

Role of the community pharmacist in emergency contraception counseling and delivery in the United States: current trends and future prospects

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Abstract: Women and couples continue to experience unintended pregnancies at high rates. In the US, 45% of all pregnancies are either mistimed or unwanted. Mishaps with contraceptives, such as condom breakage, missed pills, incorrect timing of patch or vaginal ring application, contraceptive nonuse, forced intercourse, and other circumstances, place women at risk of unintended pregnancy. There is a critical role for emergency contraception (EC) in preventing those pregnancies. There are currently three methods of EC available in the US. Levonorgestrel EC pills have been available with a prescription for over 15 years and over-the-counter since 2013. In 2010, ulipristal acetate EC pills became available with a prescription. Finally, the copper intrauterine device remains the most effective form of EC. Use of EC is increasing over time, due to wider availability and accessibility of EC methods. One strategy to expand access for both prescription and nonprescription EC products is to include pharmacies as a point of access and allow pharmacist prescribing. In eight states, pharmacists are able to prescribe and provide EC directly to women: levonorgestrel EC in eight states and ulipristal acetate in seven states. In addition to access with a prescription written by a pharmacist or other health care provider, levonorgestrel EC is available over-the-counter in pharmacies and grocery stores. Pharmacists play a critical role in access to EC in community pharmacies by ensuring product availability in the inventory, up-to-date knowledge, and comprehensive patient counseling. Looking to the future, there are opportunities to expand access to EC in pharmacies further by implementing legislation expanding the pharmacist scope of practice, ensuring third-party reimbursement for clinical services delivered by pharmacists, and including EC in pharmacy education and training.

Keywords: pharmacist, community pharmacy, emergency contraception, levonorgestrel, ulipristal acetate, intrauterine device

Introduction

Women and couples continue to experience unintended pregnancies at high rates. In the US, 45% of all pregnancies are unintended, either mistimed or unwanted.¹ Nearly all (95%) of unintended pregnancies are due to nonuse or incorrect/inconsistent use of contraception.²

Condoms and oral contraceptive pills remain the most commonly used methods of contraception in the US, with typical use-failure rates of 18% and 9%, respectively, in the first year of use.³ Both of these commonly used contraceptive methods have potential for mishaps, such as condom breakage and missed pills. Such mishaps as these, in addition to contraceptive nonuse, forced intercourse, and other circumstances,

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place women at risk of unintended pregnancy. There is a critical role for emergency contraception (EC) in preventing unintended pregnancies.

EC is any form of contraception, hormonal or nonhormonal, that prevents pregnancy after sexual intercourse. There are currently two methods of EC approved by the US Food and Drug Administration (FDA) and a third that is used off-label (see Table 1). Previously, there was a dedicated combination EC product and some combination oral contraceptives used in larger doses for EC, known as the Yuzpe regimen. The Yuzpe regimen fell out of favor, because it was less effective than methods available currently and was associated with increased adverse effects, such as nausea, vomiting, and breast tenderness.

Use of EC is increasing over time, due to wider availability and accessibility of EC methods. Whereas only 1% of women of reproductive age had ever used EC in 1995, 11% had as of 2006–2010.⁴ Among women who have used EC, most (59%) have only used it once, 24% have used it twice, and 17% have used it three or more times.⁴ EC users are more likely to be young, never married, and have some college education.⁴ Similarly, in the last decade, EC use has increased from 8% of teens in 2002 to 22% of teens in 2011–2013.⁵ A recent study among uninsured adolescents found a high rate of EC awareness and low EC knowledge.⁶ Increasing EC use

is due in part to new products being approved (ie, ulipristal acetate [UPA]) and changing regulations on existing products, namely removal of age and identification restrictions for over-the-counter (OTC) levonorgestrel.

To increase knowledge and use of EC, one strategy utilized has been expansion of access points for both prescription and nonprescription products to include pharmacies. Direct access to prescription drugs from pharmacists is called pharmacist prescribing or pharmacy access. See explanations for the various models of access in Table 2. In eight states, pharmacists are able to prescribe and provide EC directly to women (Table 3). This paper aims to review the role of the community pharmacist in EC counseling and delivery in the US. Historical and current trends are reviewed, then future prospects and opportunities presented.

Trends

Levonorgestrel

The first dedicated progestin-only EC product was approved in the US in 1999 by the FDA. The effectiveness of levonorgestrel EC products for preventing pregnancies is up to 89%, and is primarily thought to be due to the suppression of ovulation. Other possible mechanisms of action include thickening of cervical mucus and prevention of sperm transport.^{7–9} Effectiveness is greater the sooner levonorgestrel EC is taken after unprotected intercourse, and declines with time.^{7,10} The first dedicated product consisted of two tablets of 0.75 mg levonorgestrel, each to be taken 12 hours apart. Soon after FDA approval, the manufacturer pursued switching the

Table 1 Overview of emergency contraception methods

	Levonorgestrel	Ulipristal	Copper IUD
Time frame	As per package labeling for up to 72 hours, but off-label up to 120 hours	Up to 120 hours	Up to 120 hours
Dose	1.5 mg	30 mg	380 mm ²
Effectiveness^a	89%	94%	99%
Adverse effects (>10%)	Nausea, abdominal pain, fatigue, headache, menstrual bleeding changes, dizziness, breast tenderness	Headache, abdominal pain, nausea	Bleeding, pain
Drug interactions	None	CYP3A4 inducers and progestin-containing contraceptives reduce effectiveness	None
Access	OTC or Rx	Rx only	Rx only, placed by trained clinician

Notes: ^aEffectiveness results vary between studies. These values are approximate.
Abbreviations: IUD, intrauterine device; OTC, over-the-counter; Rx, prescription.

