions that preclude use of combined hormonal contraception. These patients may be seen by a pharmacist in an ambulatory care clinic who can educate and refer for complex contraceptive services. Opportunities for pharmacist intervention include patients with venous thromboembolism (VTE), diabetes that is longstanding or with complications, hypertension, inflammatory bowel disease, ischemic heart disease, stroke, lupus, solid organ transplantation, human immunodeficiency virus infection, and bariatric surgery.¹¹ Pharmacists may recommend LARC to patients and prescribers when they identify patients taking medications that may interfere with their contraceptive's effectiveness (Table 3).⁵⁷ Clinical pharmacy services can be integrated into clinics caring for these high-risk patients as well as in women's or reproductive health clinics to ensure that this element of the patient's care is addressed adequately. Pharmacists practicing in these clinics can and should

refer patients to the appropriate providers to evaluate candidacy and insertion of LARC. Anticoagulation clinic pharmacists, for example, may intervene and recommend LARC. Combined hormonal contraceptives are contraindicated in women who have either a VTE or an elevated risk of VTE; LARC is an excellent option that pharmacists can recommend for these patients. Assessment of contraception use in women of reproductive potential may be a standard element of the initial evaluation, routine monitoring, and patient education provided by clinic pharmacists.

The passage and implementation of the Patient Protection and Affordable Care Act provides numerous opportunities for pharmacists in all care settings to increase their role in chronic disease management. New opportunities include expanded medication therapy management programs and increased funding for integrated interdisciplinary care models.⁵⁸ Family planning and contraceptive services should be integrated as pharmacists continue to expand their role in chronic disease management.

Cost Considerations

LARC cost is a significant barrier to its use.⁵⁹ Federal and state policies may limit the funding of contraceptive services available, including in facilities providing abortion services.⁶⁰ Women are more likely to select a LARC method over other contraceptive methods when cost considerations are removed.^{61, 62} LARC is associated with higher initial costs; however, LARC is more economical after 1 year due to lower failure and pregnancy rates.⁶³

Pharmacists need to be familiar with expected costs of contraceptive methods as well as resources available for patient assistance. As of August 1, 2012, insurance coverage for LARC expanded in the United States with the Affordable

Table 3. U.S. Medical Eligibility Criteria for Contraceptive Use with Concurrent Use of Select Interacting Medications^{11, 57}

Concurrent medication	Combined hormonal contraceptives	Long-acting reversible contraceptives	
		Etonogestrel-releasing implant	Copper or levonorgestrel-releasing intrauterine devices
Certain anticonvulsants (barbiturates, carbamazepine, phenytoin, primidone, oxcarbazepine, topiramate)	3 ^a	2 ^a	1
Lamotrigine	3 ^a	1	1
Rifampicin or rifabutin therapy	3 ^a	2 ^a	1
Ritonavir-boosted protease inhibitors	3 ^a	2 ^a	2 or 3 ^a

1 = no restriction (method can be used); 2 = advantages generally outweigh theoretical or proven risks; 3 = theoretical or proven risks usually outweigh the advantages; 4 = unacceptable health risk (method not to be used).

^aRefer to the complete U.S. Centers for Disease Control and Prevention Medical Eligibility Criteria for Contraceptive Use¹¹ for details.

Care Act to include all FDA-approved contraceptive methods, which include LARC, prescribed for a woman by her health care provider without patient cost sharing.⁶⁴ Intrauterine and implantable devices may be covered under either pharmaceutical or medical device coverage, so pharmacists may or may not be involved in purchasing and dispensing, unlike other contraceptive options. This difference in coverage between various contraceptive options could potentially result in confusion for both patients and providers. Because pharmacists and pharmacy staff often help patients and providers navigate prescription insurance coverage issues, they should be prepared to assist with LARC coverage, regardless of how they may be covered.

Pharmacist Education, Training, and Assessment

Although pharmacists are unlikely to dispense LARC, they have a responsibility to maintain up-to-date knowledge regarding the safety and effectiveness of these products that allows them the best opportunity to educate providers and patients. Contraception is typically included to a varied extent in pharmacy school curricula, postgraduate training, continuing education programs, and board-certification examinations. LARC should be included as a critical component of contraception-related education, training, and competency assessments.

Although the American Association of Colleges of Pharmacy Women's Health Curriculum Task Force includes contraception as a core database in its recent report, and ACCP designates contraception and fertility as a tier IA status on its pharmacotherapy didactic curriculum toolkit, neither actually elaborates on LARC methods.^{65, 66} A specific focus on LARC is recommended as part of the women's health module in required pharmacotherapy curricula.

Experiential education for student and resident trainees—such as elective advanced pharmacy practice experiences in family planning clinics or other relevant settings—can reinforce knowledge, achieve competency, and increase confidence in educating patients regarding LARC.

Currently, the Board of Pharmacy Specialties lists contraception under the content outline of both the Ambulatory Care Pharmacy and Pharmacotherapy specialty certification examinations.⁶⁷ These examinations, and thus preparatory materials, should specifically address LARC.

The Association of Reproductive Health Professionals (www.arhp.org) and the Reproductive Health Access Project (www.reproductiveaccess.org) provide resources and continuing education for contraception. The ACCP Women's Health PRN regularly includes contraception in its educational sessions at the ACCP annual meetings. Other pharmacy professional associations include contraception in their educational programming as well. Pharmacists should be able to look to their professional associations, including local and state chapters, for relevant educational programs.

Little is known about pharmacists' knowledge in this domain. However, significant knowledge gaps regarding LARCs have been documented among other health care professionals including identifying appropriate candidates and providing accurate adverse-effect counseling.⁶⁸⁻⁷¹ Misconceptions about IUD safety are associated with infrequent device provision.⁶⁹ Education targeting health care professionals is warranted, particularly with regard to use in nulliparous women.⁶⁹ Provider training has been found to increase provision.⁷² Assessment of pharmacists' knowledge, attitudes, and service delivery issues will be an important step in designing future training, education, and research endeavors.

Conclusion

The Cu-IUD, two LNG-IUDs, and the etonogestrel-releasing implant are four LARC methods that are safe and highly effective in preventing pregnancy. These options, unlike more commonly used methods such as the oral contraceptive pill, have the advantage of not depending on user motivation or adherence. The risks and benefits of LARC methods must be evaluated to establish candidacy for use. Patients should be presented with information to allow for an informed choice regarding the most suitable method. Increasing the use of LARC may help reduce rates of unintended pregnancy, leading to improved individual and public health outcomes.

The ACCP Women's Health PRN advocates for an expanding role of pharmacists in advocating for and facilitating the use of LARC methods. Adequate education, training, and assessment will ensure pharmacist competency. Pharmacists are well positioned to intervene with patients at risk for unintended pregnancy, whether it is due to inconsistent or incorrect contraceptive use or a concurrent medication or condition that renders other methods inappropriate, among other

situations. Pharmacists frequently interact with patients and thus have the opportunity to discuss effective contraception in scenarios such as patients presenting to a community pharmacy for emergency contraception, to a hospital for labor and delivery, or to a clinic for chronic disease state management. The pharmacist's roles include educating patients, informing providers, facilitating access by providing referrals, and modifying institutional procedures to encourage provision of these highly safe and effective contraceptive methods.

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