History, Policy *and* Nursing Practice Implications *of the* Plan B® Emergency Contraceptive

Currently, about half (51 percent) of the pregnancies in the United States are unintended and the United States has the highest rate of unintended pregnancies among developed nations (Guttmacher Institute, 2013). According to the American College of Obstetricians and Gynecologists (ACOG, 2010), pregnancy is defined as implantation of a fertilized egg. A pregnancy that is unplanned, mistimed and/or unwanted is referred to as an unintended pregnancy (Guttmacher Institute, 2013). Unintended pregnancies may lead to poor maternal and child health outcomes, such as delayed prenatal care, premature birth, reduced likelihood of breastfeeding, maternal depression, increased risk of physical violence in pregnancy and physical and mental impacts on the baby (Guttmacher Institute, 2013; U.S. Department of Health and Human Services [DHHS], 2011). Both ACOG (2010) and *Healthy People 2020* (DHHS, 2011) recognize the inherent need to reduce unintended pregnancy by increasing the availability of emergency contraception.

Abstract: Numerous policy changes have expanded access to emergency contraception, such as Plan B®, in recent years. Plan B® is a progesterone-based medication that prevents pregnancy from occurring up to 120 hours after unprotected intercourse by preventing ovulation and tubal transport. Increased access to Plan B® allows women to make independent decisions regarding reproductive health. Nurses play an important role in providing education as well as comprehensive, compassionate and holistic care. DOI: 10.1111/1751-486X.12186

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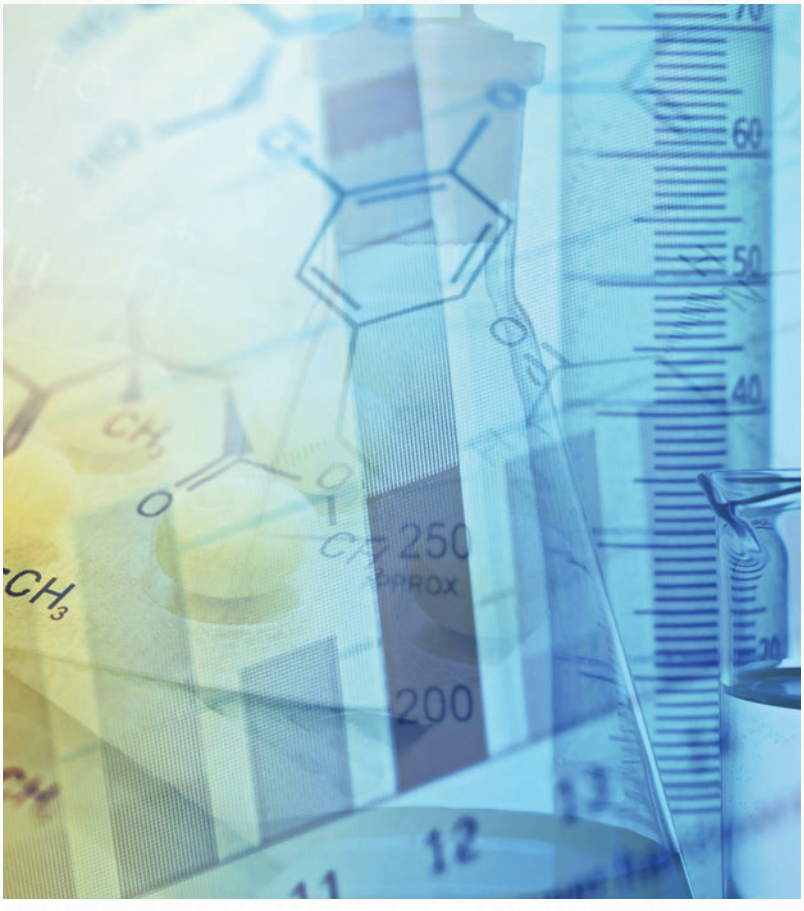
Michelle L. Munro
Alexandra C. Dulin
Elizabeth Kuzma

Over the past decade, there have been numerous advances to improve the control women have over their reproductive health and thus reduce unintended pregnancies. These advances have been visible in the media with a plethora of news coverage on reproductive health options such as emergency contraception. Within the last 7 years there have been four major policy changes that have specifically increased access to one type of emergency contraception—Plan B®.