Table 2 Models of access to emergency contraception in the US

Model	Description
Prescription only	Approved as a prescription drug by the FDA.
Pharmacist prescribing	Approved as a prescription drug by the FDA and available directly from a pharmacist without a prior prescription, either under a statewide authority or collaborative practice agreement with a prescriber. The pharmacist initiates the prescription, and can dispense the medication. This is a de facto category allowed by state laws, and not recognized by the FDA. Also known as pharmacist-initiated or pharmacy access.
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.

Abbreviation: FDA, US Food and Drug Administration.

Table 3 States allowing pharmacist prescribing of EC

State	LNG	UPA	Legislative details
Alaska ^a	Yes	Yes	Pharmacists may initiate EC under a state BOP regulation, AAC 52.240, with a written protocol agreement between a pharmacist and physician. This is a broad policy, which does not specifically include or exclude EC. Training: pharmacist-training requirements must be included in the collaborative practice agreement between the prescriber and the pharmacist, and approved by the state BOP.
California ^b	Yes	Yes	Pharmacists may initiate EC for women of all ages under state BOP regulation CCR 16-1746. The pharmacist must provide the patient with a state BOP-approved EC fact sheet. Training: completion of a minimum of 1 hour of accredited continuing education specific to EC.
Hawaii ^c	Yes	Yes	Pharmacists may initiate EC under state BOP regulation HAR 16-95-130, with a written protocol agreement between a pharmacist and physician. UPA is not specifically included in this state's EC protocol; however, "drugs approved for emergency contraception are not limited to this [protocol] list". Hawaii BOP staff state that the current EC protocol appendix is under review. Training: completion of an accredited training program that must include the following: <ul style="list-style-type: none"> • protocol procedures (of the Hawaii BOP regulations listed above) • management of the sensitive communications often encountered in EC • providing service to minors • quality assurance • referral for additional services • documentation
Maine ^d	Yes	Yes	Pharmacists may initiate EC under state BOP regulation MRS 32-12-13821, with a written protocol agreement between a pharmacist and physician. The pharmacist must provide the patient with a state BOP-approved fact sheet. Training: completion of an accredited training program that must include the following: <ul style="list-style-type: none"> • conduct of sensitive communications • quality assurance • referral to additional services • documentation
Massachusetts ^e	Yes	Yes	Pharmacists may initiate EC under state BOP regulation 2006-1, with a written protocol agreement between a pharmacist and physician. Training: completion of a minimum of 2 hours of accredited continuing education, which must include the following: <ul style="list-style-type: none"> • referring patient for additional service and follow-up • quality assurance • proper documentation
New Hampshire ^f	Yes	Yes	Pharmacists may initiate EC under a state BOP regulation, 318:16-a, with a written protocol agreement between a pharmacist and physician. This is a broad policy, which does not specifically include or exclude EC. Training: pharmacist-training requirements depend on the service provided, and must be included in the collaborative practice agreement between the prescriber and the pharmacist and approved by the state BOP.
New Mexico ^g	Yes	No	A section of the current state BOP regulation, NMAC 16.19.26.10 of the Pharmacist Prescriptive Authority Act allows pharmacists to "issue a prescription for emergency contraceptives". However, the protocol does not include UPA. New Mexico Board of Pharmacy staff state that a new hormonal contraception protocol is under review, which includes a proposal for UPA. Training: NA
Vermont ^h	No	No	Notes: Previous state BOP regulations that allowed pharmacists to initiate EC, VSA 26.036.2077–2079, expired May 2015. Pharmacists are no longer permitted to initiate prescription-only EC under a protocol in this state. Training: NA
Washington ⁱ	Yes	Yes	Pharmacists may initiate EC under state BOP regulation WAC 246-863-100, with a written protocol agreement between a pharmacist and physician. This is a broad policy, which does not specifically include or exclude EC. Training: requirements must be included in the collaborative practice agreement between the prescriber and the pharmacist, and approved by the state BOP.

Notes: Regulations can be found at: ^a<https://www.commerce.alaska.gov/web/cbpl/professionallicensing/boardofpharmacy.aspx>; ^bhttp://www.pharmacy.ca.gov/laws_regs/lawbook.pdf; ^c<http://cca.hawaii.gov/pvl/boards/pharmacy>; ^d<http://www.maine.gov/pfr/professionallicensing/professions/pharmacy/contactus.html>; ^e<http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/licensing/e-mail-the-board.html>; ^f<https://www.nh.gov/pharmacy/aboutus/staff.htm>; ^g<http://www.rld.state.nm.us/boards/pharmacy.aspx>; ^h<https://www.sec.state.vt.us/professional-regulation/list-of-professions/pharmacy/board-members.aspx>; ⁱ<http://www.doh.wa.gov/aboutus/programsandservices/healthsystemsqualityassurance/contactus>.

Abbreviations: EC, emergency contraception; LNG, levonorgestrel; UPA, ulipristal acetate; BOP, Board of Pharmacy; NA, not applicable; AAC, Alaska Administrative Code; CCR, California Code of Regulations; HAR, Hawaii Administrative Rules; MRS, Maine Revised Statutes; NMAC, New Mexico Administrative Code; VSA, Vermont Statutes Annotated; WAC, Washington Administrative Code.

product to OTC in 2003. It took several years to overcome politically charged hurdles before approval was obtained in 2006 for OTC status for women and men aged 18 years and older with government-issued identification.¹¹

With the 2006 FDA approval of brand levonorgestrel for OTC sales for consumers aged 18 years and older, the medication itself was kept behind the pharmacy counter and required a visit to a pharmacy and an interaction with a pharmacy employee to purchase it. In addition, government-issued photo identification was required to prove the age of the consumer. In 2009, following a federal court case, the minimum age to obtain EC OTC was lowered from 18 to 17 years. Ultimately, after another legal challenge, in 2013 the FDA removed the age restriction. See Figure 1 for a timeline of levonorgestrel EC.

