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Dispensing emergency contraceptive pills according to the evidence and human rights: the role of pharmacists

A CONSENSUS STATEMENT ENDORSED BY:

In most countries in Europe (and in many other countries around the world) two forms of emergency contraceptive pills are accessible: both levonorgestrel and ulipristal acetate pills are available in pharmacies without a prescription[1]. In this situation, pharmacy teams play an important role in facilitating access for women. Yet, significant variances in dispensing practices have been identified, leading to access disparities.[2]

This consensus statement aims to present the best evidence to support women's right to choose which ECP to use, as well as pharmacists' role in supporting their choice with accurate information and counseling.

About emergency contraception

Emergency contraception (EC), also known as postcoital contraception, refers to contraceptive methods that can be used to prevent pregnancy after unprotected sexual intercourse (UPSI) or contraceptive failure.[3] In addition to emergency contraception pills (ECPs), a copper intrauterine device (Cu-IUD) can be inserted post-coitally as emergency contraception, but requires a visit to a health facility.

Availability of emergency contraception in Europe

In most European countries, two ECPs, one containing 30 mg of ulipristal acetate (UPA ECPs) and the other containing 1,5 mg of levonorgestrel (LNG ECPs) are registered as pharmacy products and need to be dispensed by pharmacy staff (though a prescription is not required). They are usually held behind-the-counter (BTC). In Sweden, the Netherlands and parts of Norway, UPA and LNG ECPs are also sold over the counter (OTC); that is, ECPs are available directly on the shelf of pharmacies and retail stores. ECPs remain prescription medicines in Poland and Hungary. In addition, ECPs containing mifepristone (10 to 25 mg) are available in a few European countries: in Armenia, the Russian Federation and Ukraine as prescription medicines, and in Moldova, as BTC.[4]

Global recommendations

The World Health Organization (WHO) recommends making over-the-counter emergency contraceptive pills available without a prescription to individuals who wish to use them, in its guidelines for self-care interventions for health and well-being.[5] WHO also states that contraceptive information and services based on human rights should be non-discriminatory; available; physically and economically accessible; acceptable; of the best quality; facilitate informed decision-making; and guarantee privacy and confidentiality.[6] ECPs are considered essential to the reproductive health of all persons.[7]

The European Parliament has stated that access to modern contraception is essential for ensuring gender equality, and recalls that Member States and public authorities have a responsibility to provide evidence-based, accurate information about contraception, including emergency contraception, and to tackle and dispel barriers, myths, stigma and misconceptions.[8]

The role of pharmacies in Europe is expanding and these settings contribute significantly to increased access to sexual and reproductive health products. The Pharmaceutical Group of the European Union (PGEU) states that “Community pharmacists are recognized and supported within national health systems as key health professionals making a dynamic, sustainable, and evolving contribution to the health of individuals and communities they serve whilst strengthening European health systems.”[9]

There is no clear evidence on what (if any) information women wish to receive when procuring ECPs from a pharmacy, nor the best ways to provide it, whether on the shelf (OTC) or behind the counter (BTC). To meet the needs of most people, the WHO suggests that pharmacies offer the option of receiving less or more information.[10]

Recommendations and best practices

Within each country's regulations, the subscribing organizations (European Consortium for Emergency Contraception, European Society of Contraception and Reproductive Health, International Federation of Gynecology and Obstetrics and International Planned Parenthood Federation), agree to the following recommendations and best practices to dispense emergency contraceptive pills according to evidence and human rights:

1. Both LNG and UPA EC pills should be **available and in stock** at all times.
2. Women should be **informed about all available forms of emergency contraception**, including the option of post-coital insertion of an IUD.
3. Referral pathways to health services should be established to facilitate timely access to a qualified health provider for **IUD insertion** or other services that require a clinical visit. Signposting to a safeguarding service should be visible.
4. If regulations allow, a sign or sticker about the availability of ECPs can be posted. Identifying pharmacies as **"EC-friendly"** in this way can help women access the products more quickly, especially in settings where ECPs are not available at every pharmacy. Some pharmacies in certain European countries still "object" to providing ECPs.[11]
5. **Privacy and confidentiality** are important to women seeking reproductive health products. To the extent possible, pharmacies should have separate areas for counseling. If this is not possible, pharmacies should be organized so that there is space between the queuing customers and the pharmacy counter.
6. Pharmacists should be prepared to **provide information** about effectiveness of each emergency contraceptive method, and to offer information on special considerations, including medical eligibility criteria, breastfeeding, and desire to start an on-going hormonal contraceptive method.
7. Pharmacists may offer to **guide women** through the choice of which type of EC to use (LNG or UPA ECPs or the Cu-IUD), *if she wishes*.
8. In addition to EC, pharmacists should be prepared to provide referral to **other services** that might be desired by women seeking emergency contraception, including testing for sexually transmitted infections, sexual assault treatment, domestic violence services, or abortion. Referral pathways to these services should be established by health systems, or signposting to safeguarding services should be visible.
9. If **language** is a barrier to communicating effectively with a client, tools are available to explain what EC is in a number of languages spoken in Europe: https://www.zanzu.be/en/emergency-contraception

