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## EFFICACY OF EMERGENCY CONTRACEPTION AND BODY WEIGHT: Current Understanding and Recommendations

### Summary

- **Recent regulatory changes have raised the question of whether emergency contraceptive (EC) pills may be less effective for women with higher body weights.** Some data show that both levonorgestrel (LNG, sold in the US as Plan B One-Step<sup>®</sup>, Take Action<sup>™</sup>, and others) and ulipristal acetate (UPA, sold in the US as ella<sup>®</sup>) may be less effective for women at higher body weights, although LNG may lose effectiveness at a lower weight threshold than UPA.
- **There is significant disagreement about whether the data supporting these changes are definitive.** Whether, in fact, EC is less effective for heavier women is not proven; the precise weight at which EC may lose efficacy is not clear and could vary for individual women.
- **No woman should be refused or discouraged from using EC based on her weight.** LNG EC is often the most accessible, or only, EC option for many women. Women at higher bodyweights should be advised that LNG EC might be less effective for them, but each woman should make her own determination about whether or not to take LNG EC, taking into consideration her ability to pay for the product, her other options, her actual risk of pregnancy, and her motivation to avoid pregnancy.
- **Regardless of body weight, the most effective form of EC is the copper IUD, followed by ulipristal acetate.** All women (but particularly women at higher weights) should be offered the copper IUD or UPA if these options are accessible and acceptable.

### Background

#### Available Data

In 2011, an article based on two clinical trials concluded that “the limit of efficacy was reached at a weight of 70 kg [154 lbs] for LNG compared with 88 kg [194 lbs] in women having taken UPA.”<sup>1</sup> These findings are potentially of great clinical significance, yet there are important limitations to the data. These trials were not specifically designed to study the relationship between efficacy and weight. Weight and height were not measured at one

of the two study sites; they were self-reported by study participants, which may have introduced error into the results. The numbers of women in the “overweight” and “obese” categories were small (and the number of pregnancies in the highest weight category was extremely small).<sup>2</sup> A meta-analysis of three WHO studies, conducted primarily among populations of African and Asian women, found no trend toward reduced efficacy with increasing bodyweight.<sup>3</sup>

## Regulatory Decisions

The manufacturer of NorLevo (a 1.5 mg LNG emergency contraceptive pill (ECP)) conducted additional analyses of the data, and requested that European regulatory authorities allow a change to the product label indicating that higher weight may reduce its effectiveness. In November 2013, European authorities granted a label change warning that “in clinical trials, contraceptive efficacy was reduced in women weighing 75 kg [165 lbs] or more and levonorgestrel was not effective in women who weighed more than 80 kg [175 lbs].”<sup>4</sup> (These different weight limits resulted from further analyses of the clinical trial data referenced above.) Shortly thereafter, Health Canada (the Canadian regulatory authority) authorized the same label change for LNG EC. In July 2014, the European Medicines Agency completed a review of all available data (including data from trials conducted by the World Health Organization) and found that “the data were too limited and not robust enough to conclude with certainty that contraceptive effect is reduced with increased bodyweight”, and such statements should be removed from product labels and “emergency contraceptive pills can continue to be used to prevent unintended pregnancy in women of any weight or body mass index.”<sup>5</sup> In May 2016, the US FDA announced completion of a review of the available data and also concluded that “the data are conflicting and too limited to reach a definitive conclusion as to whether effectiveness is reduced in [women who weigh more than 165 pounds or have a BMI above 25].”<sup>6</sup>

## Significance

The U.S. Centers for Disease Control and Prevention reports that the average American woman weighs 166 pounds [75.3 kg];<sup>7</sup> therefore, millions of women fall into the weight category in which levonorgestrel ECPs (and for a smaller subset of women, possibly UPA) may not work. It is of vital importance that the most effective forms of EC (the copper IUD and UPA) be made widely available. However, both the copper IUD and UPA can only be obtained through a healthcare provider<sup>1</sup>, while LNG EC is available over the counter without age or point-of-sale restrictions. Many women purchase EC directly from stores and pharmacies without consulting a healthcare provider, and many providers may not routinely include counseling about EC in their patient interactions: a 2011 study found that only 3% of US women reported ever having received counseling about EC from a healthcare provider.<sup>8</sup>

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<sup>1</sup> In a small number of states in the US, ella® can be obtained directly from a pharmacist through collaborative practice agreements.