Before levonorgestrel EC became available OTC, multiple states (Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Vermont, and Washington) passed legislation allowing pharmacists to prescribe EC and improve access. Since this time, New Hampshire and Vermont have allowed their legislation to expire; however, the authority may be incorporated into future legislative proposals for pharmacist prescribing of hormonal contraceptives. Pharmacist prescribing of EC enabled pharmacists who underwent additional training under individual collaborative or statewide protocols to prescribe and dispense EC directly to patients. Studies examining availability of and access to EC through pharmacist prescribing have shown variable results and persistent barriers to access, in particular for adolescents.

A study in California found that English- and Spanish-speaking adolescents who called pharmacies listed as participating in pharmacist prescribing of EC (listings on www.ec-help.org) inquiring about anything that could be taken after

unprotected sex to prevent pregnancy were told to come in to obtain EC 48% and 28% of the time, respectively.¹² A 2012 study found that although EC was available at a majority of pharmacies (80%), adolescent mystery callers posing as 17-year-olds were only given the correct information about age requirements half the time, and misinformation was more common in low-income neighborhoods.¹³ More recent studies have also shown persistent barriers to access. A minority (20%) of Colorado pharmacies had EC in stock and on the shelf in 2014.¹⁴ A study published in 2016 that examined availability and access in community pharmacies in Wyoming showed that although 88% of pharmacies stocked EC, only 16% had it in stock and on the shelf.¹⁵

While levonorgestrel EC pills have been available with a prescription for over 15 years, multiple studies have shown that physician knowledge and prescribing of EC is not ideal and there is an opportunity for pharmacists to fill the gaps. A recent national multispecialty survey found that while 95% of health care providers had heard of levonorgestrel, providing it to patients was not as common. Family medicine (69%) and emergency medicine (74%) providers self-reported higher rates of providing levonorgestrel to their patients when compared to internal medicine (42%) and pediatrics (55%).¹⁶ Studies of pediatric emergency department providers have shown further evidence of knowledge deficits and underutilization of EC in emergency department settings.^{17,18} A survey of family medicine physicians found that in 1 year, an average of 3.3 EC prescriptions were written and only 63% correctly answered the question regarding the timeframe in which EC should be taken.¹⁹ A national survey of obstetrician–gynecologists found that only half (51%) offered EC to all women and a small proportion (6%) never offered it or only offered it after sexual assault (6%).²⁰

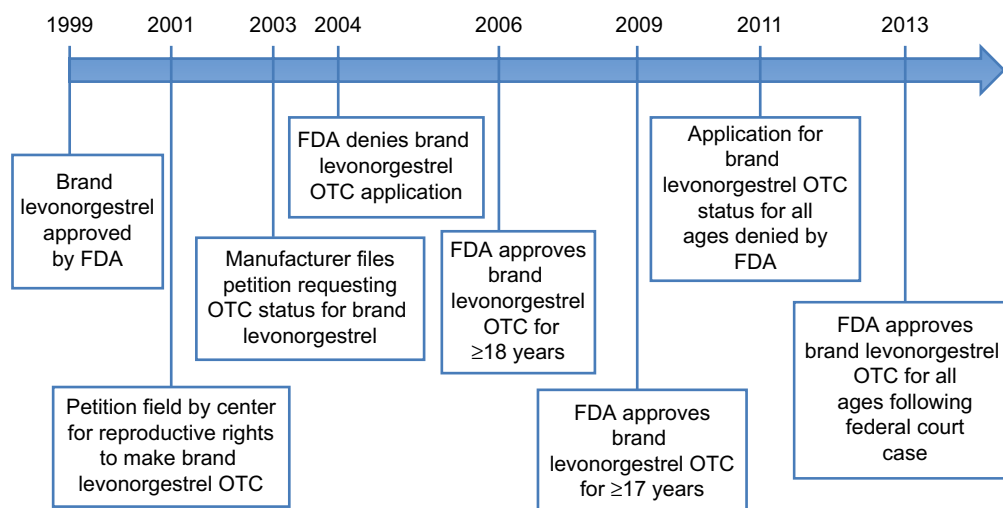


Figure 1 History of levonorgestrel EC. Data from^{65,66}

Abbreviations: EC, emergency contraception; FDA, US Food and Drug Administration; OTC, over-the-counter.

Though pharmacists are accessible providers for patients seeking information and care regarding EC, some pharmacists also have knowledge deficits regarding levonorgestrel EC. Past reports in the media and medical literature have described pharmacists as uneducated regarding EC and unwilling to dispense or stock EC.^{21–25} However, as levonorgestrel EC availability has grown, so has pharmacist knowledge and awareness increased. Other literature has been published showing pharmacists as more educated and engaged in the provision of levonorgestrel EC.^{26–28}

Pharmacists as accessible health care providers should be knowledgeable regarding different methods of EC. One study found that the most important predictor of pharmacists' dispensing EC was individual pharmacists' understanding correct information about EC, particularly mechanism of action.²⁹ Recent regulatory status changes, including the elimination of a minimum age for OTC sales of levonorgestrel EC, make the pharmacist's role in provision of EC education to patients more crucial than before. Studies have shown that a brief pharmacist-driven counseling session about EC had a positive effect on patients' knowledge of EC and that EC counseling is feasible in a retail pharmacy setting.^{30,31} Given the influence that pharmacists may have on educating patients regarding EC, pharmacists should understand and be able to counsel on the proper use, side effects, advanced provision, and effectiveness of EC.

