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FAMILY PLANNING (A BURKE, SECTION EDITOR)

New Research in Emergency and Postcoital Contraception

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Abstract Emergency contraception (EC), including both emergency contraceptive pills and the intrauterine device (IUD) used post-coitally, is a unique part of the contraceptive method mix. Clinicians still have an important role to play in making EC information and services available, even though one EC method is available without a prescription in the US and a number of other countries around the world. Women need accurate information about EC in general, and about the specific options that may be most effective for them, including ulipristal acetate and the IUD. Given confusing media messages about EC and weight and unclear clinical guidance, clinicians may wish to pro-actively raise EC in routine clinical encounters. They can also take part in ensuring that EC is offered to women who are receiving treatment after sexual assault.

Keywords Emergency contraception (EC) · Family planning · Pericoital contraception · Obstetrics/gynecology · Intrauterine device (IUD) · Emergency contraceptive pills

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Introduction

Emergency contraception (EC, sometimes called post-coital contraception) is a term used to describe contraceptive methods that can be taken to prevent pregnancy after sexual intercourse. The most widely used and well-known form of EC is the levonorgestrel-alone pill, often called the "morning after pill" and sometimes known by its US brand name, Plan B. Several other emergency contraceptive pills exist, including ulipristal acetate, currently available in Europe, the US and a number of other countries under the brand name ella, and a low dose of mifepristone, available as a post-coital pill in China, Vietnam, Russia, Ukraine, and Armenia (this last product will not be addressed in this paper). The copper intrauterine device (IUD) can also be used for EC when inserted after unprotected sex.

Since EC first became available as a commercial product in the US over two decades ago, a number of policy changes have come about, the most significant of which is the evolution of EC pills from a prescription-only medication to one that women can purchase directly over the counter. As of 2013, women and girls in the U.S. can find a levonorgestrel product on the shelves of pharmacies and bring it straight to the cash register for purchase. This follows a long period during which all EC products were available without a prescription to adult women but only with a prescription to younger women (the exact age changed several times). The "dual-label" status meant that EC products had to be kept behind the counter so pharmacy staff could check the customer's age with their official identification. Prior to this phase, EC pills were only available by prescription to U.S. women regardless of their age.

At least 14 other countries offer women over the counter (on the shelf) access to EC, and 57 more countries allow women to obtain EC behind the counter, without a prescription [1]. But whether or not they write EC prescriptions,

clinicians still play an important role in enhancing access to EC and must be aware of recent developments that may affect their practice.

EC in clinical encounters

There are a number of reasons that EC should continue to be a part of conversations between clinicians and their patients. The most important is that many women do not know about EC. Demographic and health survey (DHS) data from many developing countries indicate that the majority of women are simply unaware of the existence of EC; for these women, education about EC during other clinical encounters is essential [2].

Among women who are aware of EC, many do not use it consistently after unprotected or inadequately protected sex; rates of unintended pregnancies remain high in many settings [3]. Not all women have a clear understanding of their risk of pregnancy or when it is appropriate to use EC. A new study indicates that fully 40 % of American women do not have accurate information about when in their cycle they have the highest risk of pregnancy [4].

In addition, anecdotal evidence suggests that some women may be combining EC with elements of natural family planning or cycle awareness. Women have reported using EC if they had unprotected sexual intercourse "during the wrong time of the month." These women may then proceed to have unprotected sex later in their cycle, during what they would normally consider their safe days. Yet our understanding of EC's mechanism of action – prevention or delay of ovulation – suggests that pregnancy is possible later in the month, after EC has been taken during earlier days. Indeed, reanalysis of clinical trial data confirms pregnancies in EC users who had unprotected sexual intercourse after using EC in the same cycle [5, 6•].

Accurate information about EC (and contraception generally) is in short supply and all family planning clients who adopt short-term or user dependent methods should have information about EC as a back-up method. In addition, two important post-coital options are only available with a clinician's involvement: the copper-bearing IUD is an extremely effective method of EC that is safe for most women and provides years of on-going contraception, and the new ulipristal acetate EC pill is available only by prescription. These options may become increasingly important as new evidence emerges about the effectiveness of the levornorgestrel-alone EC regimen. See further discussion of these topics in later sections.

Finally, despite EC pills increasingly being accessed directly through pharmacies, funding, insurance and cost issues mean that some kinds of clinical settings continue to attract women seeking EC. In the US, Title X Family Planning clinics, Planned Parenthood clinics, and other clinic settings continue to play an important role in making contraception, including EC, available and affordable to women. Clinicians in these settings have a unique opportunity to provide women with the full range of EC options, unavailable to women accessing EC in an OTC setting in pharmacies.