Different political and philosophical views on reproductive health, including misunderstandings about the safety and mechanism of action of Plan B®, have fueled political turmoil, heated debates and delayed the over-the-counter (OTC) availability of Plan B®. It's imperative that nurses understand the science and policy surrounding Plan B®, as well as the needs of women accessing it. This paper reviews the history of Plan B®, including the major policy changes, properties and implications for health care providers such as nurses, midwives and advanced practice nurses.



History of Plan B®

Emergency contraception, sometimes referred to as a postcoital method, is a contraceptive method used after unprotected intercourse to prevent pregnancy, using the ACOG definition of pregnancy. Logically, emergency contraception would be used after any of three different scenarios: (1) contraceptive mishap or failure (i.e., missed pill, mistimed contraceptive injection, broken condom); (2) spontaneous intercourse without contraception and (3) sexual assault with a fear of pregnancy (Munro, Martyn, Campbell, Graham-Bermann, & Seng, 2015).

Before easily accessible and branded emergency contraception became available, patients and health care providers utilized a variety of methods and preexisting modes of combined oral contraception for "emergency" situations. Originally, combined oral contraceptive pills were utilized to provide pregnancy prevention after unprotected intercourse via the Yuzpe method, first described by a Canadian pharmacist in 1974 (Yuzpe, Thurlow, Ramzy, & Leyshon, 1974). Combined oral contraceptive pills are still utilized to provide pregnancy prevention after unprotected intercourse; a list of oral contraceptives approved for emergency contraceptive use in the United States is available from Trussell, Raymond, and Cleland (2014).

Michelle L. Munro, PhD, CNM, FNP-BC, is a research fellow; Alexandra C. Dulin is an undergraduate student; Elizabeth Kuzma RN, MSN, FNP-BC, is a clinical instructor in the School of Nursing; all authors are at the University of Michigan in Ann Arbor, MI. The authors report no conflicts of interest or relevant financial relationships. Address correspondence to: mlmunro@umich.edu.

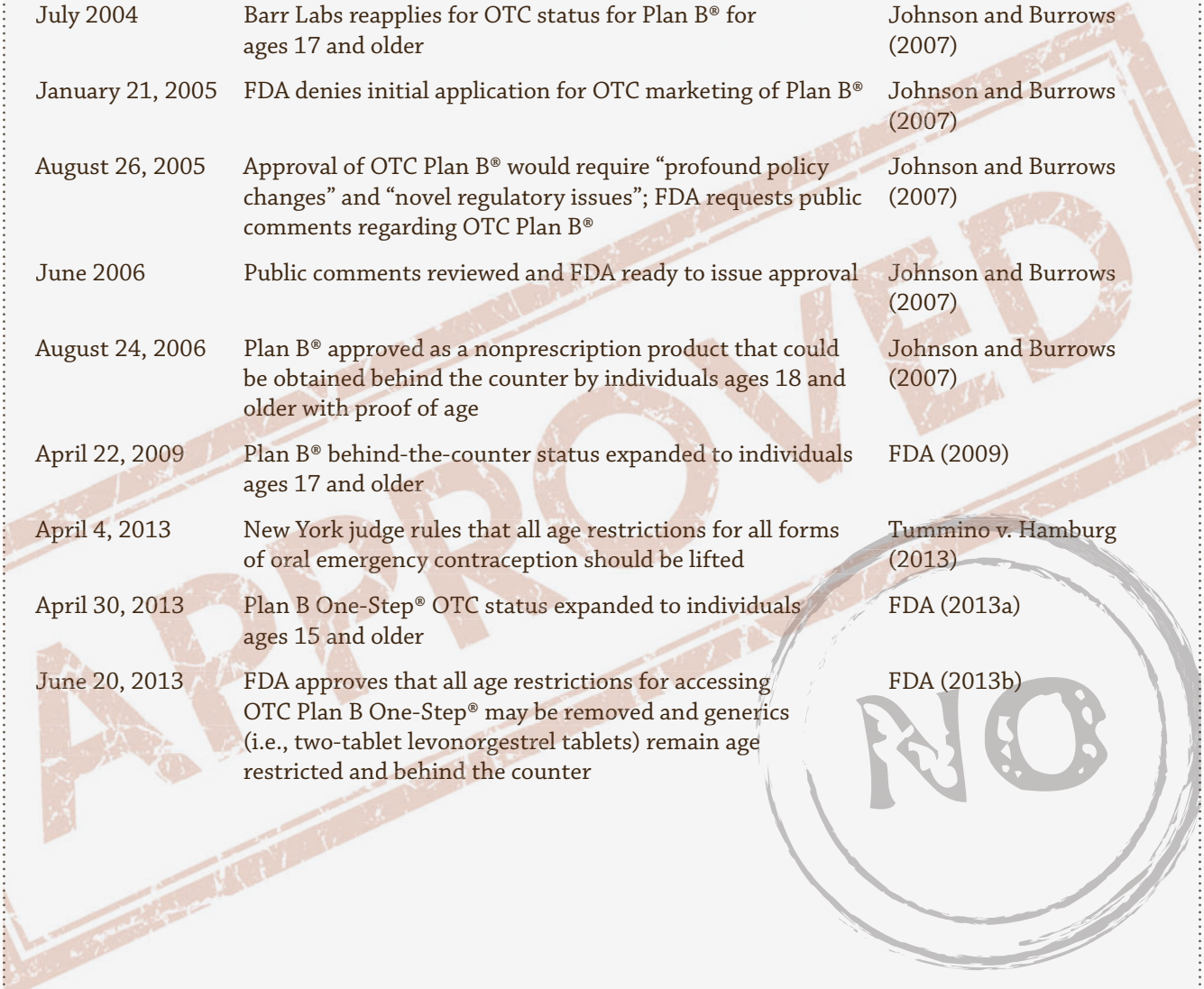
It's imperative that nurses understand the science and policy surrounding Plan B®, as well as the needs of women accessing it