Women presenting within 120 hours of unprotected intercourse should be offered EC. There is some debate regarding possible decreased effectiveness of levonorgestrel in women with a body mass index (BMI) of 25 kg/m² or greater.^{9,32,33} The FDA is asking for more data, and at this time has not recommended any labeling changes for levonorgestrel EC in women with higher BMI. There are some recommendations, however, regarding women with BMI >25 that include referrals for UPA or copper intrauterine device (IUD) and for those with a BMI >35 to be referred to a trained provider for a copper IUD, if accessible in a timely fashion. Women with higher BMI should not be denied levonorgestrel or UPA EC, but should be made aware of the possible decrease in effectiveness and referred for optimal pregnancy prevention.⁹

Ulipristal acetate

The availability of OTC levonorgestrel has opened the door for other prescription EC products to be available via pharmacist prescribing, such as UPA, known by the brand name Ella (Afaxys Inc, Charleston, SC, USA). This form of EC works as a progestin receptor antagonist, delaying or

inhibiting ovulation when taken.^{34,35} UPA is a 30 mg tablet that is taken once within 120 hours after unprotected sex to prevent pregnancy. Given its different mechanism of action compared to levonorgestrel EC, its efficacy does not decrease with time. Therefore, it works equally well on day 1 after unprotected sex as it does on day 4.³⁶

UPA was approved for use as EC in the US in August 2010, and sales began in December of that year. However, in 2014 there were significant UPA access issues when the sole US distributor discontinued this product. The manufacturer then partnered with a new distributor.³⁷ Unfortunately, as a result of this disruption in the supply chain, there was approximately 1 year where major drug wholesalers were unable to obtain and distribute UPA to retail pharmacies.³⁸ The resulting shortage likely slowed integration of this product in clinical practice, because even if patients were able to obtain a prescription, they were unable to fill their prescription at the pharmacy. Additionally, while the company did promote UPA to health care providers once it was readily available through the supply chain again, it is reasonable to assume that some providers and patients were or still are unaware that UPA is again available in pharmacies.³⁸

Ultimately, there are many factors that play into pharmacy-stocking practices, but lack of consumer demand for a product is likely a significant component. A 2016 study demonstrated that the majority of clinicians were unfamiliar with UPA as EC, with only 50% of reproductive health providers and 15% of emergency medicine providers reporting that they were familiar with UPA.¹⁶ Additionally, if patient and providers demand is low, it is less likely that the drug will be readily stocked in pharmacies. In a mystery caller study conducted in Hawaii in 2013–2014, 198 pharmacies were called and only 2.6% of pharmacies had UPA immediately available, although an additional 22.8% reported ability to order UPA and 82% had levonorgestrel in stock.³⁹ Another study conducted by Brant et al in Massachusetts in 2013 used a mystery caller to determine availability of Ella in 100 community pharmacies, of which 89% had levonorgestrel EC in stock compared to only 7% of pharmacies that had UPA in stock.⁴⁰ This disparity in EC product availability may be related in part to the previous disruption to the UPA supply chain.³⁹ In summary, these data suggest that although UPA is more effective than levonorgestrel as EC, most clinicians are not prescribing and may not be aware of UPA EC, and it is rarely immediately available in the pharmacy.

UPA remains prescription only, and seven states allow pharmacists to prescribe it under a collaborative practice agreement or statewide protocol. It is also available through several telemedicine providers and online pharmacies. These

online providers do not require a face-to-face visit with a providers to obtain a prescription; instead, the patient is asked specific screening questions and the online pharmacy collaborates with a licensed prescriber and pharmacist to prescribe, fill, and ship UPA to the patient's home.^{41,42} However, these online pharmacies are unable to ship to certain states.⁴² Purchase from an online provider may be slightly more expensive, but may still be a valuable resource for many patients who are otherwise unable to access EC. This option is best for those who want to keep EC on hand for future use, rather than urgent use following an act of unprotected intercourse.

Lastly, studies have found that pharmacists may also benefit from additional training regarding UPA for EC. The Massachusetts study revealed that pharmacy staff members often provided incorrect information regarding UPA EC, as only 25% were able to identify Ella was the superior oral EC product 72–120 hours after intercourse.⁴⁰ Regarding EC in general, only 21% of pharmacy staff gave completely medically accurate information, while 30% gave a “mixture of accurate and inaccurate” information and 34% gave “mostly inaccurate” information.⁴⁰

Copper IUDs

Nonhormonal copper-containing IUDs have been used for EC for at least 40 years.⁴³ In the US, the copper IUD has been available since 1988. Contraception is effective immediately after IUD placement.⁴⁴ The most commonly reported adverse effects associated with this IUD are abnormal menstrual bleeding and increased frequency and/or intensity of cramps and pain. The benefit of using this method of EC is the continued contraception, which lasts 10 years, although evidence suggests that copper IUDs are highly effective up to 12 years.⁴⁵ Although progestin-releasing hormonal IUDs are available (Mirena®, Skyla®, Liletta®, and Kyleena®), none of these has been studied as EC. There has been one study evaluating pregnancy rates after the use of levonorgestrel EC and concomitant placement of a levonorgestrel IUD following unprotected intercourse.⁴⁶

Various mechanisms of action have been suggested for the IUD. Prefertilization effects, including decreased sperm motility and viability, change in the speed of ovum transport, and damage or destruction of the ovum, are the likely mechanisms of the copper IUD.⁴⁷ Postfertilization effects including damage and/or destruction of the fertilized ovum are additional possible mechanisms.⁴⁸ Both prefertilization and postfertilization effects occur prior to implantation.⁴⁴

A systematic review reported that copper IUDs are the most effective method of EC, with a failure rate of less than

one per thousand.⁴⁹ This compares favorably to the reported failure rates of UPA and levonorgestrel. Unlike other methods of EC, the efficacy of the copper IUD appears to be unaffected by the user's BMI, time of menstrual cycle at insertion (after a negative urine pregnancy test), or additional acts of unprotected intercourse after placement.⁵⁰ In addition to its superior efficacy, the IUD does not require ongoing efforts for proper use either.