Offering the most effective EC method: the IUD and ulipristal acetate

The copper-bearing intrauterine device can be placed post-coitally and is almost 100 % effective in preventing pregnancy after a recent act of unprotected intercourse, and it then remains effective for years into the future. IUDs are an underutilized method in the US, currently used by only 3.5 % of women [7]. However, recent studies show that offering IUDs and other long-acting methods of contraception free of charge and with more emphasis on their long-term effectiveness can increase use [8]. Studies have assessed whether women seeking EC in clinic settings might choose to use an IUD if they are given the option, and have found that around 12 % of women will choose this method [9•, 10]. Given the cost and clinician time needed for IUD insertion, continuation with the method is an important consideration. Long-term follow-up indicates that the majority of women who choose an IUD for EC do keep the IUD in place [11, 12].

Offering the IUD as a post-coital option to prevent pregnancy may involve some reorganization of clinical services. Women must receive complete information about their EC options quickly (preferably in advance) and IUD services should ideally be offered the same day, if possible immediately, and in only one visit. Not all settings will have personnel available to place IUDs all the time, and offering "walk-in" IUD services may present scheduling challenges. Some Planned Parenthood affiliates are currently testing strategies to integrate the IUD into their emergency contraceptive services, and their results will provide valuable data from which to learn.

The other EC option that may be more effective than the over the counter levonorgestrel pill is the ulipristal acetate pill. Ulipristal acetate is very safe (although its use multiple times in one cycle has not yet been studied so the manufacturer recommends not to use it more than once per cycle). The levonorgestrel regimen is labeled to be used up to three days after sex, but may have some effectiveness on the fourth and possibly the fifth day after unprotected intercourse [13•]. The ulipristal regimen is labeled for use up to five days after unprotected intercourse and should be the preferred choice of EC pills for women seeking EC after day three; it may be somewhat more effective on all days [14, 15]. (However, taking either regimen as promptly as possible within these time frames is strongly recommended.) Some data from Europe and North America also suggest that the levonorgestrel regimen may be less effective in overweight women than in thinner women (discussed below).

Ultimately, the speed and ease of pharmacy access of the levonorgestrel-alone pills, compared with the challenges inherent in accessing the ulipristal acetate prescription product, must be balanced with the probable enhanced effectiveness of the ulipristal product. Given the decline in effectiveness over time for both types of EC pills and the fact that women are not able to assess how close they are to ovulation, women may wonder whether "levonorgrestrel today is more effective than ulipristal tomorrow." Unfortunately, we do not have data to gauge the efficacy impact of delaying taking EC in order to obtain a prescription for the ulipristal regimen and, thus, are challenged in providing guidance to women.

New concerns about weight and effectiveness

The issue of weight and effectiveness of levonorgestrel-alone emergency contraception recently received significant media coverage following one pharmaceutical company's request to change the label for its levonorgestrel-alone product in Europe [16]. The new package leaflet states: "Studies suggest that Norlevo is less effective in women weighing 75 kg or more and not effective in women weighing more than 80 kg" [15]. According to the Centers for Disease Control, the average American woman now weighs 166 lbs, [17] but overweight can no longer be characterized as a US or even a Western problem. People around the world are increasingly overweight, with Mexico recently overtaking the US as the country with the highest rates of obesity [18] and a substantial percentage of Tanzanian women being found to be obese as well [19]. It is likely that this trend towards heavier populations is relatively global and not likely to reverse itself soon.

There are now close to 100 manufacturers of levornorgestrel EC around the world [1]. At this point, only one of them has requested a label change, potentially leading to confusion and concern among women and providers as different brands of EC carry different instructions. Clarity at the global level is urgently needed, and fortunately, the European Medicines Agency announced in January 2014 that they will be reassessing the labeling for all levonorgestrel-alone brands of EC [20]. Prompt guidance from the World Health Organization and the United States Food and Drug Administration would also be extremely valuable. As of February 2014, no products in the US (or any countries other than Ireland) have been relabeled as being ineffective or less effective for heavier women.