One of the dedicated options for emergency contraception included the progesterone-only method, Plan B® (sometimes incorrectly referred to as the "morning-after pill"), which was initially approved for use as a prescription product in 1999 (Johnson & Burrows, 2007). After many years of proven safety and efficacy as a prescription product, intense policy debate followed regarding increasing its availability as an OTC product to adolescents and young adults. In 2009, a one-dose version of Plan B® became available called Plan B One-Step® (in this article we'll continue to use the term Plan B® unless specifically referring to characteristics or policy changes of Plan B One-Step®).

Despite the relative safety of Plan B® as an OTC medication, its pathway to OTC status has been met with unprecedented delays by both the U.S. Food and Drug Administration (FDA) and DHHS (see Box 1). These delays have been fueled by public misunderstandings about how Plan B® works and unease about

BOX 1
A History of the Status of Plan B®

Date	Regulatory Change	Reference
July 28, 1999	Plan B® approved for prescription use with 88 percent efficacy within 72 hours of unprotected intercourse and 95 percent efficacy within 24 hours of unprotected intercourse	Johnson and Burrows (2007)
April 2003	Women's Capital Corporation applies for OTC status for Plan B®	Johnson and Burrows (2007)
December 16, 2003	The U.S. FDA votes 23-4 in favor of OTC status for Plan B®	Johnson and Burrows (2007)
May 2004	FDA rejects the advice of its scientific committee and issues a "not approvable" letter due to "inadequate sample" of younger age groups	Johnson and Burrows (2007)
July 2004	Barr Labs reapplies for OTC status for Plan B® for ages 17 and older	Johnson and Burrows (2007)
January 21, 2005	FDA denies initial application for OTC marketing of Plan B®	Johnson and Burrows (2007)
August 26, 2005	Approval of OTC Plan B® would require "profound policy changes" and "novel regulatory issues"; FDA requests public comments regarding OTC Plan B®	Johnson and Burrows (2007)
June 2006	Public comments reviewed and FDA ready to issue approval	Johnson and Burrows (2007)
August 24, 2006	Plan B® approved as a nonprescription product that could be obtained behind the counter by individuals ages 18 and older with proof of age	Johnson and Burrows (2007)
April 22, 2009	Plan B® behind-the-counter status expanded to individuals ages 17 and older	FDA (2009)
April 4, 2013	New York judge rules that all age restrictions for all forms of oral emergency contraception should be lifted	Tummino v. Hamburg (2013)
April 30, 2013	Plan B One-Step® OTC status expanded to individuals ages 15 and older	FDA (2013a)
June 20, 2013	FDA approves that all age restrictions for accessing OTC Plan B One-Step® may be removed and generics (i.e., two-tablet levonorgestrel tablets) remain age restricted and behind the counter	FDA (2013b)