The costs of IUDs have been a barrier to their use, for both patients and providers. Prices for an IUD typically range between US\$500 and \$1,000, in addition to provider visits for insertion, removal, and confirmation that the device was properly placed.⁵¹ While many insurance plans have covered IUDs for years, prior to passage of the Affordable Care Act (ACA), women were likely to have out-of-pocket charges for the product and the associated visits. The ACA mandates coverage for the copper IUD without cost sharing. The ACA has eliminated these costs for many women. It remains to be seen if the ACA leads to increases in the use of the copper IUD as a form of contraception, including EC.⁵² The pharmacist's role pertaining to the copper IUD as EC is primarily in providing comprehensive counseling to women so they are aware of all of their options, as well as providing referrals to providers who can provide same-day or timely insertions.

Little is known about pharmacists' knowledge of copper IUDs as EC; however, several studies have reported misconceptions of other health care providers regarding IUDs. A 2013 survey found that 33% of obstetrician–gynecologists who provide IUD services believed that this method of contraception is inappropriate for nulliparous women, and 57% believed IUDs should not be used in adolescents.⁵³ Further, this study found that 26% of participants did not agree that the copper IUD can be used as EC.⁵³ Currently, both the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics promote IUD use as a first-line contraceptive option for all women, including young women and those who have never been pregnant.^{54,55} There is an inverse relationship between the effectiveness of various EC methods and pharmacist involvement, where pharmacists have the largest role with levonorgestrel.

Future prospects

Payment for pharmacist services

As the scope of practice for delivering clinical services expands for pharmacists, payment for the provision of these services must be received and models for payment sustainable. In a recent systematic review of payment to pharmacists for patient care, a majority (73%) of compensated or

remunerated clinical services were paid for by government agencies, with the remainder funded by private insurance plans.⁵⁶ This highlights the importance of obtaining support at the federal level for payment of pharmacist EC services, such as patient visits where EC is prescribed. The concept of payment for chronic care-management services has been addressed by the Centers for Medicare and Medicaid Services, but clarity for EC services has not been provided.⁵⁷

Given that services for EC may not typically involve full medication review (or comprehensive medication management), time-dependent reimbursement may be most appropriate. This time would include screening and counseling to identify the most appropriate EC method, instructing patients about the proper use of EC, and potential discussion of routine contraceptive methods. In 2014, an evaluation of 60 remunerated pharmacist clinical care programs worldwide indicated time-dependent fees were reimbursed at \$93.60 per hour.⁵⁶

Pharmacy education to include advance provision

Pharmacists must have the knowledge and confidence to provide information to patients regarding various methods of EC, their effectiveness, and how to use them properly. Studies have demonstrated gaps in pharmacist knowledge that may result in incorrect information or advice given to patients seeking EC.^{15,58,59} Furthermore, education is needed to allow access to EC in a timely manner.^{15,60} In one small study, educating pharmacists about the use of the copper IUD for EC increased referral and uptake by women of the copper IUD almost threefold.⁶¹ Suggestions to improve knowledge and behavior include standardized protocols at the community pharmacy when patients are seeking EC, updated training (eg, continuing professional education) of pharmacists, and mandatory private consultation areas to enhance the counseling environment. These types of educational initiatives have the potential to reduce unintended pregnancies now and in the future.

Additionally, advance provision of EC may increase timely use. Pharmacists should be educated to inform women and men of having EC available prior to occasions when sexual intercourse is unprotected or underprotected. EC can be purchased online for privacy and at low cost, but is not a viable option for immediate use. Furthermore, caution should be used with online purchases, as EC products may be fraudulent. In a systematic review of 17 articles, any use of EC pills was found to be two to seven times greater among women who received an advance supply of EC pills. However,

four randomized controlled trials did not show a significant reduction in unintended pregnancy over 12 months when advance provision was compared with standard provision of EC (risk ratio = 0.9, 95% confidence interval: 0.69–1.18).⁶²

Legislation to expand access in pharmacies

Since the late 1990s, individual states have taken different paths to expand access to EC.⁶³ In the early stages of access, it was limited to women who had been sexually assaulted. Whereas levonorgestrel EC is now available OTC, UPA remains available by prescription only. Although access to oral EC has expanded in many ways, access remains restrictive in some areas. Legislation to expand pharmacist-prescribing authorities in individual states can help increase access to both OTC and prescription EC products. Some states have regulations for pharmacists' (or pharmacies') right to refusal based on moral or ethical grounds. Legislation at the state level can ensure patient access is prioritized while respecting individual beliefs whenever possible.

Pharmacist counseling practices

Community pharmacists can help promote IUD use for EC by providing accurate information, dispelling myths, such as increased risk of pelvic inflammatory disease (associated with the no longer-available Dalkon Shield), and counseling about the risks and benefits. Pharmacists can further help by being familiar with local providers that can place IUDs in a timely manner. The aforementioned UK pilot program, in which trained community pharmacists evaluated women for EC IUD eligibility and referred if appropriate nearly, tripled the uptake of this EC method.⁶¹ Community pharmacists in the US are in a prime position to provide EC counseling. Given its safety, efficacy, and cost-effectiveness, the copper IUD should be included in all discussions of possible EC options if feasible and appropriate. See Table 4 for counseling points for EC.