Clinical considerations[12]

a) ECPs are **more effective the sooner they are taken** and women who choose ECPs should be informed of this. However, they should not be pressured to take the pills at the pharmacy or in front of the pharmacy team.

b) UPA is **more effective** at preventing pregnancy than LNG. Cu-IUDs are considerably more effective than either pill, and provide long term contraception.

c) The **time elapsed since last unprotected sexual intercourse** may influence the choice of method. The effectiveness of LNG is reduced after three days (72 hours), while UPA maintains its effectiveness for 5 days (120 hours).

d) There is **no basis for age restrictions** for ECPs: ECPs are equally safe for women of any age, including young women or women in perimenopause.

e) ECPs will not prevent pregnancy resulting from **future acts of unprotected intercourse** in the same cycle. For that, another method of contraception should be used. ECPs do not protect from STI/HIV.

f) **Hormonal contraception** can be started immediately after use of LNG ECPs, but not after use of UPA ECPs.

g) It is safe for women and transgender men to obtain ECPs **in advance** of need and could allow for more prompt use.

h) **Repeated use** of ECPs is safe, although ECPs are not as effective as other methods of contraception. The same regimen that had already been used (whether LNG or UPA) should be repeated if EC is needed again within a five-day period.

i) **ECPs will not cause an abortion**. Women who are concerned about ECP's mechanism of action can be reassured that it works by preventing ovulation, or possibly by preventing sperm from reaching the egg. This means if a woman suspects she is already pregnant, she should not take ECPs. She should be offered pregnancy testing and the relevant referral.

j) ECPs can be used while **breastfeeding**; if LNG ECPs are used, women should skip the next feed (express and discard breastmilk). If UPA ECPs are used, as a precautionary measure, it is recommended not to breastfeed for a week. UPA has not been shown to cause any harm but its effects on babies have not been studied.

k) ECPs may be less effective among women with a **body mass index** (BMI) ≥ 30 kg/m^2 than among women with a BMI < 25 kg/m^2. The Cu-IUD or the UPA regimen is recommended for individuals with obese-BMI.

l) The following are **recommended** tools to support and facilitate evidence -and rights-based EC counselling, and to strengthen EC knowledge and dispensing skills:

- Medical eligibility criteria wheel for contraceptive use. 2015, World Health Organization. Available in English.
- Training Resource Package for Family Planning. Emergency Contraceptive Pills (ECPs) Training for Pharmacists. 2021, USAID, WHO and UNFPA. Available in English.
- Clinical Guideline: Emergency Contraception. 2020. Faculty of Sexual and Reproductive Healthcare. Available in English.
- Emergency contraception methods decision-making tool (the EC wheel). 2016. European Consortium for Emergency Contraception and European Society of Contraception and Reproductive Health. Available in English and French.
- Emergency Contraception Pills: Medical and Service Delivery Guidance. 2018, 4th edition. International Consortium for Emergency Contraception (ICEC) and the International Federation of Gynecology and Obstetrics (FIGO). Available in English and French.

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2 Access to emergency contraception through community pharmacies in Europe: Findings from a participatory survey (2021) ECEC and YouAct. Available at: https://www.ec-ec.org/wp-content/uploads/2021/01/ECECYouAct_EC_survey_report-_2021FINALII.pdf (Accessed: 15 February 2023).

3 Emergency contraception (2021) World Health Organization. Available at: https://www.who.int/news-room/fact-sheets/detail/emergency-contraception (Accessed: 10 February2023).

4 Country-by-country information (2013) ECEC. Available at: https://www.ec-ec.org/emergency-contraception-in-europe/country-by-country-information/ (Accessed: 16 March 2023).

5 WHO guideline on self-care interventions for health and well-being, 2022 revision (2022) World Health Organization. Available at: https://www.who.int/publications/i/item/9789240052192 (Accessed: 1 February 2022).

6 Ensuring human rights in the provision of contraceptive information and services: guidance and recommendations (2014) World Health Organization. Available at: https://www.who.int/publications/i/item/9789241506748 (Accessed: 1 February 2021).

7 UN Commission on Life-Saving Commodities for Women and Children: Commissioners' Report (2012) UNFPA. Available at: https://www.unfpa.org/publications/un-commission-life-saving-commodities-women-and-children (Accessed: 24 June 2022).

8 Texts adopted - Sexual and reproductive health and rights in the EU, in the frame of women's health (2021) European Parliament. Available at: https://www.europarl.europa.eu/doceo/document/TA-9-2021-0314_EN.html (Accessed: 24 June 2022).

9 Vision and Mission (unknown) Pharmaceutical Group of the European Union. Available at: https://www.pgeu.eu/vision-and-mission/ (Accessed: 15 February 2023).

10 (WHO, 2022).

11 (ECEC and YouAct, 2021)

12 EMERGENCY CONTRACEPTIVE PILLS. Medical and Service Delivery Guidance (2018) International Federation of Gynaecology and Obstetrics (FIGO) and International Consortium for Emergency Contraception (ICEC). Available at: https://www.ec-ec.org/wp-content/uploads/2019/01/ICEC-guides_FINAL.pdf (Accessed: 15 May 2022).

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