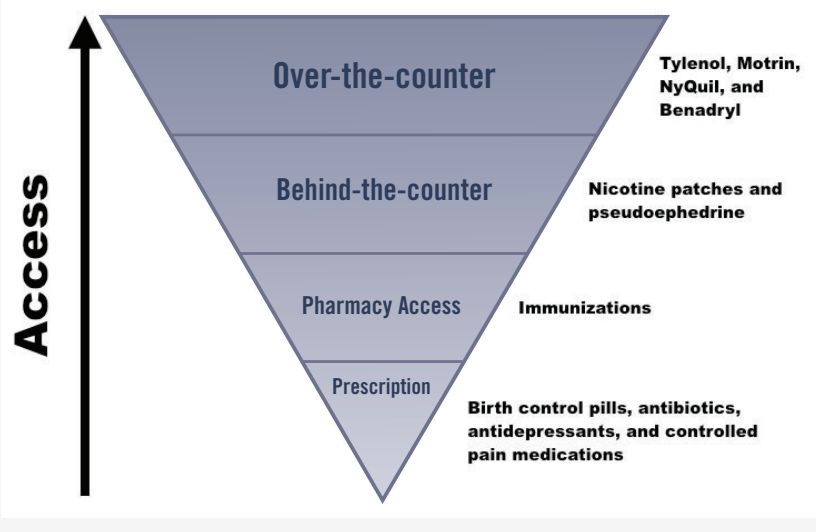
Plan B® is effective as an emergency contraceptive method by interfering with ovulation and tubal transport of sperm and ova; it is not an abortifacient, as implied by the misnomer of "the morning-after pill"

how to provide adolescents with reproductive health care and education. Opponents fear that improved access to Plan B® will contribute to risky sexual behavior among adolescents and young adults, despite an abundance of evidence that this is not the case (Raine et al., 2005). Furthermore, there are concerns about a minor's ability to consent to family planning services independently. However, based on the Supreme Court decision Carey versus Population services international (1977, 431 U.S. 678), a minor's right to access contraception services are protected (The Network for Public Health Law, 2012). Federally funded programs such as Medicaid and Title X also ensure that minors ages 13 and older must have access to confidential family planning services (Gudeman & Madge, 2011).

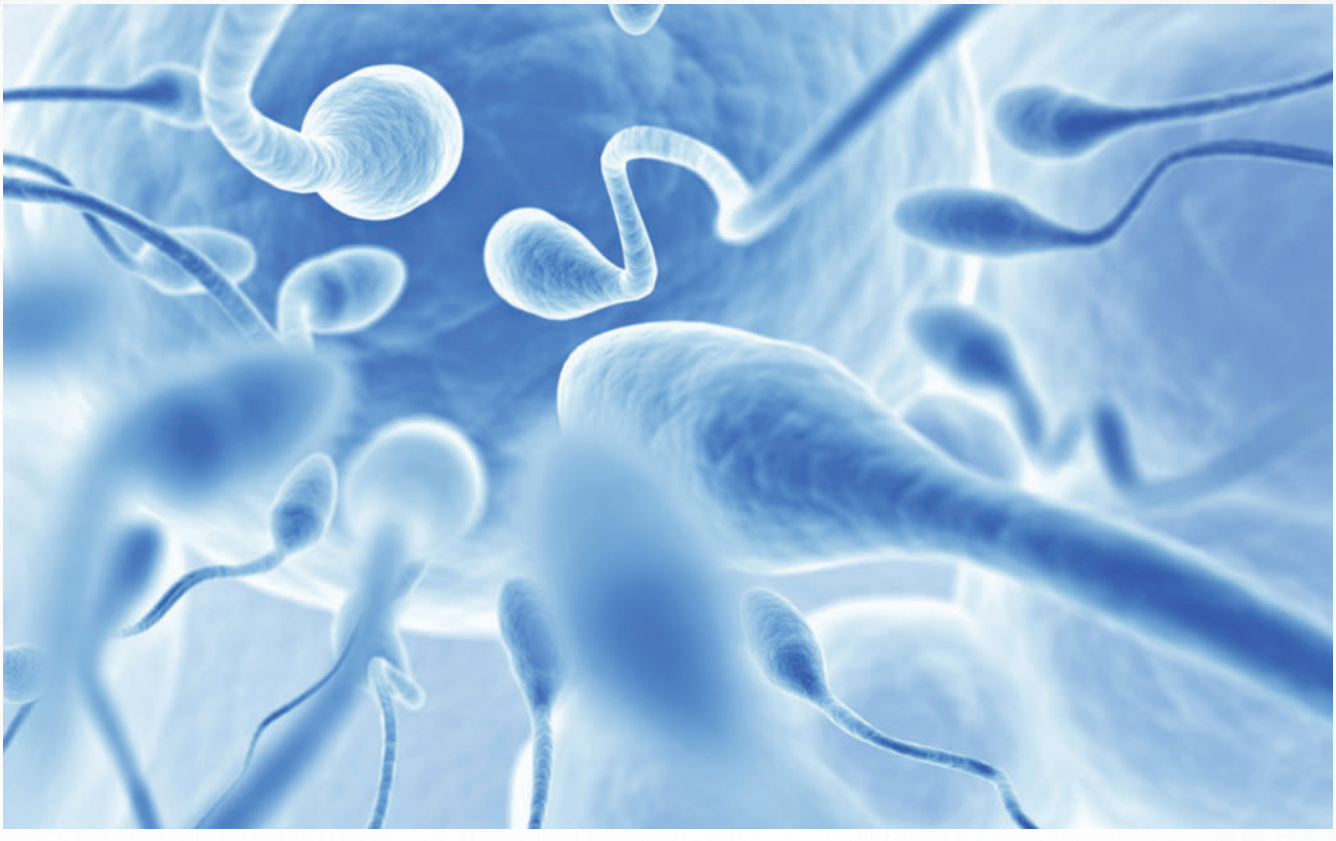
This imperative, along with the new federal regulations expanding the availability of Plan B One-Step® to individuals of any age, should abolish the concern and misconceptions about the ability of a minor to consent to family planning services, such as purchasing OTC Plan B®. Furthermore, emergency contraception products similar to Plan B® are used as postcoital methods around the globe in more than 100 countries (Johnson & Burrows, 2007). In fact, 40 other countries legalized Plan B® as an OTC medication prior to the United States without any reports of adverse events (Johnson & Burrows, 2007).