Conclusion

Use of EC is increasing over time, due to the wider availability and accessibility of EC methods. Levonorgestrel EC is available OTC without any restriction. Further, in eight states, pharmacists are able to prescribe and provide oral EC directly to women. Pharmacists play a critical role to access to EC in community pharmacies by ensuring product availability in the inventory, up-to-date knowledge, and patient counseling. There are opportunities to expand access to EC in pharmacies further by implementing legislation expanding pharmacist

Table 4 Patient counseling points for EC**Levonorgestrel (LNG)**

- LNG is approved for use up to 72 hours after unprotected sex, but studies show effectiveness in pregnancy prevention up to 120 hours after sex. LNG EC is more effective the sooner it is taken.
- LNG EC does not prevent sexually transmitted diseases, does not affect an established pregnancy, and will not cause an abortion. It should not be used in an existing pregnancy.
- If your BMI is $>25 \text{ kg/m}^2$, the other EC methods may be more effective.
- Hormonal contraceptive methods may be started immediately after taking LNG EC, but you still need to use 7 days of a backup contraceptive method.
- Common side effects include menstrual changes, with possibilities of heavier or earlier menses, breast tenderness, nausea and vomiting, and headache.
- LNG EC is not 100% effective, and you should obtain a pregnancy test if you have not received your period after 3 weeks or your period is more than 1 week late.
- There are longer term options, such as hormonal contraception (pills, patch, vaginal ring, IUD) or a copper IUD, that may be more suitable forms of regular contraception.
- LNG EC will not cause adverse effects with repeated use.

Ulipristal acetate (UPA)⁴¹

- UPA EC may be taken up to 120 hours following unprotected intercourse, and should be taken as soon as possible.
- UPA EC does not prevent sexually transmitted diseases, does not affect an established pregnancy, and will not cause an abortion. It should not be used in an existing pregnancy.
- It may be less effective if your BMI is $>30 \text{ kg/m}^2$.
- Other hormonal contraceptives should not be used for 5 days after UPA EC use, due to a potential drug interaction that counteracts the effect of UPA, and potentially renders it ineffective.
- Common side effects include menstrual cycle changes, headache, nausea, fatigue, and dizziness.
- UPA is not 100% effective, and you should obtain a pregnancy test if you have not received your period after 3 weeks or your period is more than 1 week late.
- There are other contraceptive options, such as hormonal methods (pills, patch, vaginal ring, IUD) or copper IUD that may be more suitable forms of regular contraception.
- UPA will not cause adverse effects with repeated use.
- If breastfeeding, breast milk should be discarded for 1 week following UPA use.
- Use of concurrent medications that induce CYP450 enzymes, such as St John's wort, barbiturates, bosentan, rifampin, and certain migraine, seizure, and HIV medications, may also decrease the effectiveness of UPA.

Copper IUDs

- Copper IUDs are effective as EC immediately if inserted within 5 days of unprotected intercourse. The copper IUD also immediately prevents pregnancy from future acts of intercourse, and no backup method of contraception is needed.
- These devices do not prevent sexually transmitted diseases, do not affect an established pregnancy, and do not cause an abortion. They should not be used in an existing pregnancy.
- Copper IUDs are the most effective form of EC, and can be used for up to 12 years to prevent pregnancy.
- The device is placed in your uterus by a health care professional, and requires a clinic visit.
- The effectiveness of copper IUDs is not decreased by body weight, unlike EC pills.
- The most common adverse effects include abnormal menstrual bleeding and abdominal pain and/or cramping.
- Copper IUDs prevent pregnancy by affecting the ovum and sperm to prevent fertilization.
- Previous theories that IUDs can damage a fertilized ovum or prevent implantation are not supported by current evidence.⁶⁴
- Copper IUDs do not contain hormones. IUDs containing hormones are available, but not recommended for EC.

Abbreviations: EC, emergency contraception; BMI, body mass index; IUD, intrauterine device.

scope of practice, ensuring third-party reimbursement for clinical services delivered by pharmacists, and including EC in pharmacy education and training.

Disclosure

SR is on the clinical advisory board for Afaxys Inc. The other authors report no conflicts of interest in this work.

References

1. Finer LB, Zolna MR. Declines in unintended pregnancy in the United States, 2008–2011. *N Engl J Med*. 2016;374(9):843–852.
2. Jones RK, Darroch JE, Henshaw SK. Contraceptive use among U.S. women having abortions in 2000–2001. *Perspect Sex Reprod Health*. 2002;34(6):294–303.
3. Trussell J. Contraceptive failure in the United States. *Contraception*. 2011;83(5):397–404.
4. Daniels K, Jones J, Abma J. Use of emergency contraception among women aged 15–44: United States, 2006–2010. *NCHS Data Brief*. 2013;(112):1–8.
5. Martinez GM, Abma JC. Sexual activity, contraceptive use, and childbearing of teenagers aged 15–19 in the United States. *NCHS Data Brief*. 2015;(209):1–8.
6. Yen S, Parmar DD, Lin EL, Ammerman S. Emergency contraception pill awareness and knowledge in uninsured adolescents: high rates of misconceptions concerning indications for use, side effects, and access. *J Pediatr Adolesc Gynecol*. 2015;28(5):337–342.