## Recommendations and Conclusions

Although the evidence is not clear, it is possible that there is some relationship between the efficacy of EC and the weight of the user, and there may be a weight at which ECPs, particularly LNG, are less effective at preventing pregnancy. However, it is likely that no new evidence will become available soon to clarify exactly what this relationship is or whether increasing the dose would improve efficacy. It is unclear whether reduced efficacy is related to biological processes, behavioral differences (such as repeated unprotected intercourse or taking EC too late to be effective), or a combination of the two. Therefore, women in need of EC and healthcare providers who serve women of reproductive age will most likely need to make decisions about EC without complete information about how (and whether) weight might impact efficacy.

Those who serve women seeking EC in a clinical setting are in an excellent position to counsel women on all of their options for EC. For all women, the copper IUD is the most effective EC method, followed by UPA and then LNG. For patients at higher bodyweights, special emphasis should be placed on the benefits of the copper IUD or UPA (although for very heavy women, the efficacy of UPA might be reduced as well). Providers should remind women choosing ECPs that they should be taken as soon as possible after sex.

However, most women do not obtain EC from a clinic; the majority of EC sales take place in retail outlets now that LNG ECPs are available over the counter with no age or point-of-sale restrictions. Advocates should work to spread information about all of the options for EC and encourage women with higher body weights in particular to consult a clinician if they are at risk of pregnancy after unprotected sex. Women should also be informed about the possibility of acquiring UPA online ([www.ella-kwikmed.com](http://www.ella-kwikmed.com)), and should be encouraged to acquire UPA prior to needing an ECP if possible. Women with higher body weights who are unable to access clinical care within 5 days of unprotected sex or who do not choose a copper IUD or UPA should still consider taking LNG ECPs. Health care providers and pharmacists should never deny access to LNG ECPs because of a woman's weight.

## Options for Emergency Contraception in the US

(listed in order of effectiveness)

- ➔ All emergency contraception should be used as soon as possible.
- ➔ ECPs do not prevent pregnancy from future acts of intercourse; another contraceptive method must be used to reduce risk of pregnancy following use of ECPs

### Copper IUD

*The most effective emergency contraceptive option, regardless of a woman's weight, is the copper IUD.*

**Benefits:** The copper IUD is nearly 100% effective<sup>9</sup> in preventing pregnancy after sex and provides up to 12 years of excellent ongoing contraceptive protection. It is maintenance-free and does not contain any hormones.

**Challenges:** The IUD must be inserted by a clinician, so at least one office visit is required. Some women may find the insertion process uncomfortable or invasive, some may experience changes in menstrual bleeding patterns that are unacceptable, and not all women are interested in a long-acting method. Though many insurance plans now cover the costs of IUDs through the Affordable Care Act, cost remains a significant barrier for women not covered by affected plans.

### Ulipristal acetate (ella®)

*Ulipristal acetate, sold in the United States as ella®, is a prescription-only ECP.*

**Benefits:** UPA can work after the luteinizing hormone surge has begun, when LNG is not effective. The fact that it works closer to the time of ovulation makes it more effective than LNG.<sup>10</sup> It may be more effective than LNG for women of heavier body weights.

**Challenges:** At this time, ella® is sold by prescription only, so women must obtain a prescription from their healthcare provider and find a pharmacy that stocks ella® or acquire it through an online prescription service (KwikMed). Awareness of ella® is relatively low, and it may not be routinely stocked in pharmacies. Efficacy of ella® may also be reduced in heavier women (particularly those weighing more than 196 pounds).

### Levonorgestrel ECPs (Plan B One-Step®, Take Action™, Next Choice™ One-Dose, My Way™ and others)

*LNG ECPs are available without prescription or age restrictions in the United States.*

**Benefits:** LNG ECPs are by far the most widely-available EC option. LNG ECPs (1.5 mg) are available for sale at retail outlets to women and men of any age, with no prescription or proof of age requirement.

**Challenges:** LNG ECPs are less effective than other EC methods and may be less effective in particular for women of heavier body weights. The price of LNG ECPs may also be a significant barrier; the branded product (Plan B One-Step®) costs an average of \$48, while the generic products cost about \$41<sup>11</sup> (a less expensive brand is now available for advance purchase online at [www.afterpill.com](http://www.afterpill.com) for \$20 per pill plus \$5 shipping). Some health plans may not cover OTC products or will cover them only with a prescription.

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