Plan B's® initial bid for easier availability began in 2003 when Women's Capital Corporation submitted an application for OTC status (Johnson & Burrows, 2007). Despite a favorable vote by the FDA scientific committee, the FDA did not approve this change in status (Johnson & Burrows, 2007). After Women's Capital Corporation and Plan B® were acquired by Barr Labs, a second application for OTC status was submitted in 2004 for women ages 17 and older (Johnson & Burrows, 2007). On August 24, 2006, Plan B® was finally approved as a nonprescription product that could be obtained behind the counter by individuals ages 18 and older with an identification card for proof of age (Johnson & Burrows, 2007). The importance of this behind-the-counter status is that any individual purchasing Plan B®, which is available to all genders, had to approach the pharmacy counter and show a photo identification to verify age in order to obtain the product. Thus, this method of availability did not provide the ease and anonymity that many individuals purchasing Plan B® would have desired, adding a new barrier to access. Other delays relate to finding providers and pharmacists who will write or fill such prescriptions, which can prevent women from accessing emergency contraception and possibly deter them from attempting to access it from another pharmacy or pharmacist (Gee, Shacter, Kaufman, & Long, 2008). See Figure 1 for a review of medication availability classifications.

FIGURE 1
Medication Availability Classification



On April 22, 2009, access to behind-the-counter Plan B® was expanded to individuals ages 17 and older (U.S. FDA, 2009). In 2012, Teva Pharmaceuticals filed an amendment to expand Plan B® access to an OTC venue for individuals ages 15 and older with identification required for proof of age at checkout (FDA, 2013a). Most recently, in 2013, debates about expanding



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Plan B® to an OTC product that will be displayed in pharmacy aisles and about the reduction and eventual elimination of age restrictions were introduced. On April 4, 2013, a federal judge in New York mandated that all age restrictions be removed from purchasing Plan B One-Step® and that it be available as a true OTC product in pharmacy aisles (Tummino v. Hamburg, 2013). This ruling was partially followed on April 30, 2013, when Plan B One-Step® was approved as an OTC product for individuals ages 15 and older with identification for proof of age (FDA, 2013a). Further expansion of Plan B One-Step® occurred in June 2013 when it became available as an OTC product to all age groups with no identification required at checkout (FDA, 2013b). This OTC status means that the medication should be available in aisles next to pregnancy tests, condoms, acetaminophen and other products that are available without limitations. However, at this time pharmacies are still grappling with how this product should be displayed. Thus, the current availability of OTC Plan B One-Step® is generally either pictures of the medication displayed in aisles referring potential consumers to ask the pharmacist for the medication or the medication in a lockbox in the aisles requiring that the consumer seek the help of a pharmacy employee in order to purchase it. Therefore, even with the legal ability to purchase Plan B One-Step®, there are still unnecessary barriers to access.