7. Trussell J, Schwarz EB. Emergency contraception. In: Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar MS, editors. *Contraceptive Technology*. 20th ed. Alpharetta (GA): Bridging the Gap Communications; 2011:113–146.
8. [No authors listed]. Practice bulletin no. 152: emergency contraception. *Obstet Gynecol*. 2015;126(3):e1–e11.
9. Trussell J, Raymond EG, Cleland K. Emergency contraception: a last chance to prevent unintended pregnancy. 2016. Available from: <http://ec.princeton.edu/questions/ec-review.pdf>. Accessed July 20, 2016.
10. Piaggio G, Kapp N, von Hertzen H. Effect on pregnancy rates of the delay in the administration of levonorgestrel for emergency contraception: a combined analysis of four WHO trials. *Contraception*. 2011;84(1):35–39.
11. Wood AJ, Drazen JM, Greene MF. A sad day for science at the FDA. *N Engl J Med*. 2005;353(12):1197–1199.
12. Sampson O, Navarro SK, Khan A, et al. Barriers to adolescents' getting emergency contraception through pharmacy access in California: differences by language and region. *Perspect Sex Reprod Health*. 2009;41(2):110–118.
13. Wilkinson TA, Fahey N, Suther E, Cabral HJ, Silverstein M. Access to emergency contraception for adolescents. *JAMA*. 2012;307(4):362–363.
14. Moore A, Stamm C, Borgelt L, et al. Seeking emergency contraception in Denver, CO: a health impact assessment. 2014. Available from: <http://www.ucdenver.edu/academics/colleges/medicalschoo/departments/medicine/GIM/education/PrimaryCare/Documents/Resident%20Research/2014-MooreA-EmergencyContraception-Poster.pdf>. Accessed January 30, 2017.
15. Gaffaney M, Secor-Turner M, Stamm C, et al. Outdated counseling in the pharmacy? A qualitative analysis of emergency contraception access in Wyoming. *J Pediatr Adolesc Gynecol*. 2016;29(2):177–178.
16. Batur P, Cleland K, McNamara M, Wu J, Pickle S. Emergency contraception: a multispecialty survey of clinician knowledge and practices. *Contraception*. 2016;93(2):145–152.
17. Miller MK, Plantz DM, Dowd MD, et al. Pediatric emergency health care providers' knowledge, attitudes, and experiences regarding emergency contraception. *Acad Emerg Med*. 2011;18(6):605–612.
18. Reed JL, Vaughn LM, Pomerantz WJ. Attitudes and knowledge regarding emergency contraception among emergency department adolescents and providers. *Pediatr Emerg Care*. 2012;28(8):775–779.
19. Wallace JL, Wu J, Weinstein J, Gorenflo DW, Feters MD. Emergency contraception: knowledge and attitudes of family medicine providers. *Fam Med*. 2004;36(6):417–422.
20. Lawrence RE, Rasinski KA, Yoon JD, Curlin FA. Obstetrician-gynecologist physicians' beliefs about emergency contraception: a national survey. *Contraception*. 2010;82(4):324–330.
21. Hellerstedt WL, Van Riper KK. Emergency contraceptive pills: dispensing practices, knowledge and attitudes of South Dakota pharmacists. *Perspect Sex Reprod Health*. 2005;37(1):19–24.
22. Bennett W, Petraitis C, D'Anella A, Marcella S. Pharmacists' knowledge and the difficulty of obtaining emergency contraception. *Contraception*. 2003;68(4):261–267.
23. Hopkins D, West D. Arkansas pharmacists' perceptions toward emergency contraception and nonprescription Plan B. *Pharm Pract*. 2008;6(2):98–102.
24. Fuentes EC, Azize-Vargas Y. Knowledge, attitudes and practices in a group of pharmacists in Puerto Rico regarding emergency contraception. *P R Health Sci J*. 2007;26(3):191–197.
25. French AC, Kaunitz AM. Pharmacy access to emergency hormonal contraception in Jacksonville, FL: a secret shopper survey. *Contraception*. 2007;75(2):126–130.
26. El-Ibiary SY, Raine T, McIntosh J, Darney PD, Harper CC. Pharmacy access to emergency contraception: perspectives of pharmacists at a chain pharmacy in San Francisco. *J Am Pharm Assoc (2003)*. 2007;47(6):702–710.
27. Sommers SD, Chaiyakunapruk N, Gardner JS, Winkler J. The emergency contraception collaborative prescribing experience in Washington State. *J Am Pharm Assoc (Wash)*. 2001;41(1):60–66.
28. Borrego ME, Short J, House N, Gupchup G, Naik R, Cuellar D. New Mexico pharmacists' knowledge, attitudes, and beliefs toward prescribing oral emergency contraception. *J Am Pharm Assoc (2003)*. 2006;46(1):33–43.
29. Richman AR, Daley EM, Baldwin J, Kromrey J, O'Rourke K, Perrin K. The role of pharmacists and emergency contraception: are pharmacists' perceptions of emergency contraception predictive of their dispensing practices? *Contraception*. 2012;86(4):370–375.
30. Ragland D, Payakachat N, Ounpraseuth S, Pate A, Harrod S, Ott R. Emergency contraception counseling: an opportunity for pharmacists. *J Am Pharm Assoc (2003)*. 2011;51(6):756–764.
31. Ragland D, Payakachat N, Stafford R. Emergency contraception counseling in a retail pharmacy setting: a pilot study. *J Pharm Pract*. 2015;28(3):261–265.
32. Glasier A, Cameron ST, Blithe D, et al. Can we identify women at risk of pregnancy despite using emergency contraception? Data from randomized trials of ulipristal acetate and levonorgestrel. *Contraception*. 2011;84(4):363–367.
33. US Food and Drug Administration. Plan B (0.75 mg levonorgestrel) and Plan B one-step (1.5 mg levonorgestrel) tablets information. 2016. Available from: <http://www.fda.gov/Drugs/DrugSafety/Postmarket-DrugSafetyInformationforPatientsandProviders/ucm109775.htm>. Accessed January 30, 2017.
34. Fine P, Mathé, Ginde S, Cullins V, Morfesis J, Gainer E. Ulipristal acetate taken 48–120 hours after intercourse for emergency contraception. *Obstet Gynecol*. 2010;115(2 Pt 1):257–263.
35. Stratton P, Hartog B, Hajizadeh N, et al. A single mid-follicular dose of CDB-2914, a new antiprogesterin, inhibits folliculogenesis and endometrial differentiation in normally cycling women. *Hum Reprod*. 2000;15(5):1092–1099.
36. Kim A, Bridgeman MB. Ulipristal acetate (Ella): a selective progesterone receptor modulator for emergency contraception. *PT*. 2011;36(6):325–331.
37. HRA Pharma. HRA Pharma and Afaxys join forces on emergency contraceptive Ella® in the USA. 2014. Available from: http://www.hra-pharma.com/index.php/en/you_are/media/hra_pharma_and_afaxys_join_forces_on_emergency_contraceptive_ella_in_the_usa. Accessed April 7, 2016.
38. Afaxys, Inc. Afaxys announces wider national availability of Ella® emergency contraceptive. 2014. Available from: <http://www.afaxys.com/news-and-media/emergency-contraceptive.php>. Accessed April 7, 2016.
39. Bullock H, Steele S, Kurata N, et al. Pharmacy access to ulipristal acetate in Hawaii: is a prescription enough? *Contraception*. 2016;93(5):452–454.
40. Brant A, White K, St. Marie P. Pharmacy availability of ulipristal acetate emergency contraception: an audit study. *Contraception*. 2014;90(3):338–339.
41. Ella® (ulipristal acetate) [prescribing information]. Charleston (SC): Afaxys Inc; 2015.
42. PRJKT Ruby [website on the Internet]. <https://www.prjkruby.com>. Accessed April 7, 2016.
43. Lippes J, Malik T, Tatum HJ. The postcoital copper-T. *Adv Plan Parent*. 1976;11(1):24–22.
44. American College of Obstetricians and Gynecologists. Practice bulletin no. 121: long-acting reversible contraception: implants and intrauterine devices. *Obstet Gynecol*. 2011;118(1):184–196.
45. Dean G, Schwarz ED. Intrauterine contraception. In: Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart F, Kowal D, Policar MS, editors. *Contraceptive Technology*. 20th ed. Alpharetta (GA): Bridging the Gap Communications; 2011.
46. Turok DK, Sanders JN, Thompson IS, Royer PA, Eggebroten J, Gawron LM. Preference for and efficacy of oral levonorgestrel for emergency contraception with concomitant placement of a levonorgestrel IUD: a prospective cohort study. *Contraception*. 2016;93(6):526–532.
47. Rivera R, Yacobson I, Grimes D. The mechanism of action of hormonal contraceptives and intrauterine contraceptive devices. *Am J Obstet Gynecol*. 1999;181(5 Pt 1):1263–1269.
48. Stanford JB, Mikolajczyk RT. Mechanisms of action of intrauterine devices: update and estimation of post-fertilization effects. *Am J Obstet Gynecol*. 2002;187(6):1699–1708.