While waiting for better guidance to emerge, clinicians might be wise to advise patients that the levonorgestrel brand of EC may be less effective in women with body mass index (BMI) or weight above normal ranges and to offer women the choice of the Copper IUD or the ulipristal acetate product. However, given that so many women access EC directly from pharmacies without a clinical encounter, making sure that women have the information they need to make a decision about which EC method to use remains a challenge. Compounding this challenge, media coverage that emphasizes the potential lack of effectiveness of EC in heavier women without mentioning alternatives may have the effect of discouraging women from using EC at all and could even influence trust in contraceptive methods more broadly. Clinicians should proactively raise emergency contraception, including the variety of methods of EC available, in their routine family planning discussions with clients and should widely share accurate sources of information about contraception (including written materials and websites such as bedsider.com).

Subsequent acts of unprotected intercourse and repeat and routine use of EC

Women who have taken EC once in their cycle and then have unprotected intercourse subsequently are still at risk of pregnancy [5]. Given the continuing risk of pregnancy during the cycle, women should know that if they have unprotected sex again it is always better to take another dose of EC than to risk unintended pregnancy. Women may be nervous about "overusing" EC or worry that they will be exposing their body to too high a dose of hormones if they take EC more than once. The facts show that repeat use of levonorgestrel ECPs does not pose any known health risks [21] even among women who use these ECPs multiple times *in the same menstrual cycle* [22]. As such, women should not be limited in the frequency or number of times they can access ECPs, although they should know that on-going contraceptive methods are more effective, and likely cheaper. As mentioned above, ulipristal acetate used more than once in a cycle has not been studied and cannot be recommended at this time.

EC and Sexual Assault

Emergency contraception is a critical component of comprehensive post-rape care for women, and clinicians who provide such services have a responsibility to help women avoid unwanted pregnancy caused by rape. Sexual assault survivors often face obstacles in accessing EC products and information. In the US, a study published in 2013 indicates that 40 % of hospitals do not administer EC to sexual assault survivors on-site [23]. Another sampling of US emergency departments found no improvement in EC provision between 2004 and 2009 [24]. Evidence suggests that access to EC as part of post-rape care is also low in other countries. For instance, in South Africa, one study found that only 14 % of girls between 12 and 17 received EC as part of post-rape care [25]. Similarly, a survey of multi-sectorial response services ("one-stop centers") for sexual assault survivors in Kenya and Zambia found that three out of five did not offer ECPs to survivors [26].

Global guidance from international policy-making bodies supports women's access to EC after sexual assault, and in

2013 the U.S. Justice Department issued new national guidelines for forensic medical examinations in cases of sexual assault. The guidelines recommended that rape victims be offered emergency contraception or — in instances where health professionals have moral objections — information on how to immediately obtain the medication [27].

Clinicians can help ensure that sexual assault survivors are informed in advance of their EC options and are aware of where to access EC. Where policies require health care practitioners and other front-line responders to dispense EC to rape survivors, these responders should be trained in EC provision and should be able to offer counseling about EC's effectiveness and mechanism of action. Their facilities should stock EC and provide it on-site as quickly as possible. Regular monitoring can help ensure that EC provision is not omitted. Enforcement of these policies must also address instances in which individuals, institutions, and/or governments cite "conscientious objection" as the reason for not providing rape survivors with timely access to EC.

Conclusion

Comprehensive and accurate information is an essential component of EC access. Yet with one EC method now available directly from pharmacies in many countries, and with unclear guidance available about new issues such as the relationship between women's weight and EC effectiveness, clinicians may be unclear about whether and how they should address EC with their patients.

In light of recent evidence, clinicians may be advised to convey the relative effectiveness of each type of EC with particular emphasis on interactions with weight or BMI and the number of days that have passed since unprotected sex occurred. This information may be particularly useful to women when provided in advance of an emergency, such as during routine well-woman visits. Clinicians should also inform clients that taking EC pills once during their cycle will not protect them for the rest of their cycle, and, in fact, may increase the likelihood of fertile days occurring later than usual. As such, clinicians can advise clients that they must use contraception for the rest of their cycle; if subsequent acts of unprotected intercourse occur in the same cycle, clients should know that it is safe to take emergency contraception again in that cycle. Finally, clinicians can take part in helping to ensure that sexual assault survivors access EC promptly.

Clinicians continue to play a critical role in enhancing awareness of and access to EC. They can help clients better understand the variety of EC methods available and which EC method will be best for each woman. Discussing EC during regular visits and providing honest, up-to-date information about it to all clients of reproductive age will help ensure that women are as informed as possible about emergency contraception.

Compliance with Ethics Guidelines

Conflict of Interest Elizabeth Westley, Sarah Rich, and Hilary Lawton declare that they have no conflict of interest

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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