These policy changes have important implications for other forms of emergency contraception that are currently regulated by prescription (i.e., ellaOne®) or are only available OTC to individuals ages 17 and older (i.e., My Way® and Next Choice One Dose®). For example, one-tablet generic formulations of emergency contraception pills such as My Way® and Next Choice One Dose® should also be available to consumers ages 17 and older as an OTC product located on pharmacy shelves (at this time, though, they also remain in picture form or lockboxes necessitating that a pharmacy employee be involved in acquiring the product), while generic two-tablet formulations of levonorgestrel will remain available to consumers ages 17 and older as a behind-the-counter product. Based on recent changes to the availability of Plan B One-Step®, it's possible that we will continue to see changes in the way that all emergency contraception pills are dispensed.

Research Evidence

Plan B® has been produced as two products: (1) a 0.75 mg levonorgestrel (progesterone) tablet divided into two doses taken 12 hours apart or (2) as Plan B One-Step®, a single 1.5 mg dose (Scolaro, 2007). Plan B One-Step® is the product currently available OTC. Plan B® can be safely taken by almost every woman in need of emergency contraception; according to the package insert, the only contraindication to Plan B® is a known or suspected pregnancy (Duramed Pharmaceuticals, 2009). However, Plan B® will not harm an existing pregnancy nor will it increase the frequency of fetal abnormalities (Davidoff & Trussell, 2006).

Plan B® is effective as an emergency contraceptive method

by interfering with ovulation and tubal transport of sperm and ova; it is not an abortifacient, as implied by the misnomer of "the morning-after pill" (Davidoff & Trussell, 2006; Scolaro, 2007). Studies demonstrate that Plan B® can be effective for up to 120 hours after administration following unprotected intercourse, but data indicate a higher risk of therapeutic failure after 72 hours (Scolaro, 2007). Plan B® should be taken as soon as possible after unprotected intercourse to benefit from higher efficacy rates that range from 52 percent to 94 percent (Dominguez et al., 2010). Plan B® has also demonstrated high efficacy rates when taken after sexual assault (Choi, Kim, Hwang, Lee, & Kong, 2013).

Plan B® is generally tolerated quite well, but side effects can include nausea, headache, fatigue and abdominal pain (Scolaro, 2007). Menses usually resume within 1 week before or after the expected time; however, some users may experience irregular bleeding and changes in their menstrual cycle (i.e., lighter or heavier flow) based on when they took the medication during their menstrual cycle (Allen & Goldberg, 2007). The active component of Plan B®, levonorgestrel, has a robust safety history with no link to venous thromboembolism or death (Scolaro, 2007). In fact, Plan B® is considered very safe in comparison to other OTC medications such as acetaminophen, dextromethorphan and caffeine, which have been linked to unintentional overdose and even death (Rafie et al., 2013).

Relatively new research indicates that Plan B® has demonstrated decreased efficacy among women considered overweight (body mass index [BMI] > 25; Glasier et al., 2011) and even newer research cautions that levonorgestrel-based emergency contraception is less effective in women weighing 165 pounds or more and is not effective at all in women weighing 176 pounds or more (Faculty of Sexual & Reproductive Healthcare, 2013). At this time no prescribing or packaging changes to levonorgestrel-based emergency contraceptive products (such as Plan B®, Next Choice One Dose® or My Way®) have been made until more data are available (Faculty of Sexual & Reproductive Healthcare, 2013). Nonetheless, providers should consider alternative methods of emergency contraception such as a copper intrauterine device (IUD) like Paragard or ulipristal acetate like ellaOne®, a selective progesterone receptor modulator that may be more appropriate for women weighing 165 pounds or more.

Women might be accessing OTC Plan B® without the resources to make informed decisions about follow-up care for STI testing, future contraception and what to do if Plan B® isn't effective

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Women's Needs

Research on Plan B® has focused on safety, mechanism of action, effects on promiscuity and availability; however, there has been limited research conducted on the needs of individuals using Plan B® with regard to follow-up care, education and reason for use. Plan B® is now available to a diffuse population and it's therefore necessary to consider the needs of any individual who may be utilizing it as a postcoital method.