49. Cleland K, Haoping Z, Goldstruck N, Cheng L, Trussell J. The efficacy of intrauterine devices for emergency contraception: a systematic review of 35 years of experience. *Hum Reprod*. 2012;27:1994–2000.
50. Turok DK, Godfrey EM, Wojdyla D, Dermish A, Torres L, Wu SV. Copper T380 intrauterine device for emergency contraception: highly effective at any time in the menstrual cycle. *Hum Reprod*. 2013;28(10):2672–2676.
51. Yoost J. Understanding benefits and addressing misperceptions and barriers to intrauterine device access among populations in the United States. *Patient Prefer Adherence*. 2014;8:947–957.
52. Kaiser Family Foundation. Intrauterine devices (IUDs): access for women in the U.S. 2016. Available from: <http://kff.org/womens-health-policy/fact-sheet/intrauterine-devices-iuds-access-for-women-in-the-u-s>. Accessed March 26, 2016.
53. Luchowski AT, Anderson B, Power ML, Raglan GB, Espey E, Schulkin J. Obstetrician-gynecologists and contraception: practice and opinions about the use of IUDs in nulliparous women, adolescents and other patient populations. *Contraception*. 2014;89(6):572–577.
54. Committee on Gynecologic Practice Long-Acting Reversible Contraception Working Group. Committee opinion no. 642: increasing access to contraceptive implants and intrauterine devices to reduce unintended pregnancy. *Obstet Gynecol*. 2015;126(4):e44–e48.
55. Ott MA, Sucato GS. Contraception for adolescents. *Pediatrics*. 2014;134(4):e1257–e1281.
56. Houle SK, Grindrod KA, Chatterley T, Tsuyuki RT. Paying pharmacists for patient care: a systematic review of remunerated pharmacy clinical care services. *Can Pharm J*. 2014;147(4):209–232.
57. Thompson CA. CMS explains Medicare payment for chronic care management services. *Am J Health Syst Pharm*. 2015;72(7):514–515.
58. Higgins SJ, Hattingh HL. Requests for emergency contraception in community pharmacy: an evaluation of services provided to mystery patients. *Res Social Adm Pharm*. 2013;9(1):114–119.
59. Queddeng K, Chaar B, Williams K. Emergency contraception in Australian community pharmacies: a simulated patient study. *Contraception*. 2011;83(2):176–182.
60. Bell DL, Camacho EJ, Velasquez AB. Male access to emergency contraception in pharmacies: a mystery shopper survey. *Contraception*. 2014;90(4):413–415.
61. Clement KM, Mansour DJ. Improving uptake of the copper intrauterine device for emergency contraception by educating pharmacists in the community. *J Fam Plann Reprod Health Care*. 2014;40(1):41–45.
62. Rodriguez MI, Curtis KM, Gaffield ML, Jackson E, Kapp N. Advance supply of emergency contraception: a systematic review. *Contraception*. 2013;87(5):590–601.
63. Guttmacher Institute. Emergency contraception. Available from: <https://www.guttmacher.org/state-policy/explore/emergency-contraception>. Accessed April 25, 2016.
64. Ortiz ME, Croxatto HB. Copper-T intrauterine device and levonorgestrel intrauterine system: biological bases of their mechanism of action. *Contraception*. 2007;75(6 Suppl):S16–S30.
65. Rafie S, McIntosh J, Gardner DK, et al. Over-the-counter access to emergency contraception without age restriction: an opinion of the Women's Health Practice and Research Network of the American College of Clinical Pharmacy. *Pharmacotherapy*. 2013;33(5):549–557.
66. Princeton University. History of Plan B OTC. Available from: <http://ec.princeton.edu/pills/planbhistory.html>. Accessed April 4, 2016.

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