Two years after Plan B® was released behind the counter to women ages 18 and older, the rate of women using it doubled (Kavanaugh, Williams, & Schwarz, 2011), with the most common individual during this time being a single, college-educated woman between the ages of 18 and 29 (ACOG, 2010; Kavanaugh et al., 2011). Despite this increased use, the National Survey of Family Growth conducted from 2006 to 2008 demonstrated that the number of women receiving counseling about emergency contraception from their health care providers was relatively unchanged from 2002 (Kavanaugh et al., 2011). In fact, only 4 percent of women in the National Survey of Family Growth who reported a Pap test or pelvic exam within the last year reported receiving counseling about emergency contraception from their health care providers (Kavanaugh et al., 2011). Additionally, the cost of Plan B® still limits the population that can use it, with reported ranges from $32 to $65 (American Society for Emergency Contraception, 2013). This price does appear to be much lower in university and college pharmacy settings (Munro et al., 2015).

According to ACOG (2010), after emergency contraceptive use women should be informed about additional needs including resources for sexually transmitted infection (STI) testing and continuing contraception. With the increased availability of Plan B®, it's now possible that women can access the medication in a retail setting without any interaction with a health care provider (Ragland, Payakachat, & Stafford, 2014). Furthermore, women often seek information about reproductive health options from health care personnel, friends and family and now the Internet. A recent study of the accuracy of information about emergency contraception on the Internet revealed that most websites provide accurate information about acquisition and use of emergency contraception but failed to address follow-up care and what a woman should do in a situation in which emergency contraception isn't effective (Adrian, Kim, Chu, & Kaneshiro, 2013). Thus, women might be accessing OTC Plan B® without the resources to make informed decisions about follow-up care for STI testing, future contraception and what to do if Plan B® isn't effective.

OTC Plan B® is an important emergency contraceptive option because it enables women to make their own decisions regarding their reproductive health, which in most instances is a positive change in health care. In some instances, however, women utilizing Plan B® may be in desperate need of additional resources and follow-up care. For example, sexual

BOX 2
Nursing Roles Regarding Emergency Contraception

Health education

- Educate women about the mechanism of action of emergency contraception, such as Plan B®
- Educate women and the public on the availability of emergency contraception, such as Plan B®

Compassionate care

- Employ a nonjudgmental attitude when
  - Educating others about emergency contraception
  - Providing care to those who have used emergency contraception
  - Interacting with those that choose not to use emergency contraception

Policy advocacy

- Remain abreast about policy changes regarding the provision of reproductive health resources, such as Plan B®, and learn how you can impact local, state and national health care policies

Comprehensive health care

- Ensure that women utilizing OTC emergency contraceptives are aware of the potential need for additional care such as
  - Testing for STIs
  - More reliable forms of regular or long-term contraception
  - Options if emergency contraception is not effective

Holistic care

- Be aware that some women utilizing emergency contraception may be doing so in the aftermath of a sexual assault. These women are especially in need of holistic, patient-centered care in which the health care professional can help make them aware of and locate additional resources for postassault care such as medical, psychological, advocacy and legal care.

Sources: ACOG (2010), AWHONN (2012), Kavanaugh et al. (2011), Munro et al. (2015), Westley and Schwarz (2012).

Nurses have a broad understanding of women's reproductive health care issues and must advocate for their patients through local, state and/or national policy change beyond the individual care they provide

assault survivors might be foregoing postassault care services to obtain Plan B® and comprehensive care as they might have when it was available only by prescription (Munro et al., 2015). This presents the possibility of missed opportunities for additional medical, legal and psychological care that is considered the standard of care for postassault survivors.

Nursing Practice Implications

All health care providers, including nurses, midwives and advanced practice nurses, must be knowledgeable about emergency contraceptive options and should be prepared to educate women regarding the mechanism of action, availability, side effects and public perception of options. This broad understanding is necessary to provide comprehensive, unbiased education to women and other providers regarding emergency contraception and its use. Recent studies have indicated that despite the increased availability of Plan B® there are still a number of barriers to access, including ethical and moral dilemmas and health care providers' misperceptions about the current dispensing regulations (Wilkinson, Vargas, Fahey, Suther, & Silverstein, 2014).

According to the American Nurses Association (2014), nurses focus on health promotion and prevention by protecting and optimizing the health of all groups including individuals, their families, populations and communities. This imperative means that nurses must be abreast of current policies regarding reproductive health and be able to provide education to women on different forms of contraception (Association of Women's Health, Obstetric and Neonatal Nurses [AWHONN], 2012). Nurses of all levels of education can provide compassionate, comprehensive, holistic care in addition to providing health education to all individuals in need of emergency contraception (see Box 2). Nurses have a broad understanding of women's reproductive health care issues and must advocate for their patients through local, state and/or national policy change beyond the individual care they provide.

Nurses, midwives and advanced practice nurses can utilize their skills in health education and prevention to educate women about Plan B One-Step® during annual visits, family planning visits and STI visits to increase awareness before the medication is procured, or at the time it is needed in the emergency department or hospital inpatient settings (Westley & Schwarz, 2012). Counseling about emergency contraception remains one of the strongest predictors of its use (Kavanaugh et al., 2011). Nurses can be aware of resources for women, health care professionals and the general community (see Box 3).

Nurses are often consulted by family, friends and members of the community for various reasons, and they can provide accurate, factual information. It's essential that everyone, regardless of gender, is educated on the availability of emergency contraception, such as Plan B One-Step®, before they need it (Schrager et al., 2014). Additionally, it's helpful for nurses to have a basic knowledge of current emergency contraceptive prices, availability and side effects while providing health education (see Box 4). Finally, nurses and other clinicians must be aware of personal biases and still be able to provide safe, comprehensive reproductive health care. If health care providers feel uncomfortable talking about Plan B® or caring for a woman who has used it, then they must be self-aware enough to have another provider care for that woman.

Conclusion

In conclusion, emergency contraception, such as Plan B®, affords women more control over their health and can reduce

BOX 3
Selected Resources

Website	Highlights
ellaOne® www.ella.rx.com	• Kwik med—free consultation and next-day shipping • Tab for health care professionals • Tab with prescribing information
Emergency Contraception not-2-late.com (ec.princeton.edu)	• Locate emergency contraception by zip code • Health care provider tab • Patient education
Guttmacher Institute www.guttmacher.org/statecenter/spibs/spib_EC.pdf	• Evidence-based information for health care providers
International Consortium for Emergency Contraception www.cecinfo.org	• Information about using emergency contraception in the wake of sexual assault • Country-by-country facts on availability and access to emergency contraception • More information on the opposition to emergency contraception and the legal issues surrounding it
Office of Women's Health www.womenshealth.gov/publications/our-publications/fact-sheet/emergency-contraception.cfm#a	• Government website with useful information and fact sheet • As of this writing, has not been updated with most recent policy changes
Plan B® Website www.planbonestep.com	• Store locator by zip code • $10 off coupon • Tab for health care professionals
Planned Parenthood www.plannedparenthood.org/health-topics/emergency-contraception-morning-after-pill-4363.asp	• Local office finder • Able to provide prescriptions to patients and dispense emergency contraception in office based on a sliding-fee scale • Comprehensive fact sheet about available options
TeensHealth **kidshealth.org/teen/sexual_health/contraception/contraception_emergency.html**	• Focused on educating adolescents • Audio and Spanish option
World Health Organization **www.who.int/mediacentre/factsheets/fs244/en/**	• Global reproductive health information for health care providers

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BOX 4
Discussion Points for Emergency Contraceptive Counseling

(1) Plan B® is available OTC to all ages and genders.

(2) The price of Plan B® OTC can range from $32 to $65 but may be cheaper at a local Planned Parenthood or university pharmacy or when purchased with a coupon; it may also be covered by insurance, Medicaid or a family planning wavier.

(3) Plan B® is most effective if taken within 72 hours of unprotected intercourse, but it can be used for up to 120 hours after unprotected intercourse.

(4) Side effects after taking Plan B® may include nausea, headache, fatigue abdominal pain, early or delayed menstrual cycle (up to 1 week) and lighter or heavier flow during the first cycle after taking the medication. Contact a health care provider if you experience severe abdominal pain.

(5) Plan B® is not to be used as a regular form of contraception. Consider following up with your provider to discuss other options for regular contraception.

(6) You can still become pregnant even with Plan B®. If your menstrual cycle doesn't resume within 1 week of its regular time, follow up for a pregnancy test.

(7) Plan B® doesn't protect from STIs. Routine follow-up visits with your health care provider are recommended for STI testing.

(8) Contact your health care provider with any questions or concerns about emergency contraception (including Plan B®).

Sources: ACOG (2010), Allen and Goldberg (2007), American Society for Emergency Contraception (2013), Munro et al. (2015), Scolaro (2007).

the incidence of unintended pregnancies. As with any OTC product, consumers need to be aware of issues related to policy changes, accessibility and follow-up care in order to benefit from true comprehensive care. Nurses have the opportunity to play a pivotal role in providing education and counseling about emergency contraception, such as Plan B®. NWH

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